

Philip Morris Products S.A.	Confidential
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Annex 10: Stability Monitoring and Testing	Version 1.0

Annex 10: Stability Monitoring and Testing

Product	<i>Marlboro Amber HeatSticks</i> <i>Marlboro Green Menthol HeatSticks</i> <i>Marlboro Blue Menthol HeatSticks</i> <i>IQOS System Holder and Charger</i> <i>IQOS 3 System Holder and Charger</i>
FDA STN	PM0000424-PM0000426, PM0000479 and PM0000634
Reporting Period	PM0000424-PM0000426 and PM0000479: March 1, 2020 to February 28, 2021 PM0000634: December 7, 2020 to February 28, 2021

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1. STABILITY STUDIES OVERVIEW

Following the conclusion of the 12 months' confirmatory stability studies that were reported as part of last 2020 Annual Report for the authorized *HeatSticks* (*Marlboro Amber HeatSticks*, *Marlboro Green Menthol HeatSticks*, *Marlboro Blue Menthol HeatSticks*), it was decided to extend this study up to 24 months to gather additional knowledge about the evolution of the product beyond the established Best Used Before Date (BUBD) of 12 months.

Consequently, the 12 months' stability studies of the three authorized *HeatSticks*, were extended with three additional time points at 16, 20 and 24 months based on the follow-up stability study protocol (24M STAB-2017_P1_PROTOCOL). The storage of the samples (tobacco sticks in primary packaging) was continued without interruption under 22°C 60%RH (ISO condition) and 30°C 65%RH (defined WHO) storage conditions. The same attributes were tested (b) (4)

(b) (4)

These 24 months' follow-up stability studies were completed on March 9, 2020 and the related stability reports are provided on the following pages. The stability studies were performed on 3 batches of each variant manufactured in PMMTB in Oct. 2017.

Under both 22°C 60%RH and 30°C 65%RH climatic conditions all tested aerosol constituents, physical parameters and water activity remained within the acceptance criteria for 24 months

(b) (4)

In summary, the additional stability studies demonstrated that the product is chemically and microbiologically stable beyond the defined 12 months shelf life statement which was justified with the previous study. (b) (4) the originally set shelf life of 12 months is maintained.

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2. 24 MONTH FOLLOW UP STABILITY PROTOCOL THREE VARIANTS OF HEATSTICKS

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THS2.2 STABILITY STUDY PROTOCOL FOR REGULAR, LOW MENTHOL AND HIGH MENTHOL VARIANTS - FOLLOW UP STUDY

Platform	P1												
Stability Study type	<table border="1"> <tr> <td>Initial</td> <td><input type="checkbox"/></td> </tr> <tr> <td>In use</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Confirmatory</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Transportation</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Change</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Monitoring</td> <td><input type="checkbox"/></td> </tr> </table>	Initial	<input type="checkbox"/>	In use	<input type="checkbox"/>	Confirmatory	<input checked="" type="checkbox"/>	Transportation	<input type="checkbox"/>	Change	<input type="checkbox"/>	Monitoring	<input type="checkbox"/>
Initial	<input type="checkbox"/>												
In use	<input type="checkbox"/>												
Confirmatory	<input checked="" type="checkbox"/>												
Transportation	<input type="checkbox"/>												
Change	<input type="checkbox"/>												
Monitoring	<input type="checkbox"/>												

STABILITY STUDIES PROTOCOL FOLLOW UP



PMI RESEARCH & DEVELOPMENT

STAB-2017_P1_R_1 / STAB-2017_P1_M_2 / STAB-2017_P1_M_3

PMI_RD_FOR_000651

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Quality Implementation

Effective Date: See EDMs

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STABILITY STUDIES PROTOCOL FOLLOW UP



STAB-2017_P1_R_1 / STAB-2017_P1_M_2 / STAB-2017_P1_M_3

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1 Introduction

Stability studies (STAB-2017_P1_R_1, STAB-2017_P1_M_2, STAB-2017_P1_M_3) were performed until 12 months for THS2.2 Regular, Low Menthol and High Menthol variants according to an established stability study protocol [1]. The analyses have been completed and the data evaluation is currently on-going.

In order to understand the evolution of the product beyond the established Best Used Before Date (BUBD) of 12 months and potentially to extend the BUBD of the product, a follow up of the stability studies has been requested with three additional time points at 16, 20 and 24 months.

The storage of the tobacco sticks in primary packaging will be prolonged until 24 months under 22°C 60%RH (ISO condition 0) and 30°C 65%RH (defined WHO [3]) storage conditions.

The attributes selected for the 12 months study will be continued to be monitored on all 3 batches of Dorado II Ron, Dorado I Fauvery Low and Dorado I Fauvery High.

This protocol is a follow up of the initial protocol and describe the storage and the analyses that will be performed until 24 months.

2 Batches

The batches were produced in PMMTB, Zola Predosa, Italy.

Table 1 Identification of batches Dorado II Ron (STAB-2017_P1_R_1)

Variant	Pack Batch Number	Finished Product Code	Tobacco Stick Product Code	PM MTB PO	Manufacturing Date	Batch Size (sticks)
Dorado II Ron	B-48340	ME000418.11	CONS.02873.RD	101695995	19-Oct-2017	~744 thousand
	B-48341	ME000418.11	CONS.02873.RD	101695994	17-Oct-2017	~994 thousand
	B-48342	ME000418.11	CONS.02873.RD	101695810	16-Oct-2017	~494 thousand

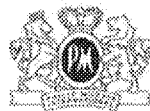
Table 2 Identification of batches Dorado I Fauvery Low (STAB-2017_P1_M_2)

Variant	Pack Batch Number	Finished Product Code	Tobacco Stick Product Code	PM MTB PO	Manufacturing Date	Batch Size (sticks)
Dorado I Fauvery Low	B-48337	ME000419.11	CONS.02807.RD	101695805	18-Oct-2017	~908 thousand
	B-48338	ME000419.11	CONS.02807.RD	101695806	19-Oct-2017	~668 thousand
	B-48339	ME000419.11	CONS.02807.RD	101699003	20-Oct-2017	~688 thousand

Table 3 Identification of batches Dorado I Fauvery High (STAB-2017_P1_M_3)

Variant	Pack Batch Number	Finished Product Code	Tobacco Stick Product Code	PM MTB PO	Manufacturing Date	Batch Size (sticks)
Dorado I Fauvery High	B-48374	ME000420.11	CONS.02806.RD	101697966	20-Oct-2017	~ 678 thousand
	B-48375	ME000420.11	CONS.02806.RD	101697967	20-Oct-2017	~ 618 thousand
	B-48376	ME000420.11	CONS.02806.RD	101697968	23-Oct-2017	~ 608 thousand

STABILITY STUDIES PROTOCOL FOLLOW UP



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2.1 Samples management

All the stick remaining from the original study were continued to be stored without interruption in the climatic chambers in R&D Neuchâtel Product testing (PT) laboratories as their disposal was not yet requested.

The storage of the remaining samples will be pronged in the climatic chambers.

For all the time points the dedicated number of samples will be removed from the climatic chambers for analyses of aerosol, physical parameters, water activity, sensorial evaluations and visual inspection.

3 Storage conditions

The same storage conditions will be kept as for the 12 months study.

Table 4 Stability Storage Conditions

Test Condition n°	Temperature (°C)	Relative Humidity (%)	Storage Period
Condition 1	22°C ± 2°C	60%RH ± 5% RH	12 + 12 months
Condition 2	30°C ± 2°C	65%RH ± 5% RH	12 + 12 months

4 Selection of Stability Parameters

The parameters tested in the 12 months study will be maintained for the additional time points as described in the initial stability study protocol and are listed in Table 5.

Table 5 List of Parameters Monitored

Parameter	Class	Type of Parameter
Nicotine	Aerosol	Product performance
Glycerin	Aerosol	Product performance
Triacetin	Aerosol	Product performance
Carbon monoxide (CO)	Aerosol	Product performance
Phenol	Aerosol	Product performance
Acrylamide	Aerosol	Product performance
Formaldehyde	Aerosol	Product performance
1,3-butadiene	Aerosol	Product performance
Benzene	Aerosol	Product performance
Menthol (for mentholated products)	Aerosol	Product performance
(b)(4)		
Tobacco stick weight	Physical	Product quality
Water activity	Microbiology	Product safety
Visual quality	Visual	Product quality
QDP	Sensorial	Product quality



5 Tests Methods, Specifications and Testing Locations

All the analyses will be performed as for the previous 12 months. The version of some of the methods (Table 6) has changed compared to the original study, however these are minor changes having no impact on the quantifications.

5.1 Aerosol constituents

Analyses of aerosol constituents will be performed in R&D Innovation Cube, Product testing, Central Analytical laboratories, Neuchâtel, Switzerland.

5.1.1 Conditioning

At each time point before aerosol analyses, in order to perform the testing under normal conditions as on freshly made products, sticks will be reconditioned for minimum 48 hours at $22\pm1^{\circ}\text{C}$ and $60\pm3\%$ RH. For determination of Menthol samples will be kept in closed packs prior analysis in order to avoid loss of menthol.

5.1.2 Analyses

Generation of the aerosol will be performed using the Health Canada (HC) smoking regimen:

- Laboratory temperature: $22\pm2^{\circ}\text{C}$
- Laboratory relative humidity: $60\pm5\%$
- Puff volume: 55 mL
- Puff duration: 2.0 s
- Puff interval: 30 s
- Number of puffs: 12

All the instruments and material are listed in the relevant work instructions in Table 6.

Device DV.000180(5) will be used to generate the aerosol, the same device and version as used for the first 12 months (NC-2019-00542).

5.2 Physical parameters

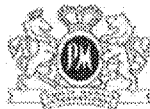
Determination of physical parameters will be performed in R&D Innovation Cube, Product testing laboratories, QA technology team, Neuchâtel, Switzerland.

5.2.1 Conditioning

Conditioning of the tobacco sticks prior measurement will be performed according to work instruction for physical measurements in open packs for minimum 24 hours at $22\pm2^{\circ}\text{C}$ and $50\pm5\%$ RH.

5.2.2 Analyses

Analyses of Tobacco stick weight and (b)(4) at the tobacco plug will be performed by Cerulean C2 Multihopper instrument.



5.3 Water activity

In the absence of validated method available at PMI, measurement of water activity in the tobacco plug will be performed by (b) (4)

5.3.1 Conditioning

Packs from the stability studies will be shipped to (b) (4) at each time point. In order to maintain sample integrity, shipment will be done with express delivery, packs will be wrapped in sealed aluminum packaging and upon arrival at (b) (4) the packs will be placed in storage condition of the stability studies as described below.

The closed packs from storage condition 22°C 60%RH will be placed prior analyses for at least 48 hours in 25°C 60%RH, while packs from storage condition 30°C 65%RH will be placed in 30°C 65%RH.

5.3.2 Analyses

Analyses will be performed by method available at (b) (4) and listed in Table 6.

5.4 Visual quality

(b) (4)

5.5 Sensorial evaluation

(b) (4)

STABILITY STUDIES PROTOCOL FOLLOW UP



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5.5.2 Analyses

(b) (4)

Table 6 Tests, Methods and Specifications

Parameter	Unit	Method Name	Method Version	Target Value	Specification (Range or Upper Limit)	Specification Version /Reference		
Nicotine	mg/stick	PMI-RRP-WKI-111801 PMI-RRP-WKI-111640	10.0.0 4.0.0	(b) (4)		3.0 [4]		
Glycerin	mg/stick					3.0 [4]		
Triacetin	mg/stick					3.0 [4]		
Carbon monoxide (CO)	mg/stick					3.0 [4]		
Phenol	µg/stick	PMI-RRP-WKI-111743 PMI-RRP-WKI-111709	13.0.0 16.0.0			3.0 [4]		
Acrylamide	µg/stick					3.0 [4]		
Formaldehyde	µg/stick					3.0 [4]		
1,3-butadiene	µg/stick					3.0 [4]		
Benzene	µg/stick	PMI-RRP-WKI-111729 PMI-RRP-WKI-111706	8.0.0 19.0.0			3.0 [4]		
Menthol (for mentholated products)	mg/stick					1.0 [5]		
(b)(4)								
Tobacco stick weight DI Ron CONS.02873.RD	mg	PMI-RRP-WKI-111657	9.0.0			5.0 [7]		
Tobacco stick weight DI Low CONS.02807.RD	mg					6.0 [8]		
Tobacco stick weight DI High CONS.02806.RD	mg					2.0 [9]		
Water activity	N/A	VM1349	1.0			1.0 [12]		
Visual quality	N/A	PMI-PMPSA-WKI-126259	2.0.0			N/A		
Quantitative Descriptive Profile (QDP)	N/A	PR.06	02	N/A				

(b) (4)

STABILITY STUDIES PROTOCOL FOLLOW UP



STAB-2017_P1_R_1 / STAB-2017_P1_M_2 / STAB-2017_P1_M_3

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6 Testing Frequency

The samples are stored in climatic chambers in R&D Neuchâtel Product testing laboratories. Packs will be taken randomly from the climatic chambers at each time point (T16, T20 and T24) according to sampling frequency describe in Table 7 to Table 9. Time points in grey were already performed they are kept in the table to have the full picture of the study design.

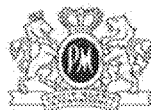
Table 7 Testing Frequency for Dorado II Ron (STAB-2017_P1_R_1)

Batch	Storage Conditions	Beginning of the Study *	Analysis Time Points (months)								
			0	2	4	6	9	12	16	20	24
Dorado II Ron (B-48340)	22±2°C / 60±5%RH	10-Nov-2017	AP	AP	AP	AP	AP	AP	AP	AP	AP
			SV	SV	SV	SV	SV	SV	SV	SV	SV
			W	W	W	W	W	W	W	W	W
	30±2°C / 65±5%RH		AP	AP	AP	AP	AP	AP	AP	AP	AP
			SV	SV	SV	SV	SV	SV	SV	SV	SV
			W	W	W	W	W	W	W	W	W
Dorado II Ron (B-48341)	22±2°C / 60±5%RH	10-Nov-2017	AP	AP	AP	AP	AP	AP	AP	AP	AP
			SV	SV	SV	SV	SV	SV	SV	SV	SV
			W	W	W	W	W	W	W	W	W
	30±2°C / 65±5%RH		AP	AP	AP	AP	AP	AP	AP	AP	AP
			SV	SV	SV	SV	SV	SV	SV	SV	SV
			W	W	W	W	W	W	W	W	W
Dorado II Ron (B-48342)	22±2°C / 60±5%RH	10-Nov-2017	AP	AP	AP	AP	AP	AP	AP	AP	AP
			SV	SV	SV	SV	SV	SV	SV	SV	SV
			W	W	W	W	W	W	W	W	W
	30±2°C / 65±5%RH		AP	AP	AP	AP	AP	AP	AP	AP	AP
			SV	SV	SV	SV	SV	SV	SV	SV	SV
			W	W	W	W	W	W	W	W	W

A: Aerosol; P: Physical measurements; S: Sensorial analysis; V: Visual inspection, W: Water activity

* Beginning of the study corresponds to the date when the packs were put in the climatic chambers.

STABILITY STUDIES PROTOCOL FOLLOW UP



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STAB-2017_P1_R_1 / STAB-2017_P1_M_2 / STAB-2017_P1_M_3

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Table 8 Testing Frequency for Dorado I Fauvery Low (STAB-2017_P1_M_2)

Batch	Storage Conditions	Beginning of the Study *	Analysis Time Points (months)								
			0	2	4	6	9	12	16	20	24
Dorado I Fauvery Low (B-48337)	22±2°C / 60±5%RH 30±2°C / 65±5%RH	20-Nov-2017	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W
				AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W
				AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W
Dorado I Fauvery Low (B-48338)	22±2°C / 60±5%RH 30±2°C / 65±5%RH	20-Nov-2017	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W
				AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W
				AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W
Dorado I Fauvery Low (B-48339)	22±2°C / 60±5%RH 30±2°C / 65±5%RH	20-Nov-2017	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W
				AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W
				AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W

Table 9 Testing Frequency for Dorado I Fauvery High (STAB-2017_P1_M_3)

Batch	Storage Conditions	Beginning of the Study *	Analysis Time Points (months)								
			0	2	4	6	9	12	16	20	18
Dorado I Fauvery High (B-48374)	22±2°C / 60±5%RH 30±2°C / 65±5%RH	20-Nov-2017	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W
				AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W
				AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W
Dorado I Fauvery High (B-48375)	22±2°C / 60±5%RH 30±2°C / 65±5%RH	20-Nov-2017	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W
				AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W
				AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W
Dorado I Fauvery High (B-48376)	22±2°C / 60±5%RH 30±2°C / 65±5%RH	20-Nov-2017	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W
				AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W
				AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W	AP SV W

STABILITY STUDIES
PROTOCOL FOLLOW UP

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The number of replicates performed per analyses will be as follows:

- Aerosol chemistry: 6 replicates/batch at each time point
- Physical parameters: 50 sticks/batch
- Water activity: 3 replicates/batch
- Visual inspection: 100 sticks/batch

7 Data Evaluation and Trending

The stability data will be evaluated as described in the original study protocol [1].

- Water activity

At all 3 time points the stability data will be evaluated:

- Individual values should be strictly below 0.7,
- One sided upper 95% Confidence Interval (CI) limit on the mean value should be below 0.7

If at least one of the above conditions is not fulfilled results will be immediately escalated to Product Stewardship who will decide whether toxicological assessment is required and/or any other further actions. In addition an OOS investigation will be triggered by the Stability Study Coordinator.

Mean values with the 95% upper CI will be plotted at each time point for each batch and condition to visually assess obvious trends on the data. An out of trend (OOT) result could lead to an OOT investigation.

- Visual quality

All observations will be reported.

In the absence of specifications, acceptability of the product from visual point of view will be evaluated during regular meetings as explained in Chapter 5.4.2.

- Sensorial perception

Analyses of the sensorial evaluation results will be performed by Sensory Evaluation Team.

8 Documentation of Results

Intermediate report:

Assessment, subsequent investigation and observations will be reported using PMI-RRP-FOR-111540. The results (mean, CI, standard deviation, number of replicates) will be presented in a tabular form at the end of each time point generated with (b) (4). The raw data will be archived and can be audited upon request.

Final report:

The analysis of the stability results will be performed and documented in a final report (PMI-RRP-FOR-111545 Stability Study Report) issued at the end of the stability study.

Individual OOT and OOS results will be documented and listed in the final report. Any critical deviation including storage conditions excursions will be discussed and impact on the study evaluated.



9 Responsibilities

Roles and responsibilities are described in Table 10.

Table 10 Roles and Responsibilities

Role	Responsibility
Stability Study Coordinator (QC Unit Coordinator)	<ul style="list-style-type: none"> - Ensure that the stability protocol is followed under the defined rules - Schedule the analysis at both time points with the Test Item Management team and testing representatives - Preparing at both time points the stability results tables - Initiate and coordinate OOS/OOT investigations when applicable - Write the stability study report together with the QC unit statistician - Inform the sponsor and Product Stewardship in case of OOS/OOT of safety parameters are observed during the study
Test Item Management	<ul style="list-style-type: none"> - Ensure that the stability conditions in the stability chambers are being met - Send samples to (b) (4) and PMP QA at both time points at the request of the QC unit coordinator
QC unit statistician	<ul style="list-style-type: none"> - Provide statistical support for the elaboration of stability results tables at each time point - Write the stability study report together with the Stability Study Coordinator
Sensory evaluation team	<ul style="list-style-type: none"> - Coordinate with SEC the sensorial evaluation test at each time point - Provide sensorial results are each time point to the QC unit coordinator with short evaluation - Write sensorial evaluation report at the end of the study
(b) (4)	<ul style="list-style-type: none"> - Ensure that the conditioning and analyses of the samples is performed according to stability protocol - Perform of investigation in case of OOS/OOT identified by the Stability Study Coordinator

10 References

- [1] P1 THS 2 2 STABILITY STUDY PROTOCOL STAB-2017_P1_R_1 STAB-2017_P1_M_2 STAB-2017_P1_M_3_signed.pdf, Rita Hajdu Schenk, V1.0, 08-Nov-2017

(b) (4)

- [2] ISO 3402:1999 Tobacco and tobacco products - Atmosphere for conditioning and testing
- [3] WHO Stability testing of active pharmaceutical ingredients and finished pharmaceutical products
- [4] Platform 1 Equivalence Specification for Aerosol Endpoints Generated under Health Canada Intense Regime, Donatien Tabin Djoko, V3.0, 11-Oct-2017

STABILITY STUDIES PROTOCOL FOLLOW UP



PMI RESEARCH & DEVELOPMENT

STAB-2017_P1_R_1 / STAB-2017_P1_M_2 / STAB-2017_P1_M_3

PMI_RD_FOR_000851

Version N°: 2.0

Effective

Global Quality Management

Quality Implementation

Effective Date: See EDMS

- [5] Menthol Threshold Levels in PMI Products, Florence Vonmoos, V1.0, 05-Oct-2017
- [6] P1 Product specifications report, Pedro Campelos, V1.0, 16-Mar-2016
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- [8] DI Low C3.2 Performance Specification Report, V6.0, Mirko Minzoni, 20-Sep-2017
- [9] DI High C3.2 Performance Specification Report, V2.0, Mirko Minzoni, 24-Oct-2016
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- [11] International Conference for Harmonization ICH Q1A R2: Q1A(R2) Stability Testing of New Drug Substances and Products – not referenced in the document
- [12] PMI Stability Study Program THS2.2.docx, V1, 06-Oct-2017

(b) (4)

11 Related Documents

PMI-RRP-SOP-111560 Stability Program for RRP Finished Products (RRPCE)

PMI-RRP-SOP-111558 Perform stability studies (RRPCE)

PMI-RRP-FOR-111540 Stability Studies Results (RDNEU)

PMI-RRP-FOR-111545 Stability Study Report (RDNEU)

12 Abbreviations

Abbreviation/Term	Explanation
BUBD	Best Use Before Date
CI	Confidence Interval
CO	Carbon monoxide
CZ	Climatic zone
HC	Health Canada
ICH	International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
ISO	International Standard Organization
(b) (4)	
OOS	Out of Specification
OOT	Out of Trend
PMI	Philip Morris International
PMMTB	Philip Morris Manufacturing Technology Bologna

STABILITY STUDIES PROTOCOL FOLLOW UP



STAB-2017_P1_R_1 / STAB-2017_P1_M_2 / STAB-2017_P1_M_3

PMI_RD_FOR_000651

Version N°: 2.0

Effective

Global Quality Management

Quality Implementation

Effective Date: See EDMS

Abbreviation/Term	Explanation
PT	Product Testing
QC	Quality Control
QDP	Quantitative Descriptive Profile
RH	Relative Humidity
SEC	Sensorial Evaluation Center (Lausanne)
SOP	Standard Operating Procedure
THS	Tobacco Heating System
WKI	Work Instruction

For complete definition, refer to PMI OPS Glossary and PMI RD Glossary.

13 Revision History for Stability Protocol

Version Nr	Description of change (including reason for change)	Justification
1.0	Creation of the protocol.	<p>Follow up of stability studies described in P1 THS 2.2 STABILITY STUDY PROTOCOL STAB-2017_P1_R_1 STAB-2017_P1_M_2 STAB-2017_P1_M_3.doc</p> <p>(b) (4)</p> <p>Addition of 3 time points (T16, T20 and T24).</p>

STABILITY STUDIES
PROTOCOL FOLLOW UP

PMI RESEARCH & DEVELOPMENT

STAB-2017_P1_R_1 / STAB-2017_P1_M_2 / STAB-2017_P1_M_3

PMI_RD_FOR_000651

Version N°: 2.0

Effective

Global Quality Management

Quality Implementation

Effective Date: See EDMS

14 Signatures

Prepared by: Rita Hajdu Schenk
Quality Control unit coordinator

Date:

14-MAR-2019

Prepared by: Céline Bies
Quality Control unit statistician

Date:

14 MAR 2019

Reviewed by: Mirko Minzoni
Sponsor

Date:

14 MAR 2019

Reviewed by: Shelley Moore
Quality Assurance

Date: 14 MAR 2019

14/03/2019

Reviewed by: Piotr Kozarewicz
Regulatory & Scientific Affairs

Date:

Approved by: Cyril Jeannet
Head of Quality Control unit

Date:

14-MAR-2019

Philip Morris Products S.A.	Confidential
2020 Annual Report for PM0000424, PM0000425, PM0000426 & PM0000479	Page 18 of 280
Annex 10: Stability Monitoring and Testing	Version 1.0

3. STABILITY REPORT FOR MARLBORO AMBER HEATSTICKS¹

¹ The update of the name for Marlboro *HeatSticks* (STN: PM0000424) to Marlboro Amber *HeatSticks* was submitted with 30-day notification dated July 31, 2020.

Confidentiality Statement

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FINAL REPORT OF THE FOLLOW-UP STABILITY STUDY FOR THS2.2 REGULAR VARIANT 24 MONTHS

PRODUCT PLATFORM:

P1

PRODUCT GENERATION:

THS2.2

PROJECT NAME FOR NEW DEVELOPMENT:

REGULAR VARIANT (C3.2)

Effective Version

Version N°	Document Name	Document Title
3.0	From EDMS	From EDMS

For historical versions and change details, refer to paragraph 12 Change Management Log.



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1 Executive Summary

A stability study on Dorado II Ron regular product was performed under 22°C 60%RH and 30°C 65%RH storage conditions during 24 months on 3 batches.

The data generated under both storage conditions, 22°C 60%RH and 30°C 65%RH, for aerosol chemistry, physical parameters and Water activity support a shelf life of 24 months.

From a sensorial point of view, the Dorado II Ron product encountered minor changes over the 24-month stability study. However, those changes do not seem to be linked with time and storage conditions as nothing consistent was observed.

(b) (4)

It has to be noticed, that the specifications used for the aerosol constituents assessment were revised during the study. While the study is reported with the specifications referenced in the study protocol, prior the revision, the impact of the new specifications on the shelf life has been evaluated. The change has no impact on the shelf life conclusion.

2 Purpose

The stability study STAB-2017_P1_R_1 was performed until 12 months on the commercial product THS2.2 Regular variant (Dorado II Ron) manufactured at Philip Morris Manufacturing & Technology Bologna (PMMTB) and is separately reported [1].

In order to understand the evolution of the product beyond the established Best Used Before Date (BUBD) of 12 months, the stability study on the same batches was extended until 24 months with three additional time points at 16, 20 and 24 months. The storage of the samples (tobacco sticks in primary packaging) was continued without interruption under 22°C 60%RH (ISO condition [14]) and 30°C 65%RH (defined WHO [15]) storage conditions.

The study and the related attributes were based on PMI Stability Study Program THS2.2 [2] and are covering the product performance, safety and quality. The same attributes as for the 12 months study were continued to be monitored until 24 months with the exception of the visual inspection in 30°C 65%RH.

This report summarizes the results of the 24 months stability study STAB-2017_P1_R_1 performed according to the stability study protocol [3] and the follow-up study protocol for 24 months [4].



3 Batches

Table 1 Identification of stability study batches Dorado II Ron (STAB-2017_P1_R_1)

Variant	Pack Batch Number	Finished Product Code	Tobacco Stick Product Code	PM MTB PO	Manufacturing Date	Beginning of the Study (T0)
THS 2.2 Dorado II Ron	B-48340	ME000418.11	CONS.02873.RD	101695995	19-Oct-2017	10-Nov-2017
	B-48341	ME000418.11	CONS.02873.RD	101695994	17-Oct-2017	10-Nov-2017
	B-48342	ME000418.11	CONS.02873.RD	101695810	16-Oct-2017	10-Nov-2017

The samples were stored in the conditioning room ($22 \pm 2^{\circ}\text{C}$ $60 \pm 5\%\text{RH}$) and in climatic chambers ($30 \pm 2^{\circ}\text{C}$ $65 \pm 5\%\text{RH}$) in wrapped packs in R&D Neuchâtel Product testing (PT) laboratories by the Test Item Management team (for ID numbers of the storage locations see Appendix 15.1). The packs were polypropylene wrapped and consisted of two collation, each collation containing 10 Heat sticks.

The beginning of the study corresponds to the date when the packs were put in the conditioning room and the climatic chamber. This date corresponds to the T0 time point.

4 Tests Methods and Specifications

The parameters tested during the study, the used methods and the specifications are listed in Table 2. All the instruments and materials are listed in the relevant work instructions. A table containing dates of analyses for each time point are available in Appendix 15.2.



Table 2 Tests, Methods and Specifications

Parameter	Unit	Method Name	Method Version				Target Value	Specification	
			Planned	Used				Range or Upper Limit	Version
				T0	T12	T24			
Nicotine	mg/stick	PMI-RRP-WKI-111801	9.0.0	9.0.0	9.0.0	11.0.0	(b) (4)	3.0 [5]	
Glycerin	mg/stick	PMI-RRP-WKI-111640 *	4.0.0	3.0.0	4.0.0	4.0.0		3.0 [5]	
Triacetin	mg/stick							3.0 [5]	
Carbon monoxide (CO)	mg/stick							3.0 [5]	
Phenol	µg/stick							3.0 [5]	
Acrylamide	µg/stick							3.0 [5]	
Formaldehyde	µg/stick	PMI-RRP-WKI-111743	13.0.0	13.0.0	13.0.0	14.0.0		3.0 [5]	
		PMI-RRP-WKI-111709	15.0.0	15.0.0	16.0.0	16.0.0			
1,3-butadiene	µg/stick	PMI-RRP-WKI-111729	7.0.0	7.0.0	8.0.0	10.0.0		3.0 [5]	
Benzene	µg/stick	PMI-RRP-WKI-111706	18.0.0	18.0.0	19.0.0	20.0.0		3.0 [5]	
(b)(4)									
Tobacco stick weight DII Ron CONS.02873. RD	mg							5.0 [7]	
Water activity	N/A	VM1349	1.0	1.0	1.0	1.0		1.0 [2]	
Visual quality	N/A	See Chapter 4.4	N/A	N/A	N/A	N/A		N/A	
QDP	N/A	PR.06	02	02	02	02		N/A	

* The referenced method in the stability study was PMI-RRP-WKI-111604 instead of PMI-RRP-WKI-111640 being a typo error in the stability protocol.

4.1 Aerosol Measurement

Measurements of Nicotine, Glycerin, Triacetin, Carbon monoxide, Phenol, Acrylamide, Formaldehyde, 1,3-butadiene and Benzene were performed after trapping the particulate



and/or the gas phase of the aerosol and subsequent analyses described in respective work instructions (Table 2).

4.1.1 Preparation and Conditioning

At each time point before aerosol generation, in order to perform the testing under normal conditions as on freshly made products, sticks were reconditioned outside of the packs following ISO standard 3402 (1999), for a minimum of 48 hours and a maximum of 10 day at 22 ± 1 °C, $60 \pm 3\%$ RH according to PMI-RRP-WKI-111777 "Preparation of items". When reached the maximum time of conditioning samples were placed in a sealed recipient and remained in the conditioning room.

The 3R4F Reference Cigarette (purchased from the University of Kentucky, USA) or P1 monitor (P1M1 or P1M2) was used as an internal monitor for aerosol chemistry (PMI-RRP-WKI-123605). Values were compared to respective upper and lower limit defined in the control charts to verify the correct functioning of the experimental setup.

4.1.2 Aerosol Generation and Analyses

The atmosphere for aerosol generation was 22 ± 2 °C, $60 \pm 5\%$ RH.

Aerosol generation was performed on linear smoking machines.

The Health Canada Intense (HCI) smoking regimen [17] using bell shaped puff profile was used with the below listed parameters to generate the aerosol for further chemical analyses:

- Puff volume: 55 mL
- Puff duration: 2.0 s
- Puff interval: 30 s
- Number of puffs: 12

In the stability protocol for 12 months [3] the device DV.000174(8) was erroneously written to be used. The tobacco heating device DV.000180(5)/B-34548 was used to generate aerosol for chemical analyses. The deviation is described in chapter 6.2 and documented as a non-conformity (NC), NC-2019-00542. The device DV.000180(5)/B-34548 was used as well for T16 time point according to the follow-up protocol [4].

For the analyses of aerosol chemistry at T20 and T24 time points the device DV.000180(7)/B-61948 was used, instead of the DV.000180(5) planned in the follow-up stability protocol. Indeed, the device DV.000180(5)/B-34548 has reached its maximum usage period and was replaced by DV.000180(7)/B-61948, which is used as a reference device in the laboratory. The deviation is described in chapter 6.4.



Aerosol is trapped on Cambridge filter pad, in impingers or the combination of both and analyses are performed by GC-MS or UPLC-MS/MS.

For T0, T12, T16, 20, 24 time points, 6 replicates/sample, for T2 to T9 time points 4 replicates/sample were performed.

4.2 Physical Measurement

(b)(4) and Tobacco Stick weight were measured as physical parameters.

4.2.1 Preparation and Conditioning

Conditioning for physical analyses was performed as described in respective work instruction, inside open packs for at least 24 hours at 22 ± 2 °C and $50 \pm 5\%$ RH.

4.2.2 Measurement

Cerulean C2 instrument was used for the determination of the physical parameters. For each time point 50 sticks/sample were measured.

4.3 Water Activity Measurement

The Water activity is the measurement of the free water available for microbiological growth.

(b) (4)

(b) (4)

4.3.1 Preparation and Conditioning

At each time point 20 packs/sample from the climatic chambers were sent to (b) (4). (b) (4) In order to maintain sample integrity, the shipment was done with express delivery with the same day of reception. Packs were wrapped in sealed aluminum packaging and upon arrival at (b) (4) the tobacco stick packs were placed in storage condition corresponding to the stability study as described below.

The closed packs from storage condition 22°C 60%RH were placed prior analyses for at least 48 hours (max. 96 hours) in $25 \pm 2^{\circ}\text{C}$ $60 \pm 5\%$ RH, while packs from storage condition 30°C 65%RH were placed in $30 \pm 2^{\circ}\text{C}$ $65 \pm 5\%$ RH. For the T0 time point, samples were placed at least 48 hours in 25°C 60%RH. The condition 25°C 60%RH was used in the absence of 22°C 60%RH as standard condition at (b) (4) and considered as not having impact on the water activity determination.

4.3.2 Analyses

Sticks were taken randomly from the packs and the tobacco was collected. This composite sample was mixed and 3 portions of approx. 2 g were filled into the sample mugs. The



samples were measured using the LabMaster-aw instrument for their Water activity at 25°C.

For each time point 3 replicates/sample were analyzed.

4.4 Visual Evaluation

4.4.1 Preparation and Conditioning

(b) (4)

4.4.2 Evaluation

(b) (4)

4.5 Sensorial Evaluation

4.5.1 Preparation and Conditioning

(b) (4)

4.5.2 Evaluation

(b) (4)



5 Stability Study Design

The study was performed according to the testing matrix described in Table 3. Samples were pulled out from the stability chambers not more than 5 days after the planned time point based on calendar months.

Table 3 Testing Matrix

Batch	Storage Conditions	Analysis Time Points (months)								
		0	2	4	6	9	12	16	20	24
Dorado II Ron (B-48340)	22±2°C / 60±5%RH	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W
	30±2°C / 65±5%RH		A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S W	A P S W	A P S W
Dorado II Ron (B-48341)	22±2°C / 60±5%RH	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W
	30±2°C / 65±5%RH		A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S W	A P S W	A P S W
Dorado II Ron (B-48342)	22±2°C / 60±5%RH	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W
	30±2°C / 65±5%RH		A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S W	A P S W	A P S W

A: Aerosol; P: Physical measurements; S: Sensorial analysis; V: Visual inspection, W: Water activity

6 Deviations to Study Protocol

6.1 Deviation Related to Method Versions

The version of several methods changed during the study compared to what was described in the study protocol (Table 2,[3],[4]).

6.1.1 Impact on the Study

The changes in the methods were all minor. They had no impact on the quantification of the tested parameters and therefore on the study results.



6.2 Deviation in Study Execution (1/3)

The device used during the stability study was DV.000180(5) instead of DV.000174(8) as the one stated in the stability protocol. The deviation is described in NC-2019-00542. The use of DV.000180(5) device was consistent during whole study (from T0 to T16).

6.2.1 Impact on the Study

The DV.000174(7) and the DV.000180(5) were released with the same Design Change Request (DCR-00310), therefore they are equivalent. The DV.000174(8) was released with the DCR-000516 which was a minor change having no impact on the aerosol. Therefore, the DV.000174(8) and the DV.000180(5) are equivalent in terms of aerosol performance and the deviation has no impact on the stability results.

6.3 Deviation in Study Execution (2/3)

At T2 and T4 time points the sensorial evaluation was performed prior reception of the Water activity data. According to the stability study protocol the sensorial analyses should have been performed only after reception and verification of the Water activity results, for all time points except T0, in order to assess and confirm the absence of toxicological risk.

6.3.1 Impact on the Study

The Water activity results (b) (4) over the whole study. The deviation has no impact on the stability study.

6.4 Deviation in Study Execution (3/3)

The device used for aerosol chemistry at T20 and T24 time points was DV.000180(7)/B-61948 instead of DV.000180(5) as the one stated in the follow-up stability protocol. The deviation was described in the intermediate report at T20. Indeed, the device DV.000180(5)/B-34548 has reached its maximum usage period and was replaced by DV.000180(7)/B-61948, which was used as a reference device in the laboratory.

6.4.1 Impact on the Study

The DV.000180(6) was released with DCR-00585 and the DV.000180(7) was released with DCR-00516, both related to a minor change having no impact on the aerosol. Therefore, the DV.000180(7) and DV.000180(5) are equivalent in terms of aerosol performance and the deviation has no impact on the stability results.



7 Stability Data Evaluation

Results for aerosol chemistry, physical measurements and Water activity are stored in SDMS (Scientific Data Management System) under the corresponding project numbers (see Sample Traceability Matrix in Appendix 15.3). Results and final report of sensory evaluation are stored in PDIMS (Product Development Information Management System).

7.1 Investigations and Excluded Values

7.1.1 Investigation at T0

An investigation was performed for B-48340 during T0 analyses as one replicate out of six provided unexpectedly high results mainly for Phenol. The level of Phenol was approximately 3 times higher than the average value of the 5 other replicates; Nicotine, Glycerin and Acrylamide were approx. 1.2 - 1.4 times higher compared to the others replicates. During the investigation it has been observed that the aerosol generation on the smoking machine of the replicate with the high Phenol value was performed right next to a sample from an exploratory study with high level of Phenol. A high probability of stick inversion has been identified between the stability sample SMP092572/B-48340 replicate 6 (LIMS number: 1729794_6) and a replicate from the exploratory study (LIMS number: 1729319_1). Consequently, a preventive action described in CAPA-RRP-NEU-2018-020 was implemented and this replicate was excluded from the stability study results for Nicotine, Glycerin, Triacetin, CO, Phenol and Acrylamide. All these constituents were obtained with the same aerosol collection (PMI-RRP-WKI-111801) and subsequent analyses (PMI-RRP-WKI-111640). The details of the investigation are described in a separate document [10].

7.1.2 Investigation at T9

An Out of Trend (OOT) investigation was performed for Phenol at T9 time point for samples B-48341 22°C/60%RH, B-48340 30°C/65%RH, B-48341 30°C/65%RH and B-48342 30°C/65%RH. The 95% confidence intervals were found to be above or very close to the specification limit. No root cause could be identified during the investigation to explain the OOT, therefore results were kept as such in the stability data. This approach represents the worst case scenario as the data are more variable and presents more risk not to meet the specifications. The investigation is described in a separate document [11].

Under the storage condition 22°C 60%RH the increase in Phenol, with high variability observed in batch B-48341 at T9 time point, was not confirmed at T12. Under the storage



condition 30°C 65%RH the increase in Phenol observed at T9 for all three batches was confirmed only for batch B-48342 at T12.

7.1.1 Investigation at T24

At T24 time point an OOT investigation was performed for Formaldehyde as replicate 6 from sample SMP130806/B-48342 30°C/65%RH_T24 was found below the limit of quantification (LOQ) of 0.378, while the 5 other replicates were quantified with an average value of 4 µg/stick.

No root cause has been identified during the investigation. As this replicate is much lower (below the limit of quantification) compared to what was expected and compared to the 5 other replicates, this replicate was excluded from the calculations. This represents the worst case scenario as by taking this replicate into account (for example by using the LOQ value itself) it would decrease the average value. The investigation is described in a separate document [12].

7.1.2 Triacetin non-conformity at T24

At T24 months, the results for Triacetin were released by the laboratory with the P1M2 monitor stick being slightly below the control chart limit for 3 replicates out of 4. Consequently, the values for Triacetin might be slightly underestimated as well in the samples. The non-conformity NC-2019-02358 was opened by the testing laboratory.

Based on historical stability studies Triacetin is known to decrease over time and to remain below the upper specification limit. When reviewing the trend plots the Triacetin results did not appear as out of trend. Therefore, even though the results at T24 could be slightly underestimated it has no impact on the estimated shelf life of 24 months for this constituent.

7.2 Statistical Assessment

The statistical assessment for the chemical and physical characterization follows Guidelines ICH Q1E [16], performed by modelling the degradation profile of the test parameters using regression models with (b) (4). The regression analysis defines the trend of a quantitative stability test parameter for each batch over time on the predetermined stress conditions. The poolability of the batches is tested through statistical analyses to determine whether the regression lines from the batches have a common slope and a common intercept as described in Appendix 15.4.



There are 3 possible models:

Model 1: Different slope / different intercept: final poolability model indicates that the batches do not have similar stability profiles with respect to starting point and change over time. This model uses individual batch intercepts and individual batch slopes with a pooled mean square error calculated from all batches and the shelf life is determined with the least favorable batch.

Model 2: Common slope / different intercept: final model indicates that the batches have a similar stability profile with regards to change over time. However, they do not have a consistent starting values. This model uses individual batch intercepts and a common slope with a pooled mean square error and the shelf life is determined from the least favorable batch.

Model 3: Common slope / common intercept: final model indicates that the batches have a similar stability profile and can therefore be pooled together for one expiry determination. The pooled model uses a common intercept and common slope with a pooled mean square error.

The shelf life period corresponds to the earliest time at which the lower or upper 95% confidence interval (CI) regression confidence bounds calculated from the model intersects with the lower or upper specification limit.

The shelf life obtained with (b) (4) is truncated to whole number. In case the shelf life calculated by (b) (4) is longer than the study duration the shelf life will be equal to the study duration.

For Water activity under both storage conditions and (b)(4) under 30°C 65%RH, the mean values along their one sided 95% CI are verified against the upper specification limits. This approach is applied as the values are not following a linear evolution over time.

Tabulated results with summary statistics are available in the Appendix 15.5 and 15.6.



7.3 Results for Storage Condition 22°C 60% RH

The Table 4 and Table 5 contain for each batch and each tested parameter per time point the reported value (mean value), together with the upper and/or lower specification levels. Figure 1 to Figure 11 contain the reported values for the 3 batches together with the specification, the linear regression and the upper and lower 95% CI of the regression depending on the final model kept (model 1, model 2 or model 3). The CIs are illustrated on the figures by the shaded area.

For Water activity the reported value with the one sided 95% CI is shown over time for the 3 batches.

The dashed red lines represent the specification limits. Whereas, the dashed blue line shows the time when the 95% CI crosses the specification or is automatically drawn at 25 months if the 95% CI crosses the specification after the study length of 24 months.

The graphs were created with x-axes above the 24 months of study duration, however this has no extrapolation purpose.

Table 4 Mean values for aerosol constituents for 3 batches T0 - T24 for 22°C 60% RH

PARAMETER	BATCH	LSL	USL	UNIT	T0	T2	T4	T6	T9	T12	T16	T20	T24
1,3 Butadiene	B-48340	(b) (4)		µg/stick	0.331	0.259	0.256	0.289	0.228	0.288	0.325	0.341	0.259
1,3 Butadiene	B-48341			µg/stick	0.305	0.259	0.253	0.279	0.234	0.269	0.327	0.327	0.250
1,3 Butadiene	B-48342			µg/stick	0.305	0.288	0.260	0.287	0.252	0.267	0.334	0.345	0.265
Acrylamide	B-48340			µg/stick	1.74	1.91	1.65	1.76	2.08	1.71	1.48	1.57	1.64
Acrylamide	B-48341			µg/stick	1.69	1.82	1.66	1.81	1.96	1.73	1.52	1.60	1.60
Acrylamide	B-48342			µg/stick	1.69	2.05	1.68	1.78	1.78	1.59	1.42	1.73	1.63
Benzene	B-48340			µg/stick	0.63	0.54	0.55	0.61	0.54	0.52	0.54	0.55	0.54
Benzene	B-48341			µg/stick	0.59	0.53	0.57	0.58	0.55	0.49	0.56	0.54	0.54
Benzene	B-48342			µg/stick	0.61	0.58	0.58	0.56	0.58	0.55	0.54	0.57	0.53
Carbon monoxide	B-48340			mg/stick	0.51	0.54	0.52	0.42	0.51	0.44	0.44	0.43	0.46
Carbon monoxide	B-48341			mg/stick	0.51	0.54	0.50	0.42	0.53	0.42	0.45	0.42	0.46
Carbon monoxide	B-48342			mg/stick	0.51	0.56	0.52	0.40	0.51	0.45	0.44	0.46	0.46
Formaldehyde	B-48340			µg/stick	4.127	4.658	4.203	4.631	4.099	3.584	3.807	3.402	3.936
Formaldehyde	B-48341			µg/stick	3.429	3.752	4.264	4.457	4.400	3.291	3.867	2.913	3.911
Formaldehyde	B-48342			µg/stick	3.926	3.977	3.943	4.471	3.412	3.961	3.233	3.038	3.737
Glycerin	B-48340			mg/stick	5.69	6.02	5.20	5.66	5.64	4.95	4.99	4.49	5.04
Glycerin	B-48341			mg/stick	5.52	5.65	5.35	5.97	5.49	5.08	5.34	4.48	5.02
Glycerin	B-48342			mg/stick	5.60	6.21	5.37	5.58	4.82	5.14	4.84	5.06	5.05



PARAMETER	BATCH	LSL	USL	UNIT	T0	T2	T4	T6	T9	T12	T16	T20	T24
Nicotine	B-48340	(b) (4)		mg/stick	1.27	1.28	1.17	1.18	1.29	1.27	1.26	1.17	1.36
Nicotine	B-48341			mg/stick	1.22	1.24	1.20	1.22	1.23	1.28	1.32	1.16	1.34
Nicotine	B-48342			mg/stick	1.23	1.30	1.16	1.22	1.13	1.28	1.22	1.25	1.36
Phenol	B-48340			µg/stick	1.36	1.45	1.23	1.51	1.83	1.66	1.55	1.28	1.75
Phenol	B-48341			µg/stick	1.58	1.54	1.46	1.71	2.45	1.77	1.97	1.71	1.86
Phenol	B-48342			µg/stick	1.74	1.99	1.70	1.94	1.80	2.00	1.96	2.14	2.11
Triacetin	B-48340			mg/stick	0.67	0.70	0.63	0.63	0.60	0.50	0.51	0.45	0.49
Triacetin	B-48341			mg/stick	0.63	0.61	0.57	0.58	0.60	0.46	0.48	0.44	0.45
Triacetin	B-48342			mg/stick	0.62	0.65	0.58	0.55	0.51	0.47	0.47	0.46	0.44

Table 5 Mean values for physical parameters and Water activity for 3 batches T0 – T24 for 22°C 60% RH

PARAMETER	BATCH	LSL	USL	UNITS	T0	T2	T4	T6	T9	T12	T16	T20	T24
		(b) (4)		(b) (4)									
Tobacco stick weight	B-48340			mg	782	785	785	782	788	786	788	777	783
Tobacco stick weight	B-48341			mg	779	791	781	784	782	788	788	780	785
Tobacco stick weight	B-48342			mg	779	788	785	786	786	782	790	783	792
Water activity	B-48340			N/A	0.42	0.48	0.52	0.55	0.56	0.56	0.58	0.58	0.59
Water activity	B-48341			N/A	0.42	0.48	0.51	0.54	0.56	0.56	0.57	0.58	0.58
Water activity	B-48342			N/A	0.43	0.49	0.53	0.55	0.56	0.56	0.57	0.57	0.59



7.3.1 Aerosol Constituents Evaluation for 22°C 60%RH

7.3.1.1 Nicotine for 22°C 60%RH

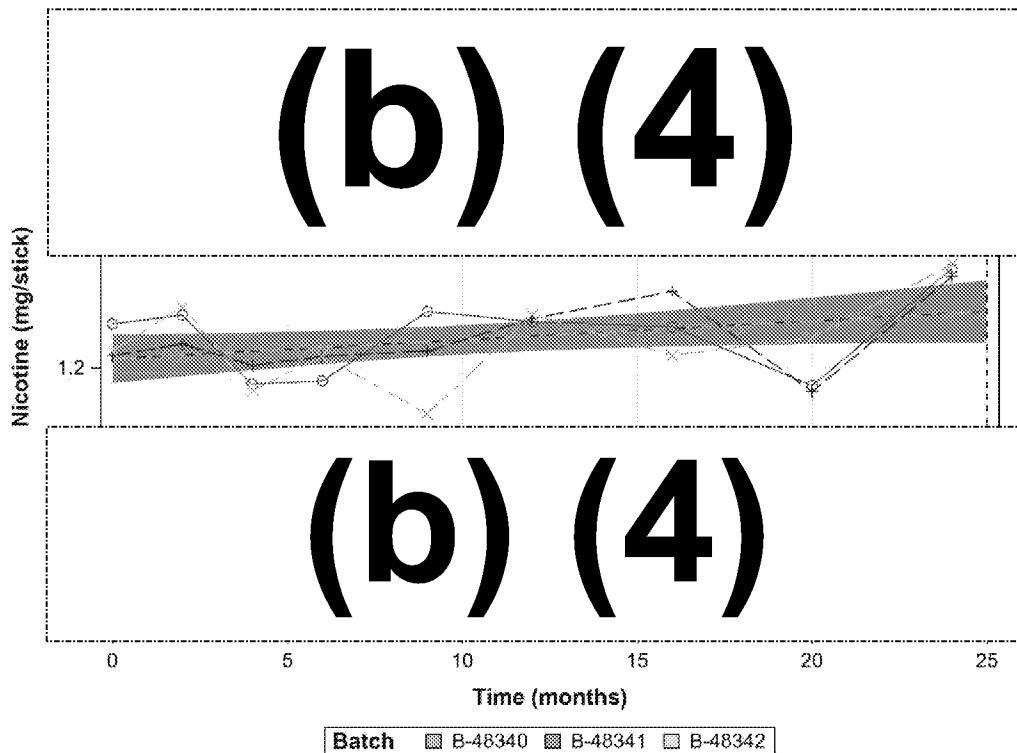


Figure 1 Evolution of Nicotine for the 3 batches together with the specification levels, the linear regression of the 3 batches and the 95% confidence interval for the regression (CI shown as the shaded area - valid for all figures in pages below)

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95 percent confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.3.1.2 Glycerin for 22°C 60%RH

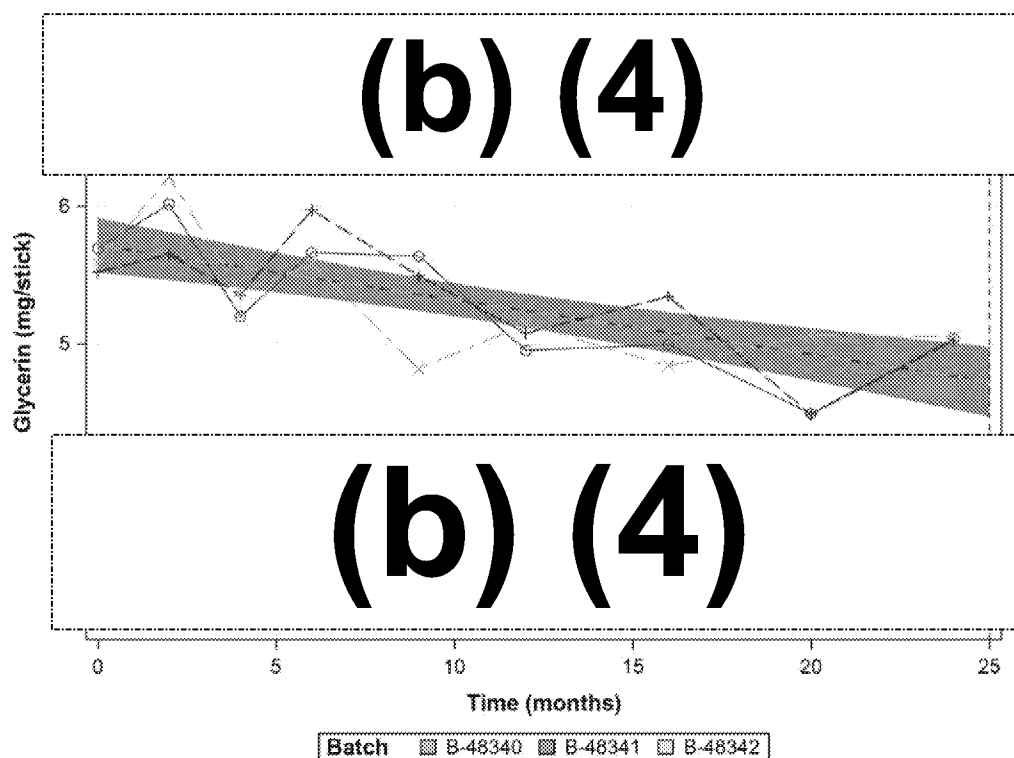


Figure 2 Evolution of Glycerin for the 3 batches together with the specification levels, the linear regression of the 3 batches and the 95% confidence interval for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95 percent confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.3.1.3 Triacetin for 22°C 60%RH

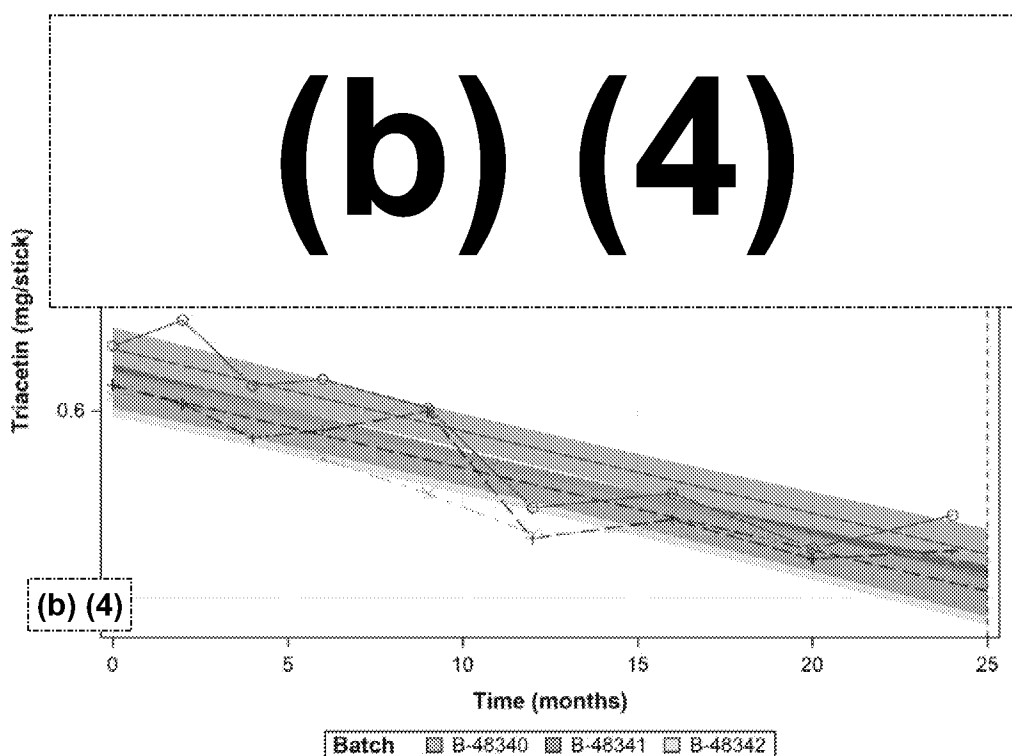


Figure 3 Evolution of Triacetin for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% confidence interval for the regression

The best model accepted at the significance level of 0.25 has Different intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95 percent confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.

7.3.1.4 Carbon monoxide for 22°C 60%RH

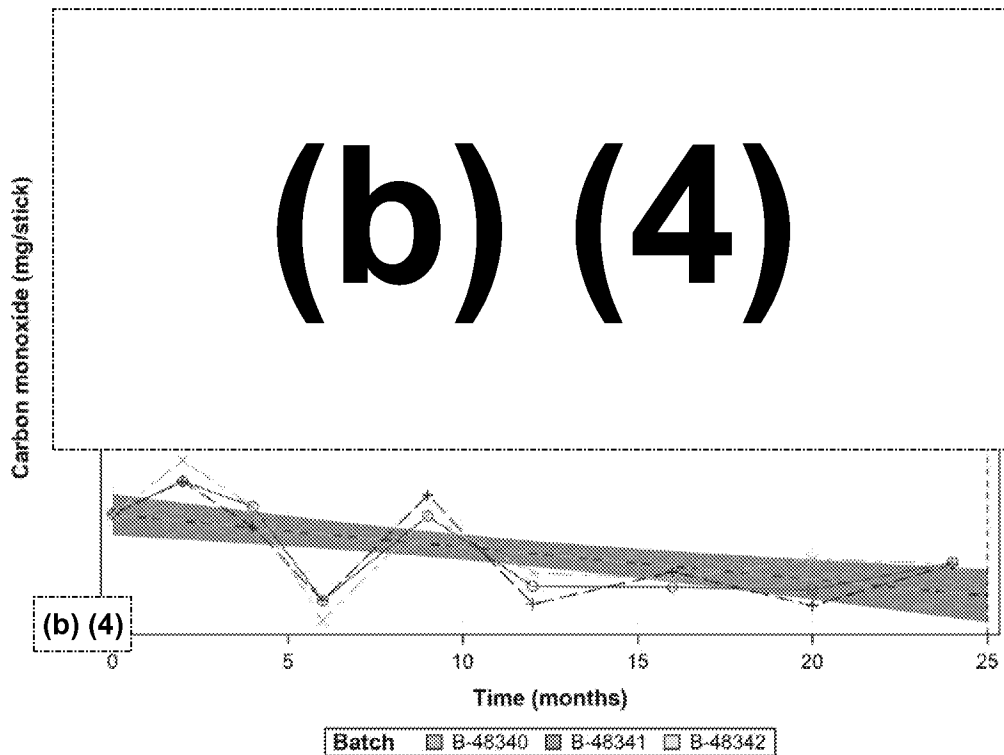


Figure 4 Evolution of Carbon monoxide for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% confidence interval for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95 percent confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.

7.3.1.5 Phenol for 22°C 60%RH

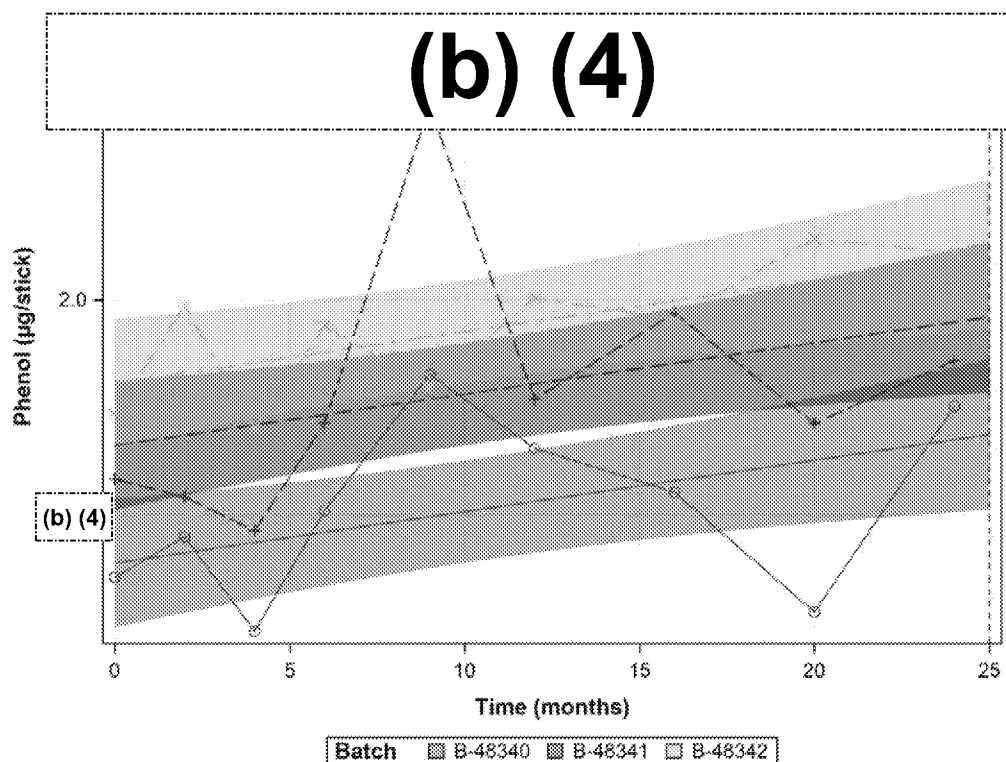


Figure 5 Evolution of Phenol for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% confidence interval for the regression

The best model accepted at the significance level of 0.25 has Different intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95 percent confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.3.1.6 Acrylamide for 22°C 60%RH

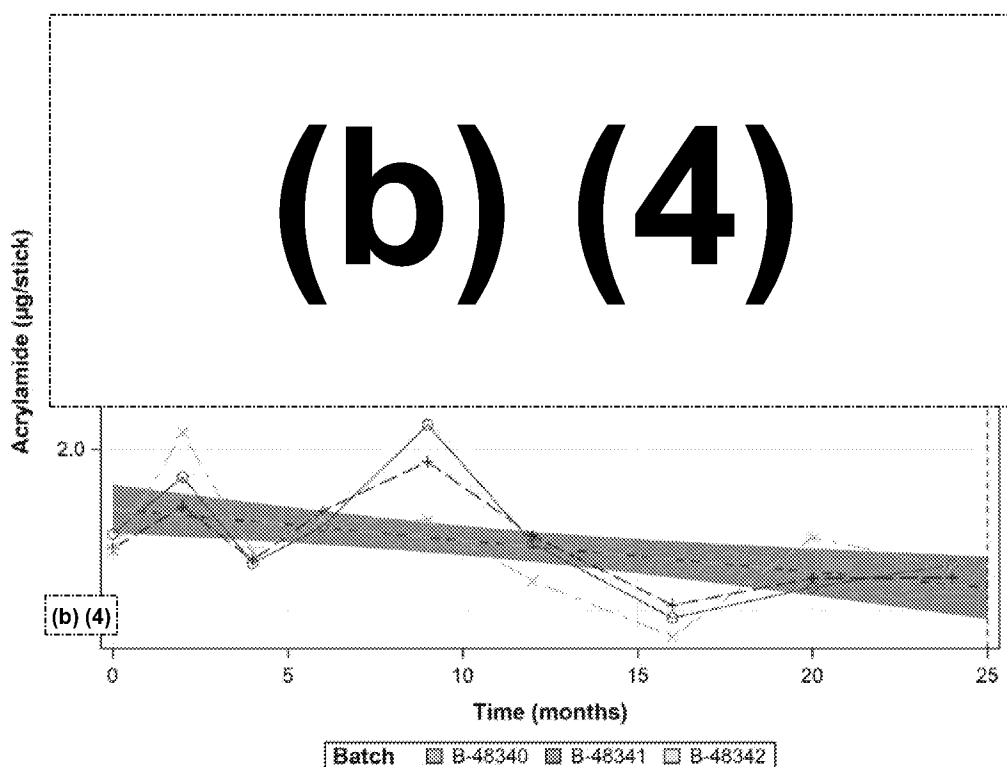


Figure 6 Evolution of Acrylamide for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% confidence interval for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95 percent confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.3.1.7 Formaldehyde for 22°C 60%RH

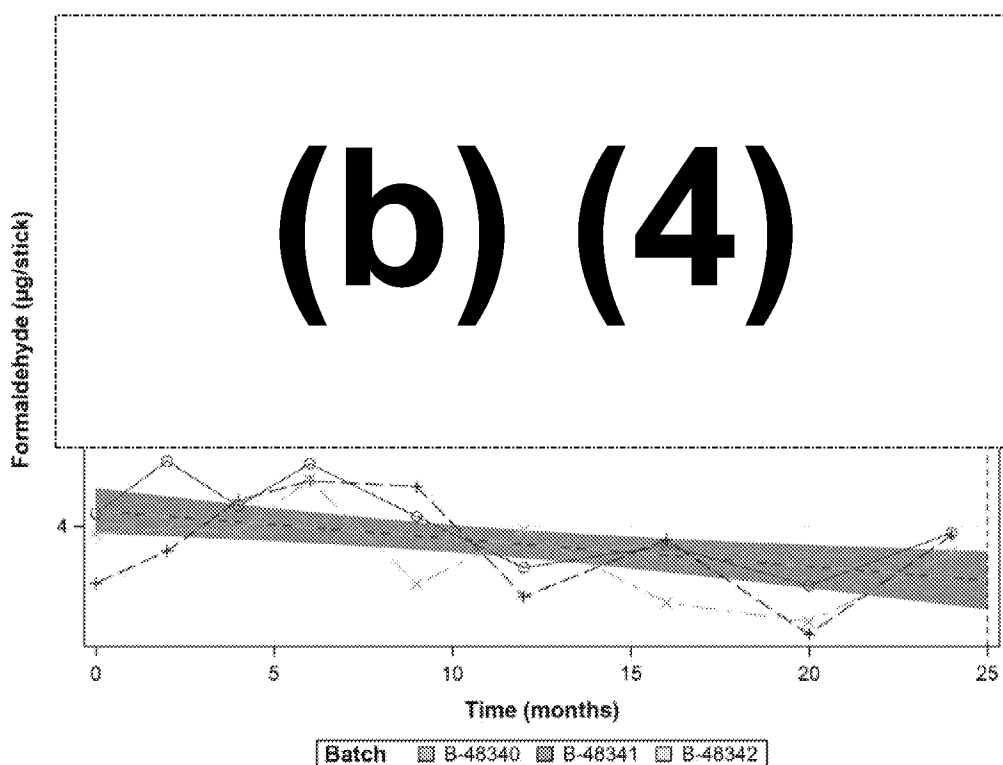


Figure 7 Evolution of Formaldehyde for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% confidence interval for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95 percent confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.3.1.8 1,3-Butadiene for 22°C 60%RH

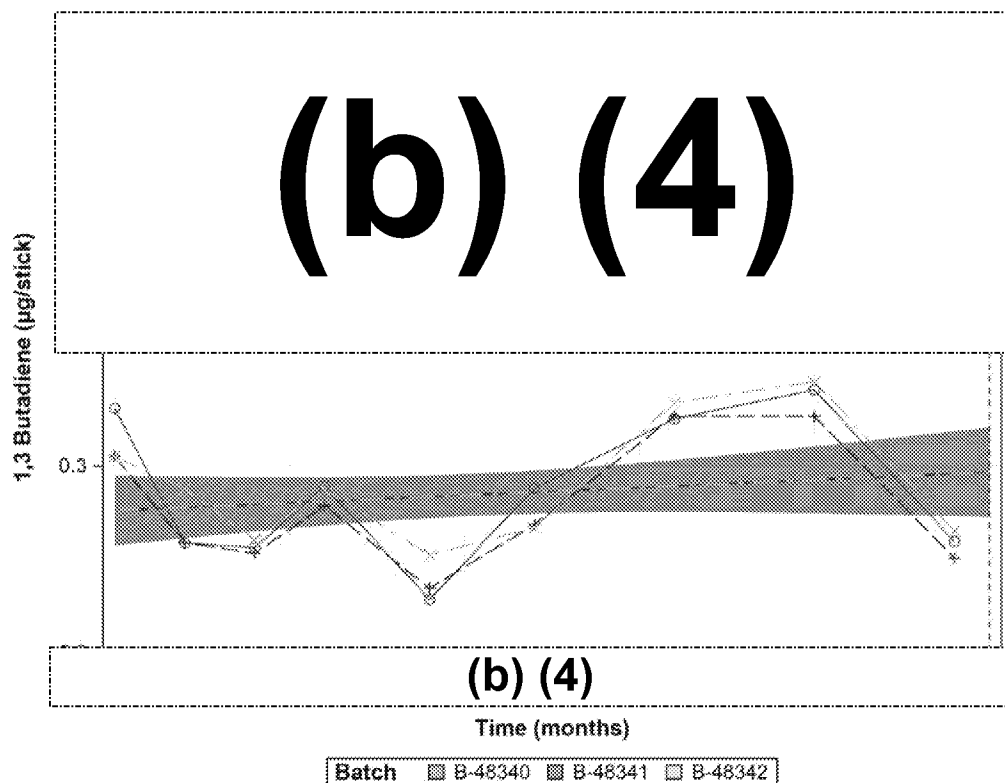


Figure 8 Evolution of 1,3-Butadiene for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% confidence interval for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95 percent confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.3.1.9 Benzene 22°C 60%RH

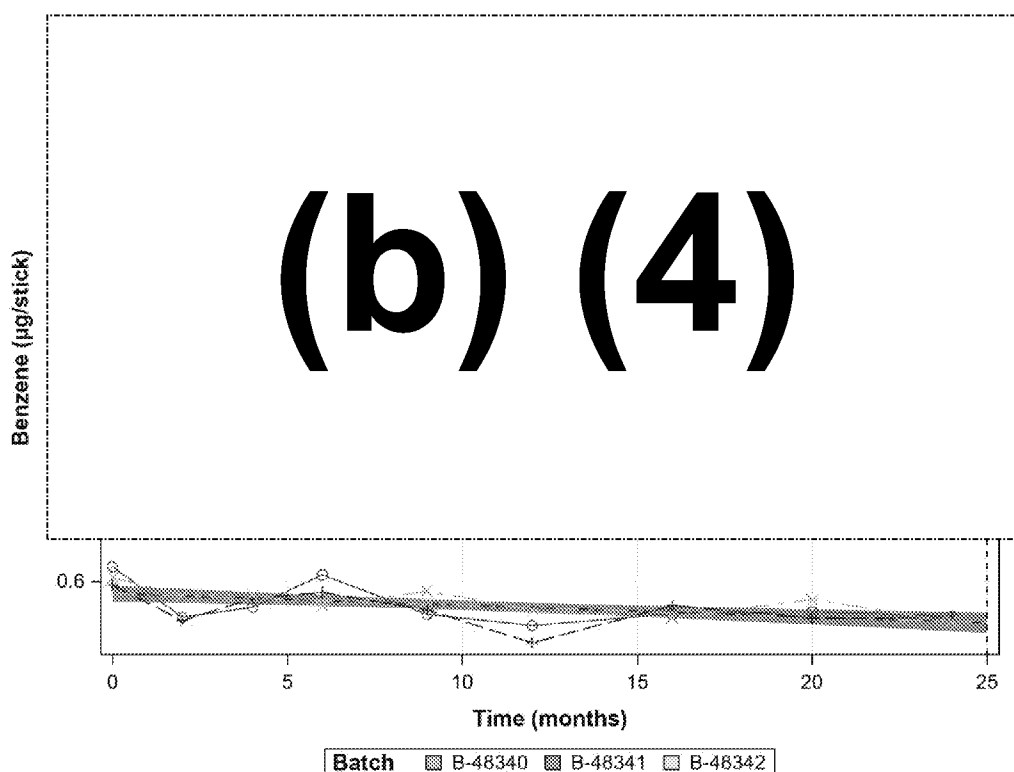


Figure 9 Evolution of Benzene for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% confidence interval for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95 percent confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.3.2 Physical Parameters Evaluation for 22°C 60%RH

(b) (4)



7.3.2.2 Tobacco Stick Weight 22°C 60%RH

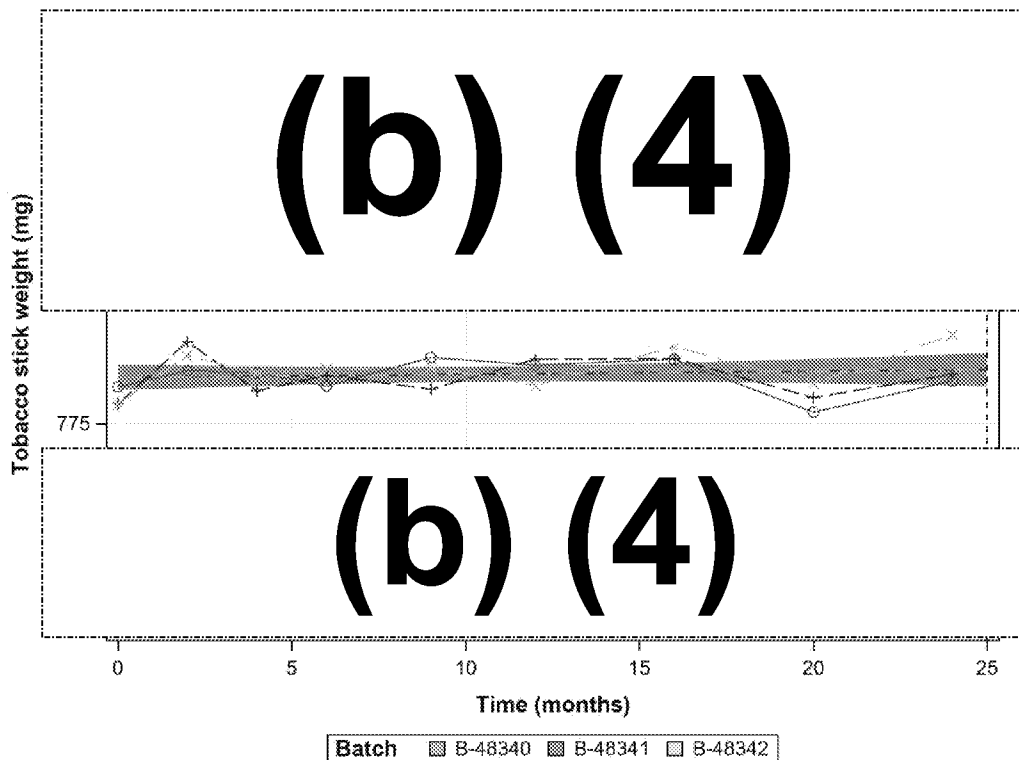


Figure 11 Evolution of Tobacco Stick weight for the 3 batches together with the specification levels, the linear regression of the 3 batches and the 95% confidence interval for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95 percent confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.3.3 Water Activity Evaluation for 22°C 60%RH

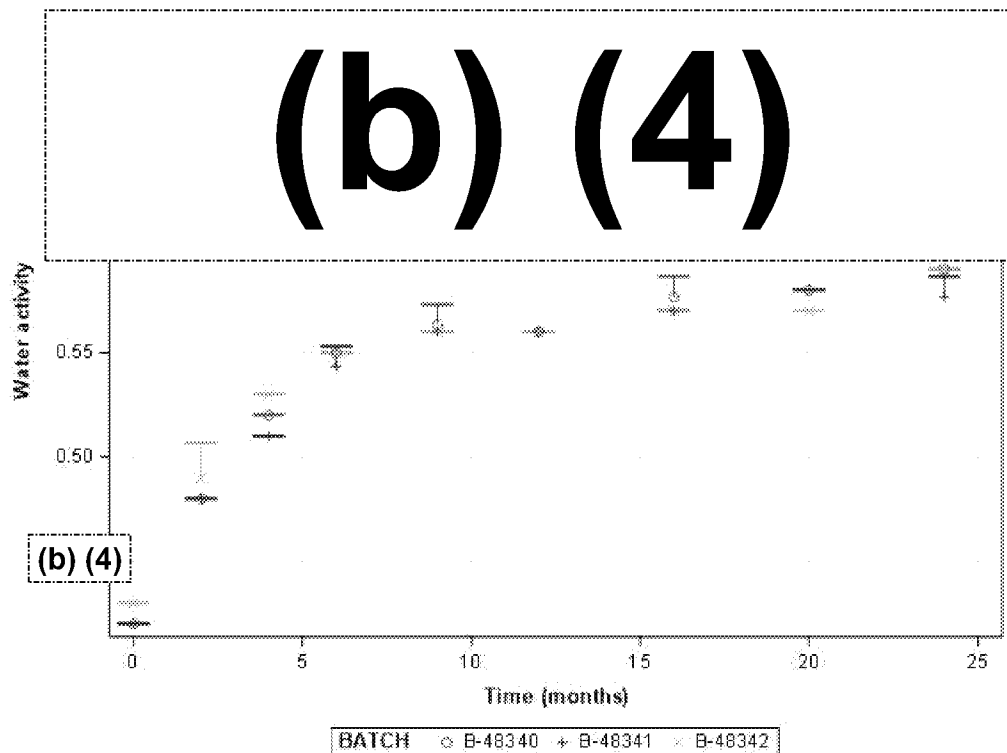


Figure 12 Evolution of Water activity for the 3 batches (mean value plus the 95% confidence intervals of the mean) together with the specification level

The mean values and the one sided upper 95% CIs limit did not exceed (b) (4)

(b) (4) Therefore, a shelf life of 24 months is acceptable.

7.3.4 Sensorial Evaluation for 22°C 60%RH

Sensorial evaluation results are described in details in a separate reports up to 12 months [8] and up to 24 months [9].

The three batches tested during this stability were relatively stable over time in 22°C 60%RH. (b) (4)

(b) (4) However, those changes do not seem to be linked with time and storage conditions as nothing consistent was observed.



7.3.5 Visual Evaluation for 22°C 60%RH

(b) (4)



(b) (4)



(b) (4)



(b) (4)

(b) (4)

(b) (4)



7.4 Results for Storage Condition 30°C 65% RH

The Table 6 and Table 7 contain for each batch and each tested parameter per time point the reported value (mean value), together with the upper and/or lower specification levels. Figure 18 to Figure 28 contain the reported value for the 3 batches together with the specification levels, the linear regression and the upper and lower 95% CI of the regression of the mean or the individual batches depending on the final model kept (model 1, model 2 or model 3). The CIs are illustrated on the figures by the shaded area.

For Water activity and **(b) (4)** the reported value with the one sided 95% CI is shown over time for the 3 batches.

The dashed red lines represent the specification limits. Whereas, the dashed blue line shows the time when the 95% CI crosses the specification or is automatically drawn at 25 months if the 95% CI crosses the specification after the study length of 24 months.

The graphs were created with x-axes above the 24 months of study duration, however this has no extrapolation purpose.

Table 6 Mean values for aerosol constituents for 3 batches T0 - T24 for 30°C 65% RH

PARAMETER	BATCH	LSL	USL	UNITS	T0	T2	T4	T6	T9	T12	T16	T20	T24
1,3 Butadiene	B-48340	(b) (4)		µg/stick	0.331	0.227	0.243	0.297	0.241	0.306	0.326	0.369	0.261
1,3 Butadiene	B-48341			µg/stick	0.305	0.240	0.246	0.297	0.260	0.272	0.324	0.378	0.256
1,3 Butadiene	B-48342			µg/stick	0.305	0.261	0.263	0.270	0.264	0.288	0.323	0.368	0.257
Acrylamide	B-48340			µg/stick	1.74	2.04	1.62	1.68	1.83	1.29	0.94	1.06	1.08
Acrylamide	B-48341			µg/stick	1.69	1.95	1.72	1.61	1.89	1.28	1.16	1.20	1.05
Acrylamide	B-48342			µg/stick	1.69	1.89	1.89	1.53	1.79	1.45	1.08	1.12	1.06
Benzene	B-48340			µg/stick	0.63	0.48	0.54	0.58	0.53	0.55	0.55	0.59	0.57
Benzene	B-48341			µg/stick	0.59	0.50	0.54	0.64	0.58	0.50	0.54	0.58	0.53
Benzene	B-48342			µg/stick	0.61	0.55	0.60	0.55	0.59	0.52	0.53	0.57	0.56
Carbon monoxide	B-48340			mg/stick	0.51	0.61	0.54	0.42	0.53	0.44	0.42	0.44	0.46
Carbon monoxide	B-48341			mg/stick	0.51	0.59	0.54	0.44	0.51	0.43	0.45	0.46	0.47
Carbon monoxide	B-48342			mg/stick	0.51	0.59	0.54	0.42	0.51	0.46	0.45	0.45	0.46
Formaldehyde	B-48340			µg/stick	4.127	4.103	3.992	4.348	4.084	3.549	3.684	2.980	4.005
Formaldehyde	B-48341			µg/stick	3.429	4.345	3.894	3.879	4.004	3.270	3.740	2.903	3.623
Formaldehyde	B-48342			µg/stick	3.926	4.654	4.489	4.274	4.871	4.323	3.864	3.075	4.030
Glycerin	B-48340			mg/stick	5.69	6.05	4.87	5.38	4.76	4.33	3.56	3.40	3.93
Glycerin	B-48341			mg/stick	5.52	6.15	5.09	5.38	4.72	4.07	4.39	3.75	3.66
Glycerin	B-48342			mg/stick	5.60	5.68	5.41	5.06	4.86	4.80	3.90	3.59	3.81



PARAMETER	BATCH	LSL	USL	UNITS	T0	T2	T4	T6	T9	T12	T16	T20	T24
Nicotine	B-48340	(b) (4)		mg/stick	1.27	1.34	1.17	1.19	1.24	1.23	1.10	1.03	1.20
Nicotine	B-48341			mg/stick	1.22	1.34	1.23	1.22	1.26	1.19	1.25	1.12	1.19
Nicotine	B-48342			mg/stick	1.23	1.27	1.27	1.15	1.26	1.33	1.19	1.06	1.16
Phenol	B-48340			µg/stick	1.36	1.52	1.45	1.80	1.85	1.63	1.26	1.25	1.64
Phenol	B-48341			µg/stick	1.58	1.76	1.76	2.07	2.31	1.67	2.08	1.83	1.83
Phenol	B-48342			µg/stick	1.74	1.65	1.99	1.88	2.50	2.34	1.95	1.69	1.88
Triacetin	B-48340			mg/stick	0.67	0.68	0.53	0.51	0.45	0.39	0.35	0.33	0.36
Triacetin	B-48341			mg/stick	0.63	0.62	0.50	0.47	0.41	0.34	0.37	0.31	0.30
Triacetin	B-48342			mg/stick	0.62	0.59	0.48	0.45	0.45	0.38	0.35	0.31	0.32

Table 7 Mean values for physical parameters and Water activity for 3 batches T0 – T24 for 30°C 65% RH

PARAMETER	BATCH	LSL	USL	UNITS	T0	T2	T4	T6	T9	T12	T16	T20	T24
(b) (4)				(b) (4)									
Tobacco stick weight	B-48340	(b) (4)		mg	782	788	781	786	790	790	802	780	788
Tobacco stick weight	B-48341			mg	779	783	787	784	790	783	789	769	789
Tobacco stick weight	B-48342			mg	779	787	788	786	790	781	793	774	783
Water activity	B-48340			N/A	0.42	0.54	0.59	0.62	0.64	0.63	0.65	0.65	0.65
Water activity	B-48341			N/A	0.42	0.55	0.59	0.62	0.64	0.62	0.65	0.65	0.65
Water activity	B-48342			N/A	0.43	0.54	0.59	0.63	0.64	0.64	0.65	0.65	0.65



7.4.1 Aerosol Constituents Evaluation for 30°C 65%RH

7.4.1.1 Nicotine for 30°C 65%RH

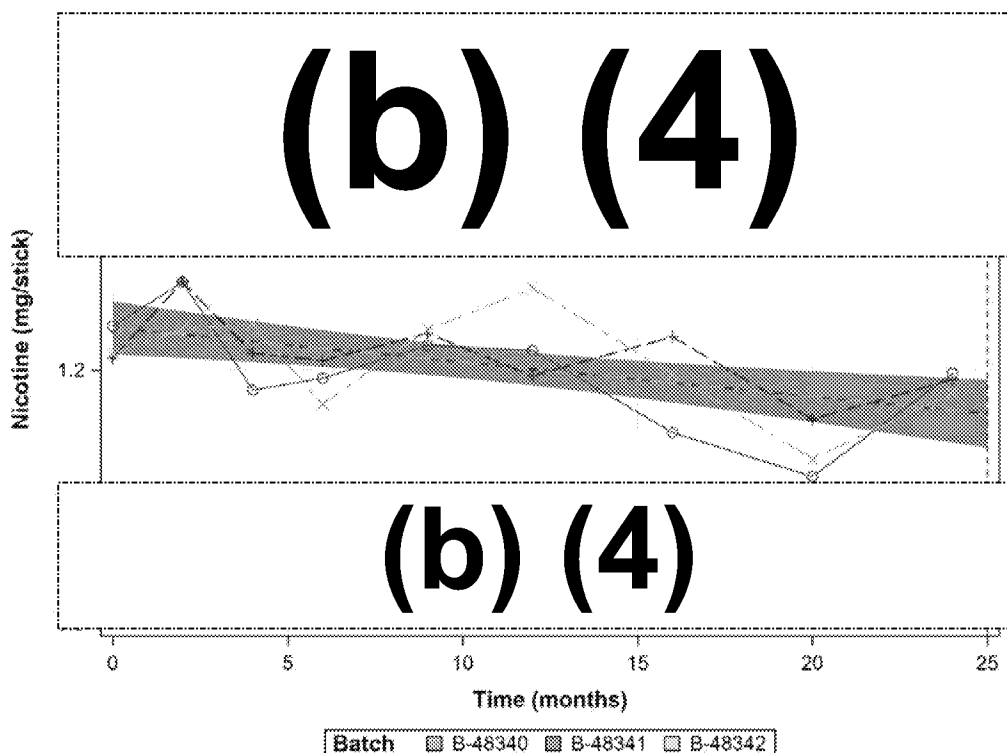


Figure 18 Evolution of Nicotine for the 3 batches together with the specification levels, the linear regression of the 3 batches and the 95% confidence interval for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95 percent confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.4.1.2 Glycerin for 30°C 65%RH

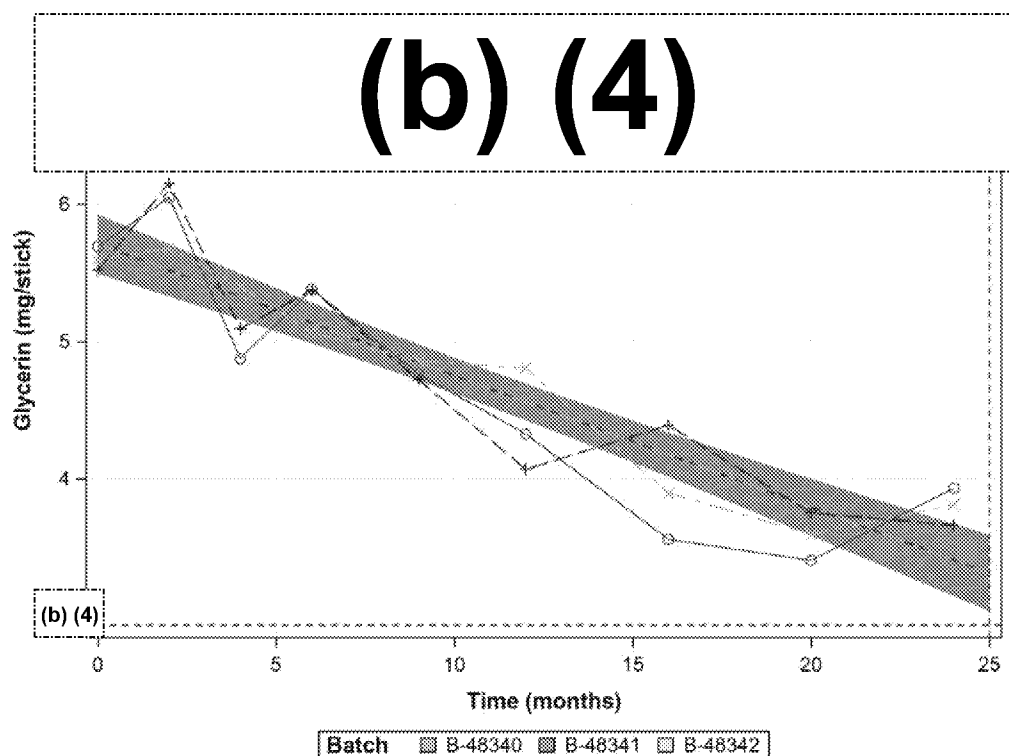


Figure 19 Evolution of Glycerin for the 3 batches together with the specification levels, the linear regression of the 3 batches and the 95% confidence interval for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95 percent confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.4.1.3 Triacetin for 30°C 65%RH

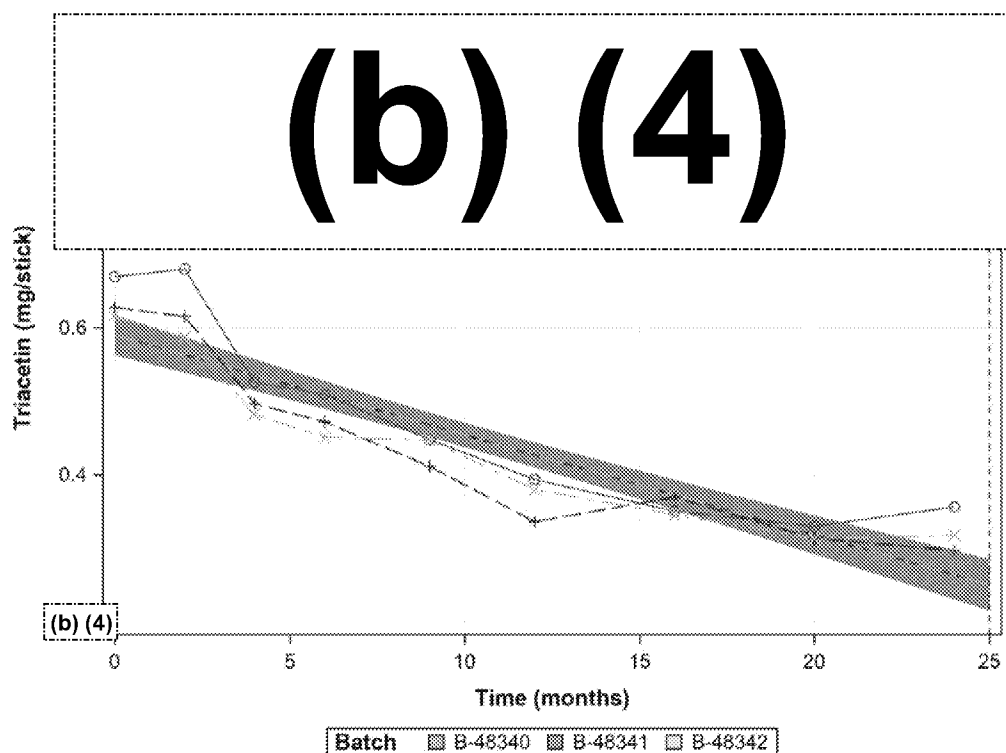


Figure 20 Evolution of Triacetin for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% confidence interval for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95 percent confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.

7.4.1.4 Carbon monoxide for 30°C 65%RH

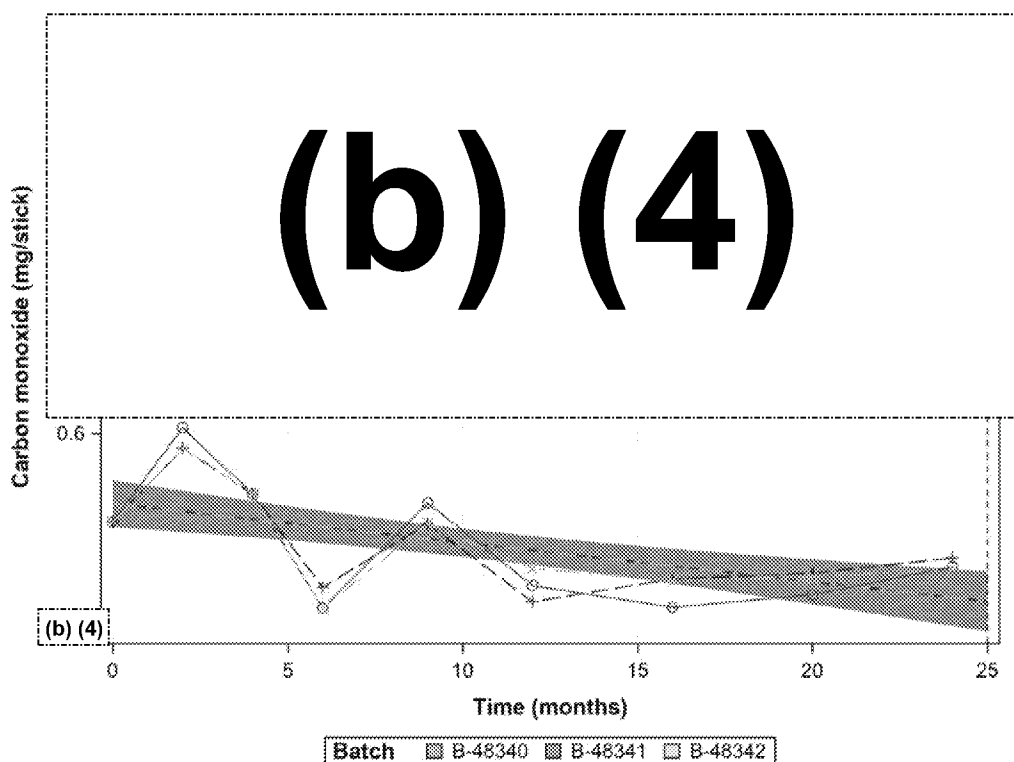


Figure 21 Evolution of Carbon monoxide for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% confidence interval for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95 percent confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.

7.4.1.5 Phenol for 30°C 65%RH

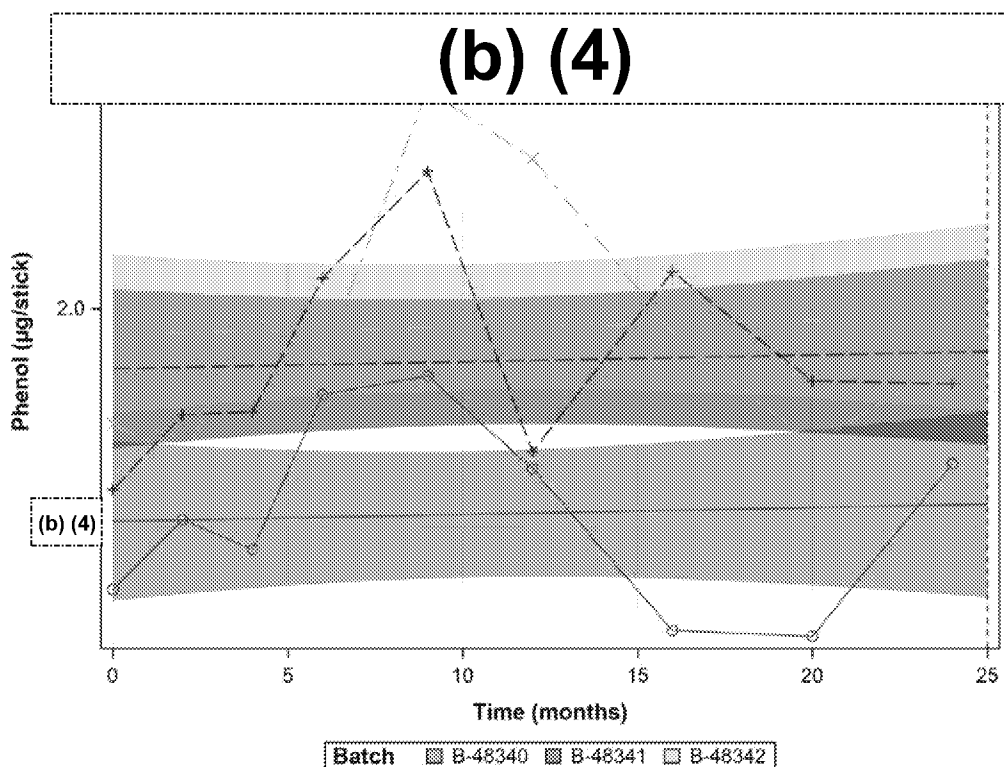


Figure 22 Evolution of Phenol for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% confidence interval for the regression

The best model accepted at the significance level of 0.25 has Different intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95 percent confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.4.1.6 Acrylamide for 30°C 65%RH

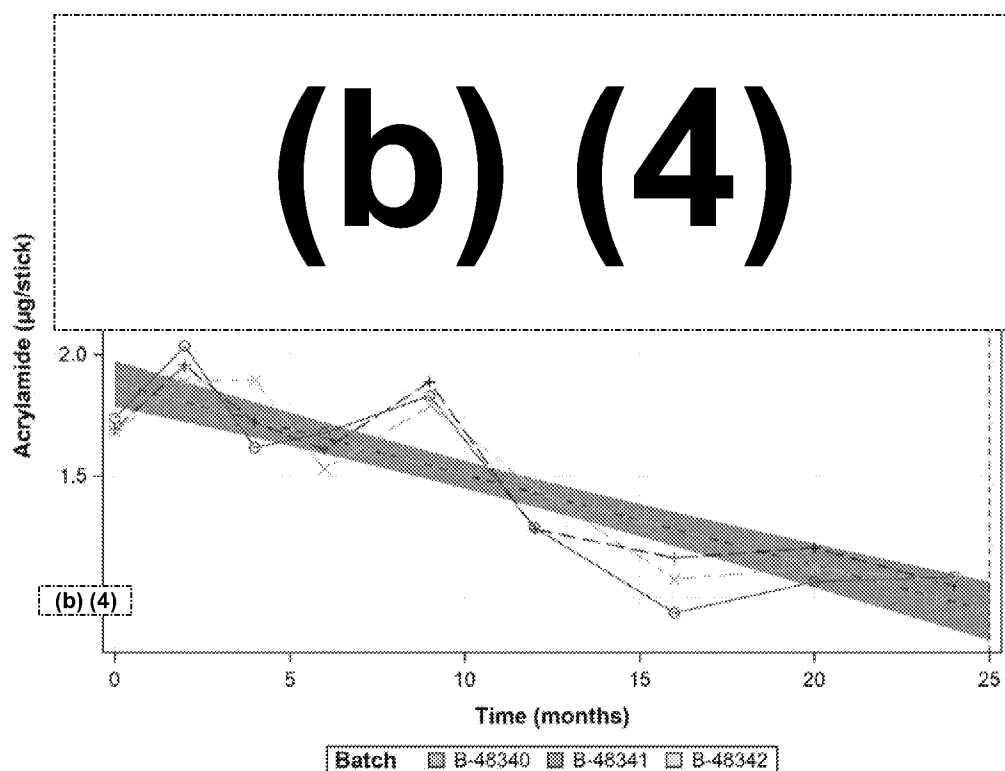


Figure 23 Evolution of Acrylamide for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% confidence interval for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95 percent confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.4.1.7 Formaldehyde for 30°C 65%RH

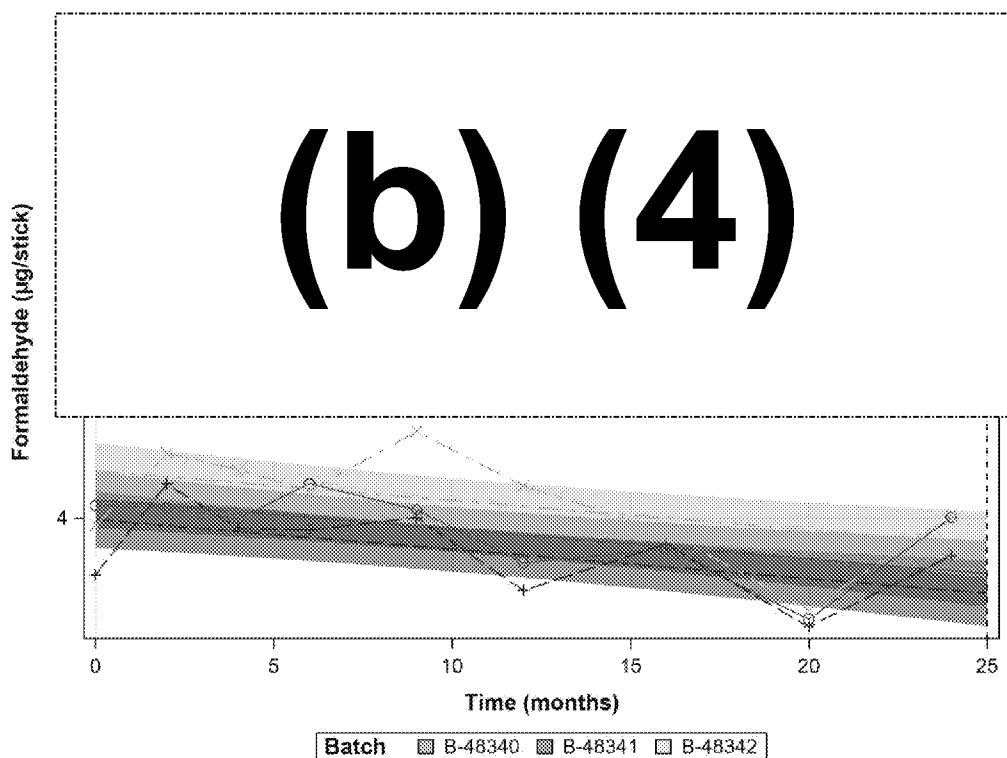


Figure 24 Evolution of Formaldehyde for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% confidence interval for the regression

The best model accepted at the significance level of 0.25 has Different intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95 percent confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.4.1.8 1,3-Butadiene for 30°C 65%RH

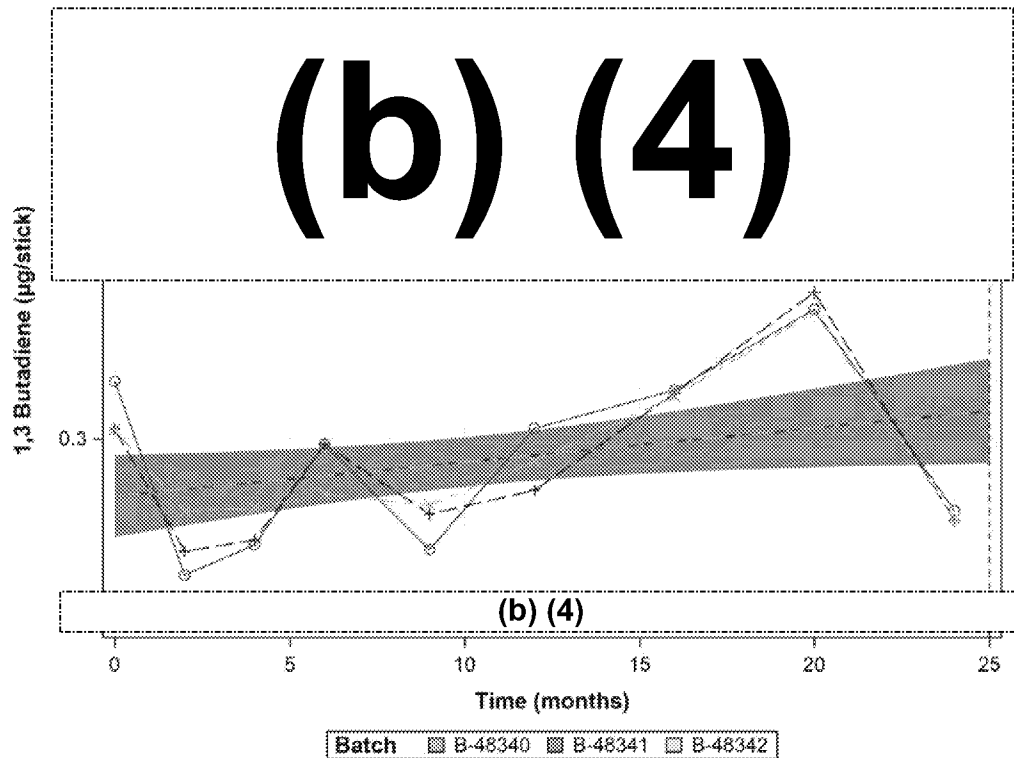


Figure 25 Evolution of 1,3-Butadiene for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% confidence interval for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95 percent confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.4.1.9 Benzene for 30°C 65%RH

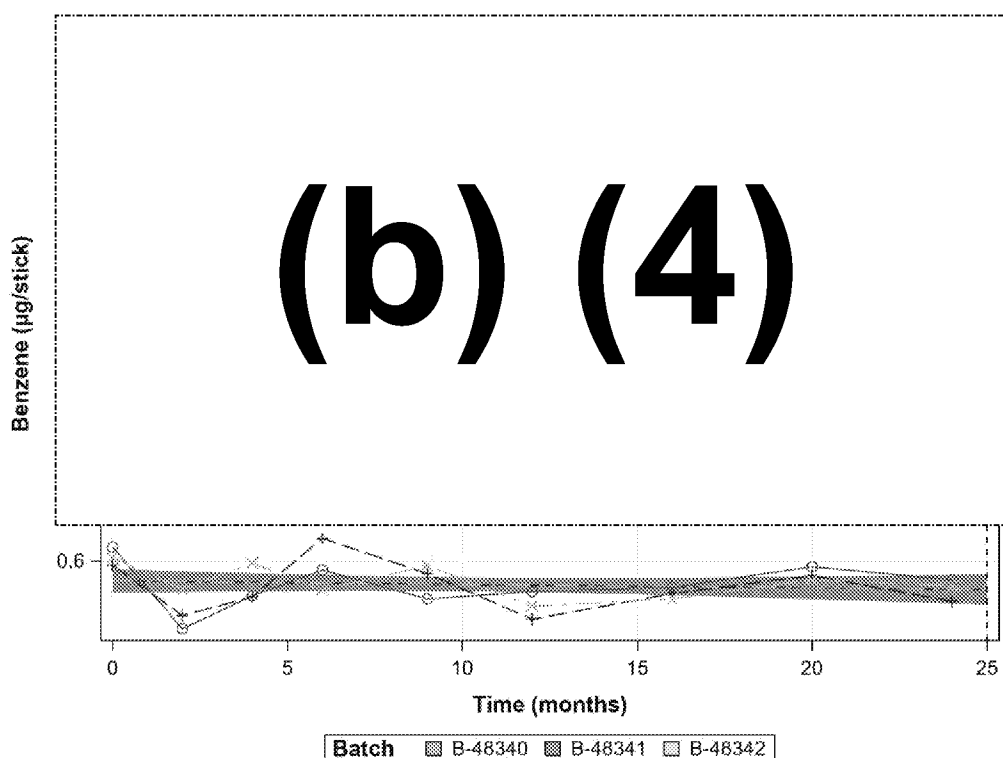


Figure 26 Evolution of Benzene for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% confidence interval for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95 percent confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.4.2 Physical Parameters Evaluation for 30°C 65%RH

(b) (4)



7.4.2.2 Tobacco Stick Weight for 30°C 65%RH

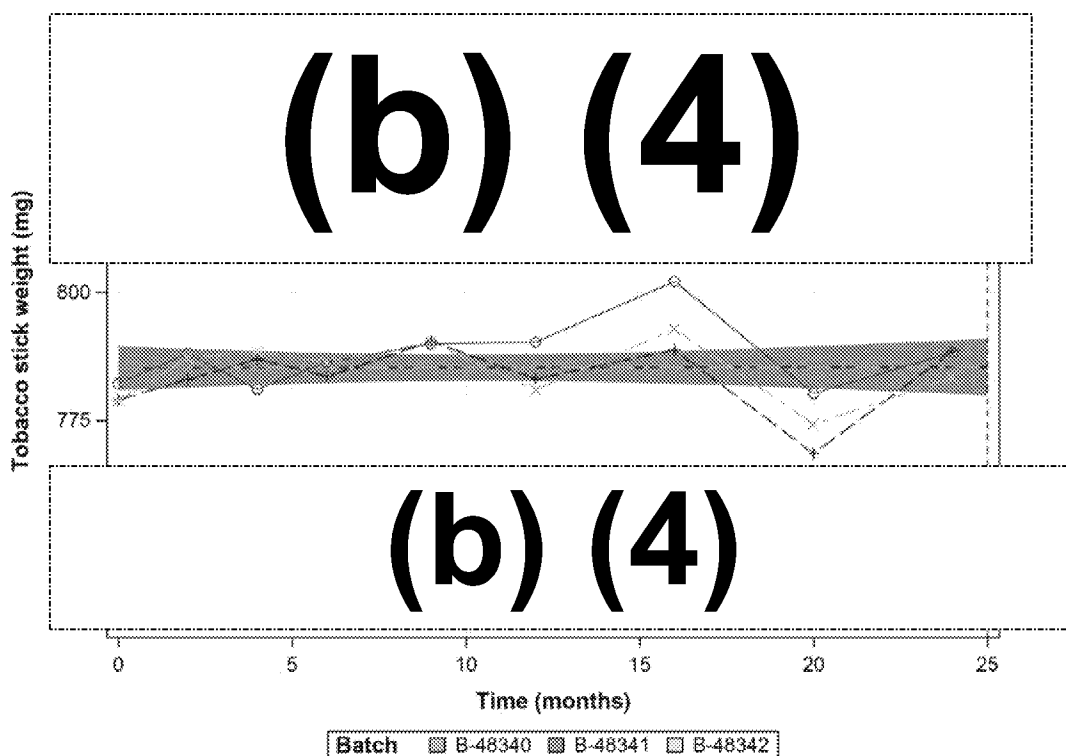


Figure 28 Evolution of Tobacco Stick weight for the 3 batches together with the specification levels, the linear regression of the 3 batches and the 95% confidence interval for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95 percent confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.4.3 Water Activity Evaluation for 30°C 65%RH

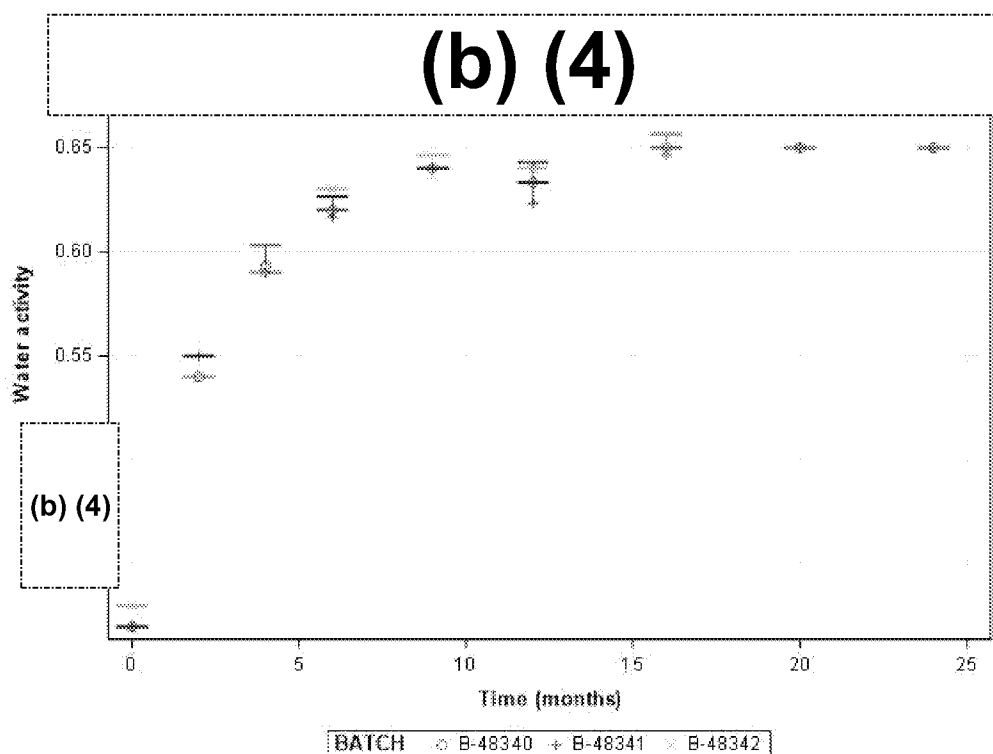


Figure 29 Evolution of Water activity for the 3 batches (mean value plus the 95% confidence intervals of the mean) together with the specification level

The mean values and the one sided upper 95% CIs limit did not exceed

(b) (4)

(b) (4) Therefore, a shelf life of 24 months is acceptable.

7.4.4 Sensorial Evaluation for 30°C 65%RH

Sensorial evaluation results are described in details in a separate reports up to 12 months [8] and up to 24 months [9].

The three batches tested during this stability were relatively stable over time in 30°C 65%RH. **(b) (4)**

(b) (4) However, those changes do not seem to be linked with time and storage conditions as nothing consistent was observed. A slight increase in Resistance to Draw (RTD) of the tobacco stick in the device was observed in the first few months and then tended to remain stable over time.



7.4.5 Visual Evaluation for 30°C 65%RH

(b) (4)



(b) (4)



(b) (4)

(b) (4)



8 Stability Assessment

Storage condition 22°C 60%RH

All tested aerosol constituents, physical parameters and Water activity remained within the acceptance criteria for 24 months.

From a sensorial point of view only minor changes could be observed over the 24 months storage.

(b) (4)

Storage condition 30°C 65%RH

In hot and humid condition, all tested aerosol constituents, physical parameters and Water activity remained within the acceptance criteria for 24 months.

From a sensorial point of view only minor changes could be observed over the 24 months storage.

(b) (4)



Table 8 Summary of the shelf life met per parameters for the storage conditions 22°C 60%RH and 30°C 65%RH

PARAMETER	22°C 60%RH	30°C 65%RH
	CRITERIA MET FOR SHELF LIFE OF: (months)	CRITERIA MET FOR SHELF LIFE OF: (months)
Nicotine	24	24
Glycerin	24	24
Triacetin	24	24
Carbon monoxide	24	24
Phenol	24	24
Acrylamide	24	24
Formaldehyde	24	24
1,3-butadiene	24	24
Benzene	24	24
(b) (4)		
Tobacco stick weight	24	24
Water activity	24	24
Visual quality	see observations in Chapter 7.3.5	see observations in Chapter 7.4.5
Sensory (QDP)	see observations in Chapter 7.3.4	see observations in Chapter 7.4.4

9 Impact Assessment of Specification Change

The specifications used for the assessment of the aerosol results were revised from Version 3.0 of 11-Oct-2017 [5] to Version 5.0 of 09-Jul-2019 [13] during the follow-up stability study (see Table 9). The stability study was evaluated versus the specifications used in the study protocol. However, the impact of those changes on the estimated shelf life period were assessed and are reported in Table 9.

The change in the specifications has no impact on the estimated shelf life period for the aerosol constituents.



Table 9 Summary of Equivalence Specifications and Corresponding Shelf Life Period

		Equivalence specifications Version 3.0, 11-Oct-2017 (Old)				Equivalence specifications Version 5.0, 09-Jul-2019 (New)			
Parameter	Unit	Limits		Criteria met for Shelf life of: (months)		Limits		Criteria met for Shelf life of: (months)	
		Lower	Upper	22°C 60%RH	30°C 65%RH	Lower	Upper	22°C 60%RH	30°C 65%RH
Nicotine	mg/stick	(b) (4)	(b) (4)	24	24	(b) (4)	(b) (4)	24	24
Glycerin	mg/stick			24	24			24	24
CO	mg/stick			24	24			24	24
Acrylamide	µg/stick			24	24			24	24
Phenol	µg/stick			24	24			24	24
Triacetin	mg/stick			24	24			24	24
1,3-butadiene	µg/stick			24	24			24	24
Benzene	µg/stick			24	24			24	24
Formaldehyde	µg/stick			24	24			24	24
Water activity	N/A			24	24			24	24



10 Related Documents

- [1] P1 THS 2 2 STABILITY STUDY REPORT STAB-2017_P1_R_1_signed.pdf
(b) (4)
- [2] PMI Stability Study Program THS2.2.docx, V1, 06-Oct-2017
(b) (4)
- [3] P1 THS 2 2 STABILITY STUDY PROTOCOL STAB-2017_P1_R_1 STAB-2017_P1_M_2 STAB-2017_P1_M_3_signed.pdf
(b) (4)
- [4] P1 THS 2 2 STABILITY STUDY FOLLOW UP PROTOCOL STAB-2017_P1_R_1 STAB-2017_P1_M_2 STAB-2017_P1_M_3_signed.pdf
(b) (4)
- [5] Platform 1 Equivalence Specification for Aerosol Endpoints Generated under Health Canada Intense Regime, Donatien Tabin Djoko, V3.0, 11-Oct-2017
(b) (4)
- [6] P1 Product specifications report, Pedro Campelos, V1.0, 16-Mar-2016
- [7] DII C3.2 Batch Release Specification Report, V5.0, Mirko Minzoni, 02-Oct-2017
- [8] P1 - THS / THD 2.4 - A02 / SEN / P1_PDev_EXPR_SS_066_2018_P1 MRTP US Regular T12
(b) (4)
- [9] P1 - THS / THD 2.4 - A02 / SEN / P1_PDev_EXPR_SS_065_2019 P1 Stability MRTP US Regular T24
(b) (4)
- [10] Investigation results STAB-2017_P1_R_1 T0_signed.pdf
(b) (4)
- [11] PMI-RRP-FOR-111546_STAB-2017_P1_R_1_OOT Phenol_T9_signed.pdf
(b) (4)



- [12] RD_STBLT_799980_THS_THS 2.2
STAB-2017_P1_R_1_OOT investigation_Formaldehyde_T24
1.0,CURRENT

(b) (4)

- [13] Platform 1 equivalence specification for aerosol endpoints generated under health
canada intense regime, Donatien Tabin Djoko, V5.0, 09-Jul-2019

(b) (4)

11 Reference Documents

- [14] ISO 3402:1999 Tobacco and tobacco products -- Atmosphere for conditioning and testing
- [15] WHO Stability testing of active pharmaceutical ingredients and finished pharmaceutical products
- [16] ICH Q1(E) Evaluation of Stability Data
- [17] ISO 20778:2018 Cigarettes -- Routine analytical cigarette smoking machine -- Definitions and standard conditions with an intense smoking regime

12 Change Management Log

Version N°	Detailed Description of change (including reason for change)
3.0	Minor change to correct typo error in version 2.0 (Header and page 1)
2.0	Images' format has been changed for the Figures' listed below to make them readable in pdf format in R3 Water Activity: Figure 12 and 29 (b) (4)
1.0	Original Issue



13 Review and Approval

This document has been approved using electronic signatures. Refer to the signature page and/or approval workflow for the signatory names, dates and functions.

14 Definitions and Abbreviations

Abbreviation	Definition
CAPA	Corrective Action Preventive Action
CI	Confidence Interval
CO	Carbon Monoxide
CSVQI	Client Sensitive Visual Quality Index
CVQA	Central Visual Quality Audit
DCR	Design Change Request
EDMS	Electronic Document Management System
FOR	Form
GC-MS	Gas Chromatography Mass Spectrometry
HAT	Hollow Acetate Tube
ICH	International Council for Harmonisation
ID number	Identification number
ISO	International Organization for Standardization
(b) (4)	
LSL	Lower Shelf Life specification limit
n	Number of Determinations
NC	Non-conformity
OOT	Out of Trend
P1	Platform 1
PMI	Philip Morris International
PDIMS	Product Development Information Management System



Abbreviation	Definition
PMMTB	Philip Morris Manufacturing & Technology Bologna (Training Center)
PMPSA	Philip Morris Products Société Anonyme
PO	Purchase Order
QA	Quality Audit
QDP	Quantitative Descriptive Profile
RDLIMS	Research Development Laboratory Information Management System
R&D	Research and Development
RH	Relative Humidity
RRP	Reduced Risk Products
SDMS	Scientific Data Management System
SEC	Sensory Evaluation Center
SOP	Standard Operating Procedure
STD	Standard Deviation
THS	Tobacco Heating System
TO	Testing Order
USL	Upper Shelf Life specification limit
UPLC-MS/MS	Ultra Performance Liquid Chromatography tandem Mass Spectrometry
VQA	Visual Quality Analysis
WHO	World Health Organization
WKI	Work Instruction



15 Appendices

15.1 Storage Locations

Storage condition: 22°C 60%RH		Storage condition: 30°C 65%RH	
PMI ID storage location	Period	PMI ID storage location	Period
T1381	From 10-Nov-2017 until 30-Nov-2019	6327	From 10-Nov-2017 until 28-Nov-2017
		6325	From 28-Nov-2017 until 08-Nov-2018
		6323	From 08-Nov-2018 until 09-Nov-2018
		6325	From 09-Nov-2018 until 30-Nov-2019



15.2 Analyses Dates per Time Point

Time Point	Analysis Type	Beginning of the Study (T0) / Sample Pull Out Day from the Storage Location (T2-T24) (1)	Conditioning Start Date (2)	Analyses Start Date (3)	Analysis End Date (4)
0	Aerosol chemistry	10-Nov-2017	13-Nov-17	16-Nov-17	29-Nov-17
	Physical		21-Nov-17	23-Nov-17	27-Nov-17
	Sensory		16-Nov-17	20-Nov-17	23-Nov-17
	Visual inspection		N/A	17-Nov-17	17-Nov-17
	Water activity		16-Nov-17	20-Nov-17	29-Nov-17
2	Aerosol chemistry	11-Jan-18	12-Jan-18	17-Jan-18	2-Feb-18
	Physical	11-Jan-18	22-Jan-18	23-Jan-18	24-Jan-17
	Sensory	11-Jan-18	12-Jan-18	15-Jan-18	25-Jan-18
	Visual inspection	11-Jan-18	N/A	22-Jan-17	24-Jan-17
	Water activity	12-Jan-18	12-Jan-18	15-Jan-18	17-Jan-17
4	Aerosol chemistry	12-Mar-18	12-Mar-18	15-Mar-18	23-Mar-18
	Physical	12-Mar-18	19-Mar-18	22-Mar-18	27-Mar-18
	Sensory	12-Mar-18	16-Mar-18	19-Mar-18	29-Mar-18
	Visual inspection	12-Mar-18	N/A	13-Mar-18	13-Mar-18
	Water activity	13-Mar-18	13-Mar-18	16-Mar-18	27-Mar-18
6	Aerosol chemistry	14-May-18	14-May-18	17-May-18	25-May-18
	Physical	14-May-18	28-May-18	31-May-18	31-May-18
	Sensory	14-May-18	24-May-18	28-May-18	6-Jun-18
	Visual inspection	14-May-18	N/A	17-May-18	17-May-18
	Water activity	14-May-18	15-May-18	17-May-18	24-May-18
9	Aerosol chemistry	13-Aug-18	13-Aug-18	15-Aug-18	27-Aug-18
	Physical	13-Aug-18	17-Aug-18	21-Aug-18	23-Aug-18
	Sensory	13-Aug-18	24-Aug-18	27-Aug-18	5-Sep-18
	Visual inspection	13-Aug-18	N/A	15-Aug-18	21-Aug-18
	Water activity	14-Aug-18	14-Aug-18	17-Aug-18	20-Aug-18
12	Aerosol chemistry	12-Nov-18	12-Nov-18	21-Nov-18	29-Nov-18
	Physical	12-Nov-18	19-Nov-18	20-Nov-18	21-Nov-18
	Sensory	12-Nov-18	23-Nov-18	26-Nov-18	5-Dec-18
	Visual inspection	12-Nov-18	N/A	14-Nov-18	14-Nov-18
	Water activity	13-Nov-18	13-Nov-18	16-Nov-18	19-Nov-18
16	Aerosol chemistry	14-Mar-2019	15-Mar-2019	20-Mar-2019	12-Apr-2019
	Physical	14-Mar-2019	15-Mar-2019	18-Mar-2019	19-Mar-2019
	Sensory	14-Mar-2019	19-Mar-2019	20-Mar-2019	28-Mar-2019



Time Point	Analysis Type	Beginning of the Study (T0) / Sample Pull Out Day from the Storage Location (T2-T24) (1)	Conditioning Start Date (2)	Analyses Start Date (3)	Analysis End Date (4)
16	Visual inspection	14-Mar-2019	N/A	19-Mar-2019	20-Mar-2019
	Water activity	15-Mar-2019	15-Mar-2019	18-Mar-2019	19-Mar-2019
20	Aerosol chemistry	11-Jul-2019	11-Jul-2019	15-Jul-2019	22-Jul-2019
	Physical	11-Jul-2019	15-Jul-2019	18-Jul-2019	22-Jul-2019
	Sensory	11-Jul-2019	19-Jul-2019	12-Aug-2019	15-Aug-2019
	Visual inspection	11-Jul-2019	N/A	17-Jul-2019	18-Jul-2019
	Water activity	12-Jul-2019	12-Jul-2019	15-Jul-2019	16-Jul-2019
24	Aerosol chemistry	11-Nov-2019	11-Nov-2019	14-Nov-2019	19-Dec-2019
	Physical	11-Nov-2019	13-Nov-2019	14-Nov-2019	19-Nov-2019
	Sensory	11-Nov-2019	22-Nov-2019	25-Nov-2019	04-Dec-2019
	Visual inspection	11-Nov-2019	N/A	15-Nov-2019	15-Nov-2019
	Water activity	12-Nov-2019	12-Nov-2019	15-Nov-2019	18-Nov-2019

(1) – Beginning of the study for T0: date when samples were placed in the conditioning room and the climatic chamber for the storage. Samples for T0 were kept in conditioning room (22°C 60%RH) for the analyses. Sample Pull Out Day from the Storage Location for T2-T24: dates when samples were taken out from the storage location for analyses.

(2) - Date of beginning of conditioning. For Water activity date of reception.

(3) - First day of analyses

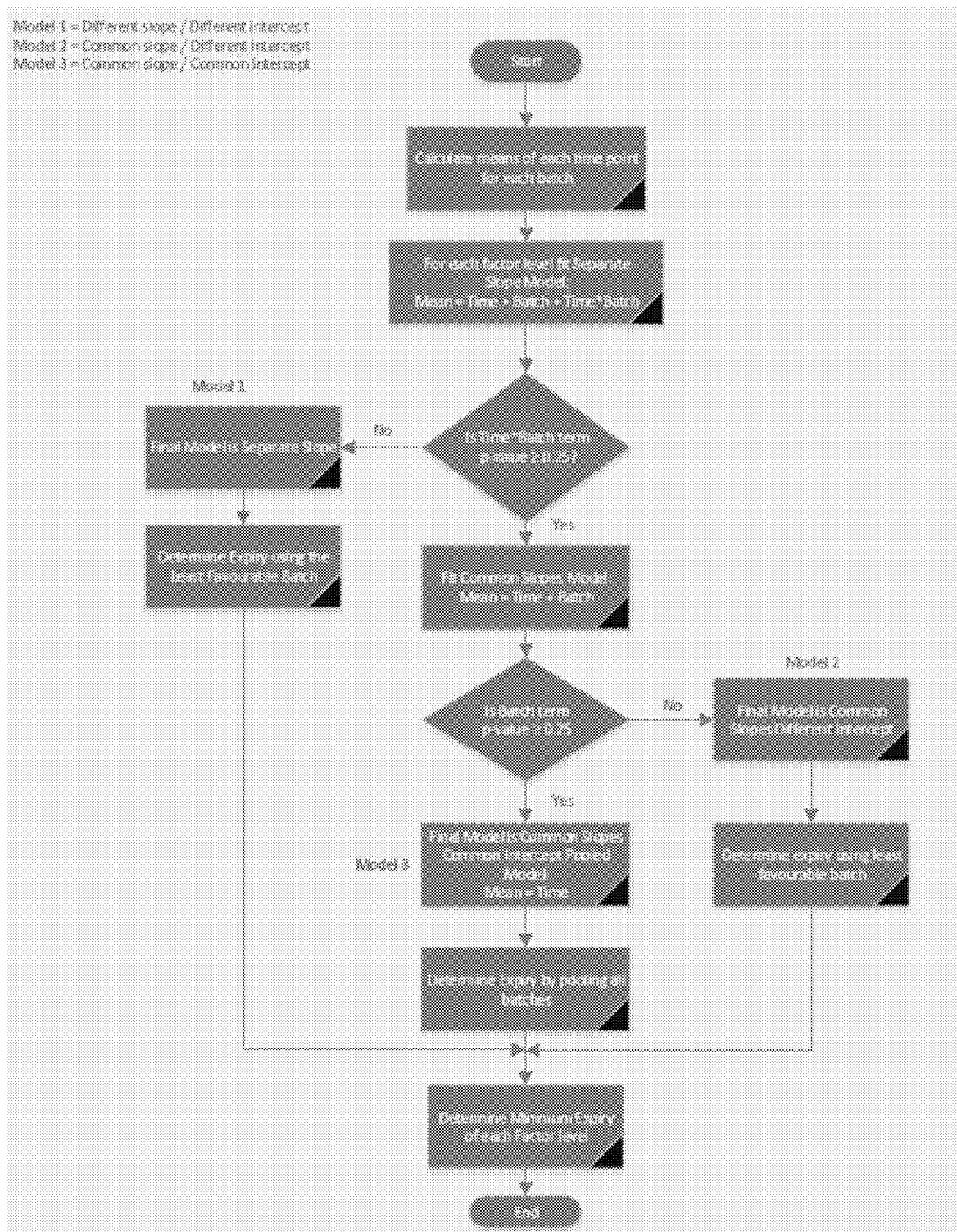
(4) - Date when results were released by the laboratory or last day of the sensorial evaluation



15.3 Sample Traceability Matrix

Time Point	Testing Order	RDLIMS Project Number	(b) (4) report number for Water activity
T0	TO-16482, TO-16463	RLS-ZRH-2017-1225	17-25232
T2	TO-16665, TO-16654	RLS-ZRH-2018-20	18-00745
T4	TO-17734, TO-17735	RLS-ZRH-2018-275	18-05494
T6	TO-18278, TO-18279	RLS-ZRH-2018-475	18-09897
T9	TO-18994, TO-19270	RLS-ZRH-2018-710	18-17053
T12	TO-20149, TO-20265	RLS-ZRH-2018-869	18-25274
T16	TO-21209, TO-21253	RLS-ZRH-2019-110	19-05868
T20	TO-22342, TO-22434	RLS-ZRH-2019-304	19-14432
T24	TO-23231, TO-23382	RLS-ZRH-2019-468	19-24282

15.4 Statistical Analyses Flowchart





15.5 Tabulated Results and Summary Statistics for 22°C 60%RH

CONDITION	VARIABLE	BATCH	Time point	LSE	USL	UNF	N	Mean	Std	CV	Lower 95%CI	Upper 95%CI
22°C/60%RH	1,3 Butadiene	B-48340	T0			µg/stick	6	0.331	0.050	15.085		
22°C/60%RH	1,3 Butadiene	B-48340	T2			µg/stick	4	0.259	0.007	2.869		
22°C/60%RH	1,3 Butadiene	B-48340	T4			µg/stick	4	0.256	0.017	6.803		
22°C/60%RH	1,3 Butadiene	B-48340	T6			µg/stick	4	0.289	0.027	9.503		
22°C/60%RH	1,3 Butadiene	B-48340	T9			µg/stick	4	0.228	0.010	4.282		
22°C/60%RH	1,3 Butadiene	B-48340	T12			µg/stick	6	0.288	0.018	6.111		
22°C/60%RH	1,3 Butadiene	B-48340	T16			µg/stick	6	0.325	0.027	8.314		
22°C/60%RH	1,3 Butadiene	B-48340	T20			µg/stick	6	0.341	0.027	7.819		
22°C/60%RH	1,3 Butadiene	B-48340	T24			µg/stick	6	0.259	0.022	8.596		
22°C/60%RH	1,3 Butadiene	B-48341	T0			µg/stick	6	0.305	0.035	11.518		
22°C/60%RH	1,3 Butadiene	B-48341	T2			µg/stick	4	0.259	0.025	9.841		
22°C/60%RH	1,3 Butadiene	B-48341	T4			µg/stick	4	0.253	0.024	9.541		
22°C/60%RH	1,3 Butadiene	B-48341	T6			µg/stick	4	0.279	0.023	8.083		
22°C/60%RH	1,3 Butadiene	B-48341	T9			µg/stick	4	0.234	0.025	10.836		
22°C/60%RH	1,3 Butadiene	B-48341	T12			µg/stick	6	0.269	0.014	5.338		
22°C/60%RH	1,3 Butadiene	B-48341	T16			µg/stick	6	0.327	0.020	6.084		
22°C/60%RH	1,3 Butadiene	B-48341	T20			µg/stick	6	0.327	0.021	6.333		
22°C/60%RH	1,3 Butadiene	B-48341	T24			µg/stick	6	0.250	0.020	7.986		
22°C/60%RH	1,3 Butadiene	B-48342	T0			µg/stick	6	0.305	0.030	9.774		
22°C/60%RH	1,3 Butadiene	B-48342	T2			µg/stick	4	0.288	0.023	8.088		
22°C/60%RH	1,3 Butadiene	B-48342	T4			µg/stick	4	0.260	0.030	11.416		
22°C/60%RH	1,3 Butadiene	B-48342	T6			µg/stick	4	0.287	0.012	4.294		
22°C/60%RH	1,3 Butadiene	B-48342	T9			µg/stick	4	0.252	0.011	4.319		
22°C/60%RH	1,3 Butadiene	B-48342	T12			µg/stick	6	0.267	0.020	7.516		
22°C/60%RH	1,3 Butadiene	B-48342	T16			µg/stick	6	0.334	0.033	9.814		
22°C/60%RH	1,3 Butadiene	B-48342	T20			µg/stick	6	0.345	0.019	5.569		
22°C/60%RH	1,3 Butadiene	B-48342	T24			µg/stick	6	0.265	0.013	5.022		
22°C/60%RH	Acrylamide	B-48340	T0			µg/stick	5	1.737	0.100	5.742		
22°C/60%RH	Acrylamide	B-48340	T2			µg/stick	4	1.913	0.161	8.436		
22°C/60%RH	Acrylamide	B-48340	T4			µg/stick	4	1.645	0.145	8.803		
22°C/60%RH	Acrylamide	B-48340	T6			µg/stick	4	1.760	0.086	4.892		
22°C/60%RH	Acrylamide	B-48340	T9			µg/stick	4	2.076	0.138	6.631		
22°C/60%RH	Acrylamide	B-48340	T12			µg/stick	6	1.707	0.149	8.732		
22°C/60%RH	Acrylamide	B-48340	T16			µg/stick	6	1.476	0.193	13.061		
22°C/60%RH	Acrylamide	B-48340	T20			µg/stick	6	1.570	0.128	8.124		
22°C/60%RH	Acrylamide	B-48340	T24			µg/stick	6	1.642	0.086	5.239		

(b) (4)

(b) (4)

STABILITY STUDY FINAL REPORT



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CONDITION	VARIABLE	BATCH	Time point	LSL	USL	UNIT	N	Mean	Std	CV	Lower 95% CI	Upper 95% CI
22°C/60%RH	Acrylamide	B-48341	T0			µg/stick	6	1.692	0.114	6.735		
22°C/60%RH	Acrylamide	B-48341	T2			µg/stick	4	1.823	0.086	4.699		
22°C/60%RH	Acrylamide	B-48341	T4			µg/stick	4	1.655	0.173	10.442		
22°C/60%RH	Acrylamide	B-48341	T6			µg/stick	4	1.808	0.134	7.405		
22°C/60%RH	Acrylamide	B-48341	T9			µg/stick	4	1.961	0.200	10.200		
22°C/60%RH	Acrylamide	B-48341	T12			µg/stick	6	1.732	0.160	9.236		
22°C/60%RH	Acrylamide	B-48341	T16			µg/stick	6	1.516	0.121	7.984		
22°C/60%RH	Acrylamide	B-48341	T20			µg/stick	6	1.599	0.093	5.840		
22°C/60%RH	Acrylamide	B-48341	T24			µg/stick	6	1.601	0.107	6.652		
22°C/60%RH	Acrylamide	B-48342	T0			µg/stick	6	1.686	0.065	3.848		
22°C/60%RH	Acrylamide	B-48342	T2			µg/stick	4	2.050	0.092	4.512		
22°C/60%RH	Acrylamide	B-48342	T4			µg/stick	4	1.682	0.185	11.003		
22°C/60%RH	Acrylamide	B-48342	T6			µg/stick	4	1.784	0.199	11.139		
22°C/60%RH	Acrylamide	B-48342	T9			µg/stick	4	1.780	0.148	8.321		
22°C/60%RH	Acrylamide	B-48342	T12			µg/stick	6	1.591	0.083	5.193		
22°C/60%RH	Acrylamide	B-48342	T16			µg/stick	6	1.419	0.086	6.039		
22°C/60%RH	Acrylamide	B-48342	T20			µg/stick	6	1.726	0.066	3.821		
22°C/60%RH	Acrylamide	B-48342	T24			µg/stick	6	1.634	0.154	9.454		
22°C/60%RH	Benzene	B-48340	T0	(b) (4)		µg/stick	6	0.625	0.061	9.823	(b) (4)	
22°C/60%RH	Benzene	B-48340	T2			µg/stick	4	0.537	0.010	1.781		
22°C/60%RH	Benzene	B-48340	T4			µg/stick	4	0.555	0.015	2.677		
22°C/60%RH	Benzene	B-48340	T6			µg/stick	4	0.611	0.069	11.242		
22°C/60%RH	Benzene	B-48340	T9			µg/stick	4	0.542	0.009	1.709		
22°C/60%RH	Benzene	B-48340	T12			µg/stick	6	0.523	0.014	2.596		
22°C/60%RH	Benzene	B-48340	T16			µg/stick	6	0.543	0.037	6.884		
22°C/60%RH	Benzene	B-48340	T20			µg/stick	6	0.547	0.025	4.501		
22°C/60%RH	Benzene	B-48340	T24			µg/stick	6	0.539	0.032	5.900		
22°C/60%RH	Benzene	B-48341	T0			µg/stick	6	0.593	0.044	7.357		
22°C/60%RH	Benzene	B-48341	T2			µg/stick	4	0.532	0.032	5.949		
22°C/60%RH	Benzene	B-48341	T4			µg/stick	4	0.569	0.055	9.607		
22°C/60%RH	Benzene	B-48341	T6			µg/stick	4	0.580	0.051	8.775		
22°C/60%RH	Benzene	B-48341	T9			µg/stick	4	0.550	0.049	8.887		
22°C/60%RH	Benzene	B-48341	T12			µg/stick	6	0.493	0.021	4.256		
22°C/60%RH	Benzene	B-48341	T16			µg/stick	6	0.558	0.030	5.411		
22°C/60%RH	Benzene	B-48341	T20			µg/stick	6	0.536	0.040	7.407		
22°C/60%RH	Benzene	B-48341	T24			µg/stick	6	0.537	0.009	1.664		
22°C/60%RH	Benzene	B-48342	T0			µg/stick	6	0.606	0.047	7.775		

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CONDITION	VARIABLE	BATCH	Time point	LSL	USL	UNIT	N	Mean	Std	CV	Lower 95% CI	Upper 95% CI
22°C/60%RH	Benzene	B-48342	T2			µg/stick	4	0.576	0.036	6.211		
22°C/60%RH	Benzene	B-48342	T4			µg/stick	4	0.576	0.045	7.756		
22°C/60%RH	Benzene	B-48342	T6			µg/stick	4	0.558	0.039	7.008		
22°C/60%RH	Benzene	B-48342	T9			µg/stick	4	0.583	0.042	7.141		
22°C/60%RH	Benzene	B-48342	T12			µg/stick	6	0.550	0.041	7.467		
22°C/60%RH	Benzene	B-48342	T16			µg/stick	6	0.536	0.050	9.326		
22°C/60%RH	Benzene	B-48342	T20			µg/stick	6	0.568	0.027	4.671		
22°C/60%RH	Benzene	B-48342	T24			µg/stick	6	0.530	0.026	4.946		
22°C/60%RH	Carbon monoxide	B-48340	T0			mg/stick	5	0.510	0.000	0.000		
22°C/60%RH	Carbon monoxide	B-48340	T2			mg/stick	4	0.543	0.084	15.385		
22°C/60%RH	Carbon monoxide	B-48340	T4			mg/stick	4	0.518	0.041	8.000		
22°C/60%RH	Carbon monoxide	B-48340	T6			mg/stick	4	0.422	0.000	0.000		
22°C/60%RH	Carbon monoxide	B-48340	T9			mg/stick	4	0.508	0.000	0.000		
22°C/60%RH	Carbon monoxide	B-48340	T12			mg/stick	6	0.437	0.022	5.046		
22°C/60%RH	Carbon monoxide	B-48340	T16			mg/stick	6	0.436	0.031	7.157		
22°C/60%RH	Carbon monoxide	B-48340	T20			mg/stick	6	0.433	0.026	6.056		
22°C/60%RH	Carbon monoxide	B-48340	T24			mg/stick	6	0.461	0.017	3.774		
22°C/60%RH	Carbon monoxide	B-48341	T0			mg/stick	6	0.510	0.000	0.000		
22°C/60%RH	Carbon monoxide	B-48341	T2			mg/stick	4	0.543	0.048	8.882		
22°C/60%RH	Carbon monoxide	B-48341	T4			mg/stick	4	0.497	0.000	0.000		
22°C/60%RH	Carbon monoxide	B-48341	T6			mg/stick	4	0.422	0.000	0.000		
22°C/60%RH	Carbon monoxide	B-48341	T9			mg/stick	4	0.529	0.042	8.000		
22°C/60%RH	Carbon monoxide	B-48341	T12			mg/stick	6	0.418	0.014	3.338		
22°C/60%RH	Carbon monoxide	B-48341	T16			mg/stick	6	0.451	0.020	4.539		
22°C/60%RH	Carbon monoxide	B-48341	T20			mg/stick	6	0.417	0.014	3.316		
22°C/60%RH	Carbon monoxide	B-48341	T24			mg/stick	6	0.459	0.017	3.689		
22°C/60%RH	Carbon monoxide	B-48342	T0			mg/stick	6	0.510	0.054	10.541		
22°C/60%RH	Carbon monoxide	B-48342	T2			mg/stick	4	0.564	0.042	7.407		
22°C/60%RH	Carbon monoxide	B-48342	T4			mg/stick	4	0.518	0.041	8.000		
22°C/60%RH	Carbon monoxide	B-48342	T6			mg/stick	4	0.401	0.042	10.526		
22°C/60%RH	Carbon monoxide	B-48342	T9			mg/stick	4	0.508	0.000	0.000		
22°C/60%RH	Carbon monoxide	B-48342	T12			mg/stick	6	0.450	0.007	1.597		

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CONDITION	VARIABLE	BATCH	Time point	LSL	USL	UNIT	N	Mean	Std	CV	Lower 95% CI	Upper 95% CI
22°C/60%RH	Carbon monoxide	B-48342	T16			mg/stick	6	0.444	0.018	4.093		
22°C/60%RH	Carbon monoxide	B-48342	T20			mg/stick	6	0.465	0.016	3.429		
22°C/60%RH	Carbon monoxide	B-48342	T24			mg/stick	6	0.459	0.029	6.348		
22°C/60%RH	Formaldehyde	B-48340	T0			µg/stick	6	4.127	0.311	7.536		
22°C/60%RH	Formaldehyde	B-48340	T2			µg/stick	4	4.658	0.273	5.860		
22°C/60%RH	Formaldehyde	B-48340	T4			µg/stick	4	4.203	0.860	20.459		
22°C/60%RH	Formaldehyde	B-48340	T6			µg/stick	4	4.631	0.302	6.513		
22°C/60%RH	Formaldehyde	B-48340	T9			µg/stick	4	4.099	0.783	19.096		
22°C/60%RH	Formaldehyde	B-48340	T12			µg/stick	6	3.584	0.583	16.251		
22°C/60%RH	Formaldehyde	B-48340	T16			µg/stick	6	3.807	0.265	6.972		
22°C/60%RH	Formaldehyde	B-48340	T20			µg/stick	6	3.402	0.746	21.914		
22°C/60%RH	Formaldehyde	B-48340	T24			µg/stick	6	3.936	0.918	23.318		
22°C/60%RH	Formaldehyde	B-48341	T0			µg/stick	6	3.429	0.923	26.928		
22°C/60%RH	Formaldehyde	B-48341	T2			µg/stick	4	3.752	0.554	14.754		
22°C/60%RH	Formaldehyde	B-48341	T4			µg/stick	4	4.264	0.895	20.988		
22°C/60%RH	Formaldehyde	B-48341	T6			µg/stick	4	4.457	0.272	6.111		
22°C/60%RH	Formaldehyde	B-48341	T9			µg/stick	4	4.400	0.631	14.333		
22°C/60%RH	Formaldehyde	B-48341	T12			µg/stick	6	3.291	0.604	18.363		
22°C/60%RH	Formaldehyde	B-48341	T16			µg/stick	6	3.867	0.308	7.959		
22°C/60%RH	Formaldehyde	B-48341	T20			µg/stick	6	2.913	0.367	12.584		
22°C/60%RH	Formaldehyde	B-48341	T24			µg/stick	6	3.911	0.775	19.807		
22°C/60%RH	Formaldehyde	B-48342	T0			µg/stick	6	3.926	0.506	12.881		
22°C/60%RH	Formaldehyde	B-48342	T2			µg/stick	4	3.977	0.603	15.153		
22°C/60%RH	Formaldehyde	B-48342	T4			µg/stick	4	3.943	0.467	11.854		
22°C/60%RH	Formaldehyde	B-48342	T6			µg/stick	4	4.471	0.637	14.247		
22°C/60%RH	Formaldehyde	B-48342	T9			µg/stick	4	3.412	0.462	13.547		
22°C/60%RH	Formaldehyde	B-48342	T12			µg/stick	6	3.961	0.651	16.425		
22°C/60%RH	Formaldehyde	B-48342	T16			µg/stick	6	3.233	0.379	11.723		
22°C/60%RH	Formaldehyde	B-48342	T20			µg/stick	6	3.038	0.497	16.345		
22°C/60%RH	Formaldehyde	B-48342	T24			µg/stick	6	3.737	0.194	5.187		
22°C/60%RH	Glycerin	B-48340	T0			mg/stick	5	5.693	0.307	5.394		
22°C/60%RH	Glycerin	B-48340	T2			mg/stick	4	6.016	0.682	11.334		
22°C/60%RH	Glycerin	B-48340	T4			mg/stick	4	5.197	0.125	2.407		
22°C/60%RH	Glycerin	B-48340	T6			mg/stick	4	5.664	0.349	6.167		
22°C/60%RH	Glycerin	B-48340	T9			mg/stick	4	5.636	0.161	2.858		
22°C/60%RH	Glycerin	B-48340	T12			mg/stick	6	4.950	0.173	3.501		

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22°C/60%RH	Glycerin	B-48340	T16			mg/stick	6	4.992	0.652	13.069		
22°C/60%RH	Glycerin	B-48340	T20			mg/stick	6	4.490	0.413	9.197		
22°C/60%RH	Glycerin	B-48340	T24			mg/stick	6	5.036	0.298	5.909		
22°C/60%RH	Glycerin	B-48341	T0			mg/stick	6	5.522	0.259	4.690		
22°C/60%RH	Glycerin	B-48341	T2			mg/stick	4	5.650	0.373	6.596		
22°C/60%RH	Glycerin	B-48341	T4			mg/stick	4	5.353	0.201	3.755		
22°C/60%RH	Glycerin	B-48341	T6			mg/stick	4	5.974	0.107	1.793		
22°C/60%RH	Glycerin	B-48341	T9			mg/stick	4	5.494	0.749	13.629		
22°C/60%RH	Glycerin	B-48341	T12			mg/stick	6	5.076	0.284	5.604		
22°C/60%RH	Glycerin	B-48341	T16			mg/stick	6	5.343	0.355	6.651		
22°C/60%RH	Glycerin	B-48341	T20			mg/stick	6	4.483	0.134	2.989		
22°C/60%RH	Glycerin	B-48341	T24			mg/stick	6	5.023	0.502	9.985		
22°C/60%RH	Glycerin	B-48342	T0			mg/stick	6	5.597	0.225	4.014		
22°C/60%RH	Glycerin	B-48342	T2			mg/stick	4	6.212	0.362	5.826		
22°C/60%RH	Glycerin	B-48342	T4			mg/stick	4	5.374	0.761	14.157		
22°C/60%RH	Glycerin	B-48342	T6			mg/stick	4	5.577	0.497	8.912		
22°C/60%RH	Glycerin	B-48342	T9			mg/stick	4	4.817	0.344	7.141		
22°C/60%RH	Glycerin	B-48342	T12			mg/stick	6	5.140	0.189	3.686		
22°C/60%RH	Glycerin	B-48342	T16			mg/stick	6	4.836	0.285	5.886		
22°C/60%RH	Glycerin	B-48342	T20			mg/stick	6	5.065	0.146	2.886		
22°C/60%RH	Glycerin	B-48342	T24			mg/stick	6	5.052	0.283	5.593		
22°C/60%RH	Nicotine	B-48340	T0			mg/stick	5	1.269	0.043	3.365		
22°C/60%RH	Nicotine	B-48340	T2			mg/stick	4	1.283	0.062	4.821		
22°C/60%RH	Nicotine	B-48340	T4			mg/stick	4	1.174	0.054	4.590		
22°C/60%RH	Nicotine	B-48340	T6			mg/stick	4	1.179	0.025	2.134		
22°C/60%RH	Nicotine	B-48340	T9			mg/stick	4	1.289	0.009	0.711		
22°C/60%RH	Nicotine	B-48340	T12			mg/stick	6	1.273	0.053	4.129		
22°C/60%RH	Nicotine	B-48340	T16			mg/stick	6	1.265	0.101	8.021		
22°C/60%RH	Nicotine	B-48340	T20			mg/stick	6	1.172	0.070	5.947		
22°C/60%RH	Nicotine	B-48340	T24			mg/stick	6	1.356	0.030	2.179		
22°C/60%RH	Nicotine	B-48341	T0			mg/stick	6	1.219	0.055	4.510		
22°C/60%RH	Nicotine	B-48341	T2			mg/stick	4	1.238	0.051	4.143		
22°C/60%RH	Nicotine	B-48341	T4			mg/stick	4	1.204	0.050	4.165		
22°C/60%RH	Nicotine	B-48341	T6			mg/stick	4	1.218	0.031	2.574		
22°C/60%RH	Nicotine	B-48341	T9			mg/stick	4	1.226	0.073	5.957		
22°C/60%RH	Nicotine	B-48341	T12			mg/stick	6	1.278	0.049	3.871		
22°C/60%RH	Nicotine	B-48341	T16			mg/stick	6	1.320	0.049	3.694		

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22°C/60%RH	Nicotine	B-48341	T20			mg/stick	6	1.163	0.043	3.662		
22°C/60%RH	Nicotine	B-48341	T24			mg/stick	6	1.344	0.043	3.234		
22°C/60%RH	Nicotine	B-48342	T0			mg/stick	6	1.226	0.040	3.235		
22°C/60%RH	Nicotine	B-48342	T2			mg/stick	4	1.296	0.046	3.528		
22°C/60%RH	Nicotine	B-48342	T4			mg/stick	4	1.164	0.060	5.133		
22°C/60%RH	Nicotine	B-48342	T6			mg/stick	4	1.218	0.069	5.691		
22°C/60%RH	Nicotine	B-48342	T9			mg/stick	4	1.127	0.014	1.284		
22°C/60%RH	Nicotine	B-48342	T12			mg/stick	6	1.284	0.040	3.153		
22°C/60%RH	Nicotine	B-48342	T16			mg/stick	6	1.220	0.062	5.098		
22°C/60%RH	Nicotine	B-48342	T20			mg/stick	6	1.247	0.021	1.695		
22°C/60%RH	Nicotine	B-48342	T24			mg/stick	6	1.363	0.095	6.933		
22°C/60%RH	Phenol	B-48340	T0			µg/stick	5	1.356	0.168	12.394		
22°C/60%RH	Phenol	B-48340	T2			µg/stick	4	1.450	0.476	32.831		
22°C/60%RH	Phenol	B-48340	T4			µg/stick	4	1.231	0.050	4.061		
22°C/60%RH	Phenol	B-48340	T6			µg/stick	4	1.511	0.230	15.201		
22°C/60%RH	Phenol	B-48340	T9			µg/stick	4	1.827	0.195	10.695		
22°C/60%RH	Phenol	B-48340	T12			µg/stick	6	1.656	0.144	8.702		
22°C/60%RH	Phenol	B-48340	T16			µg/stick	6	1.554	0.278	17.919		
22°C/60%RH	Phenol	B-48340	T20			µg/stick	6	1.276	0.141	11.088		
22°C/60%RH	Phenol	B-48340	T24			µg/stick	6	1.753	0.169	9.655		
22°C/60%RH	Phenol	B-48341	T0			µg/stick	6	1.584	0.215	13.567		
22°C/60%RH	Phenol	B-48341	T2			µg/stick	4	1.543	0.284	18.411		
22°C/60%RH	Phenol	B-48341	T4			µg/stick	4	1.465	0.248	16.965		
22°C/60%RH	Phenol	B-48341	T6			µg/stick	4	1.715	0.153	8.909		
22°C/60%RH	Phenol	B-48341	T9			µg/stick	4	2.450	0.672	27.411		
22°C/60%RH	Phenol	B-48341	T12			µg/stick	6	1.770	0.291	16.467		
22°C/60%RH	Phenol	B-48341	T16			µg/stick	6	1.970	0.235	11.923		
22°C/60%RH	Phenol	B-48341	T20			µg/stick	6	1.713	0.225	13.113		
22°C/60%RH	Phenol	B-48341	T24			µg/stick	6	1.860	0.266	14.319		
22°C/60%RH	Phenol	B-48342	T0			µg/stick	6	1.736	0.217	12.496		
22°C/60%RH	Phenol	B-48342	T2			µg/stick	4	1.986	0.119	5.984		
22°C/60%RH	Phenol	B-48342	T4			µg/stick	4	1.703	0.432	25.393		
22°C/60%RH	Phenol	B-48342	T6			µg/stick	4	1.939	0.214	11.056		
22°C/60%RH	Phenol	B-48342	T9			µg/stick	4	1.799	0.310	17.256		
22°C/60%RH	Phenol	B-48342	T12			µg/stick	6	2.004	0.290	14.485		
22°C/60%RH	Phenol	B-48342	T16			µg/stick	6	1.957	0.186	9.497		
22°C/60%RH	Phenol	B-48342	T20			µg/stick	6	2.143	0.277	12.917		

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22°C/60%RH	Phenol	B-48342	T24	(b) (4)		µg/stick	6	2.109	0.265	12.562	(b) (4)	
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22°C/60%RH	Tobacco stick weight	B-48340	T0	(b) (4)		mg	50	782.2	9.7	1.246	(b) (4)	
22°C/60%RH	Tobacco stick weight	B-48340	T2	(b) (4)		mg	50	785.4	10.4	1.330	(b) (4)	

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22°C/60%RH	Tobacco stick weight	B-48340	T4			mg	50	785.0	15.3	1.952		
22°C/60%RH	Tobacco stick weight	B-48340	T6			mg	50	782.3	10.7	1.372		
22°C/60%RH	Tobacco stick weight	B-48340	T9			mg	50	787.9	10.6	1.348		
22°C/60%RH	Tobacco stick weight	B-48340	T12			mg	50	786.4	8.2	1.042		
22°C/60%RH	Tobacco stick weight	B-48340	T16			mg	50	787.5	11.4	1.451		
22°C/60%RH	Tobacco stick weight	B-48340	T20			mg	50	777.3	9.7	1.248		
22°C/60%RH	Tobacco stick weight	B-48340	T24			mg	50	783.4	27.6	3.521		
22°C/60%RH	Tobacco stick weight	B-48341	T0			mg	50	779.0	11.0	1.407		
22°C/60%RH	Tobacco stick weight	B-48341	T2			mg	50	791.0	10.4	1.320		
22°C/60%RH	Tobacco stick weight	B-48341	T4			mg	50	781.4	8.9	1.141		
22°C/60%RH	Tobacco stick weight	B-48341	T6			mg	50	784.4	10.0	1.277		
22°C/60%RH	Tobacco stick weight	B-48341	T9			mg	50	781.7	9.1	1.161		
22°C/60%RH	Tobacco stick weight	B-48341	T12			mg	50	787.6	11.2	1.420		
22°C/60%RH	Tobacco stick weight	B-48341	T16			mg	50	787.7	12.2	1.545		
22°C/60%RH	Tobacco stick weight	B-48341	T20			mg	50	780.1	10.3	1.314		
22°C/60%RH	Tobacco stick weight	B-48341	T24			mg	50	784.7	9.8	1.250		
22°C/60%RH	Tobacco stick weight	B-48342	T0			mg	50	778.8	10.3	1.317		
22°C/60%RH	Tobacco stick weight	B-48342	T2			mg	50	788.3	9.8	1.246		
22°C/60%RH	Tobacco stick weight	B-48342	T4			mg	50	784.8	14.0	1.789		
22°C/60%RH	Tobacco stick weight	B-48342	T6			mg	50	785.6	13.0	1.652		
22°C/60%RH	Tobacco stick weight	B-48342	T9			mg	50	786.0	12.0	1.526		
22°C/60%RH	Tobacco stick weight	B-48342	T12			mg	50	782.4	12.6	1.616		
22°C/60%RH	Tobacco stick weight	B-48342	T16			mg	50	790.0	12.4	1.565		
22°C/60%RH	Tobacco stick weight	B-48342	T20			mg	50	782.9	12.3	1.566		
22°C/60%RH	Tobacco stick weight	B-48342	T24			mg	50	792.3	11.7	1.480		
22°C/60%RH	Triacetin	B-48340	T0			mg/stick	5	0.669	0.037	5.598		
22°C/60%RH	Triacetin	B-48340	T2			mg/stick	4	0.696	0.063	8.988		
22°C/60%RH	Triacetin	B-48340	T4			mg/stick	4	0.626	0.008	1.347		
22°C/60%RH	Triacetin	B-48340	T6			mg/stick	4	0.633	0.018	2.820		
22°C/60%RH	Triacetin	B-48340	T9			mg/stick	4	0.603	0.050	8.353		
22°C/60%RH	Triacetin	B-48340	T12			mg/stick	6	0.496	0.023	4.588		
22°C/60%RH	Triacetin	B-48340	T16			mg/stick	6	0.512	0.053	10.410		

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22°C/60%RH	Triacetin	B-48340	T20			mg/stick	6	0.453	0.023	5.125		
22°C/60%RH	Triacetin	B-48340	T24			mg/stick	6	0.488	0.033	6.772		
22°C/60%RH	Triacetin	B-48341	T0			mg/stick	6	0.627	0.016	2.623		
22°C/60%RH	Triacetin	B-48341	T2			mg/stick	4	0.607	0.017	2.789		
22°C/60%RH	Triacetin	B-48341	T4			mg/stick	4	0.571	0.023	3.972		
22°C/60%RH	Triacetin	B-48341	T6			mg/stick	4	0.579	0.022	3.881		
22°C/60%RH	Triacetin	B-48341	T9			mg/stick	4	0.599	0.080	13.311		
22°C/60%RH	Triacetin	B-48341	T12			mg/stick	6	0.464	0.012	2.598		
22°C/60%RH	Triacetin	B-48341	T16			mg/stick	6	0.484	0.027	5.616		
22°C/60%RH	Triacetin	B-48341	T20			mg/stick	6	0.442	0.019	4.389		
22°C/60%RH	Triacetin	B-48341	T24			mg/stick	6	0.450	0.066	14.678		
22°C/60%RH	Triacetin	B-48342	T0			mg/stick	6	0.615	0.033	5.338		
22°C/60%RH	Triacetin	B-48342	T2			mg/stick	4	0.646	0.025	3.904		
22°C/60%RH	Triacetin	B-48342	T4			mg/stick	4	0.576	0.057	9.955		
22°C/60%RH	Triacetin	B-48342	T6			mg/stick	4	0.548	0.028	5.189		
22°C/60%RH	Triacetin	B-48342	T9			mg/stick	4	0.512	0.064	12.504		
22°C/60%RH	Triacetin	B-48342	T12			mg/stick	6	0.468	0.011	2.253		
22°C/60%RH	Triacetin	B-48342	T16			mg/stick	6	0.474	0.026	5.441		
22°C/60%RH	Triacetin	B-48342	T20	(b) (4)		mg/stick	6	0.457	0.020	4.456	(b) (4)	
22°C/60%RH	Triacetin	B-48342	T24			mg/stick	6	0.443	0.028	6.219		
22°C/60%RH	Water activity	B-48340	T0			N/A	3	0.420	0.000	0.000		
22°C/60%RH	Water activity	B-48340	T2			N/A	3	0.480	0.000	0.000		
22°C/60%RH	Water activity	B-48340	T4			N/A	3	0.520	0.000	0.000		
22°C/60%RH	Water activity	B-48340	T6			N/A	3	0.550	0.000	0.000		
22°C/60%RH	Water activity	B-48340	T9			N/A	3	0.563	0.006	1.025		
22°C/60%RH	Water activity	B-48340	T12			N/A	3	0.560	0.000	0.000		
22°C/60%RH	Water activity	B-48340	T16			N/A	3	0.577	0.006	1.001		
22°C/60%RH	Water activity	B-48340	T20			N/A	3	0.580	0.000	0.000		
22°C/60%RH	Water activity	B-48340	T24			N/A	3	0.590	0.000	0.000		
22°C/60%RH	Water activity	B-48341	T0			N/A	3	0.420	0.000	0.000		
22°C/60%RH	Water activity	B-48341	T2			N/A	3	0.480	0.000	0.000		
22°C/60%RH	Water activity	B-48341	T4			N/A	3	0.510	0.000	0.000		
22°C/60%RH	Water activity	B-48341	T6			N/A	3	0.543	0.006	1.063		
22°C/60%RH	Water activity	B-48341	T9			N/A	3	0.560	0.000	0.000		
22°C/60%RH	Water activity	B-48341	T12			N/A	3	0.560	0.000	0.000		
22°C/60%RH	Water activity	B-48341	T16			N/A	3	0.570	0.000	0.000		
22°C/60%RH	Water activity	B-48341	T20			N/A	3	0.580	0.000	0.000		



CONDITION	VARIABLE	BATCH	Time point	LSE	USL	UNIT	N	Mean	Std	CV	Lower 95% CI	Upper 95% CI
22°C/60%RH	Water activity	B-48341	T24	(b) (4)	(b) (4)	N/A	3	0.577	0.006	1.001	(b) (4)	(b) (4)
22°C/60%RH	Water activity	B-48342	T0			N/A	3	0.430	0.000	0.000		
22°C/60%RH	Water activity	B-48342	T2			N/A	3	0.490	0.010	2.041		
22°C/60%RH	Water activity	B-48342	T4			N/A	3	0.530	0.000	0.000		
22°C/60%RH	Water activity	B-48342	T6			N/A	3	0.550	0.000	0.000		
22°C/60%RH	Water activity	B-48342	T9			N/A	3	0.560	0.000	0.000		
22°C/60%RH	Water activity	B-48342	T12			N/A	3	0.560	0.000	0.000		
22°C/60%RH	Water activity	B-48342	T16			N/A	3	0.570	0.000	0.000		
22°C/60%RH	Water activity	B-48342	T20			N/A	3	0.570	0.000	0.000		
22°C/60%RH	Water activity	B-48342	T24			N/A	3	0.590	0.000	0.000		

15.6 Tabulated Results and Summary Statistics for 30°C 65%RH

CONDITION	VARIABLE	BATCH	Time point	LSE	USL	UNIT	N	Mean	Std	CV	Lower 95% CI	Upper 95% CI
30°C/65%RH	1,3 Butadiene	B-48340	T0	(b) (4)	(b) (4)	µg/stick	6	0.331	0.050	15.085	(b) (4)	(b) (4)
30°C/65%RH	1,3 Butadiene	B-48340	T2			µg/stick	4	0.227	0.013	5.770		
30°C/65%RH	1,3 Butadiene	B-48340	T4			µg/stick	4	0.243	0.052	21.380		
30°C/65%RH	1,3 Butadiene	B-48340	T6			µg/stick	4	0.297	0.042	14.171		
30°C/65%RH	1,3 Butadiene	B-48340	T9			µg/stick	4	0.241	0.024	9.982		
30°C/65%RH	1,3 Butadiene	B-48340	T12			µg/stick	6	0.306	0.019	6.380		
30°C/65%RH	1,3 Butadiene	B-48340	T16			µg/stick	6	0.326	0.024	7.442		
30°C/65%RH	1,3 Butadiene	B-48340	T20			µg/stick	6	0.369	0.038	10.346		
30°C/65%RH	1,3 Butadiene	B-48340	T24			µg/stick	6	0.261	0.024	9.149		
30°C/65%RH	1,3 Butadiene	B-48341	T0			µg/stick	6	0.305	0.035	11.518		
30°C/65%RH	1,3 Butadiene	B-48341	T2			µg/stick	4	0.240	0.007	2.986		
30°C/65%RH	1,3 Butadiene	B-48341	T4			µg/stick	4	0.246	0.026	10.486		
30°C/65%RH	1,3 Butadiene	B-48341	T6			µg/stick	4	0.297	0.010	3.462		
30°C/65%RH	1,3 Butadiene	B-48341	T9			µg/stick	4	0.260	0.011	4.176		
30°C/65%RH	1,3 Butadiene	B-48341	T12			µg/stick	6	0.272	0.029	10.593		
30°C/65%RH	1,3 Butadiene	B-48341	T16			µg/stick	6	0.324	0.031	9.655		
30°C/65%RH	1,3 Butadiene	B-48341	T20			µg/stick	6	0.378	0.046	12.265		
30°C/65%RH	1,3 Butadiene	B-48341	T24			µg/stick	6	0.256	0.017	6.727		
30°C/65%RH	1,3 Butadiene	B-48342	T0			µg/stick	6	0.305	0.030	9.774		
30°C/65%RH	1,3 Butadiene	B-48342	T2			µg/stick	4	0.261	0.010	3.938		
30°C/65%RH	1,3 Butadiene	B-48342	T4			µg/stick	4	0.263	0.027	10.402		
30°C/65%RH	1,3 Butadiene	B-48342	T6			µg/stick	4	0.270	0.025	9.238		
30°C/65%RH	1,3 Butadiene	B-48342	T9			µg/stick	4	0.264	0.024	9.181		

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30°C/65%RH	1,3 Butadiene	B-48342	T12			µg/stick	6	0.288	0.022	7.741		
30°C/65%RH	1,3 Butadiene	B-48342	T16			µg/stick	6	0.323	0.025	7.889		
30°C/65%RH	1,3 Butadiene	B-48342	T20			µg/stick	6	0.368	0.027	7.449		
30°C/65%RH	1,3 Butadiene	B-48342	T24			µg/stick	6	0.257	0.019	7.546		
30°C/65%RH	Acrylamide	B-48340	T0			µg/stick	5	1.737	0.100	5.742		
30°C/65%RH	Acrylamide	B-48340	T2			µg/stick	4	2.035	0.181	8.912		
30°C/65%RH	Acrylamide	B-48340	T4			µg/stick	4	1.617	0.177	10.969		
30°C/65%RH	Acrylamide	B-48340	T6			µg/stick	4	1.676	0.112	6.696		
30°C/65%RH	Acrylamide	B-48340	T9			µg/stick	4	1.830	0.376	20.549		
30°C/65%RH	Acrylamide	B-48340	T12			µg/stick	6	1.288	0.113	8.808		
30°C/65%RH	Acrylamide	B-48340	T16			µg/stick	6	0.936	0.114	12.196		
30°C/65%RH	Acrylamide	B-48340	T20			µg/stick	6	1.064	0.100	9.355		
30°C/65%RH	Acrylamide	B-48340	T24			µg/stick	6	1.084	0.098	9.078		
30°C/65%RH	Acrylamide	B-48341	T0			µg/stick	6	1.692	0.114	6.735		
30°C/65%RH	Acrylamide	B-48341	T2			µg/stick	4	1.955	0.077	3.940		
30°C/65%RH	Acrylamide	B-48341	T4			µg/stick	4	1.721	0.098	5.685		
30°C/65%RH	Acrylamide	B-48341	T6			µg/stick	4	1.608	0.077	4.790		
30°C/65%RH	Acrylamide	B-48341	T9			µg/stick	4	1.886	0.069	3.645		
30°C/65%RH	Acrylamide	B-48341	T12	(b) (4)		µg/stick	6	1.282	0.183	14.300	(b) (4)	
30°C/65%RH	Acrylamide	B-48341	T16			µg/stick	6	1.163	0.104	8.952		
30°C/65%RH	Acrylamide	B-48341	T20			µg/stick	6	1.204	0.040	3.316		
30°C/65%RH	Acrylamide	B-48341	T24			µg/stick	6	1.048	0.117	11.160		
30°C/65%RH	Acrylamide	B-48342	T0			µg/stick	6	1.686	0.065	3.848		
30°C/65%RH	Acrylamide	B-48342	T2			µg/stick	4	1.888	0.116	6.168		
30°C/65%RH	Acrylamide	B-48342	T4			µg/stick	4	1.895	0.137	7.234		
30°C/65%RH	Acrylamide	B-48342	T6			µg/stick	4	1.526	0.135	8.867		
30°C/65%RH	Acrylamide	B-48342	T9			µg/stick	4	1.789	0.181	10.113		
30°C/65%RH	Acrylamide	B-48342	T12			µg/stick	6	1.450	0.092	6.370		
30°C/65%RH	Acrylamide	B-48342	T16			µg/stick	6	1.075	0.066	6.100		
30°C/65%RH	Acrylamide	B-48342	T20			µg/stick	6	1.123	0.088	7.829		
30°C/65%RH	Acrylamide	B-48342	T24			µg/stick	6	1.064	0.160	15.058		
30°C/65%RH	Benzene	B-48340	T0			µg/stick	6	0.625	0.061	9.823		
30°C/65%RH	Benzene	B-48340	T2			µg/stick	4	0.481	0.028	5.761		
30°C/65%RH	Benzene	B-48340	T4			µg/stick	4	0.539	0.052	9.670		
30°C/65%RH	Benzene	B-48340	T6			µg/stick	4	0.585	0.045	7.692		
30°C/65%RH	Benzene	B-48340	T9			µg/stick	4	0.534	0.048	8.998		
30°C/65%RH	Benzene	B-48340	T12			µg/stick	6	0.547	0.019	3.531		

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30°C/65%RH	Benzene	B-48340	T16			µg/stick	6	0.554	0.030	5.395		
30°C/65%RH	Benzene	B-48340	T20			µg/stick	6	0.590	0.047	8.033		
30°C/65%RH	Benzene	B-48340	T24			µg/stick	6	0.567	0.040	7.086		
30°C/65%RH	Benzene	B-48341	T0			µg/stick	6	0.593	0.044	7.357		
30°C/65%RH	Benzene	B-48341	T2			µg/stick	4	0.505	0.014	2.725		
30°C/65%RH	Benzene	B-48341	T4			µg/stick	4	0.537	0.055	10.178		
30°C/65%RH	Benzene	B-48341	T6			µg/stick	4	0.640	0.030	4.615		
30°C/65%RH	Benzene	B-48341	T9			µg/stick	4	0.578	0.012	2.036		
30°C/65%RH	Benzene	B-48341	T12			µg/stick	6	0.498	0.040	7.993		
30°C/65%RH	Benzene	B-48341	T16			µg/stick	6	0.543	0.046	8.448		
30°C/65%RH	Benzene	B-48341	T20			µg/stick	6	0.575	0.060	10.395		
30°C/65%RH	Benzene	B-48341	T24			µg/stick	6	0.529	0.044	8.283		
30°C/65%RH	Benzene	B-48342	T0			µg/stick	6	0.606	0.047	7.775		
30°C/65%RH	Benzene	B-48342	T2			µg/stick	4	0.550	0.006	1.053		
30°C/65%RH	Benzene	B-48342	T4			µg/stick	4	0.597	0.043	7.256		
30°C/65%RH	Benzene	B-48342	T6			µg/stick	4	0.549	0.062	11.240		
30°C/65%RH	Benzene	B-48342	T9			µg/stick	4	0.593	0.026	4.400		
30°C/65%RH	Benzene	B-48342	T12			µg/stick	6	0.521	0.026	4.985		
30°C/65%RH	Benzene	B-48342	T16	(b) (4)		µg/stick	6	0.534	0.042	7.869	(b) (4)	
30°C/65%RH	Benzene	B-48342	T20			µg/stick	6	0.567	0.033	5.750		
30°C/65%RH	Benzene	B-48342	T24			µg/stick	6	0.556	0.040	7.252		
30°C/65%RH	Carbon monoxide	B-48340	T0			mg/stick	5	0.510	0.000	0.000		
30°C/65%RH	Carbon monoxide	B-48340	T2			mg/stick	4	0.606	0.042	6.897		
30°C/65%RH	Carbon monoxide	B-48340	T4			mg/stick	4	0.538	0.048	8.882		
30°C/65%RH	Carbon monoxide	B-48340	T6			mg/stick	4	0.422	0.000	0.000		
30°C/65%RH	Carbon monoxide	B-48340	T9			mg/stick	4	0.529	0.042	8.000		
30°C/65%RH	Carbon monoxide	B-48340	T12			mg/stick	6	0.445	0.013	2.862		
30°C/65%RH	Carbon monoxide	B-48340	T16			mg/stick	6	0.423	0.024	5.642		
30°C/65%RH	Carbon monoxide	B-48340	T20			mg/stick	6	0.436	0.027	6.115		
30°C/65%RH	Carbon monoxide	B-48340	T24			mg/stick	6	0.464	0.014	2.948		
30°C/65%RH	Carbon monoxide	B-48341	T0			mg/stick	6	0.510	0.000	0.000		
30°C/65%RH	Carbon monoxide	B-48341	T2			mg/stick	4	0.585	0.068	11.664		
30°C/65%RH	Carbon monoxide	B-48341	T4			mg/stick	4	0.538	0.048	8.882		
30°C/65%RH	Carbon monoxide	B-48341	T6			mg/stick	4	0.443	0.042	9.524		

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30°C/65%RH	Carbon monoxide	B-48341	T9			mg/stick	4	0.508	0.000	0.000		
30°C/65%RH	Carbon monoxide	B-48341	T12			mg/stick	6	0.428	0.011	2.510		
30°C/65%RH	Carbon monoxide	B-48341	T16			mg/stick	6	0.452	0.027	6.060		
30°C/65%RH	Carbon monoxide	B-48341	T20			mg/stick	6	0.458	0.016	3.407		
30°C/65%RH	Carbon monoxide	B-48341	T24			mg/stick	6	0.473	0.045	9.446		
30°C/65%RH	Carbon monoxide	B-48342	T0			mg/stick	6	0.510	0.054	10.541		
30°C/65%RH	Carbon monoxide	B-48342	T2			mg/stick	4	0.585	0.000	0.000		
30°C/65%RH	Carbon monoxide	B-48342	T4			mg/stick	4	0.538	0.048	8.882		
30°C/65%RH	Carbon monoxide	B-48342	T6			mg/stick	4	0.422	0.000	0.000		
30°C/65%RH	Carbon monoxide	B-48342	T9			mg/stick	4	0.508	0.000	0.000		
30°C/65%RH	Carbon monoxide	B-48342	T12			mg/stick	6	0.462	0.023	4.972		
30°C/65%RH	Carbon monoxide	B-48342	T16			mg/stick	6	0.450	0.014	3.028		
30°C/65%RH	Carbon monoxide	B-48342	T20			mg/stick	6	0.454	0.023	4.985		
30°C/65%RH	Carbon monoxide	B-48342	T24			mg/stick	6	0.461	0.020	4.301		
30°C/65%RH	Formaldehyde	B-48340	T0			µg/stick	6	4.127	0.311	7.536		
30°C/65%RH	Formaldehyde	B-48340	T2	(b) (4)		µg/stick	4	4.103	0.434	10.586		(b) (4)
30°C/65%RH	Formaldehyde	B-48340	T4			µg/stick	4	3.992	0.286	7.166		
30°C/65%RH	Formaldehyde	B-48340	T6			µg/stick	4	4.348	0.528	12.138		
30°C/65%RH	Formaldehyde	B-48340	T9			µg/stick	4	4.084	0.689	16.874		
30°C/65%RH	Formaldehyde	B-48340	T12			µg/stick	6	3.549	0.529	14.908		
30°C/65%RH	Formaldehyde	B-48340	T16			µg/stick	6	3.684	0.759	20.610		
30°C/65%RH	Formaldehyde	B-48340	T20			µg/stick	6	2.980	0.482	16.179		
30°C/65%RH	Formaldehyde	B-48340	T24			µg/stick	6	4.005	0.431	10.769		
30°C/65%RH	Formaldehyde	B-48341	T0			µg/stick	6	3.429	0.923	26.928		
30°C/65%RH	Formaldehyde	B-48341	T2			µg/stick	4	4.345	0.599	13.785		
30°C/65%RH	Formaldehyde	B-48341	T4			µg/stick	4	3.894	0.436	11.204		
30°C/65%RH	Formaldehyde	B-48341	T6			µg/stick	4	3.879	1.079	27.813		
30°C/65%RH	Formaldehyde	B-48341	T9			µg/stick	4	4.004	1.040	25.976		
30°C/65%RH	Formaldehyde	B-48341	T12			µg/stick	6	3.270	0.700	21.419		
30°C/65%RH	Formaldehyde	B-48341	T16			µg/stick	6	3.740	0.539	14.406		
30°C/65%RH	Formaldehyde	B-48341	T20			µg/stick	6	2.903	0.390	13.436		
30°C/65%RH	Formaldehyde	B-48341	T24			µg/stick	6	3.623	0.611	16.879		
30°C/65%RH	Formaldehyde	B-48342	T0			µg/stick	6	3.926	0.506	12.881		
30°C/65%RH	Formaldehyde	B-48342	T2			µg/stick	4	4.654	1.729	37.142		

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30°C/65%RH	Formaldehyde	B-48342	T4			µg/stick	4	4.489	0.193	4.296		
30°C/65%RH	Formaldehyde	B-48342	T6			µg/stick	4	4.274	0.475	11.105		
30°C/65%RH	Formaldehyde	B-48342	T9			µg/stick	4	4.871	0.222	4.565		
30°C/65%RH	Formaldehyde	B-48342	T12			µg/stick	6	4.323	0.301	6.964		
30°C/65%RH	Formaldehyde	B-48342	T16			µg/stick	6	3.864	0.518	13.408		
30°C/65%RH	Formaldehyde	B-48342	T20			µg/stick	6	3.075	0.624	20.293		
30°C/65%RH	Formaldehyde	B-48342	T24			µg/stick	5	4.030	0.982	24.356		
30°C/65%RH	Glycerin	B-48340	T0			mg/stick	5	5.693	0.307	5.394		
30°C/65%RH	Glycerin	B-48340	T2			mg/stick	4	6.050	0.508	8.394		
30°C/65%RH	Glycerin	B-48340	T4			mg/stick	4	4.875	0.255	5.234		
30°C/65%RH	Glycerin	B-48340	T6			mg/stick	4	5.384	0.349	6.483		
30°C/65%RH	Glycerin	B-48340	T9			mg/stick	4	4.762	0.461	9.685		
30°C/65%RH	Glycerin	B-48340	T12			mg/stick	6	4.325	0.097	2.240		
30°C/65%RH	Glycerin	B-48340	T16			mg/stick	6	3.557	0.354	9.950		
30°C/65%RH	Glycerin	B-48340	T20			mg/stick	6	3.403	0.292	8.581		
30°C/65%RH	Glycerin	B-48340	T24			mg/stick	6	3.930	0.250	6.349		
30°C/65%RH	Glycerin	B-48341	T0			mg/stick	6	5.522	0.259	4.690		
30°C/65%RH	Glycerin	B-48341	T2			mg/stick	4	6.153	0.258	4.189		
30°C/65%RH	Glycerin	B-48341	T4	(b) (4)		mg/stick	4	5.094	0.255	5.008		(b) (4)
30°C/65%RH	Glycerin	B-48341	T6			mg/stick	4	5.375	0.353	6.575		
30°C/65%RH	Glycerin	B-48341	T9			mg/stick	4	4.721	0.141	2.987		
30°C/65%RH	Glycerin	B-48341	T12			mg/stick	6	4.068	0.181	4.449		
30°C/65%RH	Glycerin	B-48341	T16			mg/stick	6	4.389	0.425	9.687		
30°C/65%RH	Glycerin	B-48341	T20			mg/stick	6	3.752	0.274	7.297		
30°C/65%RH	Glycerin	B-48341	T24			mg/stick	6	3.659	0.489	13.364		
30°C/65%RH	Glycerin	B-48342	T0			mg/stick	6	5.597	0.225	4.014		
30°C/65%RH	Glycerin	B-48342	T2			mg/stick	4	5.680	0.083	1.456		
30°C/65%RH	Glycerin	B-48342	T4			mg/stick	4	5.406	0.132	2.444		
30°C/65%RH	Glycerin	B-48342	T6			mg/stick	4	5.065	0.228	4.495		
30°C/65%RH	Glycerin	B-48342	T9			mg/stick	4	4.859	0.736	15.148		
30°C/65%RH	Glycerin	B-48342	T12			mg/stick	6	4.803	0.219	4.569		
30°C/65%RH	Glycerin	B-48342	T16			mg/stick	6	3.896	0.385	9.877		
30°C/65%RH	Glycerin	B-48342	T20			mg/stick	6	3.594	0.289	8.030		
30°C/65%RH	Glycerin	B-48342	T24			mg/stick	6	3.810	0.524	13.756		
30°C/65%RH	Nicotine	B-48340	T0			mg/stick	5	1.269	0.043	3.365		
30°C/65%RH	Nicotine	B-48340	T2			mg/stick	4	1.339	0.067	4.975		
30°C/65%RH	Nicotine	B-48340	T4			mg/stick	4	1.169	0.046	3.929		

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CONDITION	VARIABLE	BATCH	Time point	LSL	USL	UNIT	N	Mean	Sd	CV	Lower 95% CI	Upper 95% CI
30°C/65%RH	Nicotine	B-48340	T6			mg/stick	4	1.188	0.036	3.042		
30°C/65%RH	Nicotine	B-48340	T9			mg/stick	4	1.239	0.089	7.163		
30°C/65%RH	Nicotine	B-48340	T12			mg/stick	6	1.231	0.035	2.840		
30°C/65%RH	Nicotine	B-48340	T16			mg/stick	6	1.102	0.079	7.138		
30°C/65%RH	Nicotine	B-48340	T20			mg/stick	6	1.033	0.059	5.708		
30°C/65%RH	Nicotine	B-48340	T24			mg/stick	6	1.195	0.069	5.791		
30°C/65%RH	Nicotine	B-48341	T0			mg/stick	6	1.219	0.055	4.510		
30°C/65%RH	Nicotine	B-48341	T2			mg/stick	4	1.340	0.024	1.774		
30°C/65%RH	Nicotine	B-48341	T4			mg/stick	4	1.227	0.051	4.125		
30°C/65%RH	Nicotine	B-48341	T6			mg/stick	4	1.215	0.006	0.515		
30°C/65%RH	Nicotine	B-48341	T9			mg/stick	4	1.258	0.036	2.872		
30°C/65%RH	Nicotine	B-48341	T12			mg/stick	6	1.191	0.064	5.400		
30°C/65%RH	Nicotine	B-48341	T16			mg/stick	6	1.253	0.087	6.951		
30°C/65%RH	Nicotine	B-48341	T20			mg/stick	6	1.123	0.057	5.092		
30°C/65%RH	Nicotine	B-48341	T24			mg/stick	6	1.185	0.093	7.815		
30°C/65%RH	Nicotine	B-48342	T0			mg/stick	6	1.226	0.040	3.235		
30°C/65%RH	Nicotine	B-48342	T2			mg/stick	4	1.265	0.053	4.223		
30°C/65%RH	Nicotine	B-48342	T4			mg/stick	4	1.272	0.051	4.044		
30°C/65%RH	Nicotine	B-48342	T6			mg/stick	4	1.146	0.034	2.942		
30°C/65%RH	Nicotine	B-48342	T9			mg/stick	4	1.264	0.043	3.366		
30°C/65%RH	Nicotine	B-48342	T12			mg/stick	6	1.330	0.045	3.378		
30°C/65%RH	Nicotine	B-48342	T16			mg/stick	6	1.194	0.037	3.121		
30°C/65%RH	Nicotine	B-48342	T20			mg/stick	6	1.060	0.042	3.995		
30°C/65%RH	Nicotine	B-48342	T24			mg/stick	6	1.164	0.098	8.391		
30°C/65%RH	Phenol	B-48340	T0			µg/stick	5	1.356	0.168	12.394		
30°C/65%RH	Phenol	B-48340	T2			µg/stick	4	1.516	0.544	35.912		
30°C/65%RH	Phenol	B-48340	T4			µg/stick	4	1.448	0.192	13.233		
30°C/65%RH	Phenol	B-48340	T6			µg/stick	4	1.802	0.094	5.213		
30°C/65%RH	Phenol	B-48340	T9			µg/stick	4	1.846	0.562	30.471		
30°C/65%RH	Phenol	B-48340	T12			µg/stick	6	1.633	0.109	6.645		
30°C/65%RH	Phenol	B-48340	T16			µg/stick	6	1.262	0.247	19.595		
30°C/65%RH	Phenol	B-48340	T20			µg/stick	6	1.248	0.187	15.006		
30°C/65%RH	Phenol	B-48340	T24			µg/stick	6	1.644	0.200	12.139		
30°C/65%RH	Phenol	B-48341	T0			µg/stick	6	1.584	0.215	13.567		
30°C/65%RH	Phenol	B-48341	T2			µg/stick	4	1.756	0.414	23.587		
30°C/65%RH	Phenol	B-48341	T4			µg/stick	4	1.763	0.244	13.834		
30°C/65%RH	Phenol	B-48341	T6			µg/stick	4	2.069	0.178	8.604		

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CONDITION	VARIABLE	BATCH	Time point	LSL	USL	UNIT	N	Mean	Std	CV	Lower 95% CI	Upper 95% CI
30°C/65%RH	Phenol	B-48341	T9			µg/stick	4	2.315	0.236	10.186		
30°C/65%RH	Phenol	B-48341	T12			µg/stick	6	1.671	0.251	14.994		
30°C/65%RH	Phenol	B-48341	T16			µg/stick	6	2.084	0.457	21.921		
30°C/65%RH	Phenol	B-48341	T20			µg/stick	6	1.834	0.248	13.519		
30°C/65%RH	Phenol	B-48341	T24			µg/stick	6	1.827	0.484	26.490		
30°C/65%RH	Phenol	B-48342	T0			µg/stick	6	1.736	0.217	12.496		
30°C/65%RH	Phenol	B-48342	T2			µg/stick	4	1.654	0.330	19.935		
30°C/65%RH	Phenol	B-48342	T4			µg/stick	4	1.986	0.331	16.682		
30°C/65%RH	Phenol	B-48342	T6			µg/stick	4	1.882	0.247	13.119		
30°C/65%RH	Phenol	B-48342	T9			µg/stick	4	2.500	0.217	8.691		
30°C/65%RH	Phenol	B-48342	T12			µg/stick	6	2.344	0.285	12.157		
30°C/65%RH	Phenol	B-48342	T16			µg/stick	6	1.946	0.198	10.157		
30°C/65%RH	Phenol	B-48342	T20			µg/stick	6	1.690	0.126	7.434		
30°C/65%RH	Phenol	B-48342	T24			µg/stick	6	1.880	0.340	18.109		

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CONDITION	VARIABLE	BATCH	Time point	LSL	USL	UNIT	N	Mean	Std	CV	Lower 95% CI	Upper 95% CI
(b) (4)												
30°C/65%RH	Tobacco stick weight	B-48340	T0			mg	50	782.2	9.7	1.246		
30°C/65%RH	Tobacco stick weight	B-48340	T2			mg	50	788.0	13.3	1.691		
30°C/65%RH	Tobacco stick weight	B-48340	T4			mg	50	781.0	11.5	1.466		
30°C/65%RH	Tobacco stick weight	B-48340	T6			mg	50	786.3	10.7	1.367		
30°C/65%RH	Tobacco stick weight	B-48340	T9			mg	50	789.9	10.1	1.278		
30°C/65%RH	Tobacco stick weight	B-48340	T12			mg	50	790.2	11.3	1.436		
30°C/65%RH	Tobacco stick weight	B-48340	T16			mg	50	802.1	9.5	1.190		
30°C/65%RH	Tobacco stick weight	B-48340	T20			mg	50	780.2	11.5	1.479		
30°C/65%RH	Tobacco stick weight	B-48340	T24			mg	50	788.2	9.4	1.187		
30°C/65%RH	Tobacco stick weight	B-48341	T0			mg	50	779.0	11.0	1.407		
30°C/65%RH	Tobacco stick weight	B-48341	T2			mg	50	783.0	10.1	1.292		
30°C/65%RH	Tobacco stick weight	B-48341	T4			mg	50	786.9	10.5	1.331		
30°C/65%RH	Tobacco stick weight	B-48341	T6			mg	50	783.5	10.1	1.286		
30°C/65%RH	Tobacco stick weight	B-48341	T9			mg	50	790.4	8.4	1.061		
30°C/65%RH	Tobacco stick weight	B-48341	T12			mg	50	783.0	10.4	1.328		
30°C/65%RH	Tobacco stick weight	B-48341	T16			mg	50	788.7	10.7	1.359		
30°C/65%RH	Tobacco stick weight	B-48341	T20			mg	50	768.5	7.8	1.013		
30°C/65%RH	Tobacco stick weight	B-48341	T24			mg	50	788.5	11.3	1.438		
30°C/65%RH	Tobacco stick weight	B-48342	T0			mg	50	778.8	10.3	1.317		
30°C/65%RH	Tobacco stick weight	B-48342	T2			mg	50	787.1	10.3	1.302		
30°C/65%RH	Tobacco stick weight	B-48342	T4			mg	50	788.4	15.1	1.920		
30°C/65%RH	Tobacco stick weight	B-48342	T6			mg	50	786.3	10.3	1.315		

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CONDITION	VARIABLE	BATCH	Time point	LSL	USL	UNIT	N	Mean	Sd	CV	Lower 95% CI	Upper 95% CI
30°C/65%RH	Tobacco stick weight	B-48342	T9			mg	50	790.2	10.1	1.273		
30°C/65%RH	Tobacco stick weight	B-48342	T12			mg	50	780.9	14.5	1.856		
30°C/65%RH	Tobacco stick weight	B-48342	T16			mg	50	792.8	12.0	1.511		
30°C/65%RH	Tobacco stick weight	B-48342	T20			mg	50	774.2	12.6	1.622		
30°C/65%RH	Tobacco stick weight	B-48342	T24			mg	50	783.4	27.6	3.521		
30°C/65%RH	Triacetin	B-48340	T0			mg/stick	5	0.669	0.037	5.598		
30°C/65%RH	Triacetin	B-48340	T2			mg/stick	4	0.679	0.100	14.678		
30°C/65%RH	Triacetin	B-48340	T4			mg/stick	4	0.526	0.022	4.264		
30°C/65%RH	Triacetin	B-48340	T6			mg/stick	4	0.509	0.025	4.933		
30°C/65%RH	Triacetin	B-48340	T9			mg/stick	4	0.448	0.033	7.335		
30°C/65%RH	Triacetin	B-48340	T12			mg/stick	6	0.394	0.016	3.965		
30°C/65%RH	Triacetin	B-48340	T16			mg/stick	6	0.351	0.028	7.904		
30°C/65%RH	Triacetin	B-48340	T20			mg/stick	6	0.330	0.014	4.206		
30°C/65%RH	Triacetin	B-48340	T24			mg/stick	6	0.357	0.018	4.995		
30°C/65%RH	Triacetin	B-48341	T0			mg/stick	6	0.627	0.016	2.623		
30°C/65%RH	Triacetin	B-48341	T2			mg/stick	4	0.615	0.077	12.556		
30°C/65%RH	Triacetin	B-48341	T4			mg/stick	4	0.497	0.051	10.228		
30°C/65%RH	Triacetin	B-48341	T6			mg/stick	4	0.472	0.020	4.181		
30°C/65%RH	Triacetin	B-48341	T9			mg/stick	4	0.412	0.053	12.794		
30°C/65%RH	Triacetin	B-48341	T12			mg/stick	6	0.337	0.009	2.672		
30°C/65%RH	Triacetin	B-48341	T16			mg/stick	6	0.370	0.026	7.152		
30°C/65%RH	Triacetin	B-48341	T20			mg/stick	6	0.314	0.015	4.740		
30°C/65%RH	Triacetin	B-48341	T24			mg/stick	6	0.298	0.025	8.521		
30°C/65%RH	Triacetin	B-48342	T0			mg/stick	6	0.615	0.033	5.338		
30°C/65%RH	Triacetin	B-48342	T2			mg/stick	4	0.587	0.062	10.623		
30°C/65%RH	Triacetin	B-48342	T4			mg/stick	4	0.482	0.019	3.858		
30°C/65%RH	Triacetin	B-48342	T6			mg/stick	4	0.451	0.025	5.647		
30°C/65%RH	Triacetin	B-48342	T9			mg/stick	4	0.447	0.086	19.324		
30°C/65%RH	Triacetin	B-48342	T12			mg/stick	6	0.380	0.019	4.891		
30°C/65%RH	Triacetin	B-48342	T16			mg/stick	6	0.346	0.026	7.440		
30°C/65%RH	Triacetin	B-48342	T20			mg/stick	6	0.314	0.013	4.066		
30°C/65%RH	Triacetin	B-48342	T24			mg/stick	6	0.318	0.032	10.171		
30°C/65%RH	Water activity	B-48340	T0			N/A	3	0.420	0.000	0.000		
30°C/65%RH	Water activity	B-48340	T2			N/A	3	0.540	0.000	0.000		
30°C/65%RH	Water activity	B-48340	T4			N/A	3	0.593	0.006	0.973		
30°C/65%RH	Water activity	B-48340	T6			N/A	3	0.620	0.000	0.000		

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STABILITY STUDY FINAL REPORT



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CONDITION	VARIABLE	BATCH	Time point	LSL	USL	UNIT	N	Mean	Std	CV	Lower 95% CI	Upper 95% CI
30°C/65%RH	Water activity	B-48340	T9			N/A	3	0.640	0.000	0.000		
30°C/65%RH	Water activity	B-48340	T12			N/A	3	0.633	0.006	0.912		
30°C/65%RH	Water activity	B-48340	T16			N/A	3	0.650	0.000	0.000		
30°C/65%RH	Water activity	B-48340	T20			N/A	3	0.650	0.000	0.000		
30°C/65%RH	Water activity	B-48340	T24			N/A	3	0.650	0.000	0.000		
30°C/65%RH	Water activity	B-48341	T0			N/A	3	0.420	0.000	0.000		
30°C/65%RH	Water activity	B-48341	T2			N/A	3	0.550	0.000	0.000		
30°C/65%RH	Water activity	B-48341	T4			N/A	3	0.590	0.000	0.000		
30°C/65%RH	Water activity	B-48341	T6			N/A	3	0.617	0.006	0.936		
30°C/65%RH	Water activity	B-48341	T9			N/A	3	0.640	0.000	0.000		
30°C/65%RH	Water activity	B-48341	T12			N/A	3	0.623	0.006	0.926		
30°C/65%RH	Water activity	B-48341	T16			N/A	3	0.647	0.006	0.893		
30°C/65%RH	Water activity	B-48341	T20			N/A	3	0.650	0.000	0.000		
30°C/65%RH	Water activity	B-48341	T24			N/A	3	0.650	0.000	0.000		
30°C/65%RH	Water activity	B-48342	T0			N/A	3	0.430	0.000	0.000		
30°C/65%RH	Water activity	B-48342	T2			N/A	3	0.540	0.000	0.000		
30°C/65%RH	Water activity	B-48342	T4			N/A	3	0.590	0.000	0.000		
30°C/65%RH	Water activity	B-48342	T6			N/A	3	0.630	0.000	0.000		
30°C/65%RH	Water activity	B-48342	T9			N/A	3	0.637	0.006	0.907		
30°C/65%RH	Water activity	B-48342	T12			N/A	3	0.640	0.000	0.000		
30°C/65%RH	Water activity	B-48342	T16			N/A	3	0.647	0.006	0.893		
30°C/65%RH	Water activity	B-48342	T20			N/A	3	0.650	0.000	0.000		
30°C/65%RH	Water activity	B-48342	T24			N/A	3	0.650	0.000	0.000		

(b) (4)

(b) (4)

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4. STABILITY REPORT FOR MARLBORO GREEN MENTHOL HEATSTICKS²

² The update of the name for Marlboro Smooth Menthol *HeatSticks* (STN: PM0000425) to Marlboro Green Menthol *HeatSticks* was submitted with 30-day notification dated July 31, 2020.

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FINAL REPORT OF THE FOLLOW-UP STABILITY STUDY FOR THS2.2 LOW MENTHOL VARIANT 24 MONTHS

PRODUCT PLATFORM:

P1

PRODUCT GENERATION:

THS2.2

PROJECT NAME FOR NEW DEVELOPMENT:

LOW MENTHOL VARIANT (C3.2)

Effective Version

Version N°	Document Name	Document Title
3.0	From EDMS	From EDMS

For historical versions and change details, refer to paragraph 12 Change Management Log.



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1 Executive Summary

A stability study on Dorado I Fauvery Low menthol product was performed under 22°C 60%RH and 30°C 65%RH storage conditions during 24 months on 3 batches.

The data generated under the storage condition of 22°C 60%RH for aerosol chemistry, physical parameters and Water activity support a shelf life of 24 months. (b) (4)

(b) (4)

The data generated under the storage condition of 30°C 65%RH for aerosol chemistry, Tobacco stick weight and Water activity support a shelf life of 24 months. (b) (4)

(b) (4)

It has to be noticed, that the specifications used for the aerosol constituents assessment, excluding Menthol, were revised during the study. While the study is reported with the specifications referenced in the study protocol, prior the revision, the impact of the new specifications on the shelf life has been evaluated. The change has no impact on the shelf life conclusion.



2 Purpose

The stability study STAB-2017_P1_M_2 was performed until 12 months on the commercial product THS2.2 Low Menthol variant (Dorado I Fauvery) manufactured at Philip Morris Manufacturing & Technology Bologna (PMMTB) and is separately reported [1].

In order to understand the evolution of the product beyond the established Best Used Before Date (BUBD) of 12 months, the stability study on the same batches was extended until 24 months with three additional time points at 16, 20 and 24 months. The storage of the samples (tobacco sticks in their primary packaging) was continued without interruption under 22°C 60%RH (ISO condition [13]) and 30°C 65%RH (defined WHO [14]) storage conditions.

The study and the related attributes were based on PMI Stability Study Program THS2.2 [2] and are covering the product performance, safety and quality. The same attributes as for the 12 months study were continued to be monitored until 24 months with the exception of the visual inspection in 30°C 65%RH.

This report summarizes the results of the 24 months stability study STAB-2017_P1_M_2 performed according to the stability study protocol [3] and the follow-up study protocol for 24 months [4].

3 Batches

Table 1 Identification of batches Dorado I Fauvery Low (STAB-2017_P1_M_2)

Variant	Pack Batch Number	Finished Product Code	Tobacco Stick Product Code	PM MTB PO	Manufacturing Date	End of Equilibration Date	Beginning of the Study (T0)
THS 2.2 Dorado I Fauvery Low	B-48337	ME000419.11	CONS.02807.RD	101695805	18-Oct-2017	15-Nov-2017	20-Nov-2017
	B-48338	ME000419.11	CONS.02807.RD	101695806	19-Oct-2017	16-Nov-2017	20-Nov-2017
	B-48339	ME000419.11	CONS.02807.RD	101699003	20-Oct-2017	17-Nov-2017	20-Nov-2017

The samples were stored in the conditioning room ($22 \pm 2^\circ\text{C}$ $60 \pm 5\%\text{RH}$) and in climatic chambers ($30 \pm 2^\circ\text{C}$ $65 \pm 5\%\text{RH}$) in wrapped packs in R&D Neuchâtel Product Testing (PT) laboratories by the Test Item Management team (for ID numbers of the storage locations see Appendix 15.1). The packs were polypropylene wrapped and consisted of two collations, each collation containing 10 Heat sticks.



The end of equilibration corresponds to the date when the products passed the 28 days of equilibration used for mentholated products.

The beginning of the study corresponds to the date when the packs were put in the conditioning room and climatic chamber for one year storage. This date corresponds to the T0 time point.

4 Tests Methods and Specifications

The parameters tested during the study, the used methods and the specifications are listed in Table 2. All the instruments and materials are listed in the relevant work instructions.

A table containing dates of analyses for each time point is available in Appendix 15.2.

Table 2 Tests, Methods and Specifications

Parameter	Unit	Method Name	Method Version				Target Value	Specification		
			Planned	Used				Range or Upper Limit	Version	
				T0	T12	T24				
Nicotine	mg/stick	PMI-RRP-WKI-111801	9.0.0	9.0.0	9.0.0	11.0.0	(b) (4)	(b) (4)	3.0 [5]	
Glycerin	mg/stick								3.0 [5]	
Triacetin	mg/stick	PMI-RRP-WKI-111640*	4.0.0	3.0.0	4.0.0	4.0.0			3.0 [5]	
Carbon monoxide (CO)	mg/stick								3.0 [5]	
Phenol	µg/stick								3.0 [5]	
Acrylamide	µg/stick								3.0 [5]	
Formaldehyde	µg/stick	PMI-RRP-WKI-111743	13.0.0	13.0.0	13.0.0	14.0.0			3.0 [5]	
		PMI-RRP-WKI-111709	15.0.0	15.0.0	16.0.0	16.0.0				
1,3-butadiene	µg/stick	PMI-RRP-WKI-111729	7.0.0	7.0.0	8.0.0	10.0.0			3.0 [5]	
Benzene	µg/stick		PMI-RRP-WKI-111706	18.0.0	18.0.0	19.0.0			20.0.0	3.0 [5]
Menthol	mg/stick	PMI-RRP-WKI-111801	9.0.0	9.0.0	9.0.0	11.0.0				1.0 [6]
		PMI-RRP-WKI-111604*	4.0.0	3.0.0	4.0.0	4.0.0				



Parameter	Unit	Method Name	Method Version				Target Value	Specification	
			Planned	Used				Range or Upper Limit	Version
				T0	T12	T24			
(b) (4)							(b) (4)	(b) (4)	
Tobacco stick weight DI Low CONS.02807. RD	mg								6.0 [8]
Water activity	N/A	VM1349	1.0	1.0	1.0	1.0			1.0 [2]
Visual quality	N/A	See Chapter 4.4	N/A	N/A	N/A	N/A			N/A
QDP	N/A	PR.06	02	02	02	02			N/A

* The referenced method in the stability study was PMI-RRP-WKI-111604 instead of PMI-RRP-WKI-111640 being a typo error in the stability protocol.

4.1 Aerosol Measurement

Measurements of Nicotine, Glycerin, Triacetin, Carbon monoxide, Phenol, Menthol, Acrylamide, Formaldehyde, 1,3-butadiene and Benzene were performed after trapping the particulate and/or the gas phase of the aerosol and subsequent analyses described in respective work instructions (Table 2).

4.1.1 Preparation and Conditioning

At each time point before aerosol generation, in order to perform the testing under normal conditions as on freshly made products, sticks were reconditioned outside of the packs following ISO standard 3402 (1999), for a minimum of 48 hours and a maximum of 10 days at 22 ± 1 °C, $60 \pm 3\%$ RH according to PMI-RRP-WKI-111777 "Preparation of items". When reached the maximum time of conditioning samples were placed in a sealed recipient and remained in the conditioning room. For determination of Menthol, samples were kept in closed packs prior to analysis in order to avoid loss of menthol.

The 3R4F Reference Cigarette (purchased from the University of Kentucky, USA) or P1 monitor (P1M1 or P1M2) was used as an internal monitor for aerosol chemistry (PMI-RRP-WKI-123605). Values were compared to respective upper and lower limits defined in the control charts to verify the correct functioning of the experimental setup.

4.1.2 Aerosol Generation and Analyses

The atmosphere for aerosol generation was 22 ± 2 °C, $60 \pm 5\%$ RH.

Aerosol generation was performed on linear smoking machines.



The Health Canada Intense (HCI) smoking regimen [16] using bell shaped puff profile was used with the below listed parameters to generate the aerosol for further chemical analyses:

- Puff volume: 55 mL
- Puff duration: 2.0 s
- Puff interval: 30 s
- Number of puffs: 12

In the stability protocol for 12 months [3] the device DV.000174(8) was erroneously written to be used. The tobacco heating device DV.000180(5)/B-34548 was used to generate aerosol for chemical analyses. The deviation is described in chapter 6.2 and documented as a non-conformity (NC), NC-2019-00542. The device DV.000180(5)/B-34548 was used as well for T16 time point according to the follow-up protocol [4].

For the analyses of aerosol chemistry at T20 and T24 time points the device DV.000180(7)/B-61948 was used instead of the DV.000180(5) planned in the follow-up stability protocol. Indeed, the device DV.000180(5)/B-34548 has reached its maximum usage period and was replaced by DV.000180(7)/B-61948, which is used as a reference device in the laboratory. The deviation is described in chapter 6.4.

Aerosol was trapped on Cambridge filter pad, in impingers or the combination of both and analyses were performed by GC-MS or UPLC-MS/MS.

For T0, T12, T16, 20, 24 time points, 6 replicates/sample, for T2 to T9 time points 4 replicates/sample were performed.

4.2 Physical Measurement

(b) (4)

Tobacco Stick weight were measured as physical parameters.

4.2.1 Preparation and Conditioning

Conditioning for physical analyses was performed as per the respective work instruction, inside open packs for at least 24 hours at 22 ± 2 °C and $50 \pm 5\%$ RH.

4.2.2 Measurement

Cerulean C2 instrument was used for the determination of the physical parameters. For each time point 50 sticks/sample were measured.



4.3 Water Activity Measurement

The Water activity is the measurement of the free water available for microbiological growth. (b) (4) the risk of mold development in cured tobacco is considered negligible, therefore the (b) (4)

4.3.1 Preparation and Conditioning

At each time point 20 packs/sample from the climatic chambers were sent to (b) (4) (b) (4) In order to maintain sample integrity, shipment was done with express delivery with same day reception. Packs were wrapped in sealed aluminum packaging and upon arrival at (b) (4) the tobacco stick packs were placed under the stability studies' storage condition as described below.

The closed packs from storage condition 22°C 60%RH were placed prior analyses for at least 48 hours (max. 96 hours) in $25 \pm 2^\circ\text{C}$ $60 \pm 5\%\text{RH}$, while packs from storage condition 30°C 65%RH were placed in $30 \pm 2^\circ\text{C}$ $65 \pm 5\%\text{RH}$. For the T0 time point, samples were placed at least 48 hours in 25°C 60%RH. The condition 25°C 60%RH was used in the absence of 22°C 60%RH as standard condition at (b) (4) and considered as not having an impact on the water activity determination.

4.3.2 Analyses

Sticks were taken randomly from the packs and the tobacco was collected. This composite sample was mixed and 3 portions of approx. 2 g were filled into the sample mugs. The samples were measured using the LabMaster-aw instrument for their Water activity at 25°C.

For each time point 3 replicates/sample were analyzed.

4.4 Visual Evaluation

4.4.1 Preparation and Conditioning

(b) (4)

4.4.2 Evaluation

(b) (4)



(b) (4)

4.5 Sensorial Evaluation

4.5.1 Preparation and Conditioning

(b) (4)

4.5.2 Evaluation

(b) (4)



5 Stability Study Design

The study was performed according to the testing matrix described in Table 3. Samples were pulled out from the stability chambers not more than 6 days after the planned time point based on calendar months.

Table 3 Testing Matrix

Batch	Storage Conditions	Analysis Time Points (months)								
		0	2	4	6	9	12	16	20	24
Dorado I Fauvery Low (B-48337)	22±2°C / 60±5%RH	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W
	30±2°C / 65±5%RH		A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S W	A P S W	A P S W
Dorado I Fauvery Low (B-48338)	22±2°C / 60±5%RH	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W
	30±2°C / 65±5%RH		A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S W	A P S W	A P S W
Dorado I Fauvery Low (B-48339)	22±2°C / 60±5%RH	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W
	30±2°C / 65±5%RH		A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S W	A P S W	A P S W

A: Aerosol; P: Physical measurements; S: Sensorial analysis; V: Visual inspection, W: Water activity

6 Deviations to Study Protocol

6.1 Deviation Related to Method Versions

The version of several methods changed during the study compared to what was described in the study protocol (Table 2,[3],[4]).

6.1.1 Impact on the Study

The changes in the methods were all minor. They had no impact on the quantification of the tested parameters and therefore on the study results.



6.2 Deviation in Study Execution (1/3)

The device used during the stability study was DV.000180(5) instead of DV.000174(8) as stated in the stability protocol. The deviation is described in NC-2019-00542. The use of DV.000180(5) device was consistent during whole study (from T0 to T16).

6.2.1 Impact on the Study

The DV.000174(7) and the DV.000180(5) were released with the same Design Change Request (DCR-00310), therefore they are equivalent. The DV.000174(8) was released with the DCR-000516 which was a minor change having no impact on the aerosol. Therefore, the DV.000174(8) and the DV.000180(5) are equivalent in terms of aerosol performance and the deviation has no impact on the stability results.

6.3 Deviation in Study Execution (2/3)

At T2 and T4 time points the sensorial evaluation started prior to the reception of the Water activity data. According to the stability study protocol the sensorial analyses should have been performed only after reception and verification of the Water activity results, for all time point except T0, in order to assess and confirm the absence of toxicological risk.

6.3.1 Impact on the Study

The Water activity results were below the (b) (4) The deviation has no impact on the stability study.

6.4 Deviation in Study Execution (3/3)

The device used for aerosol chemistry at T20 and T24 time points was DV.000180(7)/B-61948 instead of DV.000180(5) as stated in the follow-up stability protocol. The deviation was described in the intermediate report at T20. Indeed, the device DV.000180(5)/B-34548 has reached its maximum usage period and was replaced by DV.000180(7)/B-61948, which was used as a reference device in the laboratory.

6.4.1 Impact on the Study

The DV.000180(6) was released with DCR-00585 and the DV.000180(7) was released with DCR-00516, both related to a minor change having no impact on the aerosol. Therefore, the DV.000180(7) and DV.000180(5) are equivalent in terms of aerosol performance and the deviation has no impact on the stability results.



7 Stability Data Evaluation

Results for aerosol chemistry, physical measurements and Water activity are stored in SDMS (Scientific Data Management System) under the corresponding project numbers (see Sample Traceability Matrix in Appendix 15.3). Results and final report of sensory evaluation are stored in PDIMS (Product Development Information Management System).

7.1 Investigations and Excluded Values

There were no Out of Trend (OOT) investigations performed and there are no excluded values.

7.1.1 Investigation at T16

An Out of Specification (OOS) investigation was opened (b) (4) for B-48339 stored under 30°C 65%RH. (b) (4)

(b) (4) No analytical reason could be identified to explain the result (b) (4)

(b) (4)

(b) (4) The details of the investigation are described in separate document [11].

7.2 Statistical Assessment

The statistical assessment for the chemical and physical characterization follows Guidelines ICH Q1E [15], performed by modelling the degradation profile of the test parameters using regression models with (b) (4). The regression analysis defines the trend of a quantitative stability test parameter for each batch over time on the predetermined stress conditions. The poolability of the batches is tested through statistical analyses to determine whether the regression lines from the batches have a common slope and a common intercept as described in Appendix 15.4.

There are 3 possible models:

Model 1: Different slope / different intercept: final poolability model indicates that the batches do not have similar stability profiles with respect to starting point and change over time. This model uses individual batch intercepts and individual batch slopes with a pooled mean square error calculated from all batches and the shelf life is determined with the least favorable batch.

Model 2: Common slope / different intercept: final model indicates that the batches have a similar stability profile with regards to change over time. However, they do not have a



consistent starting value. This model uses individual batch intercepts and a common slope with a pooled mean square error and the shelf life is determined from the least favorable batch.

Model 3: Common slope / common intercept: final model indicates that the batches have a similar stability profile and can therefore be pooled together for one expiry determination. The pooled model uses a common intercept and common slope with a pooled mean square error.

The shelf life period corresponds to the earliest time at which the lower or upper 95% confidence interval (CI) regression confidence bounds calculated from the model intersects with the lower or upper specification limit.

The shelf life obtained with (b) (4) is truncated to whole number. In case the shelf life calculated by (b) (4) is longer than the study duration the shelf life will be equal to the study duration.

For Menthol and Water activity under both storage conditions, and (b) (4)
(b) (4)
(b) (4) This approach is applied as the values are not following a linear evolution over time.

Tabulated results with summary statistics are presented in the Appendix 15.5 and 15.6.

7.3 Results for Storage Condition 22°C 60% RH

The Table 4 and Table 5 contain for each batch and each tested parameter per time point the reported value (mean value), together with the upper and/or lower specifications.

Figure 1 to Figure 12 (except for Menthol) contain the reported values for the 3 batches together with the specification, the linear regression and the upper and lower 95% CI of the regression depending on the final model kept (model 1, model 2 or model 3). The CIs are illustrated on the figures by the shaded area.

For Menthol and Water activity the reported value with the one sided 95% CI is shown over time for the 3 batches.

The dashed red lines represent the specification limits. Whereas, the dashed blue line shows the time when the 95% CI crosses the specification or is automatically drawn at 25 months if the 95% CI crosses the specification after the study length of 24 months.



The graphs were created with x-axes above the 24 months of study duration, however this has no extrapolation purpose.

Table 4 Mean values for aerosol constituents for 3 batches T0 – T24 for 22°C 60% RH

PARAMETER	BATCH	LSL	USL	UNIT	T0	T2	T4	T6	T9	T12	T16	T20	T24
1,3 Butadiene	B-48337	(b) (4)		µg/stick	0.283	0.262	0.292	0.268	0.242	0.257	0.288	0.272	0.266
1,3 Butadiene	B-48338			µg/stick	0.260	0.254	0.269	0.233	0.239	0.240	0.272	0.276	0.240
1,3 Butadiene	B-48339			µg/stick	0.288	0.255	0.277	0.268	0.247	0.314	0.289	0.319	0.268
Acrylamide	B-48337			µg/stick	2.05	1.89	2.02	2.03	2.11	1.95	1.58	1.54	1.69
Acrylamide	B-48338			µg/stick	1.86	1.88	1.95	1.95	2.21	1.93	1.47	1.57	1.73
Acrylamide	B-48339			µg/stick	1.88	1.97	1.86	2.12	1.88	1.95	1.47	1.80	1.81
Benzene	B-48337			µg/stick	0.63	0.60	0.61	0.60	0.59	0.56	0.56	0.53	0.55
Benzene	B-48338			µg/stick	0.57	0.60	0.54	0.51	0.58	0.53	0.53	0.53	0.52
Benzene	B-48339			µg/stick	0.62	0.59	0.56	0.58	0.59	0.56	0.54	0.55	0.56
Carbon monoxide	B-48337			mg/stick	0.58	0.56	0.61	0.42	0.48	0.42	0.42	0.44	0.48
Carbon monoxide	B-48338			mg/stick	0.52	0.58	0.59	0.42	0.42	0.41	0.41	0.43	0.49
Carbon monoxide	B-48339			mg/stick	0.56	0.54	0.57	0.42	0.44	0.43	0.41	0.45	0.49
Formaldehyde	B-48337			µg/stick	4.793	4.653	3.583	3.867	3.693	4.242	3.411	4.027	3.750
Formaldehyde	B-48338			µg/stick	3.777	3.832	4.335	3.079	4.166	3.741	3.808	3.538	3.979
Formaldehyde	B-48339			µg/stick	3.906	4.842	4.565	4.425	4.079	4.120	3.876	4.314	4.572
Glycerin	B-48337			mg/stick	5.18	5.48	4.70	4.94	5.18	4.48	4.59	4.34	4.72
Glycerin	B-48338			mg/stick	4.84	5.52	4.89	5.01	5.16	4.64	4.34	4.33	4.96
Glycerin	B-48339			mg/stick	5.14	5.63	4.97	5.50	5.04	4.86	4.45	4.82	5.28
Menthol	B-48337			mg/stick	1.3	2.0	1.9	2.1	2.1	1.9	1.8	1.9	2.0
Menthol	B-48338			mg/stick	1.1	2.0	2.0	1.9	2.1	1.8	1.9	1.9	2.2
Menthol	B-48339			mg/stick	1.3	1.9	2.1	2.1	2.1	2.0	1.9	1.9	2.1
Nicotine	B-48337			mg/stick	1.25	1.24	1.21	1.26	1.26	1.22	1.27	1.13	1.30
Nicotine	B-48338			mg/stick	1.18	1.23	1.19	1.24	1.29	1.25	1.26	1.16	1.34
Nicotine	B-48339			mg/stick	1.25	1.28	1.24	1.33	1.24	1.27	1.25	1.24	1.37
Phenol	B-48337			µg/stick	1.22	1.06	0.94	0.78	1.13	0.78	0.98	0.76	1.29
Phenol	B-48338			µg/stick	1.25	1.33	1.09	1.05	1.20	1.02	1.04	0.79	1.51
Phenol	B-48339			µg/stick	1.22	1.07	1.02	1.14	1.14	1.03	0.94	0.99	1.59
Triacetin	B-48337			mg/stick	0.64	0.62	0.53	0.51	0.53	0.46	0.42	0.41	0.43
Triacetin	B-48338			mg/stick	0.61	0.65	0.53	0.51	0.51	0.46	0.40	0.43	0.43
Triacetin	B-48339			mg/stick	0.57	0.59	0.51	0.51	0.50	0.47	0.39	0.43	0.45



Table 5 Mean values for physical parameters and Water activity for 3 batches T0 – T24 for 22°C 60% RH

PARAMETER	BATCH	LSL	USL	UNIT	T0	T2	T4	T6	T9	T12	T16	T20	T24
				b) (4)									
Tobacco stick weight	B-48337	b) (4)		mg	812	821	810	822	816	817	819	807	835
Tobacco stick weight	B-48338			mg	828	827	834	831	821	826	831	827	835
Tobacco stick weight	B-48339			mg	814	822	818	816	817	822	812	813	814
Water activity	B-48337			N/A	0.43	0.48	0.51	0.53	0.54	0.55	0.55	0.59	0.59
Water activity	B-48338			N/A	0.43	0.48	0.51	0.52	0.54	0.55	0.56	0.58	0.58
Water activity	B-48339			N/A	0.43	0.48	0.50	0.53	0.54	0.54	0.56	0.58	0.57

7.3.1 Aerosol Constituents Evaluation for 22°C 60%RH

7.3.1.1 Nicotine for 22°C 60%RH

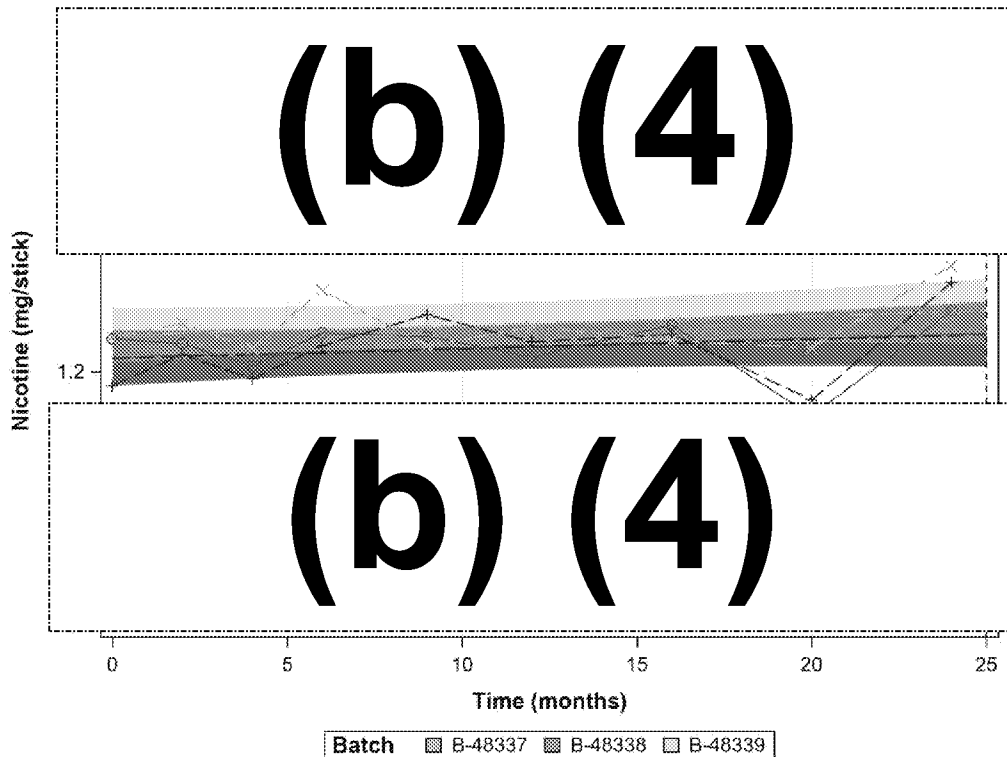


Figure 1 Evolution of Nicotine for the 3 batches together with the specification levels, the linear regression of the 3 batches and the 95% CI for the regression (CI shown as the shaded area - valid for all figures presented below)

The best model accepted at the significance level of 0.25 has Different intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.3.1.2 Glycerin for 22°C 60%RH

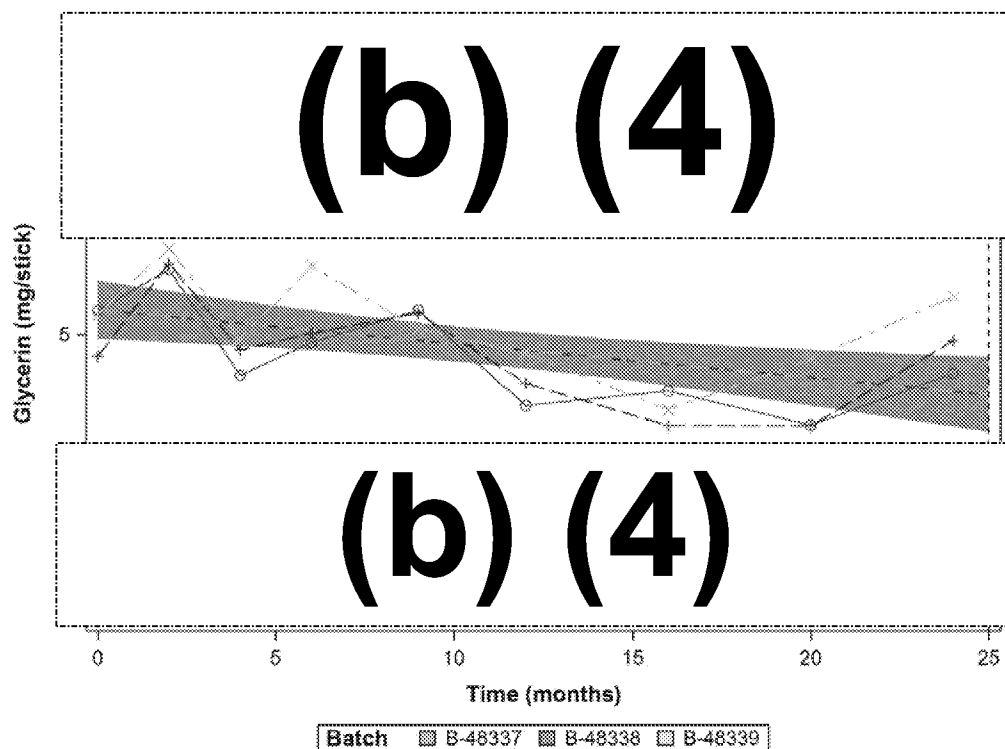


Figure 2 Evolution of Glycerin for the 3 batches together with the specification levels, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.3.1.3 Triacetin for 22°C 60%RH

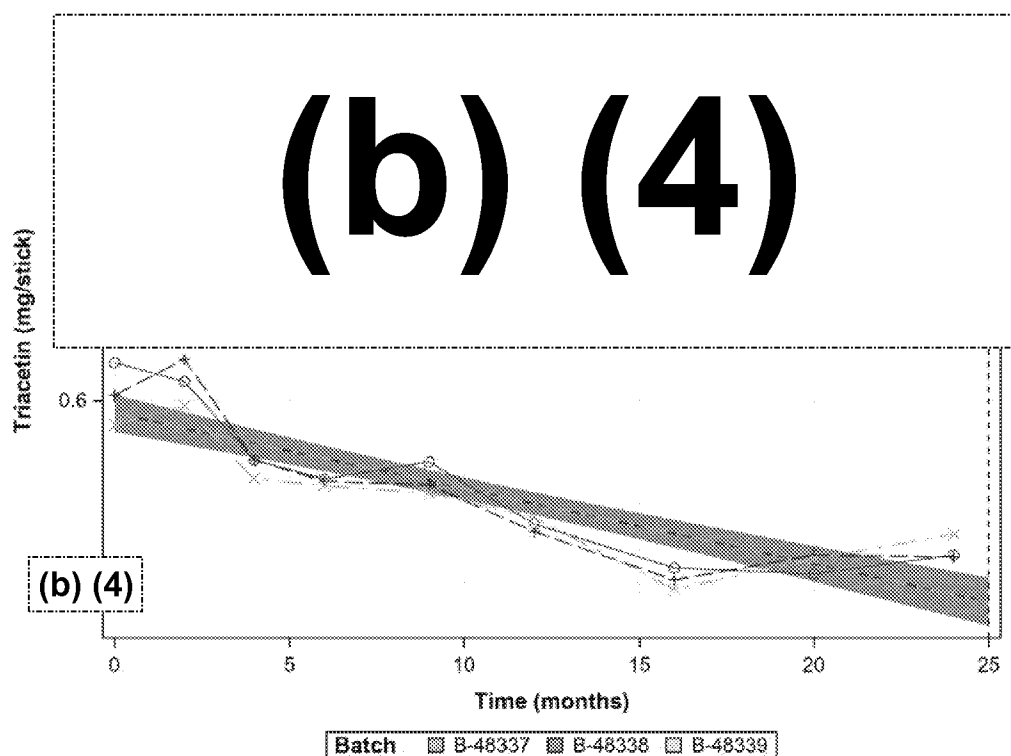


Figure 3 Evolution of Triacetin for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.3.1.4 Carbon monoxide for 22°C 60%RH

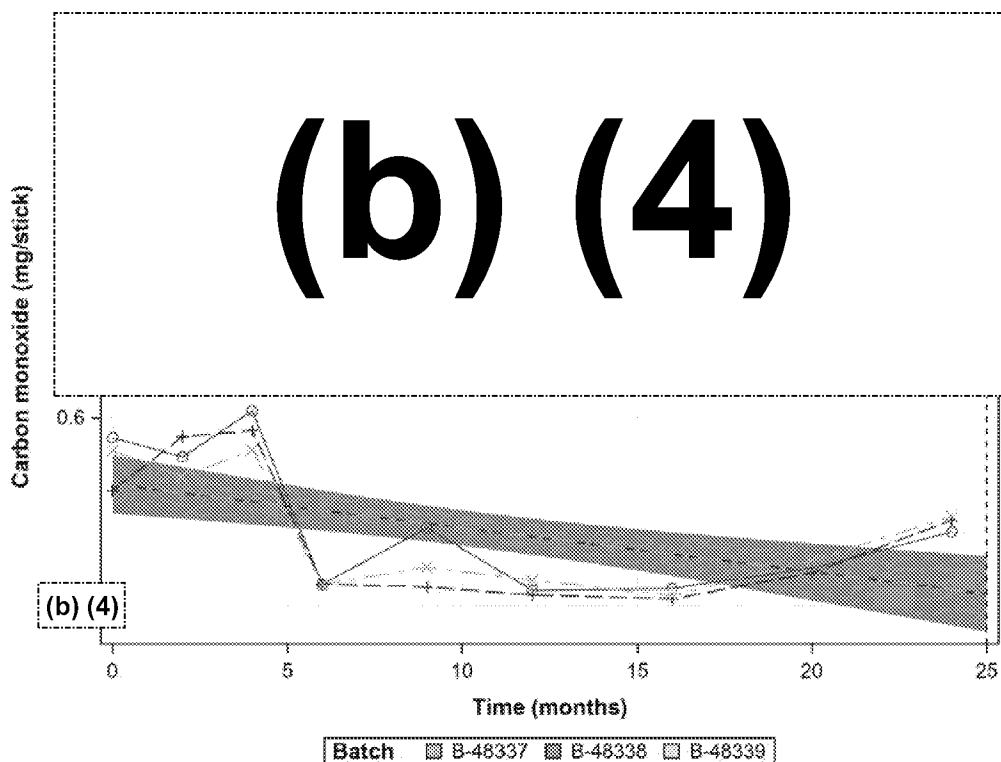


Figure 4 Evolution of Carbon monoxide for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.3.1.5 Phenol for 22°C 60%RH

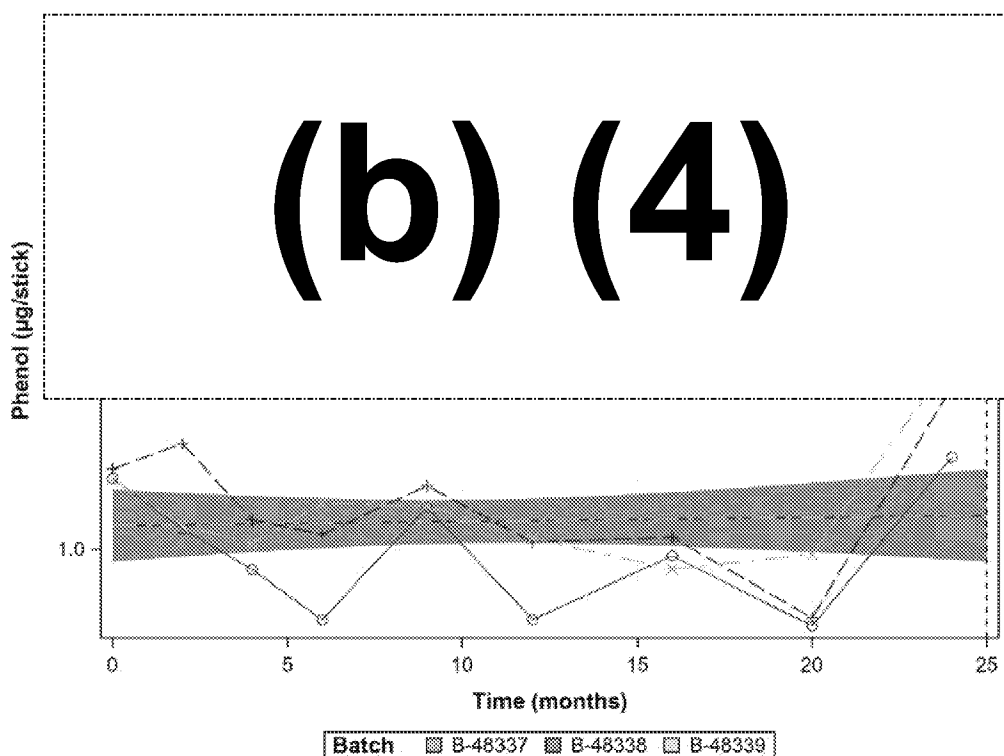


Figure 5 Evolution of Phenol for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.3.1.6 Acrylamide for 22°C 60%RH

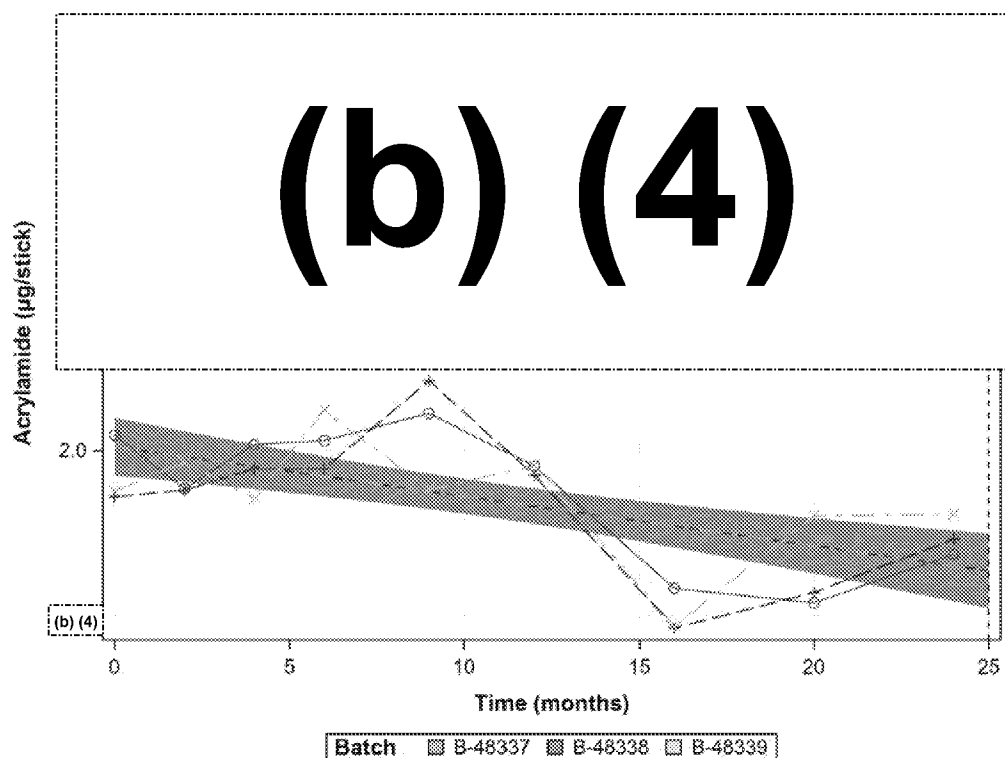


Figure 6 Evolution of Acrylamide for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% CI for the regression (mcg = µg)

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.3.1.7 Menthol for 22°C 60%RH

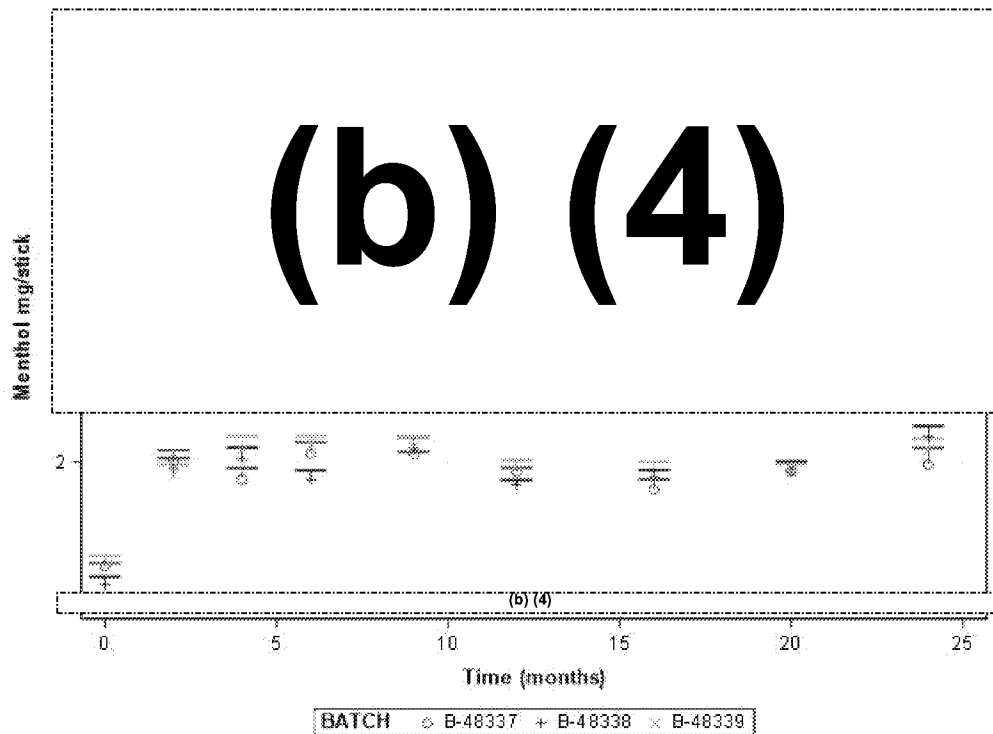


Figure 7 Evolution of Menthol (mg/stick) for the 3 batches (mean value plus the one sided 95% CIs of the mean) together with the specification level

The mean values and their one sided upper 95% CIs are not exceeding the specification level for Menthol. Therefore, a shelf life of 24 months is acceptable.



7.3.1.8 Formaldehyde for 22°C 60%RH

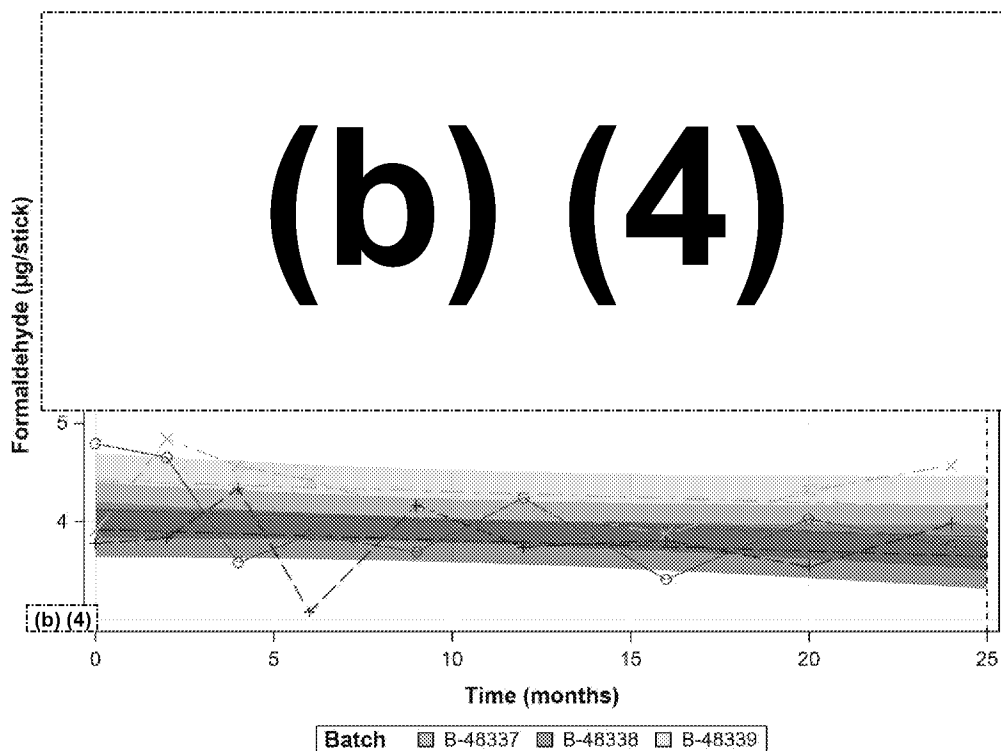


Figure 8 Evolution of Formaldehyde for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Different intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.3.1.9 1,3-Butadiene for 22°C 60%RH

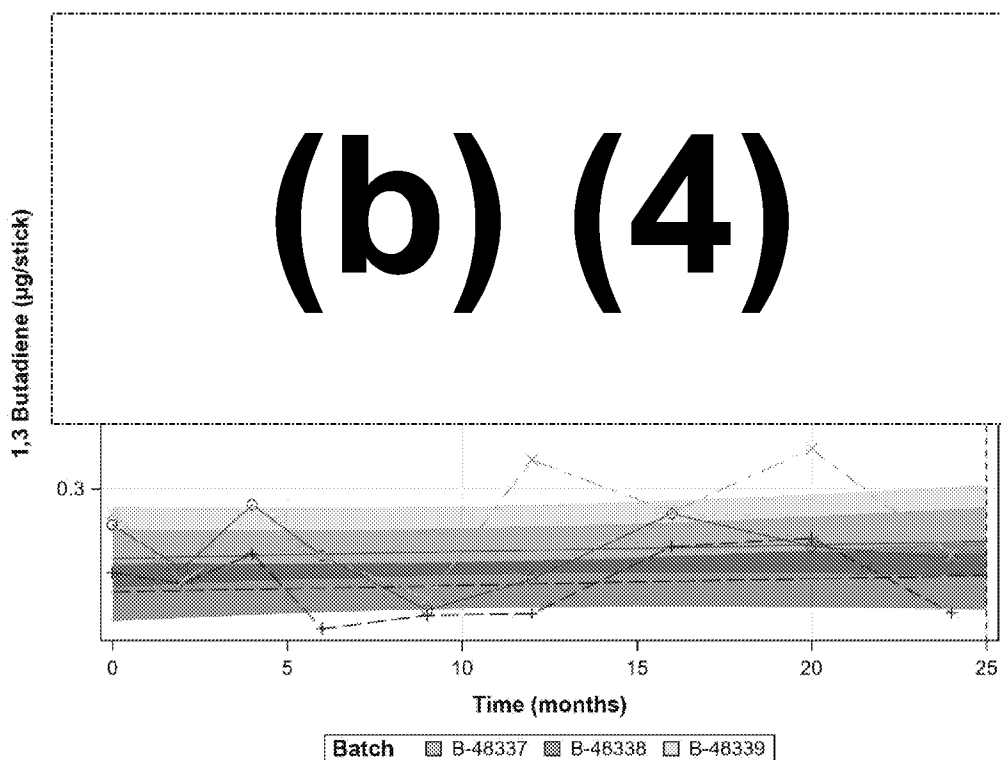


Figure 9 Evolution of 1,3-Butadiene for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Different intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.3.1.10 Benzene 22°C 60%RH

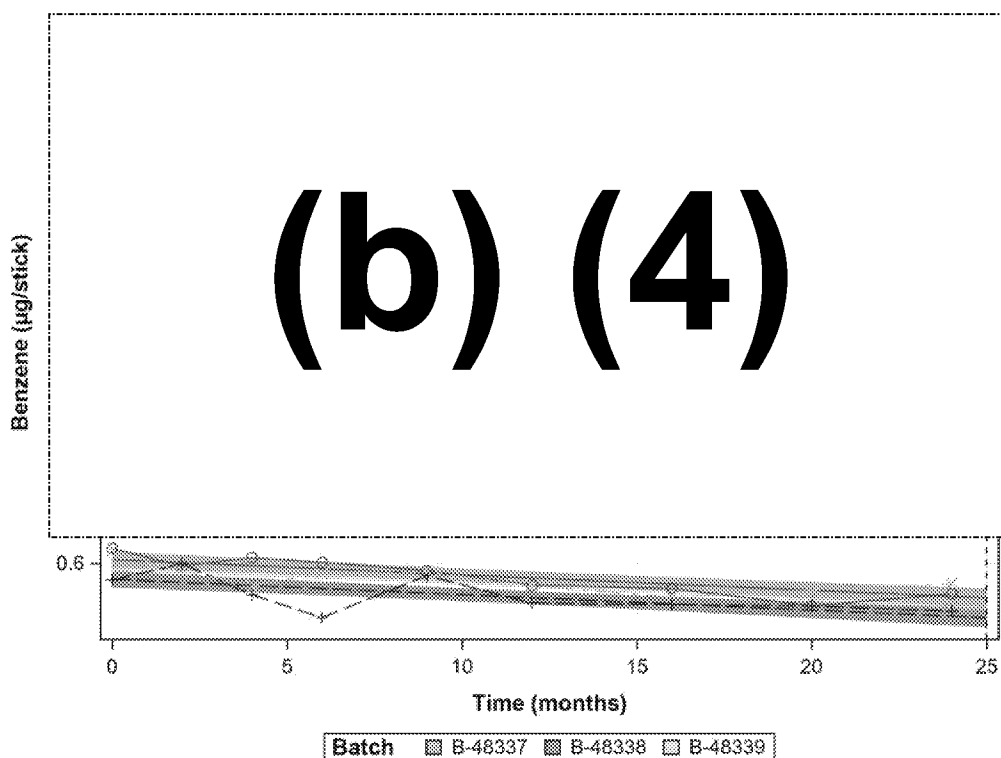


Figure 10 Evolution of Benzene for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Different intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.3.2 Physical Parameters Evaluation for 22°C 60%RH

(b) (4)



7.3.2.2 Tobacco Stick Weight 22°C 60%RH

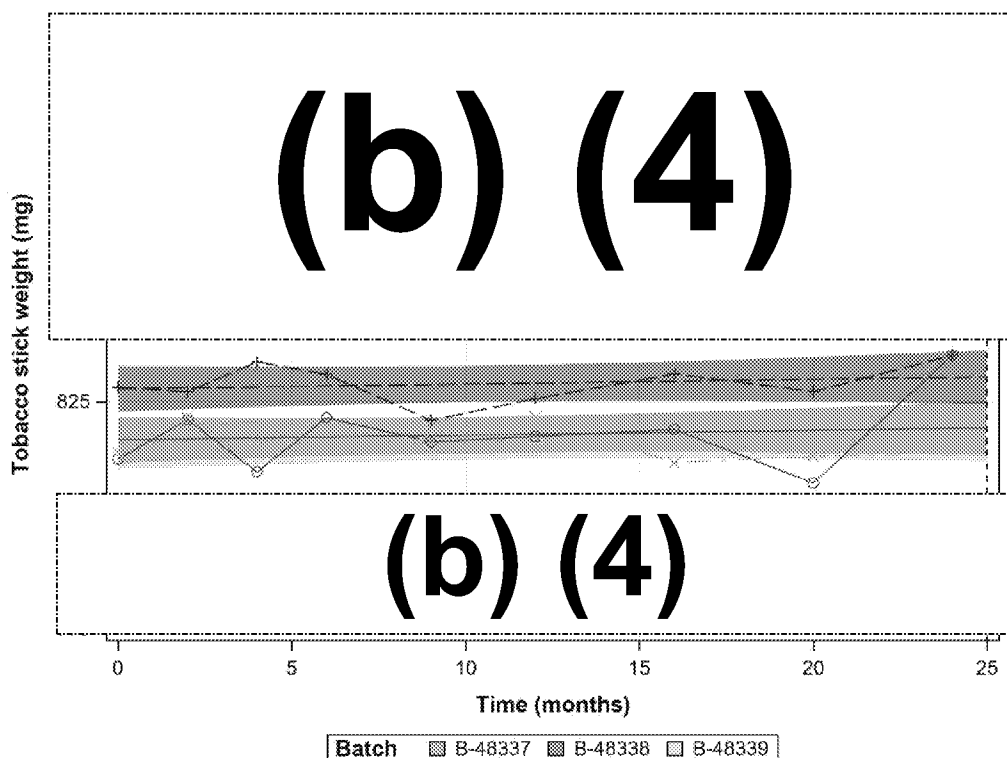


Figure 12 Evolution of Tobacco Stick weight for the 3 batches together with the specification levels, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Different intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.3.3 Water Activity Evaluation for 22°C 60%RH

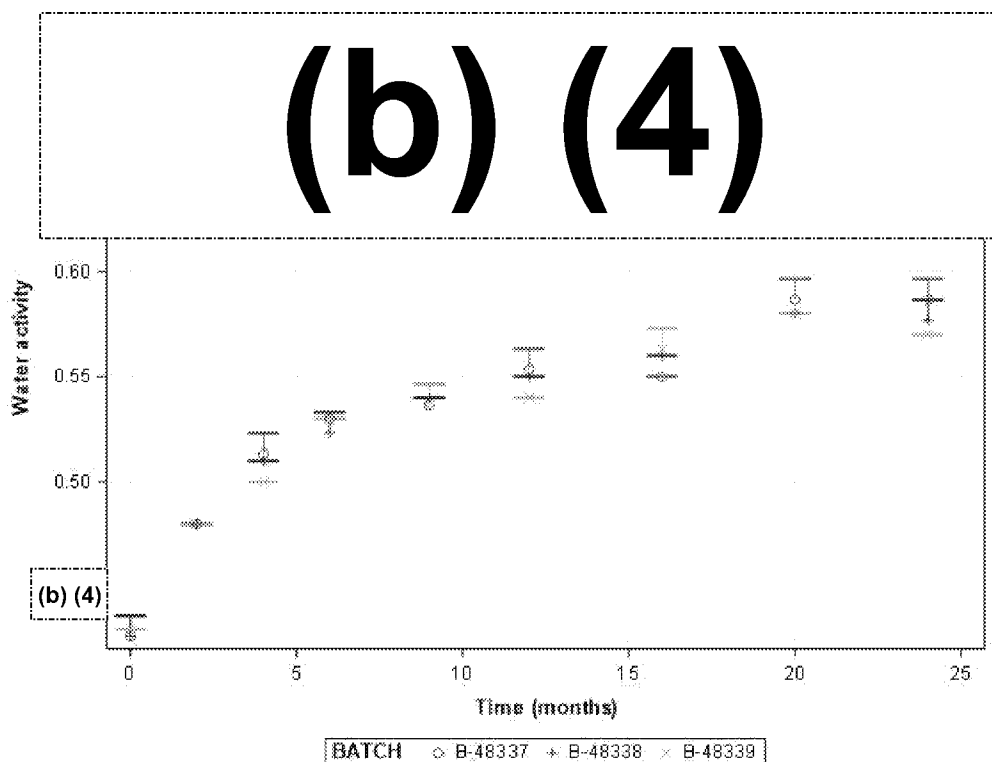


Figure 13 Evolution of Water activity for the 3 batches (mean value plus the one sided 95% CIs of the mean) together with the specification level

The mean values and the one sided upper 95% CIs limit did not exceed the **(b) (4)**.
(b) (4) Therefore, a shelf life of 24 months is acceptable.

7.3.4 Sensorial Evaluation for 22°C 60%RH

Sensorial evaluation results are described in details in a separate reports up to 12 months [9] and up to 24 months [10].

Overall, the sensory profile of the three tested batches did not undergo major sensory changes at condition 22°C 60%RH over the 24 months storage. Low magnitude changes could be observed for the following attributes:

Minty: the product was perceived significantly more Minty at T2, T6, T9 and T12 compared to T0, T4, T16, T20 and T24 (95% confidence level).



(b) (4)

7.3.5 Visual Evaluation for 22°C 60%RH

(b) (4)



(b) (4)



(b) (4)



(b) (4)



(b) (4)

(b) (4)

7.4 Results for Storage Condition 30°C 65% RH

The Table 6 and Table 7 contain for each batch and each tested parameter per time point the reported value (mean value), together with the upper and/or lower specification levels. Figure 19 to Figure 31 (except for Menthol) contain the reported value for the 3 batches together with the specification levels, the linear regression and the upper and lower 95% CI of the regression of the mean or the individual batches depending on the final model kept (model 1, model 2 or model 3). The CIs are illustrated on the figures by the shaded area.

For Menthol, Water activity and the **(b) (4)**
(b) (4)

The dashed red lines represent the specification limits. Whereas, the dashed blue line shows the time when the 95% CI crosses the specification or is automatically drawn at 25 months if the 95% CI crosses the specification after the study length of 24 months.

The graphs were created with x-axes above the 24 months of study duration, however this has no extrapolation purpose.



Table 6 Mean values for aerosol constituents for 3 batches T0 – T24 for 30°C 65% RH

PARAMETER	BATCH	LSL	USL	UNITS	T0	T2	T4	T6	T9	T12	T16	T20	T24
1,3 Butadiene	B-48337	(b) (4)	(b) (4)	µg/stick	0.283	0.266	0.297	0.281	0.273	0.250	0.348	0.283	0.252
1,3 Butadiene	B-48338			µg/stick	0.260	0.253	0.269	0.248	0.257	0.237	0.317	0.305	0.254
1,3 Butadiene	B-48339			µg/stick	0.288	0.244	0.298	0.277	0.250	0.263	0.339	0.306	0.272
Acrylamide	B-48337			µg/stick	2.05	1.85	1.77	1.71	1.39	1.44	1.01	0.97	0.93
Acrylamide	B-48338			µg/stick	1.86	1.83	1.70	1.68	1.68	1.47	0.98	1.11	1.00
Acrylamide	B-48339			µg/stick	1.88	1.83	1.69	1.86	1.86	1.51	1.02	1.07	1.01
Benzene	B-48337			µg/stick	0.63	0.59	0.59	0.61	0.62	0.56	0.54	0.53	0.53
Benzene	B-48338			µg/stick	0.57	0.59	0.54	0.53	0.58	0.53	0.51	0.53	0.53
Benzene	B-48339			µg/stick	0.62	0.57	0.57	0.58	0.60	0.56	0.54	0.53	0.57
Carbon monoxide	B-48337			mg/stick	0.58	0.58	0.59	0.42	0.40	0.42	0.43	0.44	0.46
Carbon monoxide	B-48338			mg/stick	0.52	0.58	0.59	0.40	0.40	0.42	0.42	0.45	0.47
Carbon monoxide	B-48339			mg/stick	0.56	0.56	0.59	0.42	0.46	0.43	0.41	0.43	0.46
Formaldehyde	B-48337			µg/stick	4.793	4.042	3.649	3.631	4.554	3.307	3.535	3.792	3.818
Formaldehyde	B-48338			µg/stick	3.777	4.082	3.430	3.634	4.476	3.740	4.033	3.806	3.730
Formaldehyde	B-48339			µg/stick	3.906	4.468	4.497	3.846	4.659	3.825	4.759	3.742	3.848
Glycerin	B-48337			mg/stick	5.18	5.30	4.62	4.80	4.01	3.97	3.77	3.46	3.44
Glycerin	B-48338			mg/stick	4.84	5.20	4.29	4.49	4.34	3.95	3.60	3.64	3.51
Glycerin	B-48339			mg/stick	5.14	5.23	4.39	4.85	4.59	4.10	3.66	3.60	3.66
Menthol	B-48337			mg/stick	1.3	2.1	1.9	1.9	1.8	1.6	1.6	1.5	1.7
Menthol	B-48338			mg/stick	1.1	2.2	2.1	1.9	1.8	1.5	1.6	1.5	1.5
Menthol	B-48339			mg/stick	1.3	2.3	2.0	1.9	1.8	1.6	1.6	1.5	1.6
Nicotine	B-48337			mg/stick	1.25	1.22	1.13	1.18	1.09	1.14	1.11	0.98	1.05
Nicotine	B-48338			mg/stick	1.18	1.21	1.11	1.17	1.16	1.15	1.10	1.07	1.09
Nicotine	B-48339			mg/stick	1.25	1.23	1.14	1.24	1.19	1.16	1.14	1.05	1.11
Phenol	B-48337			µg/stick	1.22	1.07	1.04	0.91	0.86	0.82	0.86	0.67	0.90
Phenol	B-48338			µg/stick	1.25	1.03	1.00	0.84	1.01	0.94	0.92	0.87	1.19
Phenol	B-48339			µg/stick	1.22	1.14	0.87	1.10	1.19	0.90	0.93	0.73	1.15
Triacetin	B-48337			mg/stick	0.64	0.52	0.42	0.38	0.35	0.34	0.30	0.29	0.27
Triacetin	B-48338			mg/stick	0.61	0.52	0.41	0.37	0.38	0.34	0.30	0.29	0.28
Triacetin	B-48339			mg/stick	0.57	0.50	0.41	0.37	0.40	0.33	0.29	0.30	0.29



Table 7 Mean values for physical parameters and Water activity for 3 batches T0 – T24 for 30°C 65% RH

PARAMETER	BATCH	LSL	USL	UNITS	T0	T2	T4	T6	T9	T12	T16	T20	T24
		b) (4)											
Tobacco stick weight	B-48337	(b) (4)		mg	812	815	811	822	806	814	810	809	814
Tobacco stick weight	B-48338			mg	828	837	820	830	820	823	816	805	833
Tobacco stick weight	B-48339			mg	814	818	810	820	813	823	816	811	817
Water activity	B-48337			N/A	0.43	0.54	0.58	0.60	0.61	0.62	0.62	0.63	0.64
Water activity	B-48338			N/A	0.43	0.55	0.58	0.61	0.61	0.62	0.61	0.63	0.64
Water activity	B-48339			N/A	0.43	0.54	0.58	0.60	0.61	0.61	0.62	0.63	0.64



7.4.1 Aerosol Constituents Evaluation for 30°C 65%RH

7.4.1.1 Nicotine for 30°C 65%RH

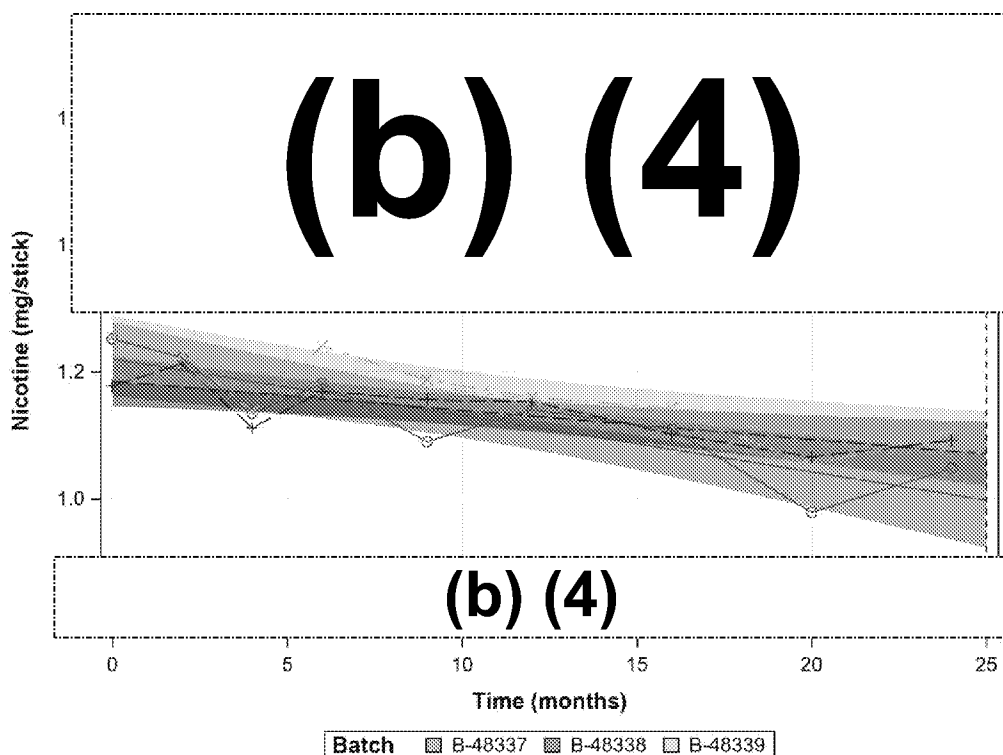


Figure 19 Evolution of Nicotine for the 3 batches together with the specification levels, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Different intercepts and Different slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.4.1.2 Glycerin for 30°C 65%RH

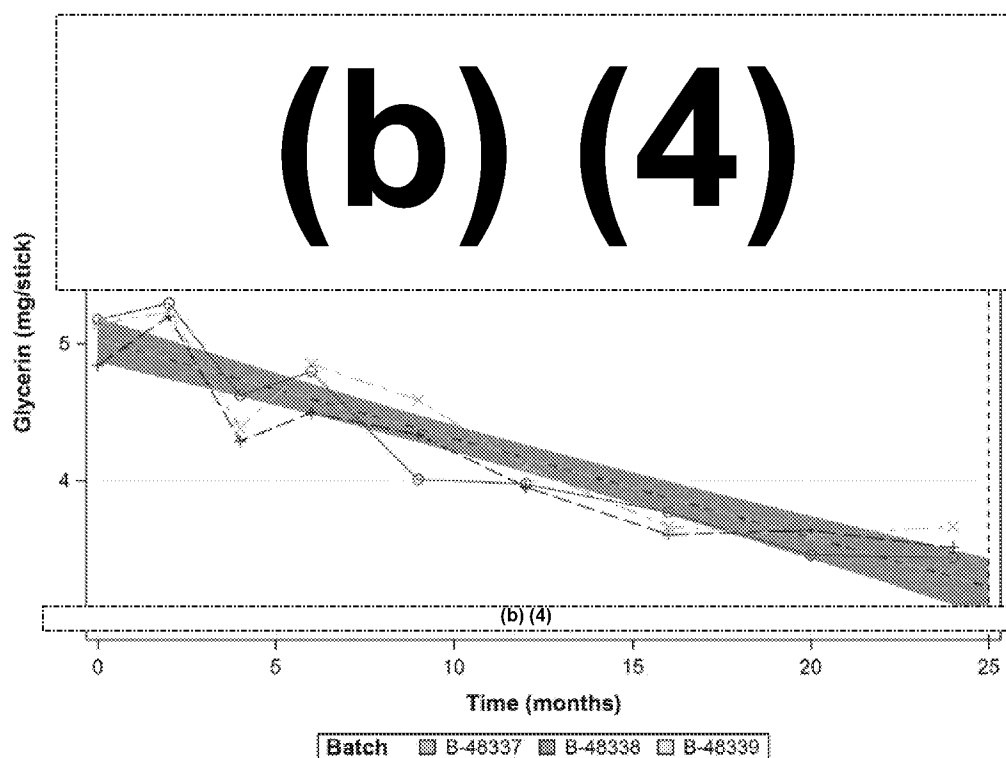


Figure 20 Evolution of Glycerin for the 3 batches together with the specification levels, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.4.1.3 Triacetin for 30°C 65%RH

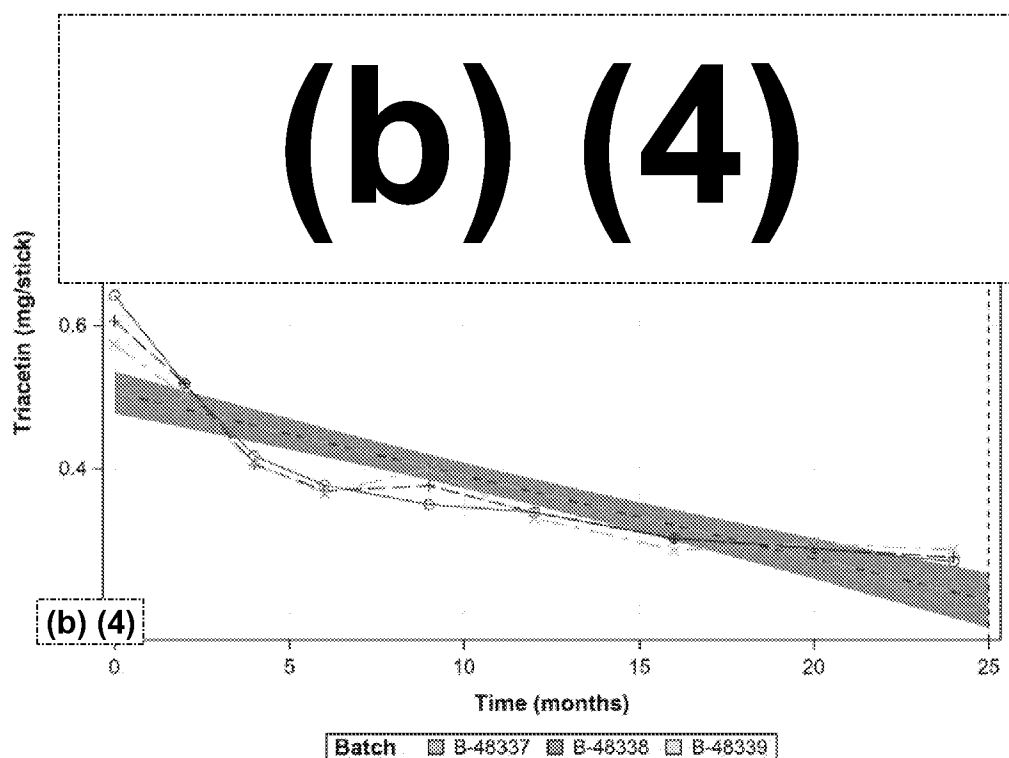


Figure 21 Evolution of Triacetin for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.4.1.4 Carbon monoxide for 30°C 65%RH

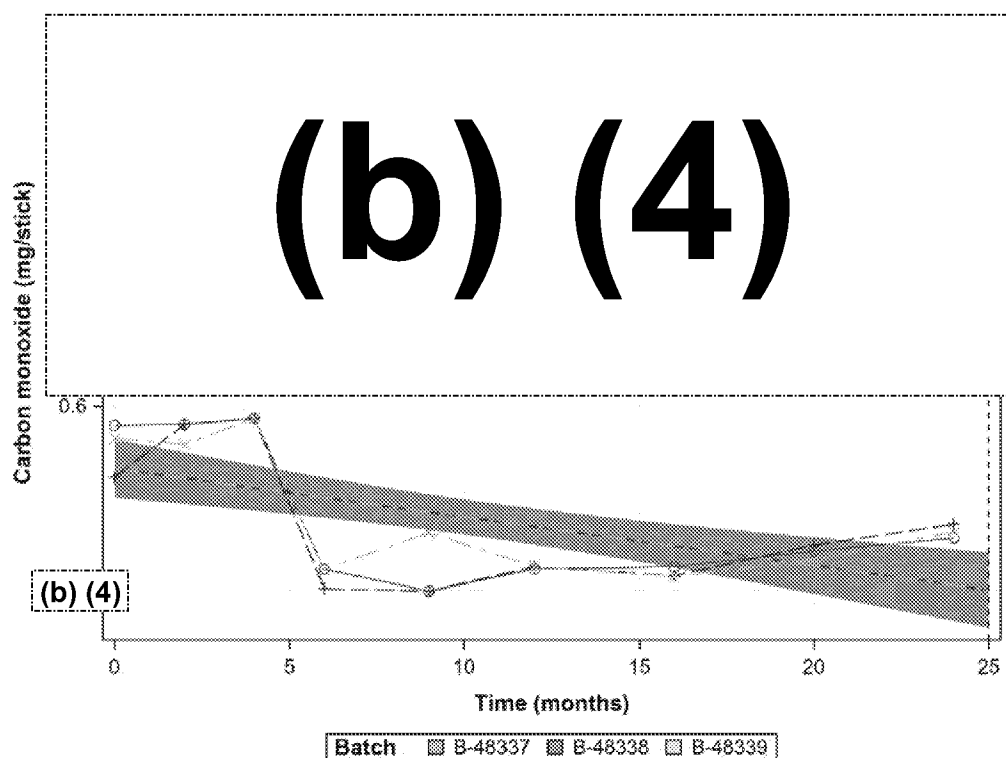


Figure 22 Evolution of Carbon monoxide for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.4.1.5 Phenol for 30°C 65%RH

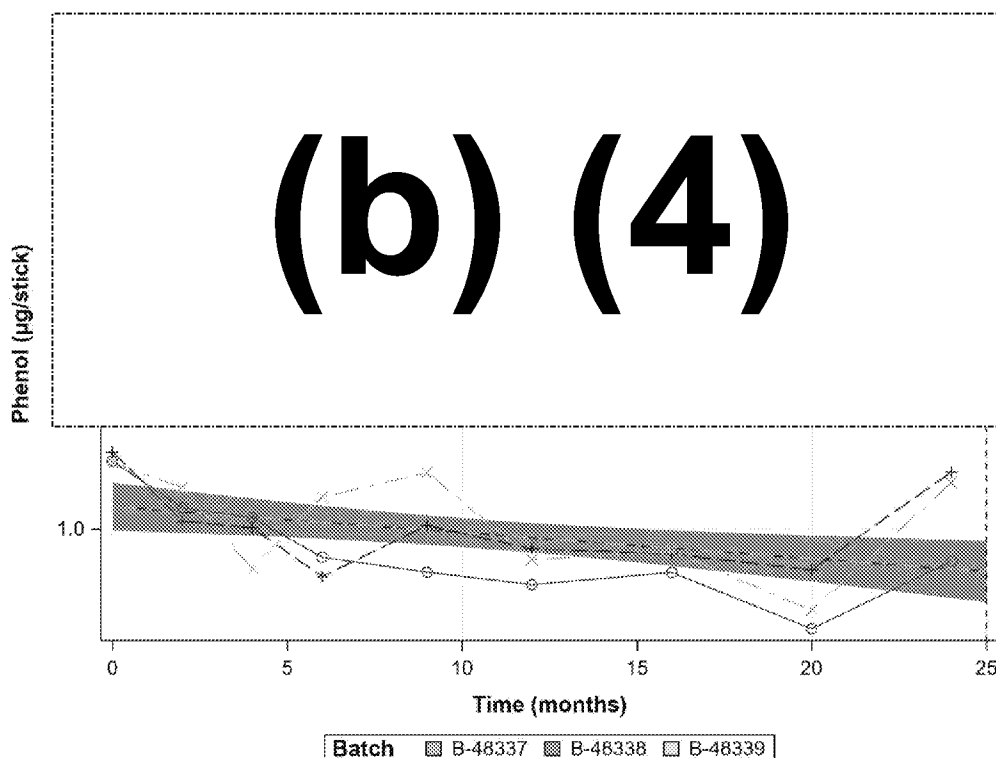


Figure 23 Evolution of Phenol for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.4.1.6 Acrylamide for 30°C 65%RH

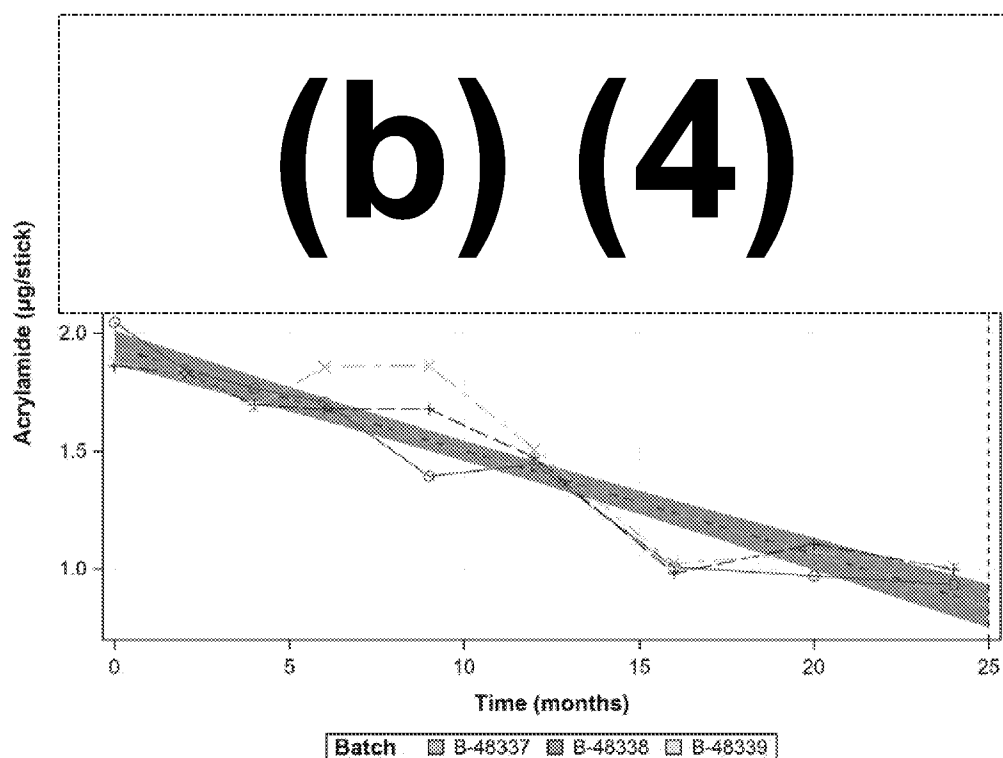


Figure 24 Evolution of Acrylamide for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.4.1.7 Menthol for 30°C 65%RH

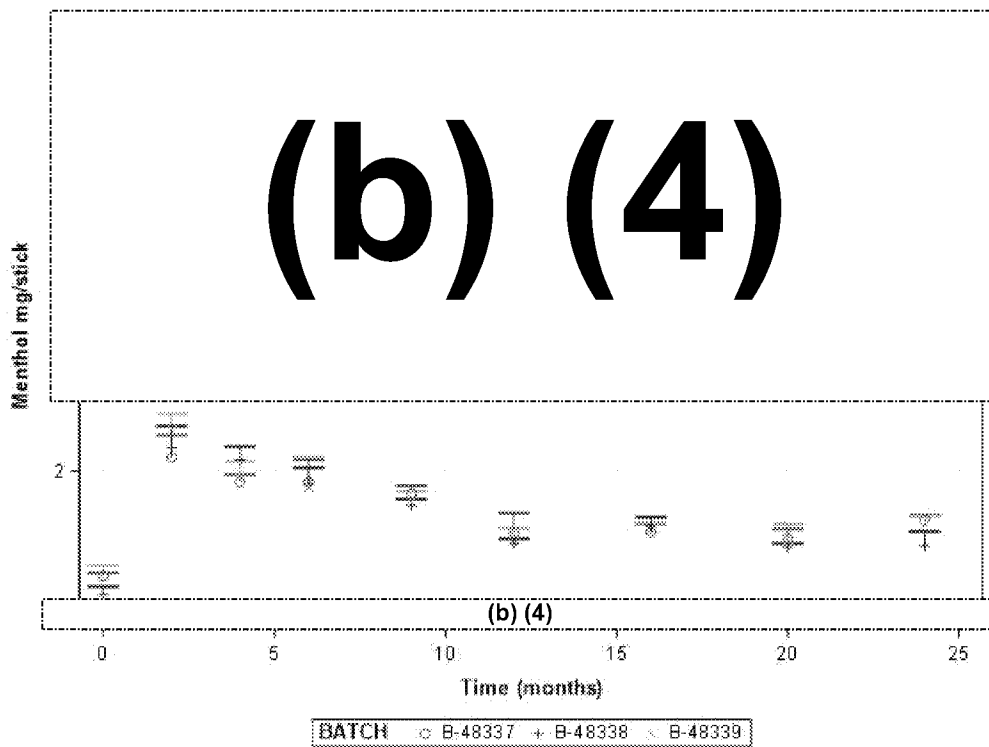


Figure 25 Evolution of Menthol (mg/stick) for the 3 batches (mean value plus the one sided 95% CIs of the mean) together with the specification level

The mean values and their one sided upper 95% CIs are not exceeding the specification level for Menthol. Therefore, a shelf life of 24 months is acceptable.

7.4.1.8 Formaldehyde for 30°C 65%RH

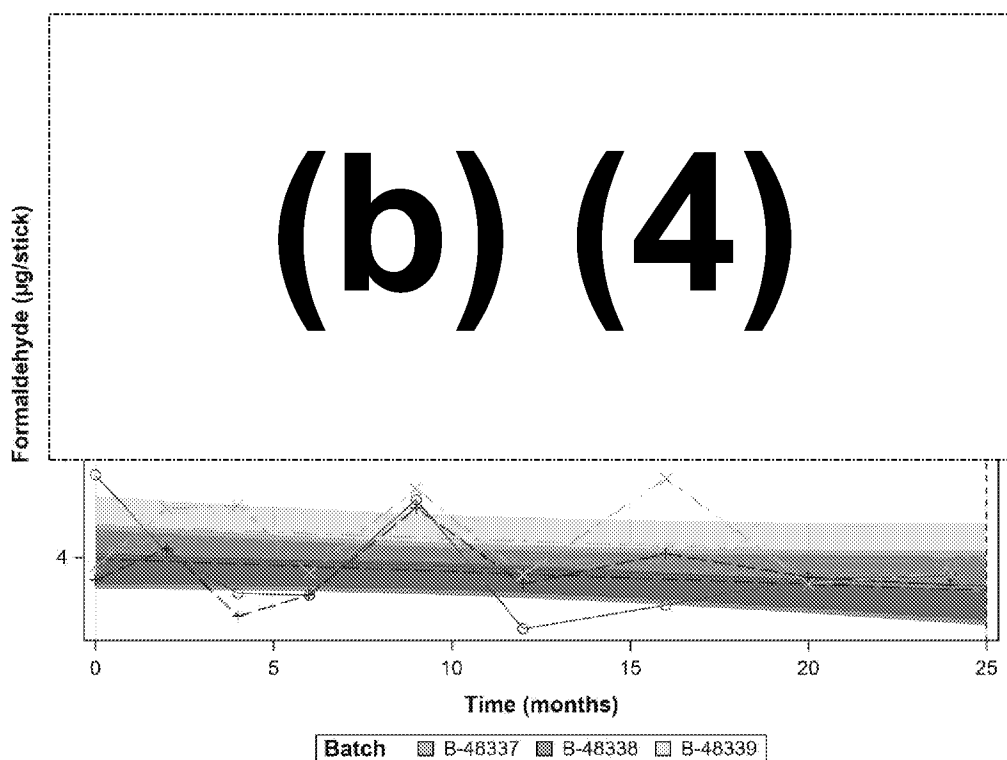


Figure 26 Evolution of Formaldehyde for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Different intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.

7.4.1.9 1,3-Butadiene for 30°C 65%RH

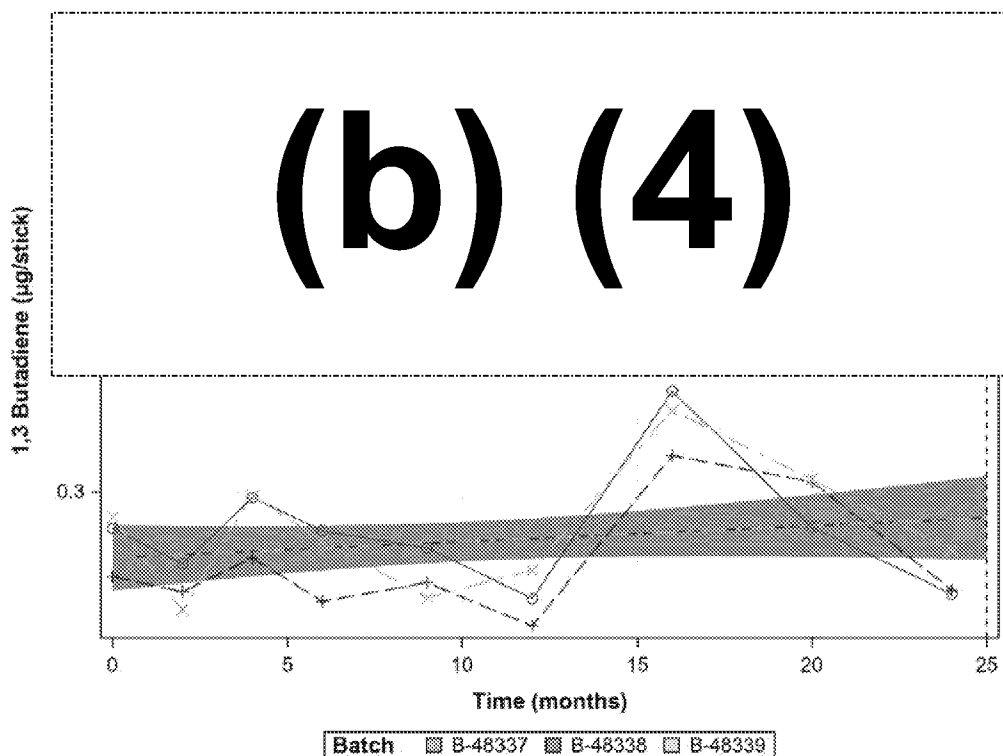


Figure 27 Evolution of 1,3-Butadiene for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.4.1.10 Benzene for 30°C 65%RH

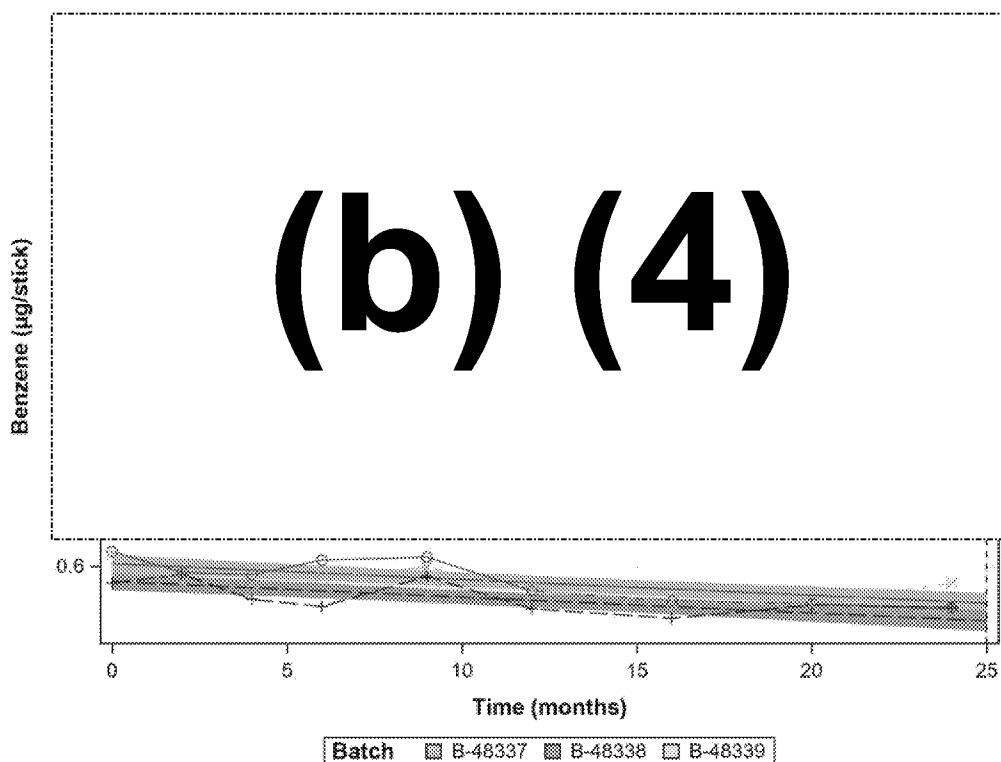


Figure 28 Evolution of Benzene for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Different intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.4.2 Physical Parameters Evaluation for 30°C 65%RH

(b) (4)



7.4.2.2 Tobacco Stick Weight for 30°C 65%RH

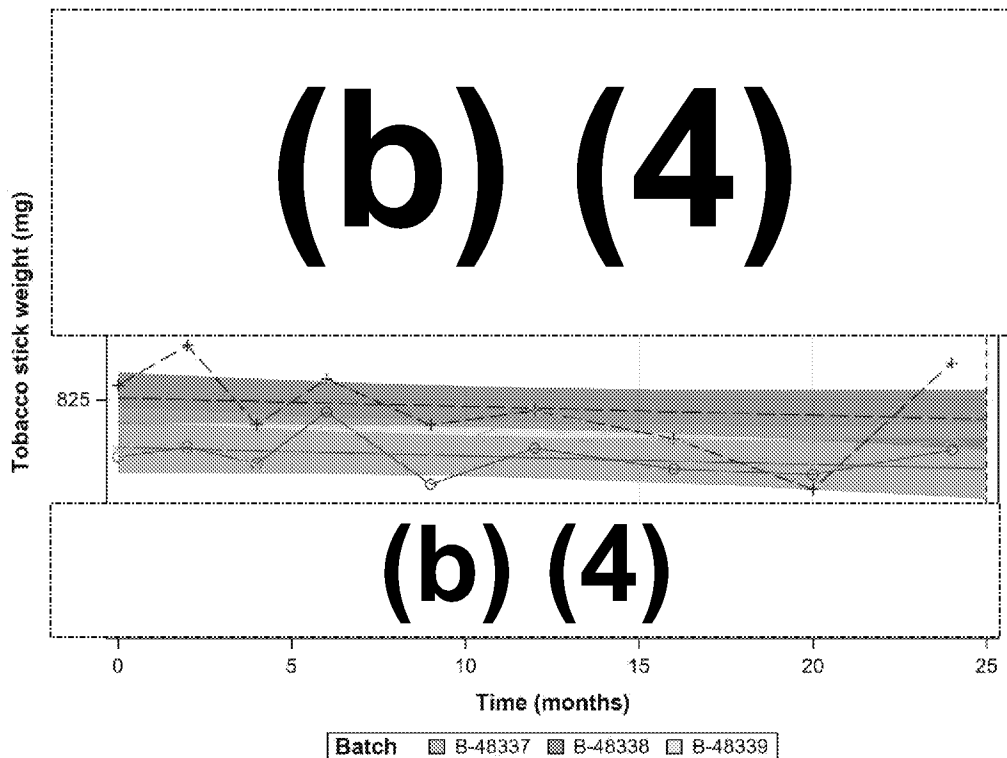


Figure 30 Evolution of Tobacco Stick weight for the 3 batches together with the specification levels, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Different intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.4.3 Water Activity Evaluation for 30°C 65%RH

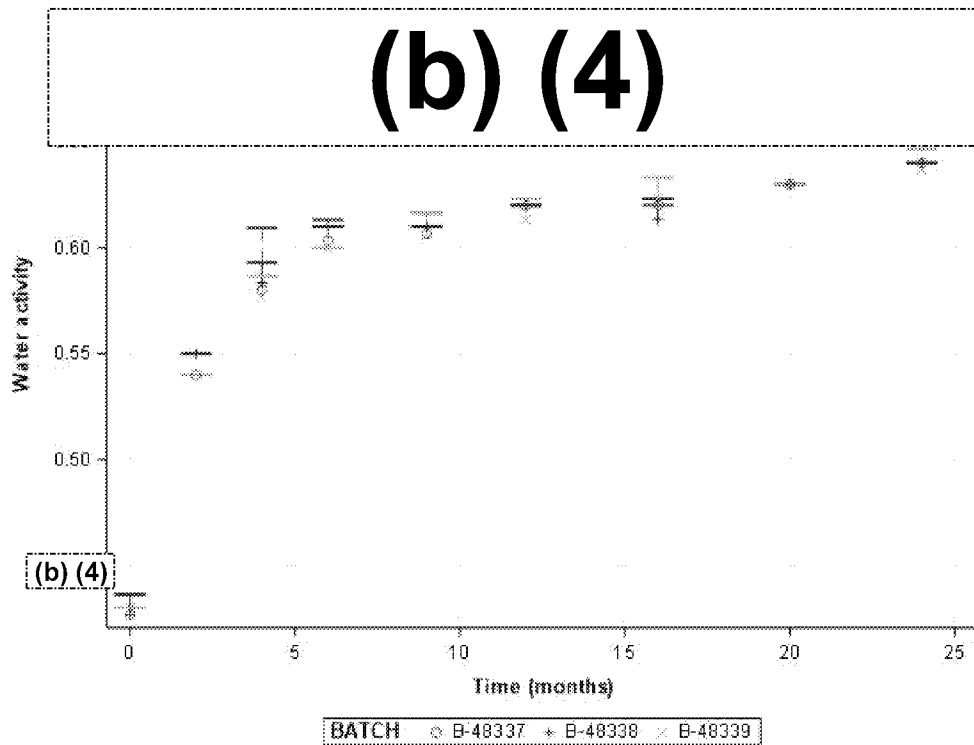


Figure 31 Evolution of Water activity for the 3 batches (mean value plus the 95% CIs of the mean) together with the specification level

The mean values and the one sided upper 95% CIs limit did not exceed the (b) (4). Therefore, a shelf life of 24 months is acceptable.



7.4.4 Sensorial Evaluation for 30°C 65%RH

Sensorial evaluation results are described in details in a separate reports up to 12 months [9] and up to 24 months [10].

Overall, the sensory profile of the three tested batches did not undergo major sensory changes at condition 30°C 65%RH over the 24 months period.

(b) (4)

7.4.5 Visual Evaluation for 30°C 65%RH

(b) (4)



(b) (4)



(b) (4)



(b) (4)



8 Stability Assessment

Storage condition 22°C 60%RH

All tested aerosol constituents, physical parameters and Water activity remained within the acceptance criteria for 24 months.

The sensory profile of the three tested batches did not undergo major sensory changes. (b) (4)

(b) (4)

Storage condition 30°C 65%RH

In hot and humid condition, all tested aerosol constituents, Tobacco stick weight and Water activity remained within the acceptance criteria for 24 months. (b) (4)

(b) (4)

(b) (4)

(b) (4)



Table 8 Summary of shelf life met per parameters for the storage conditions 22°C 60%RH and 30°C 65%RH

PARAMETER	22°C 60%RH	30°C 65%RH
	CRITERIA MET FOR SHELF LIFE OF: (months)	CRITERIA MET FOR SHELF LIFE OF: (months)
Nicotine	24	24
Glycerin	24	24
Triacetin	24	24
Carbon monoxide	24	24
Phenol	24	24
Acrylamide	24	24
Menthol	24	24
Formaldehyde	24	24
1,3-butadiene	24	24
Benzene	24	24
(b) (4)		
Tobacco stick weight	24	24
Water activity	24	24
Visual quality	see observations in Chapter 7.3.5	see observations in Chapter 7.4.5
Sensory (QDP)	see observations in Chapter 7.3.4	see observations in Chapter 7.4.4

9 Impact Assessment of Specification Change

The specifications used for the assessment of the aerosol results, excluding Menthol, were revised from Version 3.0 of 11-Oct-2017 [4] to Version 5.0 of 09-Jul-2019 [12] during the follow-up stability study (see Table 9). The stability study was evaluated versus the specifications used in the study protocol. However, the impact of those changes on the estimated shelf life period were assessed and are reported in Table 9.

The change in the specifications has no impact on the estimated shelf life period for the aerosol constituents.



Table 9 Summary of Equivalence Specifications and Corresponding Shelf Life Period

		Equivalence specifications Version 3.0, 11-Oct-2017 (Old)				Equivalence specifications Version 5.0, 09-Jul-2019 (New)			
Parameter	Unit	Limits		Criteria met for Shelf life of: (months)		Limits		Criteria met for Shelf life of: (months)	
		Lower	Upper	22°C 60%RH	30°C 65%RH	Lower	Upper	22°C 60%RH	30°C 65%RH
Nicotine	mg/stick	(b) (4)		24	24	(b) (4)		24	24
Glycerin	mg/stick			24	24			24	24
CO	mg/stick			24	24			24	24
Acrylamide	µg/stick			24	24			24	24
Phenol	µg/stick			24	24			24	24
Triacetin	mg/stick			24	24			24	24
1,3 butadiene	µg/stick			24	24			24	24
Benzene	µg/stick			24	24			24	24
Formaldehyde	µg/stick			24	24			24	24
Water activity	N/A			24	24			24	24



10 Related Documents

- [1] P1 THS 2 2 STABILITY STUDY REPORT DI LM STAB-2017_P1_M_2_signed.pdf

(b) (4)

- [2] PMI Stability Study Program THS2.2.docx, V1, 06-Oct-2017

(b) (4)

- [3] P1 THS 2 2 STABILITY STUDY PROTOCOL STAB-2017_P1_R_1 STAB-2017_P1_M_2 STAB-2017_P1_M_3_signed.pdf

(b) (4)

- [4] P1 THS 2 2 STABILITY STUDY FOLLOW UP PROTOCOL STAB-2017_P1_R_1 STAB-2017_P1_M_2 STAB-2017_P1_M_3_signed.pdf

(b) (4)

- [5] Platform 1 Equivalence Specification for Aerosol Endpoints Generated under Health Canada Intense Regime, Donatien Tabin Djoko, V3.0, 11-Oct-2017

(b) (4)

- [6] Menthol Threshold Levels in PMI Products, Florence Vonmoos, V1.0, 05-Oct-2017

(b) (4)

- [7] P1 Product specifications report, Pedro Campelos, V1.0, 16-Mar-2016

- [8] DI Low C3.2 Performance Specification Report, V6.0, Mirko Minzoni, 20-Sep-2017

- [9] P1 - THS / THD 2.4 - A02 / SEN / P1_PDev_EXPR_SS_067_2018_P1 MRTP US Low T12

(b) (4)

- [10] P1 - THS / THD 2.4 - A02 / SEN / P1_Pdev_EXPR_SS_069_2019_P1 MRTP Low Menthol T24

(b) (4)

- [11] PMI-RRP-FOR-111546_STAB-2017_P1_M_2 and STAB-2017_P1_M_3_OOS (b)(4) T16_signed.pdf

(b) (4)



- [12] Platform 1 equivalence specification for aerosol endpoints generated under health canada intense regime, Donatien Tabin Djoko, V5.0, 09-Jul-2019

(b) (4)

11 Reference Documents

- [13] ISO 3402:1999 Tobacco and tobacco products -- Atmosphere for conditioning and testing
- [14] WHO Stability testing of active pharmaceutical ingredients and finished pharmaceutical products
- [15] ICH Q1(E) Evaluation of Stability Data
- [16] ISO 20778:2018 Cigarettes -- Routine analytical cigarette smoking machine -- Definitions and standard conditions with an intense smoking regime

12 Change Management Log

Version N°	Detailed Description of change (including reason for change)
3.0	Minor change to correct typo error in version 2.0 (Header and page 1)
2.0	Images' format has been changed for the Figure listed below to make them readable in pdf format in R3: Menthol: Figure 7 and 25 Water Activity: Figure 13 and 31 Diameter: Figure 29
1.0	Original Issue

13 Review and Approval

This document has been approved using electronic signatures. Refer to the signature page and/or approval workflow for the signatory names, dates and functions.



14 Definitions and Abbreviations

Abbreviation	Definition
CO	Carbon Monoxide
CSVQI	Client Sensitive Visual Quality Index
CVQA	Central Visual Quality Audit
DCR	Design Change Request
EDMS	Electronic Document Management System
FOR	Form
GC-MS	Gas Chromatography Mass Spectrometry
ICH	International Council for Harmonisation
ID number	Identification number
ISO	International Organization for Standardization
HAT	Hollow Acetate Tube
(b) (4)	
LSL	Lower Shelf Life specification limit
n	Number of Determinations
N/A	Not Applicable
NC	Non-conformity
OOS	Out of Specification
OOT	Out of Trend
P1	Platform 1
PMI	Philip Morris International



Abbreviation	Definition
PDIMS	Product Development Information Management System
PMMTB	Philip Morris Manufacturing & Technology Bologna (Training Center)
PO	Purchase Order
QA	Quality Audit
QDP	Quantitative Descriptive Profile
R&D	Research and Development
RDLIMS	Research Development Laboratory Information Management System
RH	Relative Humidity
RRP	Reduced Risk Products
RTD	Resistance to Draw
SDMS	Scientific Data Management System
SEC	Sensory Evaluation Center
STD	Standard Deviation
THS	Tobacco Heating System
TO	Testing Order
UPLC-MS/MS	Ultra Performance Liquid Chromatography tandem Mass Spectrometry
USL	Upper Shelf Life specification limit
WHO	World Health Organization
WKI	Work Instruction



15 Appendices

15.1 Storage Locations

Storage condition: 22°C 60%RH		Storage condition: 30°C 65%RH	
PMI ID storage location	Period	PMI ID storage location	Period
T1381	From 20-Nov-2017 until 30-Nov-2019	6328	From 20-Nov-2017 until 08-Dec-2017
		6329	From 08-Dec-2017 until 22-Nov-2018
		6323	From 22-Nov-2018 until 23-Nov-2018
		6329	From 23-Nov-2018 until 13-Aug-2019
		13017	From 13-Aug-2019 until 30-Nov-2019

15.2 Analyses Dates per Time Point

Time Point	Analysis Type	Beginning of the Study (T0) / Sample Pull Out Day from the Storage Location (T2-T24) (1)	Conditioning Start Date (2)	Analyses Start Date (3)	Analysis End Date (4)
0	Aerosol chemistry	20-Nov-17	17-Nov-17	20-Nov-17	28-Nov-17
	Physical		23-Nov-17	29-Nov-17	4-Dec-17
	Sensory		17-Nov-17	20-Nov-17	23-Nov-17
	Visual inspection		N/A	21-Nov-17	4-Dec-17
	Water activity		20-Nov-17	24-Nov-17	29-Nov-17
2	Aerosol chemistry	22-Jan-18	25-Jan-18	29-Jan-18	6-Feb-18
	Physical	22-Jan-18	30-Jan-18	31-Jan-18	21-Feb-17
	Sensory	22-Jan-18	23-Jan-18	25-Jan-18	2-Feb-18
	Visual inspection	22-Jan-18	N/A	29-Jan-17	29-Jan-17
	Water activity	25-Jan-18	25-Jan-18	29-Jan-18	30-Jan-17
4	Aerosol chemistry	23-Mar-18	23-Mar-18	29-Mar-18	13-Apr-18
	Physical	23-Mar-18	26-Mar-18	28-Mar-18	9-Apr-18
	Sensory	23-Mar-18	23-Mar-18	26-Mar-18	3-Apr-18
	Visual inspection	23-Mar-18	N/A	23-Mar-18	26-Mar-18
	Water activity	26-Mar-18	26-Mar-18	29-Mar-18	4-Apr-18
6	Aerosol chemistry	22-May-18	22-May-18	25-May-18	13-Jun-18
	Physical	22-May-18	29-May-18	31-May-18	5-Jun-18
	Sensory	22-May-18	07-Jun-18	11-Jun-18	19-Jun-18
	Visual inspection	22-May-18	N/A	23-May-18	24-May-18



Time Point	Analysis Type	Beginning of the Study (T0) / Sample Pull Out Day from the Storage Location (T2-T24) (1)	Conditioning Start Date (2)	Analyses Start Date (3)	Analysis End Date (4)
6	Water activity	22-May-18	23-May-18	25-May-18	30-May-18
9	Aerosol chemistry	20-Aug-18	20-Aug-18	24-Aug-18	7-Sep-18
	Physical	20-Aug-18	24-Aug-18	27-Aug-18	29-Aug-18
	Sensory	20-Aug-18	31-Aug-18	03-Sep-18	10-Sep-18
	Visual inspection	20-Aug-18	N/A	22-Aug-18	28-Aug-18
	Water activity	21-Aug-18	22-Aug-18	24-Aug-18	27-Aug-18
12	Aerosol chemistry	20-Nov-18	20-Nov-18	23-Nov-18	10-Dec-18
	Physical	20-Nov-18	21-Nov-18	23-Nov-18	23-Nov-18
	Sensory	20-Nov-18	30-Nov-18	4-Dec-18	13-Dec-18
	Visual inspection	20-Nov-18	N/A	27-Nov-18	27-Nov-18
	Water activity	23-Nov-18	23-Nov-18	26-Nov-18	28-Nov-18
16	Aerosol chemistry	21-Mar-2019	21-Mar-2019	27-Mar-2019	11-Apr-2019
	Physical	21-Mar-2019	12-Apr-2019	15-Apr-2019	18-Apr-2019
	Sensory	21-Mar-2019	27-Mar-2019	04-Apr-2019	12-Apr-2019
	Visual inspection	21-Mar-2019	N/A	26-Mar-2019	27-Mar-2019
	Water activity	22-Mar-2019	22-Mar-2019	25-Mar-2019	27-Mar-2019
20	Aerosol chemistry	22-Jul-2019	22-Jul-2019	25-Jul-2019	05-Aug-2019
	Physical	22-Jul-2019	25-Jul-2019	29-Jul-2019	31-Jul-2019
	Sensory	22-Jul-2019	25-Jul-2019	29-Jul-2019	02-Aug-2019
	Visual inspection	22-Jul-2019	N/A	24-Jul-2019	25-Jul-2019
	Water activity	23-Jul-2019	23-Jul-2019	25-Jul-2019	26-Jul-2019
24	Aerosol chemistry	21-Nov-2019	21-Nov-2019	25-Nov-2019	10-Dec-2019
	Physical	21-Nov-2019	22-Nov-2019	25-Nov-2019	28-Nov-2019
	Sensory	21-Nov-2019	03-Dec-2019	05-Dec-2019	13-Dec-2019
	Visual inspection	21-Nov-2019	N/A	27-Nov-2019	28-Nov-2019
	Water activity	22-Nov-2019	22-Nov-2019	25-Nov-2019	27-Nov-2019

(1) – Beginning of the study for T0: date when samples were placed in the conditioning room and the climatic chamber for the one year storage. Samples for T0 were kept in conditioning room (22°C 60%RH) for the analyses. Sample Pull Out Day from the Storage Location for T2-T24: dates when samples were taken out from the storage location for analyses.

(2) - Date of beginning of conditioning. For Water activity date of reception.

(3) - First day of analyses

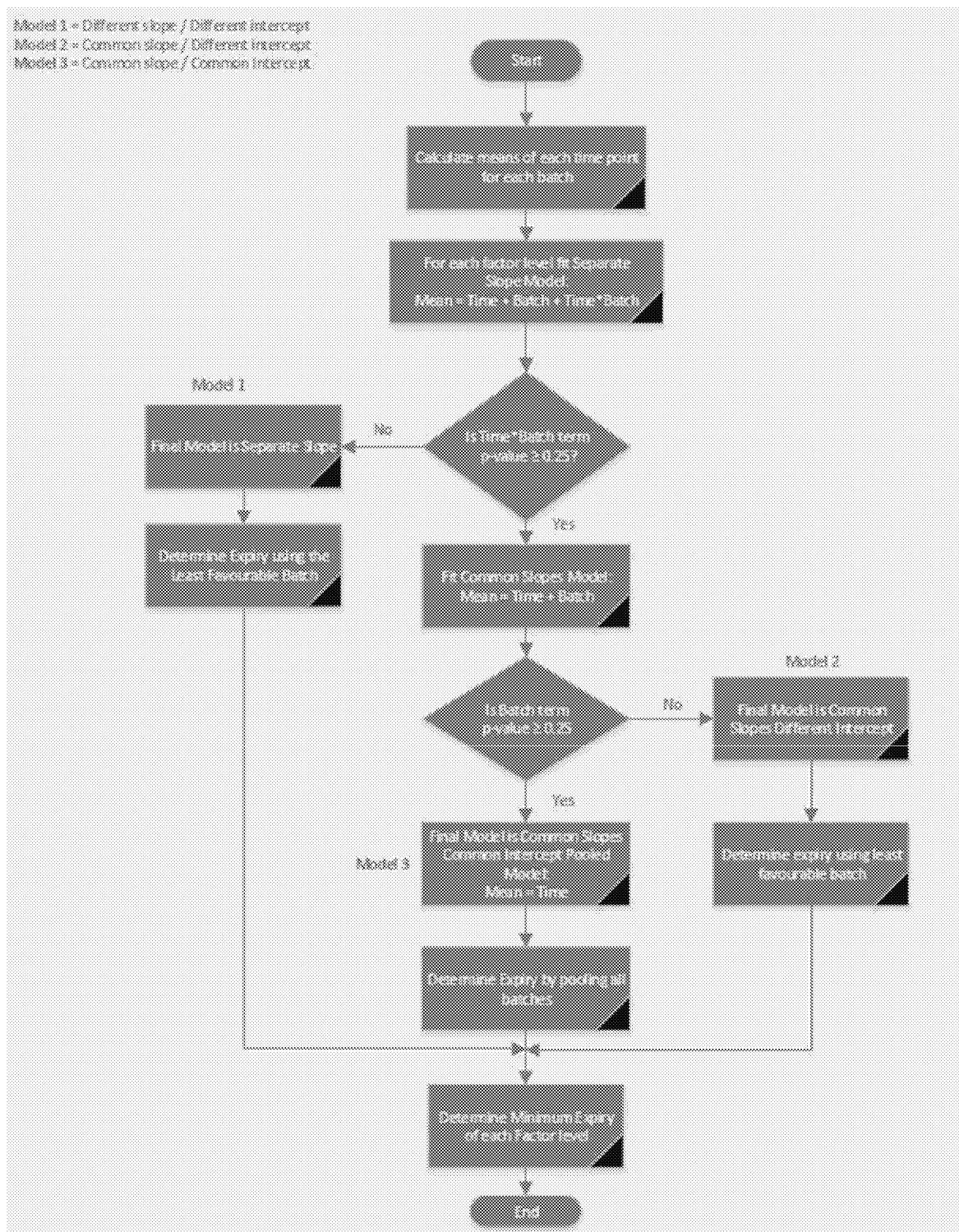
(4) - Date when results were released by the laboratory or last day of the sensorial evaluation



15.3 Sample Traceability Matrix

Time Point	Testing Order	RDLIMS Project Number	(b) (4) report number for Water activity
T0	TO-16486, TO-16699	RLS-ZRH-2017-1247	17-25232
T2	TO-16675, TO-16641	RLS-ZRH-2018-75	18-01850
T4	TO-17732, TO-17737	RLS-ZRH-2018-322	18-06421
T6	TO-18276, TO-18281	RLS-ZRH-2018-492	18-10464
T9	TO-19191, TO-19306	RLS-ZRH-2018-726	18-17635
T12	TO-20215, TO-20335	RLS-ZRH-2018-874	18-26274
T16	TO-21260, TO-21354	RLS-ZRH-2019-116	19-06397
T20	TO-22435, TO-22436	RLS-ZRH-2019-314	19-15088
T24	TO-23287, TO-23446	RLS-ZRH-2019-491	19-25162

15.4 Statistical Analyses Flowchart





15.5 Tabulated Results and Summary Statistics for 22°C 60%RH

CONDITION	VARIABLE	BATCH	Time point	LSL	USL	UNIT	N	Mean	Std	CV	Lower 95% CI	Upper 95% CI
22°C/60%RH	1,3 Butadiene	B-48337	T0			µg/stick	6	0.283	0.019	6.784		
22°C/60%RH	1,3 Butadiene	B-48337	T2			µg/stick	4	0.262	0.042	15.873		
22°C/60%RH	1,3 Butadiene	B-48337	T4			µg/stick	4	0.292	0.032	10.839		
22°C/60%RH	1,3 Butadiene	B-48337	T6			µg/stick	4	0.268	0.020	7.567		
22°C/60%RH	1,3 Butadiene	B-48337	T9			µg/stick	4	0.242	0.029	11.807		
22°C/60%RH	1,3 Butadiene	B-48337	T12			µg/stick	6	0.257	0.021	8.359		
22°C/60%RH	1,3 Butadiene	B-48337	T16			µg/stick	6	0.288	0.018	6.406		
22°C/60%RH	1,3 Butadiene	B-48337	T20			µg/stick	6	0.272	0.012	4.337		
22°C/60%RH	1,3 Butadiene	B-48337	T24			µg/stick	6	0.266	0.018	6.646		
22°C/60%RH	1,3 Butadiene	B-48338	T0			µg/stick	6	0.260	0.007	2.746		
22°C/60%RH	1,3 Butadiene	B-48338	T2			µg/stick	4	0.254	0.037	14.675		
22°C/60%RH	1,3 Butadiene	B-48338	T4			µg/stick	4	0.269	0.021	7.650		
22°C/60%RH	1,3 Butadiene	B-48338	T6			µg/stick	4	0.233	0.035	15.042		
22°C/60%RH	1,3 Butadiene	B-48338	T9			µg/stick	4	0.239	0.026	11.022		
22°C/60%RH	1,3 Butadiene	B-48338	T12			µg/stick	6	0.240	0.026	10.640		
22°C/60%RH	1,3 Butadiene	B-48338	T16			µg/stick	6	0.272	0.030	10.861		
22°C/60%RH	1,3 Butadiene	B-48338	T20			µg/stick	6	0.276	0.020	7.073		
22°C/60%RH	1,3 Butadiene	B-48338	T24			µg/stick	6	0.240	0.026	10.608		
22°C/60%RH	1,3 Butadiene	B-48339	T0			µg/stick	6	0.288	0.027	9.441		
22°C/60%RH	1,3 Butadiene	B-48339	T2			µg/stick	4	0.255	0.015	5.856		
22°C/60%RH	1,3 Butadiene	B-48339	T4			µg/stick	4	0.277	0.019	7.019		
22°C/60%RH	1,3 Butadiene	B-48339	T6			µg/stick	4	0.268	0.018	6.859		
22°C/60%RH	1,3 Butadiene	B-48339	T9			µg/stick	4	0.247	0.024	9.612		
22°C/60%RH	1,3 Butadiene	B-48339	T12			µg/stick	6	0.314	0.016	5.010		
22°C/60%RH	1,3 Butadiene	B-48339	T16			µg/stick	6	0.289	0.025	8.574		
22°C/60%RH	1,3 Butadiene	B-48339	T20			µg/stick	6	0.319	0.024	7.381		
22°C/60%RH	1,3 Butadiene	B-48339	T24			µg/stick	6	0.268	0.020	7.588		
22°C/60%RH	Acrylamide	B-48337	T0			µg/stick	6	2.047	0.184	8.984		
22°C/60%RH	Acrylamide	B-48337	T2			µg/stick	4	1.885	0.113	6.016		
22°C/60%RH	Acrylamide	B-48337	T4			µg/stick	4	2.019	0.266	13.155		
22°C/60%RH	Acrylamide	B-48337	T6			µg/stick	4	2.031	0.208	10.232		
22°C/60%RH	Acrylamide	B-48337	T9			µg/stick	4	2.113	0.194	9.187		
22°C/60%RH	Acrylamide	B-48337	T12			µg/stick	6	1.953	0.200	10.216		
22°C/60%RH	Acrylamide	B-48337	T16			µg/stick	6	1.584	0.103	6.530		
22°C/60%RH	Acrylamide	B-48337	T20			µg/stick	6	1.540	0.089	5.753		

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CONDITION	VARIABLE	BATCH	Time point	LSL	USL	UNIT	N	Mean	Std	CV	Lower 95% CI	Upper 95% CI
22°C/60%RH	Acrylamide	B-48337	T24			µg/stick	6	1.686	0.081	4.820		
22°C/60%RH	Acrylamide	B-48338	T0			µg/stick	6	1.860	0.135	7.244		
22°C/60%RH	Acrylamide	B-48338	T2			µg/stick	4	1.881	0.107	5.683		
22°C/60%RH	Acrylamide	B-48338	T4			µg/stick	4	1.945	0.234	12.006		
22°C/60%RH	Acrylamide	B-48338	T6			µg/stick	4	1.945	0.188	9.678		
22°C/60%RH	Acrylamide	B-48338	T9			µg/stick	4	2.212	0.166	7.513		
22°C/60%RH	Acrylamide	B-48338	T12			µg/stick	6	1.926	0.145	7.516		
22°C/60%RH	Acrylamide	B-48338	T16			µg/stick	6	1.465	0.150	10.255		
22°C/60%RH	Acrylamide	B-48338	T20			µg/stick	6	1.572	0.133	8.445		
22°C/60%RH	Acrylamide	B-48338	T24			µg/stick	6	1.731	0.214	12.341		
22°C/60%RH	Acrylamide	B-48339	T0			µg/stick	6	1.877	0.165	8.771		
22°C/60%RH	Acrylamide	B-48339	T2			µg/stick	4	1.966	0.101	5.125		
22°C/60%RH	Acrylamide	B-48339	T4			µg/stick	4	1.856	0.207	11.151		
22°C/60%RH	Acrylamide	B-48339	T6			µg/stick	4	2.123	0.079	3.741		
22°C/60%RH	Acrylamide	B-48339	T9			µg/stick	4	1.882	0.105	5.574		
22°C/60%RH	Acrylamide	B-48339	T12			µg/stick	6	1.955	0.119	6.073		
22°C/60%RH	Acrylamide	B-48339	T16			µg/stick	6	1.470	0.267	18.202		
22°C/60%RH	Acrylamide	B-48339	T20			µg/stick	6	1.802	0.059	3.255		
22°C/60%RH	Acrylamide	B-48339	T24			µg/stick	6	1.808	0.082	4.516		
22°C/60%RH	Benzene	B-48337	T0			µg/stick	6	0.626	0.052	8.295		
22°C/60%RH	Benzene	B-48337	T2			µg/stick	4	0.595	0.046	7.745		
22°C/60%RH	Benzene	B-48337	T4			µg/stick	4	0.610	0.094	15.447		
22°C/60%RH	Benzene	B-48337	T6			µg/stick	4	0.602	0.011	1.849		
22°C/60%RH	Benzene	B-48337	T9			µg/stick	4	0.587	0.052	8.887		
22°C/60%RH	Benzene	B-48337	T12			µg/stick	6	0.562	0.020	3.487		
22°C/60%RH	Benzene	B-48337	T16			µg/stick	6	0.556	0.016	2.926		
22°C/60%RH	Benzene	B-48337	T20			µg/stick	6	0.526	0.030	5.693		
22°C/60%RH	Benzene	B-48337	T24			µg/stick	6	0.546	0.032	5.887		
22°C/60%RH	Benzene	B-48338	T0			µg/stick	6	0.571	0.049	8.671		
22°C/60%RH	Benzene	B-48338	T2			µg/stick	4	0.599	0.070	11.660		
22°C/60%RH	Benzene	B-48338	T4			µg/stick	4	0.545	0.042	7.675		
22°C/60%RH	Benzene	B-48338	T6			µg/stick	4	0.505	0.070	13.783		
22°C/60%RH	Benzene	B-48338	T9			µg/stick	4	0.579	0.046	7.950		
22°C/60%RH	Benzene	B-48338	T12			µg/stick	6	0.530	0.036	6.711		
22°C/60%RH	Benzene	B-48338	T16			µg/stick	6	0.528	0.046	8.661		
22°C/60%RH	Benzene	B-48338	T20			µg/stick	6	0.525	0.024	4.506		

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22°C/60%RH	Benzene	B-48338	T24			µg/stick	6	0.516	0.051	9.892		
22°C/60%RH	Benzene	B-48339	T0			µg/stick	6	0.622	0.037	5.866		
22°C/60%RH	Benzene	B-48339	T2			µg/stick	4	0.585	0.037	6.373		
22°C/60%RH	Benzene	B-48339	T4			µg/stick	4	0.562	0.055	9.740		
22°C/60%RH	Benzene	B-48339	T6			µg/stick	4	0.582	0.042	7.263		
22°C/60%RH	Benzene	B-48339	T9			µg/stick	4	0.585	0.050	8.468		
22°C/60%RH	Benzene	B-48339	T12			µg/stick	6	0.560	0.010	1.843		
22°C/60%RH	Benzene	B-48339	T16			µg/stick	6	0.541	0.037	6.755		
22°C/60%RH	Benzene	B-48339	T20			µg/stick	6	0.553	0.021	3.831		
22°C/60%RH	Benzene	B-48339	T24			µg/stick	6	0.564	0.042	7.471		
22°C/60%RH	Carbon monoxide	B-48337	T0			mg/stick	6	0.579	0.035	5.974		
22°C/60%RH	Carbon monoxide	B-48337	T2			mg/stick	4	0.558	0.050	8.882		
22°C/60%RH	Carbon monoxide	B-48337	T4			mg/stick	4	0.607	0.042	6.897		
22°C/60%RH	Carbon monoxide	B-48337	T6			mg/stick	4	0.422	0.000	0.000		
22°C/60%RH	Carbon monoxide	B-48337	T9			mg/stick	4	0.483	0.080	16.651		
22°C/60%RH	Carbon monoxide	B-48337	T12			mg/stick	6	0.416	0.015	3.680		
22°C/60%RH	Carbon monoxide	B-48337	T16			mg/stick	6	0.418	0.018	4.287		
22°C/60%RH	Carbon monoxide	B-48337	T20			mg/stick	6	0.439	0.027	6.146		
22°C/60%RH	Carbon monoxide	B-48337	T24			mg/stick	6	0.478	0.043	8.994		
22°C/60%RH	Carbon monoxide	B-48338	T0			mg/stick	6	0.522	0.035	6.620		
22°C/60%RH	Carbon monoxide	B-48338	T2			mg/stick	4	0.580	0.043	7.407		
22°C/60%RH	Carbon monoxide	B-48338	T4			mg/stick	4	0.586	0.000	0.000		
22°C/60%RH	Carbon monoxide	B-48338	T6			mg/stick	4	0.422	0.000	0.000		
22°C/60%RH	Carbon monoxide	B-48338	T9			mg/stick	4	0.420	0.000	0.000		
22°C/60%RH	Carbon monoxide	B-48338	T12			mg/stick	6	0.412	0.009	2.282		
22°C/60%RH	Carbon monoxide	B-48338	T16			mg/stick	6	0.407	0.025	6.129		
22°C/60%RH	Carbon monoxide	B-48338	T20			mg/stick	6	0.434	0.019	4.283		
22°C/60%RH	Carbon monoxide	B-48338	T24			mg/stick	6	0.491	0.040	8.218		
22°C/60%RH	Carbon monoxide	B-48339	T0			mg/stick	6	0.565	0.044	7.746		
22°C/60%RH	Carbon monoxide	B-48339	T2			mg/stick	4	0.537	0.043	8.000		
22°C/60%RH	Carbon monoxide	B-48339	T4			mg/stick	4	0.565	0.042	7.407		
22°C/60%RH	Carbon monoxide	B-48339	T6			mg/stick	4	0.422	0.000	0.000		

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22°C/60%RH	Carbon monoxide	B-48339	T9			mg/stick	4	0.441	0.042	9.524		
22°C/60%RH	Carbon monoxide	B-48339	T12			mg/stick	6	0.427	0.019	4.537		
22°C/60%RH	Carbon monoxide	B-48339	T16			mg/stick	6	0.411	0.026	6.264		
22°C/60%RH	Carbon monoxide	B-48339	T20			mg/stick	6	0.448	0.013	2.974		
22°C/60%RH	Carbon monoxide	B-48339	T24			mg/stick	6	0.494	0.039	7.937		
22°C/60%RH	Formaldehyde	B-48337	T0			µg/stick	6	4.793	1.646	34.337		
22°C/60%RH	Formaldehyde	B-48337	T2			µg/stick	4	4.653	0.491	10.547		
22°C/60%RH	Formaldehyde	B-48337	T4			µg/stick	4	3.583	0.651	18.162		
22°C/60%RH	Formaldehyde	B-48337	T6			µg/stick	4	3.867	0.279	7.215		
22°C/60%RH	Formaldehyde	B-48337	T9			µg/stick	4	3.693	1.066	28.878		
22°C/60%RH	Formaldehyde	B-48337	T12			µg/stick	6	4.242	0.518	12.202		
22°C/60%RH	Formaldehyde	B-48337	T16			µg/stick	6	3.411	0.599	17.555		
22°C/60%RH	Formaldehyde	B-48337	T20			µg/stick	6	4.027	0.319	7.930		
22°C/60%RH	Formaldehyde	B-48337	T24			µg/stick	6	3.750	0.477	12.716		
22°C/60%RH	Formaldehyde	B-48338	T0			µg/stick	6	3.777	0.531	14.067		
22°C/60%RH	Formaldehyde	B-48338	T2			µg/stick	4	3.832	0.261	6.816		
22°C/60%RH	Formaldehyde	B-48338	T4			µg/stick	4	4.335	0.451	10.402		
22°C/60%RH	Formaldehyde	B-48338	T6			µg/stick	4	3.079	0.655	21.267		
22°C/60%RH	Formaldehyde	B-48338	T9			µg/stick	4	4.166	0.313	7.502		
22°C/60%RH	Formaldehyde	B-48338	T12			µg/stick	6	3.741	0.577	15.436		
22°C/60%RH	Formaldehyde	B-48338	T16			µg/stick	6	3.808	0.505	13.255		
22°C/60%RH	Formaldehyde	B-48338	T20			µg/stick	6	3.538	0.197	5.579		
22°C/60%RH	Formaldehyde	B-48338	T24			µg/stick	6	3.979	0.697	17.509		
22°C/60%RH	Formaldehyde	B-48339	T0			µg/stick	6	3.906	0.775	19.842		
22°C/60%RH	Formaldehyde	B-48339	T2			µg/stick	4	4.842	0.349	7.215		
22°C/60%RH	Formaldehyde	B-48339	T4			µg/stick	4	4.565	0.229	5.022		
22°C/60%RH	Formaldehyde	B-48339	T6			µg/stick	4	4.425	0.662	14.955		
22°C/60%RH	Formaldehyde	B-48339	T9			µg/stick	4	4.079	0.638	15.646		
22°C/60%RH	Formaldehyde	B-48339	T12			µg/stick	6	4.120	0.763	18.528		
22°C/60%RH	Formaldehyde	B-48339	T16			µg/stick	6	3.876	0.664	17.138		
22°C/60%RH	Formaldehyde	B-48339	T20			µg/stick	6	4.314	0.376	8.724		
22°C/60%RH	Formaldehyde	B-48339	T24			µg/stick	6	4.572	0.339	7.409		
22°C/60%RH	Glycerin	B-48337	T0			mg/stick	6	5.177	0.454	8.774		
22°C/60%RH	Glycerin	B-48337	T2			mg/stick	4	5.476	0.100	1.835		
22°C/60%RH	Glycerin	B-48337	T4			mg/stick	4	4.704	0.302	6.419		

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22°C/60%RH	Glycerin	B-48337	T6			mg/stick	4	4.943	0.558	11.295		
22°C/60%RH	Glycerin	B-48337	T9			mg/stick	4	5.180	0.279	5.387		
22°C/60%RH	Glycerin	B-48337	T12			mg/stick	6	4.482	0.345	7.701		
22°C/60%RH	Glycerin	B-48337	T16			mg/stick	6	4.591	0.320	6.968		
22°C/60%RH	Glycerin	B-48337	T20			mg/stick	6	4.340	0.223	5.127		
22°C/60%RH	Glycerin	B-48337	T24			mg/stick	6	4.718	0.279	5.910		
22°C/60%RH	Glycerin	B-48338	T0			mg/stick	6	4.842	0.315	6.509		
22°C/60%RH	Glycerin	B-48338	T2			mg/stick	4	5.520	0.354	6.413		
22°C/60%RH	Glycerin	B-48338	T4			mg/stick	4	4.887	0.585	11.973		
22°C/60%RH	Glycerin	B-48338	T6			mg/stick	4	5.010	0.476	9.494		
22°C/60%RH	Glycerin	B-48338	T9			mg/stick	4	5.158	0.270	5.225		
22°C/60%RH	Glycerin	B-48338	T12			mg/stick	6	4.645	0.327	7.036		
22°C/60%RH	Glycerin	B-48338	T16			mg/stick	6	4.336	0.345	7.954		
22°C/60%RH	Glycerin	B-48338	T20			mg/stick	6	4.333	0.427	9.862		
22°C/60%RH	Glycerin	B-48338	T24			mg/stick	6	4.956	0.562	11.337		
22°C/60%RH	Glycerin	B-48339	T0			mg/stick	6	5.145	0.395	7.681		
22°C/60%RH	Glycerin	B-48339	T2			mg/stick	4	5.631	0.067	1.191		
22°C/60%RH	Glycerin	B-48339	T4			mg/stick	4	4.968	0.522	10.513		
22°C/60%RH	Glycerin	B-48339	T6			mg/stick	4	5.502	0.315	5.721		
22°C/60%RH	Glycerin	B-48339	T9			mg/stick	4	5.043	0.411	8.146		
22°C/60%RH	Glycerin	B-48339	T12			mg/stick	6	4.864	0.282	5.798		
22°C/60%RH	Glycerin	B-48339	T16			mg/stick	6	4.452	0.488	10.952		
22°C/60%RH	Glycerin	B-48339	T20			mg/stick	6	4.822	0.203	4.207		
22°C/60%RH	Glycerin	B-48339	T24			mg/stick	6	5.277	0.247	4.678		
22°C/60%RH	Menthol	B-48337	T0			mg/stick	6	1.277	0.026	2.031		
22°C/60%RH	Menthol	B-48337	T2			mg/stick	4	2.013	0.059	2.910		
22°C/60%RH	Menthol	B-48337	T4			mg/stick	4	1.879	0.068	3.601		
22°C/60%RH	Menthol	B-48337	T6			mg/stick	4	2.060	0.067	3.269		
22°C/60%RH	Menthol	B-48337	T9			mg/stick	4	2.053	0.014	0.666		
22°C/60%RH	Menthol	B-48337	T12			mg/stick	6	1.934	0.031	1.610		
22°C/60%RH	Menthol	B-48337	T16			mg/stick	6	1.809	0.086	4.735		
22°C/60%RH	Menthol	B-48337	T20			mg/stick	6	1.937	0.073	3.752		
22°C/60%RH	Menthol	B-48337	T24			mg/stick	6	1.983	0.141	7.128		
22°C/60%RH	Menthol	B-48338	T0			mg/stick	6	1.147	0.068	5.964		
22°C/60%RH	Menthol	B-48338	T2			mg/stick	4	1.954	0.061	3.138		
22°C/60%RH	Menthol	B-48338	T4			mg/stick	4	2.022	0.068	3.382		

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22°C/60%RH	Menthol	B-48338	T6			mg/stick	4	1.878	0.055	2.906		
22°C/60%RH	Menthol	B-48338	T9			mg/stick	4	2.093	0.067	3.213		
22°C/60%RH	Menthol	B-48338	T12			mg/stick	6	1.842	0.040	2.145		
22°C/60%RH	Menthol	B-48338	T16			mg/stick	6	1.897	0.057	3.009		
22°C/60%RH	Menthol	B-48338	T20			mg/stick	6	1.932	0.086	4.430		
22°C/60%RH	Menthol	B-48338	T24			mg/stick	6	2.175	0.093	4.296		
22°C/60%RH	Menthol	B-48339	T0			mg/stick	6	1.276	0.090	7.048		
22°C/60%RH	Menthol	B-48339	T2			mg/stick	4	1.910	0.059	3.110		
22°C/60%RH	Menthol	B-48339	T4			mg/stick	4	2.089	0.079	3.779		
22°C/60%RH	Menthol	B-48339	T6			mg/stick	4	2.128	0.047	2.202		
22°C/60%RH	Menthol	B-48339	T9			mg/stick	4	2.107	0.062	2.931		
22°C/60%RH	Menthol	B-48339	T12			mg/stick	6	1.976	0.045	2.261		
22°C/60%RH	Menthol	B-48339	T16			mg/stick	6	1.896	0.126	6.667		
22°C/60%RH	Menthol	B-48339	T20			mg/stick	6	1.931	0.067	3.453		
22°C/60%RH	Menthol	B-48339	T24			mg/stick	6	2.087	0.092	4.401		
22°C/60%RH	Nicotine	B-48337	T0			mg/stick	6	1.252	0.058	4.607		
22°C/60%RH	Nicotine	B-48337	T2			mg/stick	4	1.244	0.061	4.922		
22°C/60%RH	Nicotine	B-48337	T4			mg/stick	4	1.209	0.069	5.719		
22°C/60%RH	Nicotine	B-48337	T6			mg/stick	4	1.261	0.094	7.468		
22°C/60%RH	Nicotine	B-48337	T9			mg/stick	4	1.256	0.036	2.868		
22°C/60%RH	Nicotine	B-48337	T12			mg/stick	6	1.224	0.061	5.007		
22°C/60%RH	Nicotine	B-48337	T16			mg/stick	6	1.274	0.050	3.895		
22°C/60%RH	Nicotine	B-48337	T20			mg/stick	6	1.130	0.036	3.161		
22°C/60%RH	Nicotine	B-48337	T24			mg/stick	6	1.296	0.037	2.826		
22°C/60%RH	Nicotine	B-48338	T0			mg/stick	6	1.178	0.048	4.117		
22°C/60%RH	Nicotine	B-48338	T2			mg/stick	4	1.228	0.020	1.659		
22°C/60%RH	Nicotine	B-48338	T4			mg/stick	4	1.189	0.045	3.786		
22°C/60%RH	Nicotine	B-48338	T6			mg/stick	4	1.241	0.065	5.213		
22°C/60%RH	Nicotine	B-48338	T9			mg/stick	4	1.290	0.018	1.396		
22°C/60%RH	Nicotine	B-48338	T12			mg/stick	6	1.247	0.063	5.047		
22°C/60%RH	Nicotine	B-48338	T16			mg/stick	6	1.259	0.060	4.780		
22°C/60%RH	Nicotine	B-48338	T20			mg/stick	6	1.156	0.055	4.732		
22°C/60%RH	Nicotine	B-48338	T24			mg/stick	6	1.341	0.109	8.154		
22°C/60%RH	Nicotine	B-48339	T0			mg/stick	6	1.255	0.065	5.178		
22°C/60%RH	Nicotine	B-48339	T2			mg/stick	4	1.276	0.044	3.417		
22°C/60%RH	Nicotine	B-48339	T4			mg/stick	4	1.236	0.107	8.624		

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22°C/60%RH	Nicotine	B-48339	T6			mg/stick	4	1.329	0.057	4.265		
22°C/60%RH	Nicotine	B-48339	T9			mg/stick	4	1.241	0.036	2.932		
22°C/60%RH	Nicotine	B-48339	T12			mg/stick	6	1.271	0.027	2.134		
22°C/60%RH	Nicotine	B-48339	T16			mg/stick	6	1.250	0.082	6.546		
22°C/60%RH	Nicotine	B-48339	T20			mg/stick	6	1.238	0.025	2.008		
22°C/60%RH	Nicotine	B-48339	T24			mg/stick	6	1.367	0.040	2.958		
22°C/60%RH	Phenol	B-48337	T0			µg/stick	6	1.222	0.204	16.667		
22°C/60%RH	Phenol	B-48337	T2			µg/stick	4	1.064	0.218	20.538		
22°C/60%RH	Phenol	B-48337	T4			µg/stick	4	0.937	0.288	30.759		
22°C/60%RH	Phenol	B-48337	T6			µg/stick	4	0.783	0.183	23.345		
22°C/60%RH	Phenol	B-48337	T9			µg/stick	4	1.132	0.298	26.279		
22°C/60%RH	Phenol	B-48337	T12			µg/stick	6	0.783	0.127	16.271		
22°C/60%RH	Phenol	B-48337	T16			µg/stick	6	0.980	0.112	11.406		
22°C/60%RH	Phenol	B-48337	T20			µg/stick	6	0.764	0.109	14.274		
22°C/60%RH	Phenol	B-48337	T24			µg/stick	6	1.287	0.289	22.480		
22°C/60%RH	Phenol	B-48338	T0			µg/stick	6	1.251	0.125	9.994		
22°C/60%RH	Phenol	B-48338	T2			µg/stick	4	1.330	0.180	13.542		
22°C/60%RH	Phenol	B-48338	T4			µg/stick	4	1.092	0.186	17.070		
22°C/60%RH	Phenol	B-48338	T6			µg/stick	4	1.047	0.106	10.104		
22°C/60%RH	Phenol	B-48338	T9			µg/stick	4	1.199	0.143	11.919		
22°C/60%RH	Phenol	B-48338	T12			µg/stick	6	1.023	0.182	17.795		
22°C/60%RH	Phenol	B-48338	T16			µg/stick	6	1.038	0.134	12.939		
22°C/60%RH	Phenol	B-48338	T20			µg/stick	6	0.789	0.142	18.021		
22°C/60%RH	Phenol	B-48338	T24			µg/stick	6	1.506	0.343	22.772		
22°C/60%RH	Phenol	B-48339	T0			µg/stick	6	1.217	0.166	13.611		
22°C/60%RH	Phenol	B-48339	T2			µg/stick	4	1.074	0.171	15.945		
22°C/60%RH	Phenol	B-48339	T4			µg/stick	4	1.018	0.240	23.572		
22°C/60%RH	Phenol	B-48339	T6			µg/stick	4	1.144	0.056	4.896		
22°C/60%RH	Phenol	B-48339	T9			µg/stick	4	1.136	0.219	19.265		
22°C/60%RH	Phenol	B-48339	T12			µg/stick	6	1.035	0.181	17.445		
22°C/60%RH	Phenol	B-48339	T16			µg/stick	6	0.939	0.262	27.936		
22°C/60%RH	Phenol	B-48339	T20			µg/stick	6	0.985	0.129	13.130		
22°C/60%RH	Phenol	B-48339	T24			µg/stick	6	1.592	0.192	12.061		
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CONDITION	VARIABLE	BATCH	Time point	LSL	USL	UNIT	N	Mean	Std. n	Std.	CV	Lower 95% CI	Upper 95% CI
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22°C/60%RH	Tobacco stick weight	B-48337	T0			mg	50	812.4	15.0	1.85			
22°C/60%RH	Tobacco stick weight	B-48337	T2			mg	50	821.1	12.4	1.51			
22°C/60%RH	Tobacco stick weight	B-48337	T4			mg	50	809.6	10.0	1.23			
22°C/60%RH	Tobacco stick weight	B-48337	T6			mg	50	821.6	9.6	1.17			
22°C/60%RH	Tobacco stick weight	B-48337	T9			mg	50	816.2	11.4	1.39			
22°C/60%RH	Tobacco stick weight	B-48337	T12			mg	50	817.4	14.8	1.81			

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CONDITION	VARIABLE	BATCH	Time point	LSL	USL	UNIT	N	Mean	Std	CV	Lower 95% CI	Upper 95% CI
22°C/60%RH	Tobacco stick weight	B-48337	T16			mg	50	819.0	10.1	1.23		
22°C/60%RH	Tobacco stick weight	B-48337	T20			mg	50	807.1	11.6	1.44		
22°C/60%RH	Tobacco stick weight	B-48337	T24			mg	50	835.4	13.0	1.55		
22°C/60%RH	Tobacco stick weight	B-48338	T0			mg	50	828.3	14.5	1.76		
22°C/60%RH	Tobacco stick weight	B-48338	T2			mg	50	827.3	14.2	1.72		
22°C/60%RH	Tobacco stick weight	B-48338	T4			mg	50	833.9	7.9	0.95		
22°C/60%RH	Tobacco stick weight	B-48338	T6			mg	50	831.1	11.4	1.37		
22°C/60%RH	Tobacco stick weight	B-48338	T9			mg	50	821.0	12.1	1.47		
22°C/60%RH	Tobacco stick weight	B-48338	T12			mg	50	825.7	10.2	1.24		
22°C/60%RH	Tobacco stick weight	B-48338	T16			mg	50	831.2	13.0	1.56		
22°C/60%RH	Tobacco stick weight	B-48338	T20			mg	50	827.3	11.1	1.34		
22°C/60%RH	Tobacco stick weight	B-48338	T24			mg	50	835.3	11.1	1.33		
22°C/60%RH	Tobacco stick weight	B-48339	T0			mg	50	813.7	10.8	1.32		
22°C/60%RH	Tobacco stick weight	B-48339	T2			mg	50	821.5	9.6	1.17		
22°C/60%RH	Tobacco stick weight	B-48339	T4			mg	50	818.1	9.7	1.19		
22°C/60%RH	Tobacco stick weight	B-48339	T6			mg	50	815.7	8.5	1.04		
22°C/60%RH	Tobacco stick weight	B-48339	T9			mg	50	816.8	13.7	1.68		
22°C/60%RH	Tobacco stick weight	B-48339	T12			mg	50	821.8	10.7	1.30		
22°C/60%RH	Tobacco stick weight	B-48339	T16			mg	50	811.7	10.8	1.34		
22°C/60%RH	Tobacco stick weight	B-48339	T20			mg	50	813.0	9.7	1.19		
22°C/60%RH	Tobacco stick weight	B-48339	T24			mg	50	814.1	10.1	1.24		
22°C/60%RH	Triacetin	B-48337	T0			mg/stick	6	0.641	0.068	10.635		
22°C/60%RH	Triacetin	B-48337	T2			mg/stick	4	0.621	0.011	1.737		
22°C/60%RH	Triacetin	B-48337	T4			mg/stick	4	0.534	0.014	2.641		
22°C/60%RH	Triacetin	B-48337	T6			mg/stick	4	0.514	0.041	8.032		
22°C/60%RH	Triacetin	B-48337	T9			mg/stick	4	0.532	0.042	7.796		
22°C/60%RH	Triacetin	B-48337	T12			mg/stick	6	0.464	0.010	2.092		
22°C/60%RH	Triacetin	B-48337	T16			mg/stick	6	0.416	0.026	6.264		
22°C/60%RH	Triacetin	B-48337	T20			mg/stick	6	0.409	0.020	4.856		
22°C/60%RH	Triacetin	B-48337	T24			mg/stick	6	0.430	0.059	13.655		
22°C/60%RH	Triacetin	B-48338	T0			mg/stick	6	0.606	0.043	7.063		
22°C/60%RH	Triacetin	B-48338	T2			mg/stick	4	0.645	0.040	6.260		

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CONDITION	VARIABLE	BATCH	Time point	LSL	USL	UNIT	N	Mean	Std	CV	Lower 95% CI	Upper 95% CI
22°C/60%RH	Triacetin	B-48338	T4			mg/stick	4	0.534	0.048	8.920		
22°C/60%RH	Triacetin	B-48338	T6			mg/stick	4	0.511	0.011	2.178		
22°C/60%RH	Triacetin	B-48338	T9			mg/stick	4	0.507	0.025	5.019		
22°C/60%RH	Triacetin	B-48338	T12			mg/stick	6	0.455	0.030	6.597		
22°C/60%RH	Triacetin	B-48338	T16			mg/stick	6	0.403	0.034	8.333		
22°C/60%RH	Triacetin	B-48338	T20			mg/stick	6	0.430	0.028	6.525		
22°C/60%RH	Triacetin	B-48338	T24			mg/stick	6	0.428	0.041	9.519		
22°C/60%RH	Triacetin	B-48339	T0			mg/stick	6	0.573	0.025	4.365		
22°C/60%RH	Triacetin	B-48339	T2			mg/stick	4	0.594	0.030	5.113		
22°C/60%RH	Triacetin	B-48339	T4			mg/stick	4	0.514	0.033	6.332		
22°C/60%RH	Triacetin	B-48339	T6			mg/stick	4	0.506	0.023	4.461		
22°C/60%RH	Triacetin	B-48339	T9			mg/stick	4	0.498	0.036	7.267		
22°C/60%RH	Triacetin	B-48339	T12			mg/stick	6	0.470	0.028	5.939		
22°C/60%RH	Triacetin	B-48339	T16			mg/stick	6	0.393	0.040	10.242		
22°C/60%RH	Triacetin	B-48339	T20			mg/stick	6	0.426	0.023	5.406		
22°C/60%RH	Triacetin	B-48339	T24			mg/stick	6	0.453	0.021	4.532		
22°C/60%RH	Water activity	B-48337	T0			N/A	3	0.427	0.006	1.353		
22°C/60%RH	Water activity	B-48337	T2			N/A	3	0.480	0.000	0.000		
22°C/60%RH	Water activity	B-48337	T4			N/A	3	0.513	0.006	1.125		
22°C/60%RH	Water activity	B-48337	T6			N/A	3	0.530	0.000	0.000		
22°C/60%RH	Water activity	B-48337	T9			N/A	3	0.537	0.006	1.076		
22°C/60%RH	Water activity	B-48337	T12			N/A	3	0.553	0.006	1.043		
22°C/60%RH	Water activity	B-48337	T16			N/A	3	0.550	0.000	0.000		
22°C/60%RH	Water activity	B-48337	T20			N/A	3	0.587	0.006	0.984		
22°C/60%RH	Water activity	B-48337	T24			N/A	3	0.587	0.006	0.984		
22°C/60%RH	Water activity	B-48338	T0			N/A	3	0.427	0.006	1.353		
22°C/60%RH	Water activity	B-48338	T2			N/A	3	0.480	0.000	0.000		
22°C/60%RH	Water activity	B-48338	T4			N/A	3	0.510	0.000	0.000		
22°C/60%RH	Water activity	B-48338	T6			N/A	3	0.523	0.006	1.103		
22°C/60%RH	Water activity	B-48338	T9			N/A	3	0.540	0.000	0.000		
22°C/60%RH	Water activity	B-48338	T12			N/A	3	0.550	0.000	0.000		
22°C/60%RH	Water activity	B-48338	T16			N/A	3	0.560	0.000	0.000		
22°C/60%RH	Water activity	B-48338	T20			N/A	3	0.580	0.000	0.000		
22°C/60%RH	Water activity	B-48338	T24			N/A	3	0.577	0.006	1.001		
22°C/60%RH	Water activity	B-48339	T0			N/A	3	0.430	0.000	0.000		
22°C/60%RH	Water activity	B-48339	T2			N/A	3	0.480	0.000	0.000		

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CONDITION	VARIABLE	BATCH	Time point	LSL	USL	UNIT	N	Mean	Std	CV	Lower 95% CI	Upper 95% CI
22°C/60%RH	Water activity	B-48339	T4	(b) (4)	(b) (4)	N/A	3	0.500	0.000	0.000	(b) (4)	(b) (4)
22°C/60%RH	Water activity	B-48339	T6			N/A	3	0.530	0.000	0.000		
22°C/60%RH	Water activity	B-48339	T9			N/A	3	0.537	0.006	1.076		
22°C/60%RH	Water activity	B-48339	T12			N/A	3	0.540	0.000	0.000		
22°C/60%RH	Water activity	B-48339	T16			N/A	3	0.563	0.006	1.025		
22°C/60%RH	Water activity	B-48339	T20			N/A	3	0.580	0.000	0.000		
22°C/60%RH	Water activity	B-48339	T24			N/A	3	0.570	0.000	0.000		

15.6 Tabulated Results and Summary Statistics for 30°C 65%RH

CONDITION	VARIABLE	BATCH	Time point	LSL	USL	UNIT	N	Mean	Std	CV	Lower 95% CI	Upper 95% CI
30°C/65%RH	1,3 Butadiene	B-48337	T0	(b) (4)	(b) (4)	µg/stick	6	0.283	0.019	6.784	(b) (4)	(b) (4)
30°C/65%RH	1,3 Butadiene	B-48337	T2			µg/stick	4	0.266	0.028	10.407		
30°C/65%RH	1,3 Butadiene	B-48337	T4			µg/stick	4	0.297	0.025	8.390		
30°C/65%RH	1,3 Butadiene	B-48337	T6			µg/stick	4	0.281	0.008	3.010		
30°C/65%RH	1,3 Butadiene	B-48337	T9			µg/stick	4	0.273	0.017	6.056		
30°C/65%RH	1,3 Butadiene	B-48337	T12			µg/stick	6	0.250	0.021	8.294		
30°C/65%RH	1,3 Butadiene	B-48337	T16			µg/stick	6	0.348	0.044	12.635		
30°C/65%RH	1,3 Butadiene	B-48337	T20			µg/stick	6	0.283	0.030	10.503		
30°C/65%RH	1,3 Butadiene	B-48337	T24			µg/stick	6	0.252	0.017	6.569		
30°C/65%RH	1,3 Butadiene	B-48338	T0			µg/stick	6	0.260	0.007	2.746		
30°C/65%RH	1,3 Butadiene	B-48338	T2			µg/stick	4	0.253	0.009	3.648		
30°C/65%RH	1,3 Butadiene	B-48338	T4			µg/stick	4	0.269	0.012	4.548		
30°C/65%RH	1,3 Butadiene	B-48338	T6			µg/stick	4	0.248	0.024	9.616		
30°C/65%RH	1,3 Butadiene	B-48338	T9			µg/stick	4	0.257	0.041	15.804		
30°C/65%RH	1,3 Butadiene	B-48338	T12			µg/stick	6	0.237	0.011	4.563		
30°C/65%RH	1,3 Butadiene	B-48338	T16			µg/stick	6	0.317	0.024	7.444		
30°C/65%RH	1,3 Butadiene	B-48338	T20			µg/stick	6	0.305	0.009	3.098		
30°C/65%RH	1,3 Butadiene	B-48338	T24			µg/stick	6	0.254	0.018	6.920		
30°C/65%RH	1,3 Butadiene	B-48339	T0			µg/stick	6	0.288	0.027	9.441		
30°C/65%RH	1,3 Butadiene	B-48339	T2			µg/stick	4	0.244	0.034	13.977		
30°C/65%RH	1,3 Butadiene	B-48339	T4			µg/stick	4	0.298	0.032	10.604		
30°C/65%RH	1,3 Butadiene	B-48339	T6			µg/stick	4	0.277	0.022	7.926		
30°C/65%RH	1,3 Butadiene	B-48339	T9			µg/stick	4	0.250	0.030	11.956		
30°C/65%RH	1,3 Butadiene	B-48339	T12			µg/stick	6	0.263	0.010	3.739		
30°C/65%RH	1,3 Butadiene	B-48339	T16			µg/stick	6	0.339	0.051	15.131		

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30°C/65%RH	1,3 Butadiene	B-48339	T20			µg/stick	6	0.306	0.010	3.376		
30°C/65%RH	1,3 Butadiene	B-48339	T24			µg/stick	6	0.272	0.010	3.709		
30°C/65%RH	Acrylamide	B-48337	T0			µg/stick	6	2.047	0.184	8.984		
30°C/65%RH	Acrylamide	B-48337	T2			µg/stick	4	1.845	0.027	1.469		
30°C/65%RH	Acrylamide	B-48337	T4			µg/stick	4	1.765	0.030	1.707		
30°C/65%RH	Acrylamide	B-48337	T6			µg/stick	4	1.708	0.147	8.583		
30°C/65%RH	Acrylamide	B-48337	T9			µg/stick	4	1.393	0.325	23.305		
30°C/65%RH	Acrylamide	B-48337	T12			µg/stick	6	1.444	0.074	5.154		
30°C/65%RH	Acrylamide	B-48337	T16			µg/stick	6	1.008	0.065	6.493		
30°C/65%RH	Acrylamide	B-48337	T20			µg/stick	6	0.970	0.072	7.442		
30°C/65%RH	Acrylamide	B-48337	T24			µg/stick	6	0.934	0.075	8.043		
30°C/65%RH	Acrylamide	B-48338	T0			µg/stick	6	1.860	0.135	7.244		
30°C/65%RH	Acrylamide	B-48338	T2			µg/stick	4	1.832	0.047	2.585		
30°C/65%RH	Acrylamide	B-48338	T4			µg/stick	4	1.696	0.095	5.584		
30°C/65%RH	Acrylamide	B-48338	T6			µg/stick	4	1.676	0.219	13.054		
30°C/65%RH	Acrylamide	B-48338	T9			µg/stick	4	1.678	0.210	12.529		
30°C/65%RH	Acrylamide	B-48338	T12			µg/stick	6	1.472	0.162	11.001		
30°C/65%RH	Acrylamide	B-48338	T16			µg/stick	6	0.981	0.106	10.791		
30°C/65%RH	Acrylamide	B-48338	T20	(b) (4)		µg/stick	6	1.106	0.056	5.075	(b) (4)	
30°C/65%RH	Acrylamide	B-48338	T24			µg/stick	6	0.998	0.083	8.276		
30°C/65%RH	Acrylamide	B-48339	T0			µg/stick	6	1.877	0.165	8.771		
30°C/65%RH	Acrylamide	B-48339	T2			µg/stick	4	1.830	0.104	5.708		
30°C/65%RH	Acrylamide	B-48339	T4			µg/stick	4	1.688	0.143	8.482		
30°C/65%RH	Acrylamide	B-48339	T6			µg/stick	4	1.856	0.065	3.483		
30°C/65%RH	Acrylamide	B-48339	T9			µg/stick	4	1.862	0.193	10.368		
30°C/65%RH	Acrylamide	B-48339	T12			µg/stick	6	1.507	0.064	4.267		
30°C/65%RH	Acrylamide	B-48339	T16			µg/stick	6	1.023	0.100	9.801		
30°C/65%RH	Acrylamide	B-48339	T20			µg/stick	6	1.071	0.058	5.449		
30°C/65%RH	Acrylamide	B-48339	T24			µg/stick	6	1.010	0.060	5.894		
30°C/65%RH	Benzene	B-48337	T0			µg/stick	6	0.626	0.052	8.295		
30°C/65%RH	Benzene	B-48337	T2			µg/stick	4	0.589	0.050	8.456		
30°C/65%RH	Benzene	B-48337	T4			µg/stick	4	0.585	0.028	4.848		
30°C/65%RH	Benzene	B-48337	T6			µg/stick	4	0.611	0.019	3.058		
30°C/65%RH	Benzene	B-48337	T9			µg/stick	4	0.616	0.014	2.341		
30°C/65%RH	Benzene	B-48337	T12			µg/stick	6	0.557	0.020	3.594		
30°C/65%RH	Benzene	B-48337	T16			µg/stick	6	0.540	0.049	9.040		
30°C/65%RH	Benzene	B-48337	T20			µg/stick	6	0.534	0.047	8.769		

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30°C/65%RH	Benzene	B-48337	T24			µg/stick	6	0.527	0.033	6.242		
30°C/65%RH	Benzene	B-48338	T0			µg/stick	6	0.571	0.049	8.671		
30°C/65%RH	Benzene	B-48338	T2			µg/stick	4	0.586	0.006	0.969		
30°C/65%RH	Benzene	B-48338	T4			µg/stick	4	0.542	0.043	7.859		
30°C/65%RH	Benzene	B-48338	T6			µg/stick	4	0.530	0.026	4.878		
30°C/65%RH	Benzene	B-48338	T9			µg/stick	4	0.583	0.066	11.364		
30°C/65%RH	Benzene	B-48338	T12			µg/stick	6	0.526	0.023	4.459		
30°C/65%RH	Benzene	B-48338	T16			µg/stick	6	0.509	0.026	5.148		
30°C/65%RH	Benzene	B-48338	T20			µg/stick	6	0.532	0.020	3.731		
30°C/65%RH	Benzene	B-48338	T24			µg/stick	6	0.528	0.026	4.911		
30°C/65%RH	Benzene	B-48339	T0			µg/stick	6	0.622	0.037	5.866		
30°C/65%RH	Benzene	B-48339	T2			µg/stick	4	0.573	0.037	6.410		
30°C/65%RH	Benzene	B-48339	T4			µg/stick	4	0.570	0.067	11.723		
30°C/65%RH	Benzene	B-48339	T6			µg/stick	4	0.581	0.046	7.897		
30°C/65%RH	Benzene	B-48339	T9			µg/stick	4	0.599	0.073	12.240		
30°C/65%RH	Benzene	B-48339	T12			µg/stick	6	0.558	0.022	3.979		
30°C/65%RH	Benzene	B-48339	T16			µg/stick	6	0.538	0.076	14.047		
30°C/65%RH	Benzene	B-48339	T20			µg/stick	6	0.533	0.020	3.763		
30°C/65%RH	Benzene	B-48339	T24			µg/stick	6	0.570	0.033	5.713		
30°C/65%RH	Carbon monoxide	B-48337	T0			mg/stick	6	0.579	0.035	5.974		
30°C/65%RH	Carbon monoxide	B-48337	T2			mg/stick	4	0.580	0.082	14.184		
30°C/65%RH	Carbon monoxide	B-48337	T4			mg/stick	4	0.586	0.000	0.000		
30°C/65%RH	Carbon monoxide	B-48337	T6			mg/stick	4	0.422	0.000	0.000		
30°C/65%RH	Carbon monoxide	B-48337	T9			mg/stick	4	0.399	0.080	20.156		
30°C/65%RH	Carbon monoxide	B-48337	T12			mg/stick	6	0.422	0.020	4.666		
30°C/65%RH	Carbon monoxide	B-48337	T16			mg/stick	6	0.425	0.012	2.878		
30°C/65%RH	Carbon monoxide	B-48337	T20			mg/stick	6	0.442	0.027	6.009		
30°C/65%RH	Carbon monoxide	B-48337	T24			mg/stick	6	0.456	0.038	8.296		
30°C/65%RH	Carbon monoxide	B-48338	T0			mg/stick	6	0.522	0.035	6.620		
30°C/65%RH	Carbon monoxide	B-48338	T2			mg/stick	4	0.580	0.043	7.407		
30°C/65%RH	Carbon monoxide	B-48338	T4			mg/stick	4	0.586	0.000	0.000		
30°C/65%RH	Carbon monoxide	B-48338	T6			mg/stick	4	0.401	0.042	10.526		
30°C/65%RH	Carbon monoxide	B-48338	T9			mg/stick	4	0.399	0.042	10.526		
30°C/65%RH	Carbon monoxide	B-48338	T12			mg/stick	6	0.425	0.027	6.308		

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30°C/65%RH	Carbon monoxide	B-48338	T16			mg/stick	6	0.415	0.020	4.723		
30°C/65%RH	Carbon monoxide	B-48338	T20			mg/stick	6	0.448	0.021	4.671		
30°C/65%RH	Carbon monoxide	B-48338	T24			mg/stick	6	0.471	0.024	5.196		
30°C/65%RH	Carbon monoxide	B-48339	T0			mg/stick	6	0.565	0.044	7.746		
30°C/65%RH	Carbon monoxide	B-48339	T2			mg/stick	4	0.558	0.050	8.882		
30°C/65%RH	Carbon monoxide	B-48339	T4			mg/stick	4	0.586	0.000	0.000		
30°C/65%RH	Carbon monoxide	B-48339	T6			mg/stick	4	0.422	0.000	0.000		
30°C/65%RH	Carbon monoxide	B-48339	T9			mg/stick	4	0.462	0.084	18.182		
30°C/65%RH	Carbon monoxide	B-48339	T12			mg/stick	6	0.425	0.021	5.052		
30°C/65%RH	Carbon monoxide	B-48339	T16			mg/stick	6	0.414	0.011	2.566		
30°C/65%RH	Carbon monoxide	B-48339	T20			mg/stick	6	0.432	0.008	1.822		
30°C/65%RH	Carbon monoxide	B-48339	T24			mg/stick	6	0.463	0.014	3.043		
30°C/65%RH	Formaldehyde	B-48337	T0			µg/stick	6	4.793	1.646	34.337		
30°C/65%RH	Formaldehyde	B-48337	T2			µg/stick	4	4.042	0.656	16.238		
30°C/65%RH	Formaldehyde	B-48337	T4			µg/stick	4	3.649	0.238	6.531		
30°C/65%RH	Formaldehyde	B-48337	T6			µg/stick	4	3.631	0.635	17.488		
30°C/65%RH	Formaldehyde	B-48337	T9			µg/stick	4	4.554	0.280	6.139		
30°C/65%RH	Formaldehyde	B-48337	T12			µg/stick	6	3.307	0.232	7.025		
30°C/65%RH	Formaldehyde	B-48337	T16			µg/stick	6	3.535	0.586	16.574		
30°C/65%RH	Formaldehyde	B-48337	T20			µg/stick	6	3.792	0.341	9.001		
30°C/65%RH	Formaldehyde	B-48337	T24			µg/stick	6	3.818	0.200	5.245		
30°C/65%RH	Formaldehyde	B-48338	T0			µg/stick	6	3.777	0.531	14.067		
30°C/65%RH	Formaldehyde	B-48338	T2			µg/stick	4	4.082	0.687	16.840		
30°C/65%RH	Formaldehyde	B-48338	T4			µg/stick	4	3.430	0.396	11.538		
30°C/65%RH	Formaldehyde	B-48338	T6			µg/stick	4	3.634	0.261	7.185		
30°C/65%RH	Formaldehyde	B-48338	T9			µg/stick	4	4.476	0.444	9.917		
30°C/65%RH	Formaldehyde	B-48338	T12			µg/stick	6	3.740	0.522	13.953		
30°C/65%RH	Formaldehyde	B-48338	T16			µg/stick	6	4.033	0.690	17.117		
30°C/65%RH	Formaldehyde	B-48338	T20			µg/stick	6	3.806	0.178	4.687		
30°C/65%RH	Formaldehyde	B-48338	T24			µg/stick	6	3.730	0.521	13.975		
30°C/65%RH	Formaldehyde	B-48339	T0			µg/stick	6	3.906	0.775	19.842		
30°C/65%RH	Formaldehyde	B-48339	T2			µg/stick	4	4.468	0.703	15.725		
30°C/65%RH	Formaldehyde	B-48339	T4			µg/stick	4	4.497	1.082	24.066		
30°C/65%RH	Formaldehyde	B-48339	T6			µg/stick	4	3.846	1.017	26.433		

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30°C/65%RH	Formaldehyde	B-48339	T9			µg/stick	4	4.659	0.814	17.471		
30°C/65%RH	Formaldehyde	B-48339	T12			µg/stick	6	3.825	0.218	5.690		
30°C/65%RH	Formaldehyde	B-48339	T16			µg/stick	6	4.759	0.793	16.668		
30°C/65%RH	Formaldehyde	B-48339	T20			µg/stick	6	3.742	0.376	10.051		
30°C/65%RH	Formaldehyde	B-48339	T24			µg/stick	6	3.848	0.599	15.575		
30°C/65%RH	Glycerin	B-48337	T0			mg/stick	6	5.177	0.454	8.774		
30°C/65%RH	Glycerin	B-48337	T2			mg/stick	4	5.295	0.231	4.367		
30°C/65%RH	Glycerin	B-48337	T4			mg/stick	4	4.624	0.291	6.287		
30°C/65%RH	Glycerin	B-48337	T6			mg/stick	4	4.797	0.436	9.097		
30°C/65%RH	Glycerin	B-48337	T9			mg/stick	4	4.009	0.446	11.124		
30°C/65%RH	Glycerin	B-48337	T12			mg/stick	6	3.975	0.253	6.373		
30°C/65%RH	Glycerin	B-48337	T16			mg/stick	6	3.771	0.217	5.746		
30°C/65%RH	Glycerin	B-48337	T20			mg/stick	6	3.457	0.067	1.939		
30°C/65%RH	Glycerin	B-48337	T24			mg/stick	6	3.438	0.179	5.215		
30°C/65%RH	Glycerin	B-48338	T0			mg/stick	6	4.842	0.315	6.509		
30°C/65%RH	Glycerin	B-48338	T2			mg/stick	4	5.201	0.419	8.054		
30°C/65%RH	Glycerin	B-48338	T4			mg/stick	4	4.289	0.445	10.377		
30°C/65%RH	Glycerin	B-48338	T6			mg/stick	4	4.495	0.684	15.224		
30°C/65%RH	Glycerin	B-48338	T9			mg/stick	4	4.336	0.320	7.370		
30°C/65%RH	Glycerin	B-48338	T12			mg/stick	6	3.953	0.426	10.778		
30°C/65%RH	Glycerin	B-48338	T16			mg/stick	6	3.605	0.409	11.348		
30°C/65%RH	Glycerin	B-48338	T20			mg/stick	6	3.636	0.199	5.487		
30°C/65%RH	Glycerin	B-48338	T24			mg/stick	6	3.511	0.217	6.194		
30°C/65%RH	Glycerin	B-48339	T0			mg/stick	6	5.145	0.395	7.681		
30°C/65%RH	Glycerin	B-48339	T2			mg/stick	4	5.230	0.295	5.636		
30°C/65%RH	Glycerin	B-48339	T4			mg/stick	4	4.390	0.335	7.627		
30°C/65%RH	Glycerin	B-48339	T6			mg/stick	4	4.852	0.389	8.021		
30°C/65%RH	Glycerin	B-48339	T9			mg/stick	4	4.589	0.387	8.438		
30°C/65%RH	Glycerin	B-48339	T12			mg/stick	6	4.101	0.199	4.863		
30°C/65%RH	Glycerin	B-48339	T16			mg/stick	6	3.664	0.398	10.854		
30°C/65%RH	Glycerin	B-48339	T20			mg/stick	6	3.597	0.145	4.038		
30°C/65%RH	Glycerin	B-48339	T24			mg/stick	6	3.665	0.144	3.925		
30°C/65%RH	Menthol	B-48337	T0			mg/stick	6	1.277	0.026	2.031		
30°C/65%RH	Menthol	B-48337	T2			mg/stick	4	2.094	0.131	6.263		
30°C/65%RH	Menthol	B-48337	T4			mg/stick	4	1.925	0.045	2.339		
30°C/65%RH	Menthol	B-48337	T6			mg/stick	4	1.925	0.132	6.837		
30°C/65%RH	Menthol	B-48337	T9			mg/stick	4	1.845	0.048	2.596		

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30°C/65%RH	Menthol	B-48337	T12			mg/stick	6	1.579	0.163	10.324		
30°C/65%RH	Menthol	B-48337	T16			mg/stick	6	1.579	0.071	4.516		
30°C/65%RH	Menthol	B-48337	T20			mg/stick	6	1.533	0.080	5.230		
30°C/65%RH	Menthol	B-48337	T24			mg/stick	6	1.662	0.045	2.716		
30°C/65%RH	Menthol	B-48338	T0			mg/stick	6	1.147	0.068	5.964		
30°C/65%RH	Menthol	B-48338	T2			mg/stick	4	2.162	0.129	5.989		
30°C/65%RH	Menthol	B-48338	T4			mg/stick	4	2.077	0.079	3.792		
30°C/65%RH	Menthol	B-48338	T6			mg/stick	4	1.911	0.095	4.967		
30°C/65%RH	Menthol	B-48338	T9			mg/stick	4	1.762	0.038	2.130		
30°C/65%RH	Menthol	B-48338	T12			mg/stick	6	1.500	0.042	2.781		
30°C/65%RH	Menthol	B-48338	T16			mg/stick	6	1.621	0.076	4.697		
30°C/65%RH	Menthol	B-48338	T20			mg/stick	6	1.475	0.032	2.159		
30°C/65%RH	Menthol	B-48338	T24			mg/stick	6	1.486	0.120	8.056		
30°C/65%RH	Menthol	B-48339	T0			mg/stick	6	1.276	0.090	7.048		
30°C/65%RH	Menthol	B-48339	T2			mg/stick	4	2.292	0.091	3.950		
30°C/65%RH	Menthol	B-48339	T4			mg/stick	4	1.990	0.065	3.247		
30°C/65%RH	Menthol	B-48339	T6			mg/stick	4	1.896	0.172	9.061		
30°C/65%RH	Menthol	B-48339	T9			mg/stick	4	1.791	0.061	3.428		
30°C/65%RH	Menthol	B-48339	T12			mg/stick	6	1.566	0.051	3.276		
30°C/65%RH	Menthol	B-48339	T16			mg/stick	6	1.573	0.085	5.427		
30°C/65%RH	Menthol	B-48339	T20			mg/stick	6	1.529	0.128	8.382		
30°C/65%RH	Menthol	B-48339	T24			mg/stick	6	1.624	0.077	4.762		
30°C/65%RH	Nicotine	B-48337	T0			mg/stick	6	1.252	0.058	4.607		
30°C/65%RH	Nicotine	B-48337	T2			mg/stick	4	1.222	0.025	2.072		
30°C/65%RH	Nicotine	B-48337	T4			mg/stick	4	1.134	0.022	1.958		
30°C/65%RH	Nicotine	B-48337	T6			mg/stick	4	1.181	0.024	2.069		
30°C/65%RH	Nicotine	B-48337	T9			mg/stick	4	1.090	0.073	6.657		
30°C/65%RH	Nicotine	B-48337	T12			mg/stick	6	1.140	0.027	2.408		
30°C/65%RH	Nicotine	B-48337	T16			mg/stick	6	1.109	0.055	4.938		
30°C/65%RH	Nicotine	B-48337	T20			mg/stick	6	0.978	0.027	2.752		
30°C/65%RH	Nicotine	B-48337	T24			mg/stick	6	1.048	0.042	4.012		
30°C/65%RH	Nicotine	B-48338	T0			mg/stick	6	1.178	0.048	4.117		
30°C/65%RH	Nicotine	B-48338	T2			mg/stick	4	1.212	0.037	3.082		
30°C/65%RH	Nicotine	B-48338	T4			mg/stick	4	1.112	0.017	1.531		
30°C/65%RH	Nicotine	B-48338	T6			mg/stick	4	1.169	0.099	8.485		
30°C/65%RH	Nicotine	B-48338	T9			mg/stick	4	1.156	0.055	4.795		
30°C/65%RH	Nicotine	B-48338	T12			mg/stick	6	1.153	0.059	5.074		

(b) (4)

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CONDITION	VARIABLE	BATCH	Time point	LSL	USL	UNIT	N	Mean	Std	CV	Lower 95% CI	Upper 95% CI
30°C/65%RH	Nicotine	B-48338	T16			mg/stick	6	1.102	0.047	4.273		
30°C/65%RH	Nicotine	B-48338	T20			mg/stick	6	1.066	0.049	4.591		
30°C/65%RH	Nicotine	B-48338	T24			mg/stick	6	1.092	0.048	4.405		
30°C/65%RH	Nicotine	B-48339	T0			mg/stick	6	1.255	0.065	5.178		
30°C/65%RH	Nicotine	B-48339	T2			mg/stick	4	1.227	0.045	3.652		
30°C/65%RH	Nicotine	B-48339	T4			mg/stick	4	1.138	0.067	5.889		
30°C/65%RH	Nicotine	B-48339	T6			mg/stick	4	1.240	0.051	4.072		
30°C/65%RH	Nicotine	B-48339	T9			mg/stick	4	1.187	0.058	4.861		
30°C/65%RH	Nicotine	B-48339	T12			mg/stick	6	1.160	0.016	1.381		
30°C/65%RH	Nicotine	B-48339	T16			mg/stick	6	1.142	0.055	4.804		
30°C/65%RH	Nicotine	B-48339	T20			mg/stick	6	1.052	0.043	4.100		
30°C/65%RH	Nicotine	B-48339	T24			mg/stick	6	1.107	0.043	3.870		
30°C/65%RH	Phenol	B-48337	T0			µg/stick	6	1.222	0.204	16.667		
30°C/65%RH	Phenol	B-48337	T2			µg/stick	4	1.070	0.171	16.029		
30°C/65%RH	Phenol	B-48337	T4			µg/stick	4	1.037	0.099	9.580		
30°C/65%RH	Phenol	B-48337	T6			µg/stick	4	0.908	0.092	10.146		
30°C/65%RH	Phenol	B-48337	T9			µg/stick	4	0.859	0.266	31.005		
30°C/65%RH	Phenol	B-48337	T12			µg/stick	6	0.818	0.117	14.268		
30°C/65%RH	Phenol	B-48337	T16			µg/stick	6	0.858	0.187	21.803		
30°C/65%RH	Phenol	B-48337	T20			µg/stick	6	0.674	0.162	23.990		
30°C/65%RH	Phenol	B-48337	T24			µg/stick	6	0.895	0.109	12.136		
30°C/65%RH	Phenol	B-48338	T0			µg/stick	6	1.251	0.125	9.994		
30°C/65%RH	Phenol	B-48338	T2			µg/stick	4	1.025	0.130	12.671		
30°C/65%RH	Phenol	B-48338	T4			µg/stick	4	1.004	0.117	11.658		
30°C/65%RH	Phenol	B-48338	T6			µg/stick	4	0.845	0.303	35.879		
30°C/65%RH	Phenol	B-48338	T9			µg/stick	4	1.012	0.193	19.101		
30°C/65%RH	Phenol	B-48338	T12			µg/stick	6	0.935	0.130	13.889		
30°C/65%RH	Phenol	B-48338	T16			µg/stick	6	0.918	0.186	20.293		
30°C/65%RH	Phenol	B-48338	T20			µg/stick	6	0.867	0.105	12.119		
30°C/65%RH	Phenol	B-48338	T24			µg/stick	6	1.186	0.106	8.960		
30°C/65%RH	Phenol	B-48339	T0			µg/stick	6	1.217	0.166	13.611		
30°C/65%RH	Phenol	B-48339	T2			µg/stick	4	1.135	0.184	16.185		
30°C/65%RH	Phenol	B-48339	T4			µg/stick	4	0.871	0.241	27.629		
30°C/65%RH	Phenol	B-48339	T6			µg/stick	4	1.103	0.211	19.087		
30°C/65%RH	Phenol	B-48339	T9			µg/stick	4	1.185	0.297	25.102		
30°C/65%RH	Phenol	B-48339	T12			µg/stick	6	0.900	0.100	11.075		
30°C/65%RH	Phenol	B-48339	T16			µg/stick	6	0.927	0.207	22.306		

(b) (4)

(b) (4)



CONDITION	VARIABLE	BATCH	Time point	LSL	USL	UNIT	N	Mean	Std	CV	Lower 95% CI	Upper 95% CI
30°C/65%RH	Phenol	B-48339	T20			µg/stick	6	0.734	0.139	18.885		
30°C/65%RH	Phenol	B-48339	T24			µg/stick	6	1.151	0.121	10.500		
(b) (4)												
30°C/65%RH	Tobacco stick weight	B-48337	T0			mg	50	0.812	0.015	1.847		
30°C/65%RH	Tobacco stick weight	B-48337	T2			mg	50	0.815	0.011	1.338		

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CONDITION	VARIABLE	BATCH	Time point	LSL	USL	UNIT	N	Mean	Std	CV	Lower 95% CI	Upper 95% CI
30°C/65%RH	Tobacco stick weight	B-48337	T4			mg	50	0.811	0.011	1.376		
30°C/65%RH	Tobacco stick weight	B-48337	T6			mg	50	0.822	0.012	1.467		
30°C/65%RH	Tobacco stick weight	B-48337	T9			mg	50	0.806	0.012	1.435		
30°C/65%RH	Tobacco stick weight	B-48337	T12			mg	50	0.814	0.010	1.260		
30°C/65%RH	Tobacco stick weight	B-48337	T16			mg	50	0.810	0.015	1.803		
30°C/65%RH	Tobacco stick weight	B-48337	T20			mg	50	0.809	0.013	1.568		
30°C/65%RH	Tobacco stick weight	B-48337	T24			mg	50	0.814	0.010	1.276		
30°C/65%RH	Tobacco stick weight	B-48338	T0			mg	50	0.828	0.015	1.756		
30°C/65%RH	Tobacco stick weight	B-48338	T2			mg	50	0.837	0.011	1.275		
30°C/65%RH	Tobacco stick weight	B-48338	T4			mg	50	0.820	0.011	1.288		
30°C/65%RH	Tobacco stick weight	B-48338	T6			mg	50	0.830	0.012	1.495		
30°C/65%RH	Tobacco stick weight	B-48338	T9			mg	50	0.820	0.011	1.359		
30°C/65%RH	Tobacco stick weight	B-48338	T12			mg	50	0.823	0.010	1.157		
30°C/65%RH	Tobacco stick weight	B-48338	T16			mg	50	0.816	0.013	1.532		
30°C/65%RH	Tobacco stick weight	B-48338	T20			mg	50	0.805	0.011	1.366		
30°C/65%RH	Tobacco stick weight	B-48338	T24			mg	50	0.833	0.012	1.381		
30°C/65%RH	Tobacco stick weight	B-48339	T0			mg	50	0.814	0.011	1.322		
30°C/65%RH	Tobacco stick weight	B-48339	T2			mg	50	0.818	0.011	1.295		
30°C/65%RH	Tobacco stick weight	B-48339	T4			mg	50	0.810	0.012	1.539		
30°C/65%RH	Tobacco stick weight	B-48339	T6			mg	50	0.820	0.010	1.253		
30°C/65%RH	Tobacco stick weight	B-48339	T9			mg	50	0.813	0.010	1.207		
30°C/65%RH	Tobacco stick weight	B-48339	T12			mg	50	0.823	0.009	1.130		
30°C/65%RH	Tobacco stick weight	B-48339	T16			mg	50	0.816	0.009	1.162		
30°C/65%RH	Tobacco stick weight	B-48339	T20			mg	50	0.811	0.014	1.756		
30°C/65%RH	Tobacco stick weight	B-48339	T24			mg	50	0.817	0.011	1.325		
30°C/65%RH	Triacetin	B-48337	T0			mg/stick	6	0.641	0.068	10.635		
30°C/65%RH	Triacetin	B-48337	T2			mg/stick	4	0.518	0.044	8.536		
30°C/65%RH	Triacetin	B-48337	T4			mg/stick	4	0.417	0.019	4.617		
30°C/65%RH	Triacetin	B-48337	T6			mg/stick	4	0.377	0.020	5.338		
30°C/65%RH	Triacetin	B-48337	T9			mg/stick	4	0.350	0.011	3.248		
30°C/65%RH	Triacetin	B-48337	T12			mg/stick	6	0.339	0.021	6.170		
30°C/65%RH	Triacetin	B-48337	T16			mg/stick	6	0.303	0.009	3.106		

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CONDITION	VARIABLE	BATCH	Time point	LSL	USL	UNIT	N	Mean	Std	CV	Lower 95% CI	Upper 95% CI
30°C/65%RH	Triacetin	B-48337	T20			mg/stick	6	0.289	0.017	5.979		
30°C/65%RH	Triacetin	B-48337	T24			mg/stick	6	0.271	0.021	7.821		
30°C/65%RH	Triacetin	B-48338	T0			mg/stick	6	0.606	0.043	7.063		
30°C/65%RH	Triacetin	B-48338	T2			mg/stick	4	0.519	0.032	6.164		
30°C/65%RH	Triacetin	B-48338	T4			mg/stick	4	0.406	0.018	4.487		
30°C/65%RH	Triacetin	B-48338	T6			mg/stick	4	0.369	0.025	6.872		
30°C/65%RH	Triacetin	B-48338	T9			mg/stick	4	0.376	0.004	1.061		
30°C/65%RH	Triacetin	B-48338	T12			mg/stick	6	0.338	0.020	5.902		
30°C/65%RH	Triacetin	B-48338	T16			mg/stick	6	0.302	0.028	9.400		
30°C/65%RH	Triacetin	B-48338	T20			mg/stick	6	0.288	0.012	4.127		
30°C/65%RH	Triacetin	B-48338	T24			mg/stick	6	0.276	0.016	5.934		
30°C/65%RH	Triacetin	B-48339	T0			mg/stick	6	0.573	0.025	4.365		
30°C/65%RH	Triacetin	B-48339	T2			mg/stick	4	0.503	0.013	2.604		
30°C/65%RH	Triacetin	B-48339	T4			mg/stick	4	0.406	0.015	3.728		
30°C/65%RH	Triacetin	B-48339	T6			mg/stick	4	0.366	0.008	2.253		
30°C/65%RH	Triacetin	B-48339	T9			mg/stick	4	0.399	0.039	9.836		
30°C/65%RH	Triacetin	B-48339	T12			mg/stick	6	0.331	0.014	4.207		
30°C/65%RH	Triacetin	B-48339	T16			mg/stick	6	0.287	0.025	8.792		
30°C/65%RH	Triacetin	B-48339	T20			mg/stick	6	0.295	0.012	4.125		
30°C/65%RH	Triacetin	B-48339	T24			mg/stick	6	0.287	0.014	4.888		
30°C/65%RH	Water activity	B-48337	T0			N/A	3	0.427	0.006	1.353		
30°C/65%RH	Water activity	B-48337	T2			N/A	3	0.540	0.000	0.000		
30°C/65%RH	Water activity	B-48337	T4			N/A	3	0.580	0.017	2.986		
30°C/65%RH	Water activity	B-48337	T6			N/A	3	0.603	0.006	0.957		
30°C/65%RH	Water activity	B-48337	T9			N/A	3	0.607	0.006	0.952		
30°C/65%RH	Water activity	B-48337	T12			N/A	3	0.620	0.000	0.000		
30°C/65%RH	Water activity	B-48337	T16			N/A	3	0.620	0.000	0.000		
30°C/65%RH	Water activity	B-48337	T20			N/A	3	0.630	0.000	0.000		
30°C/65%RH	Water activity	B-48337	T24			N/A	3	0.640	0.000	0.000		
30°C/65%RH	Water activity	B-48338	T0			N/A	3	0.427	0.006	1.353		
30°C/65%RH	Water activity	B-48338	T2			N/A	3	0.550	0.000	0.000		
30°C/65%RH	Water activity	B-48338	T4			N/A	3	0.583	0.006	0.990		
30°C/65%RH	Water activity	B-48338	T6			N/A	3	0.610	0.000	0.000		
30°C/65%RH	Water activity	B-48338	T9			N/A	3	0.610	0.000	0.000		
30°C/65%RH	Water activity	B-48338	T12			N/A	3	0.620	0.000	0.000		
30°C/65%RH	Water activity	B-48338	T16			N/A	3	0.613	0.006	0.941		
30°C/65%RH	Water activity	B-48338	T20			N/A	3	0.630	0.000	0.000		

(b) (4)

(b) (4)

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CONDITION	VARIABLE	BATCH	Time point	LSL	USL	UNIT	N	Mean	Std	CV	Lower 95% CI	Upper 95% CI
30°C/65%RH	Water activity	B-48338	T24	(b) (4)	(b) (4)	N/A	3	0.640	0.000	0.000	(b) (4)	(b) (4)
30°C/65%RH	Water activity	B-48339	T0			N/A	3	0.430	0.000	0.000		
30°C/65%RH	Water activity	B-48339	T2			N/A	3	0.540	0.000	0.000		
30°C/65%RH	Water activity	B-48339	T4			N/A	3	0.577	0.006	1.001		
30°C/65%RH	Water activity	B-48339	T6			N/A	3	0.600	0.000	0.000		
30°C/65%RH	Water activity	B-48339	T9			N/A	3	0.607	0.006	0.952		
30°C/65%RH	Water activity	B-48339	T12			N/A	3	0.613	0.006	0.941		
30°C/65%RH	Water activity	B-48339	T16			N/A	3	0.623	0.006	0.926		
30°C/65%RH	Water activity	B-48339	T20			N/A	3	0.630	0.000	0.000		
30°C/65%RH	Water activity	B-48339	T24			N/A	3	0.637	0.006	0.907		

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5. STABILITY REPORT FOR MARLBORO FRESH MENTHOL HEATSTICKS³

³ The update of the name for Marlboro Fresh Menthol *HeatSticks* (STN: PM0000426) to Marlboro Blue Menthol *HeatSticks* was submitted with 30-day notification dated July 31, 2020.

Confidentiality Statement

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FINAL REPORT OF THE FOLLOW-UP STABILITY STUDY FOR THS2.2 HIGH MENTHOL VARIANT 24 MONTHS

PRODUCT PLATFORM:

P1

PRODUCT GENERATION:

THS2.2

PROJECT NAME FOR NEW DEVELOPMENT:

HIGH MENTHOL VARIANT (C3.2)

Effective Version

Version N°	Document Name	Document Title
3.0	From EDMS	From EDMS

For historical versions and change details, refer to paragraph 12 Change Management Log.



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1 Executive Summary

A stability study on Dorado I Fauvery High menthol product was performed under 22°C 60%RH and 30°C 65%RH storage conditions during 24 months on 3 batches.

The data generated under the 22°C 60%RH storage condition support a shelf life of 24 months for aerosol chemistry, Water activity and the Tobacco stick weight. (b) (4)

(b) (4)

The data generated under the 30°C 65%RH storage condition support a shelf life of 24 months for Water activity, Tobacco stick weight and aerosol chemistry (b) (4)

(b) (4)

It has to be noticed, that the specifications used for the aerosol constituents assessment, excluding Menthol, were revised during the study. While the study is reported with the specifications referenced in the study protocol, prior the revision, the impact of the new specifications on the shelf life has been evaluated. The change has no impact on the study results with the exception of Glycerin under 30°C 65%RH storage condition, which support a shelf life of 24 months, instead of 20 months.



2 Purpose

The stability study STAB-2017_P1_M_3 was performed until 12 months on the commercial product THS2.2 High Menthol variant (Dorado I Fauvery) manufactured at Philip Morris Manufacturing & Technology Bologna (PMMTB) and is separately reported [1].

In order to understand the evolution of the product beyond the established Best Used Before Date (BUBD) of 12 months, the stability study on the same batches was extended until 24 months with three additional time points at 16, 20 and 24 months. The storage of the samples (tobacco sticks in primary packaging) was continued without interruption under 22°C 60%RH (ISO condition [17]) and 30°C 65%RH (defined WHO [18]) storage conditions.

The study and the related attributes were based on PMI Stability Study Program THS2.2 [2] and are covering the product performance, safety and quality. The same attributes as for the 12 months study were continued to be monitored until 24 months with the exception of the visual inspection in 30°C 65%RH.

This report summarizes the results of the 24 months stability study STAB-2017_P1_M_3 performed according to the stability study protocol [3] and the follow-up study protocol for 24 months [4].

3 Batches

Table 1 Identification of batches Dorado I Fauvery High (STAB-2017_P1_M_3)

Variant	Pack Batch Number	Finished Product Code	Tobacco Stick Product Code	PM MTB PO	Manufacturing Date	End of Equilibration Date	Beginning of the Study (T0)
THS 2.2 Dorado I Fauvery High	B-48374	ME000420.11	CONS.02806.RD	101697966	20-Oct-2017	17-Nov-2017	20-Nov-2017
	B-48375	ME000420.11	CONS.02806.RD	101697967	20-Oct-2017	17-Nov-2017	20-Nov-2017
	B-48376	ME000420.11	CONS.02806.RD	101697968	23-Oct-2017	20-Nov-2017	20-Nov-2017

The samples were stored in the conditioning room (22 ± 2°C 60 ± 5%RH) and in climatic chambers (30 ± 2°C 65 ± 5%RH) in wrapped packs in R&D Neuchâtel Product Testing (PT) laboratories by the Test Item Management team (for ID numbers of the storage



locations see Appendix 15.1). The packs were polypropylene wrapped and consisted of two collations, each collation contains 10 Heat sticks.

The end of equilibration corresponds to the date when the products passed the 28 days of equilibration used for mentholated products.

The beginning of the study corresponds to the date when the packs were put in the conditioning room and climatic chamber. This date corresponds to the T0 time point.

4 Tests Methods and Specifications

The parameters tested during the study, the methods used and the specifications are listed in Table 2. All the instruments and materials are listed in the relevant work instructions.

A table containing dates of analyses for each time point is presented in Appendix 15.2.

Table 2 Tests, Methods and Specifications

Parameter	Unit	Method Name	Method Version				Target Value	Specification	
			Planned	Used				Range or Upper Limit	Version
				T0	T12	T24			
Nicotine	mg/stick	PMI-RRP-WKI-111801	9.0.0	9.0.0	9.0.0	11.0.0	(b) (4)		3.0 [5]
Glycerin	mg/stick	PMI-RRP-WKI-111640	4.0.0	3.0.0	4.0.0	4.0.0			3.0 [5]
Triacetin	mg/stick	*							3.0 [5]
Carbon monoxide (CO)	mg/stick								3.0 [5]
Phenol	µg/stick								3.0 [5]
Acrylamide	µg/stick								3.0 [5]
Formaldehyde	µg/stick	PMI-RRP-WKI-111743	13.0.0	13.0.0	13.0.0	14.0.0			3.0 [5]
		PMI-RRP-WKI-111709	15.0.0	15.0.0	16.0.0	16.0.0			
1,3-butadiene	µg/stick	PMI-RRP-WKI-111729	7.0.0	7.0.0	8.0.0	10.0.0			3.0 [5]
Benzene	µg/stick	PMI-RRP-WKI-111706	18.0.0	18.0.0	19.0.0	20.0.0			3.0 [5]



Parameter	Unit	Method Name	Method Version				Target Value	Specification	
			Planned	Used				Range or Upper Limit	Version
				T0	T12	T24			
Menthol	mg/stick	PMI-RRP-WKI-111801	9.0.0	9.0.0	9.0.0	11.0.0	(b) (4)		1.0 [6]
		PMI-RRP-WKI-111604*	4.0.0	3.0.0	4.0.0	4.0.0			
(b) (4)									
Tobacco stick weight DI High CONS.02806. RD	mg								2.0 [8]
Water activity	N/A	VM1349	1.0	1.0	1.0	1.0			1.0 [2]
Visual quality	N/A	See Chapter 4.4	N/A	N/A	N/A	N/A			N/A
QDP	N/A	PR.06	02	02	02	02			N/A

* The referenced method in the stability study was PMI-RRP-WKI-111604 instead of PMI-RRP-WKI-111640, which was a typographical error in the stability protocol.

4.1 Aerosol Measurement

Measurements of Nicotine, Glycerin, Triacetin, Carbon monoxide, Phenol, Menthol, Acrylamide, Formaldehyde, 1,3-butadiene and Benzene were performed after trapping the particulate and/or the gas phase of the aerosol and subsequent analyses described in respective work instructions (Table 2).

4.1.1 Preparation and Conditioning

At each time point before aerosol generation, in order to perform the testing under normal conditions as on freshly made products, sticks were reconditioned outside the packs following ISO standard 3402 (1999), for a minimum of 48 hours and a maximum of 10 days at 22 ± 1 °C, $60 \pm 3\%$ RH according to PMI-RRP-WKI-111777 "Preparation of items". When reached the maximum time of conditioning, samples were placed in a sealed recipient and remained in the conditioning room. For the determination of Menthol, samples were kept in closed packs prior to analysis in order to avoid loss of menthol.



The 3R4F Reference Cigarette (purchased from the University of Kentucky, USA) or P1 monitor (P1M1 or P1M2) was used as an internal monitor for aerosol chemistry (PMI-RRP-WKI-123605). Values were compared to respective upper and lower limits defined in the control charts to verify the correct functioning of the experimental setup.

4.1.2 Aerosol Generation and Analyses

The atmosphere for aerosol generation was $22 \pm 2^\circ\text{C}$, $60 \pm 5\%$ RH.

Aerosol generation was performed on linear smoking machines.

The Health Canada Intense (HCI) smoking regimen [20] using bell shaped puff profile was used with the below listed parameters to generate the aerosol for further chemical analyses:

- Puff volume: 55 mL
- Puff duration: 2.0 s
- Puff interval: 30 s
- Number of puffs: 12

In the stability protocol for 12 months [3] the device DV.000174(8) was erroneously written to be used. The tobacco heating device DV.000180(5)/B-34548 was used to generate aerosol for chemical analyses. The deviation is described in chapter 6.2 and documented as a non-conformity (NC), NC-2019-00542. The device DV.000180(5)/B-34548 was used as well for T16 time point according to the follow-up protocol [4].

For the analyses of aerosol chemistry at T20 and T24 time points the device DV.000180(7)/B-61948 was used, instead of the DV.000180(5) planned in the follow-up stability protocol. Indeed, the device DV.000180(5)/B-34548 has reached its maximum usage period and was replaced by DV.000180(7)/B-61948, which is used as a reference device in the laboratory. The deviation is described in chapter 6.4.

Aerosol was trapped on Cambridge filter pad, in impingers or the combination of both and the analyses were performed by GC-MS or UPLC-MS/MS.

For T0, T12, T16, 20, 24 time points, 6 replicates/sample, for T2 to T9 time points 4 replicates/sample were performed.

4.2 Physical Measurement

(b) (4)

Tobacco Stick weight were measured as physical parameters.



4.2.1 Preparation and Conditioning

Conditioning for physical analyses was performed as described in respective work instruction, inside open packs for at least 24 hours at 22 ± 2 °C and $50 \pm 5\%$ RH.

4.2.2 Measurement

Cerulean C2 instrument was used for the determination of the physical parameters. For each time point 50 sticks/sample were measured.

4.3 Water Activity Measurement

The Water activity is the measurement of the free water available for microbiological growth. (b) (4) the risk of mold development in cured tobacco is considered negligible, (b) (4)

4.3.1 Preparation and Conditioning

At each time point 20 packs/sample from the climatic chambers were sent to (b) (4) (b) (4). In order to maintain sample integrity, the shipment was done with express delivery with the same day of reception. Packs were wrapped in sealed aluminum packaging and upon arrival at (b) (4) the packs were placed under the stability studies' storage condition as described below.

The closed packs from storage condition 22°C 60%RH were placed prior to analyses for at least 48 hours (max. 96 hours) in $25 \pm 2^{\circ}\text{C}$ $60 \pm 5\%$ RH, while packs from storage condition 30°C 65%RH were placed in $30 \pm 2^{\circ}\text{C}$ $65 \pm 5\%$ RH. For the T0 time point, samples were placed at least 48 hours in 25°C 60%RH. The condition 25°C 60%RH was used in the absence of 22°C 60%RH as standard condition at (b) (4) and considered as not having impact on the water activity determination.

4.3.2 Analyses

Sticks were taken randomly from the packs and the tobacco was collected. This composite sample was mixed and 3 portions of approx. 2 g were filled into the sample mugs. The samples were measured using the LabMaster-aw instrument for their Water activity at 25°C .

For each time point 3 replicates/sample were analyzed.



4.4 Visual Evaluation

4.4.1 Preparation and Conditioning

(b) (4)

4.4.2 Evaluation

(b) (4)

4.5 Sensorial Evaluation

4.5.1 Preparation and Conditioning

(b) (4)

4.5.2 Evaluation

(b) (4)



5 Stability Study Design

The study was performed according to the testing matrix described in Table 3. Samples were pulled out from the stability chambers not more than 6 days after the planned time point based on calendar months.

Table 3 Testing Matrix

Batch	Storage Conditions	Analysis Time Points (months)								
		0	2	4	6	9	12	16	20	24
Dorado I Fauvery High (B-48374)	22±2°C / 60±5%RH	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W
	30±2°C / 65±5%RH		A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S W	A P S W	A P S W
Dorado I Fauvery High (B-48375)	22±2°C / 60±5%RH	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W
	30±2°C / 65±5%RH		A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S W	A P S W	A P S W
Dorado I Fauvery High (B-48376)	22±2°C / 60±5%RH	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S V W
	30±2°C / 65±5%RH		A P S V W	A P S V W	A P S V W	A P S V W	A P S V W	A P S W	A P S W	A P S W

A: Aerosol; P: Physical measurements; S: Sensorial analysis; V: Visual inspection, W: Water activity

6 Deviations to Study Protocol

6.1 Deviation Related to Method Versions

The version of several methods changed during the study compared to what was described in the study protocol (Table 2, [3],[4]).



6.1.1 Impact on the Study

The changes in the methods were all minor. They had no impact on the quantification of the tested parameters and therefore on the study results.

6.2 Deviation in Study Execution (1/3)

The device used during the stability study was DV.000180(5) instead of DV.000174(8) as stated in the stability protocol. The deviation is described in NC-2019-00542. The use of DV.000180(5) device was consistent during whole study (from T0 to T16).

6.2.1 Impact on the Study

The DV.000174(7) and the DV.000180(5) were released with the same Design Change Request (DCR-00310), therefore they are equivalent. The DV.000174(8) was released with the DCR-000516 which was a minor change having no impact on the aerosol. Therefore, the DV.000174(8) and DV.000180(5) are equivalent in terms of aerosol performance and the deviation has no impact on the stability results.

6.3 Deviation in Study Execution (2/3)

At T4 time point the sensorial evaluation started prior to the reception of the Water activity data. According to the stability study protocol the sensorial analyses should have been performed only after reception and verification of the Water activity results, for each time point except T0, in order to assess and confirm the absence of toxicological risk.

6.3.1 Impact on the Study

The Water activity results were below the (b) (4) The deviation has no impact on the stability study.

6.4 Deviation in Study Execution (3/3)

The device used for aerosol chemistry at T20 and T24 time points was DV.000180(7)/B-61948 instead of DV.000180(5) as stated in the follow-up stability protocol. The deviation was described in the intermediate report at T20. Indeed, the device DV.000180(5)/B-34548 has reached its maximum usage period and was replaced by DV.000180(7)/B-61948, which was used as a reference device in the laboratory.



6.4.1 Impact on the Study

The DV.000180(6) was released with DCR-00585 and the DV.000180(7) was released with DCR-00516, both related to a minor change having no impact on the aerosol. Therefore, the DV.000180(7) and DV.000180(5) are equivalent in terms of aerosol performance and the deviation has no impact on the stability results.

6.5 Deviation in Study Storage Condition 30°C 65%RH

Around the T9 time point, for a period of approximately one month (from 01-Aug-2018 until 06-Sep-2018), the temperature was out of the tolerance ($30 \pm 2^\circ\text{C}$) in the climatic chamber (ID 13017). During the same period the Relative Humidity (RH) was out of tolerance ($65 \pm 5\%\text{RH}$) for approximately 3.5 days, in total six excursions with a maximum of 25 hours per excursion were observed. The pull out dates of samples for the different time points and the periods of the NC for temperature and RH are schematically represented on Figure 1.

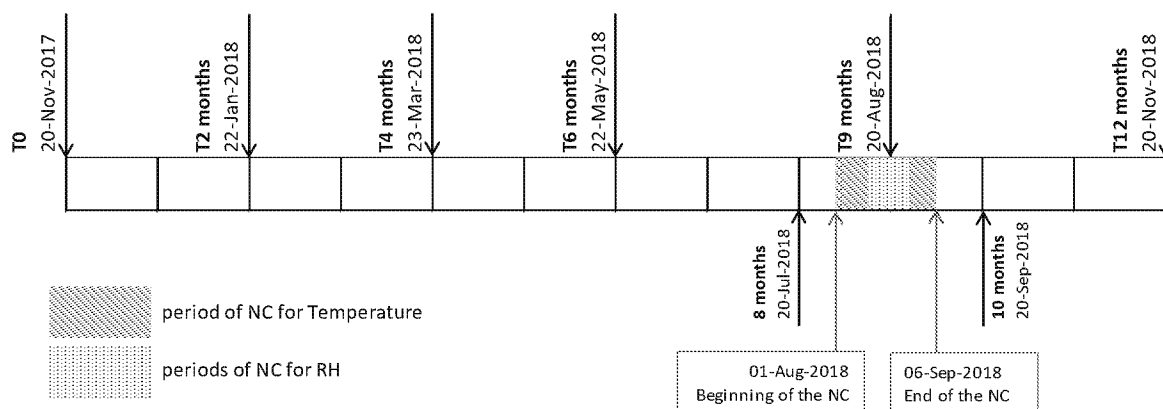


Figure 1 Study time points and NC periods for Temperature and RH

On the 06-Sep-2018, after downloading the data from datalogger placed in the climatic chamber ID 13017, it was observed that the environmental conditions were out of tolerances for temperature and RH despite the daily check of the conditions found within tolerance levels. The daily check was performed on the conditions shown by the (b) (4). No alarm and no anomalies were observed during that period. A loss of connection between the software and the climatic chamber was suspected.



On 06-Sep-2018, the climatic chamber was restarted and the environment conditions went back within the tolerance levels.

The NC-RRP-NEU-2018-622 was initiated to report the deviation occurred in the climatic chamber (ID 13017). The description of the failure together with the preventive actions are described in the CAPA-2018-00014.

Description of the deviation for the Temperature:

From 01-Aug-2018 until 06-Sep-2018, the temperature decreased below the lower tolerance of 28°C. On 01-Aug-2018 at 9:30 am the temperature went out of tolerance and decreased until 24°C on 02-Aug-2018 at 11:57 am (Figure 2). Between 02-Aug-2018 at 12:02 pm and 06-Sep-2018 at 10:20 am the temperature was at an average value of 23.6°C (fluctuating between 22.7°C and 24.4°C) (Figure 3). The datalogger was taken out from the chamber on 02-Aug-2018 at 11:57 am and put back at 12:02 pm which explains the two different charts with few minutes discrepancy.

Description of the deviation for the Relative Humidity:

The RH increased and crossed the (b) (4) on 01-Aug-2018 at 6:21 am reaching a maximum value (b) (4) and decreased within the tolerance limit on 04-Aug-2018 at 10:26 pm (after approx. 3.5 days) (Figure 2 and Figure 3). From 13-Aug-2018 until 28-Aug-2018 the mean value was 61.9%RH but dropped 6 times below (b) (4) 5/6 times was shorter than 17 hours and 1/6 times was of 25 hours (Figure 3).

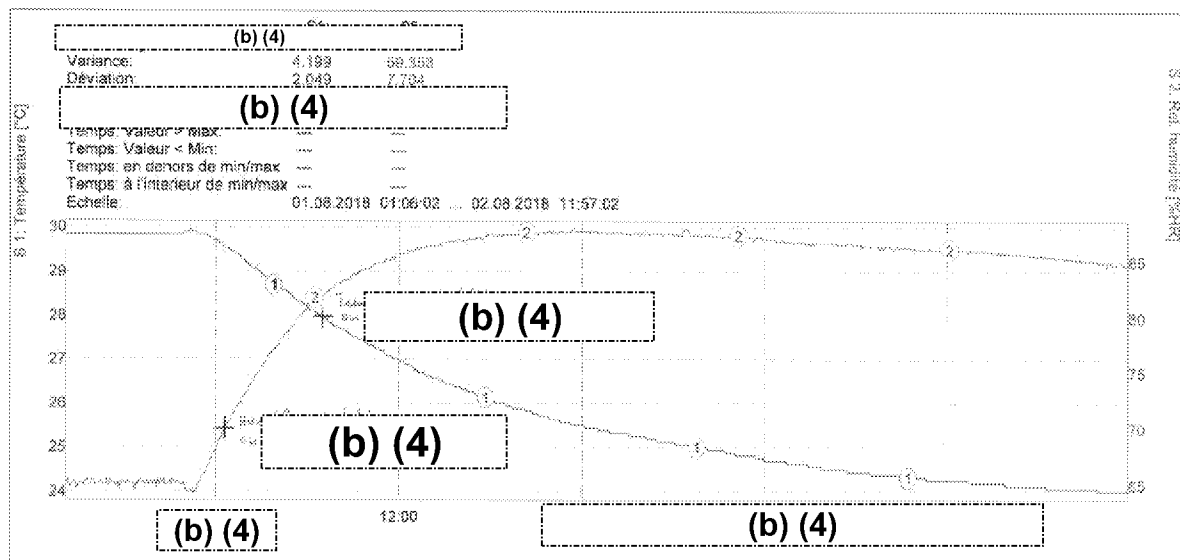


Figure 2 Evolution of Temperature and RH between 01-Aug-2018 and 02-Aug-2018

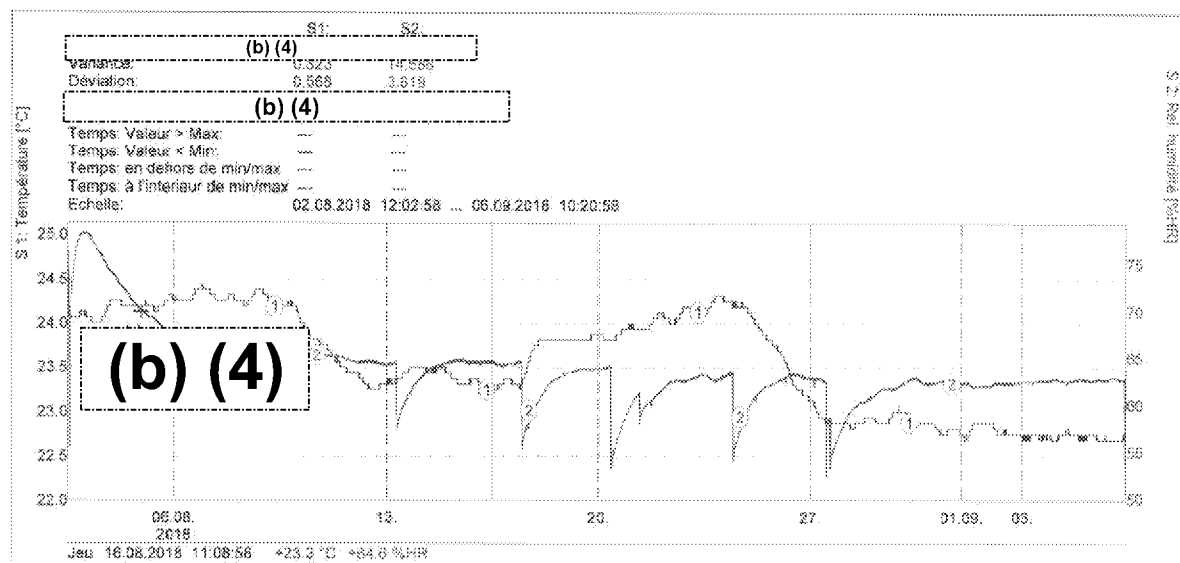


Figure 3 Evolution of Temperature and RH between 02-Aug-2018 and 06-Sep-2018

6.5.1 Impact on the Study

To assess the potential impact on the stability study results, the results from 3 recently completed stability studies STAB-2017_P1_R_1 (3 batches), STAB-2017_P1_M_2 (3 batches) were compared with the current study STAB-2017_P1_M_3 (3 batches). The impact assessment is detailed in separate document (action item AI-001880 linked to

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CAPA-2018-00014). The degradation profiles (slope of linear regression) for all constituents except (Menthol and Water activity) were compared across the 9 batches. An analyses of covariance (ANCOVA) at a significance level of 0.05 was performed. Following the review of all parameters (except Menthol and Water activity) it was concluded that the impact of the temperature and the RH excursion was minor, no significant statistical difference between the slopes was observed on the data reviewed.

7 Stability Data Evaluation

Results for aerosol chemistry, physical measurements and Water activity are stored in SDMS (Scientific Data Management System) under the corresponding project numbers (see Sample Traceability Matrix in Appendix 15.3). Results and final report of sensory evaluation are stored in PDIMS (Product Development Information Management System).

7.1 Investigations and Excluded Values

7.1.1 Investigation at T6

At T6, under 30°C 65%RH an investigation was performed on B-48376 as the (b) (4)

(b) (4)

(b) (4)

No analytical root cause was identified during the investigation. It was decided that no retest will be performed, data are reported as such. The investigation is described in a separate document [11].

7.1.2 Investigation at T9 (1/2)

An Out of Trend (OOT) investigation was performed for Menthol on batch B-48376 stored under 22°C 60%RH due to high variability between the replicates. No analytical reason could be identified to explain the OOT. (b) (4)

(b) (4)

(b) (4)

The details of the investigation can be found in a separate document [12].



7.1.3 Investigation at T9 (2/2)

An Out of Specification (OOS) investigation was performed for B-48376 stored under 30°C 65%RH [REDACTED] (b) (4)

[REDACTED] (b) (4)

[REDACTED] (b) (4) No analytical root cause was identified to explain the OOS. Data were reported as such. The investigation is described in a separate document [13].

7.1.4 Investigation at T12

An OOS investigation was performed for B-48376 stored under 30°C 65%RH as the [REDACTED] (b) (4)

[REDACTED] (b) (4) Results were reported as such. The investigation is available in document [14].

[REDACTED] (b) (4)

[REDACTED] (b) (4) Measurement was performed on the 3 batches on both conditions 22°C 60%RH and 30°C 65%RH with Instron instrument in R&D Neuchâtel using P1 device 2.4+. The [REDACTED] (b) (4) method is not validated therefore provides only indicative results. Results are stored in project RLS-ZRH-2019-1.

The results are shown in Table 4 and Figure 4 below. Tabulated results and description of the statistical analysis are provided in Appendix 15.7.

[REDACTED] (b) (4)



(b) (4)

(b) (4)

7.1.1 Investigation at T24

An Out of Specification investigation was opened for (b) (4) for B-48374 stored under 30°C 65%RH as (b) (4)

2.93 mg/stick in one batch, however Glycerin was close to the lower specification limit in (b) (4) No analytical reason was found to explain the result. (b) (4)

(b) (4)

(b) (4) All results are reported no values are excluded. The investigation is available in separate document [15].



7.2 Statistical Assessment

The statistical assessment for the chemical and physical characterization follows Guidelines ICH Q1E [19], performed by modelling the degradation profile of the test parameters using regression models with (b) (4). The regression analysis defines the trend of a quantitative stability test parameter for each batch over time on the predetermined stress conditions. The poolability of the batches is tested through statistical analyses to determine whether the regression lines from the batches have a common slope and a common intercept as described in Appendix 15.4.

There are 3 possible models:

Model 1: Different slope / different intercept: final poolability model indicates that the batches do not have similar stability profiles with respect to starting point and change over time. This model uses individual batch intercepts and individual batch slopes with a pooled mean square error calculated from all batches and the shelf life is determined with the least favorable batch.

Model 2: Common slope / different intercept: final model indicates that the batches have a similar stability profile with regards to change over time. However, they do not have a consistent starting values. This model uses individual batch intercepts and a common slope with a pooled mean square error and the shelf life is determined from the least favorable batch.

Model 3: Common slope / common intercept: final model indicates that the batches have a similar stability profile and can therefore be pooled together for one expiry determination. The pooled model uses a common intercept and common slope with a pooled mean square error.

The shelf life period corresponds to the earliest time at which the lower or upper 95% confidence interval (CI) regression confidence bounds calculated from the model intersects with the lower or upper specification limit.

The shelf life obtained with (b) (4) is truncated to whole number. In case the shelf life calculated by (b) (4) is longer than the study duration the shelf life will be equal to the study duration.

For Menthol and Water activity under both storage conditions, (b) (4) (b) (4) the mean values along their one sided 95% CI are verified against the



upper specification limits. This approach is applied as the values are not following a linear evolution over time. Tabulated results with summary statistics are presented in the Appendix 15.5 and 15.6.

7.3 Results for Storage Condition 22°C 60% RH

The Table 5 and Table 6 contain for each batch and each tested parameter per time point the reported value (mean value), together with the upper and/or lower specification levels. Figure 5 to Figure 17 Figure 14 contain the reported values for the 3 batches together with the specification, the linear regression and the upper and lower 95% CI of the regression depending on the final model kept (model 1, model 2 or model 3). The CIs are illustrated on the figures by the shaded area.

For Menthol and Water activity the reported value with the one sided 95% CI is shown over time for the 3 batches.

The dashed red lines represent the specification limits. Whereas, the dashed blue line shows the time when the 95% CI crosses the specification or is automatically drawn at 25 months if the 95% CI crosses the specification after the study length of 24 months.

The graphs were created with x-axes above the 24 months of study duration, however this has no extrapolation purpose.

Table 5 Mean values for aerosol constituents for 3 batches T0 – T24 for 22°C 60% RH

PARAMETER	BATCH	LSL	USL	UNIT	T0	T2	T4	T6	T9	T12	T16	T20	T24
1,3 Butadiene	B-48374	(b) (4)		µg/stick	0.267	0.274	0.296	0.253	0.246	0.296	0.236	0.362	0.241
1,3 Butadiene	B-48375			µg/stick	0.275	0.266	0.299	0.234	0.229	0.279	0.253	0.379	0.229
1,3 Butadiene	B-48376			µg/stick	0.262	0.258	0.310	0.244	0.239	0.280	0.270	0.358	0.244
Acrylamide	B-48374			µg/stick	1.97	1.85	1.86	1.99	1.94	1.89	1.59	1.38	1.55
Acrylamide	B-48375			µg/stick	1.99	1.86	1.82	1.96	2.12	1.87	1.63	1.51	1.70
Acrylamide	B-48376			µg/stick	2.01	1.96	1.82	2.01	1.97	1.91	1.74	1.53	1.75
Benzene	B-48374			µg/stick	0.59	0.57	0.54	0.61	0.58	0.60	0.51	0.56	0.56
Benzene	B-48375			µg/stick	0.59	0.57	0.54	0.60	0.54	0.54	0.53	0.57	0.53
Benzene	B-48376			µg/stick	0.59	0.54	0.56	0.57	0.56	0.56	0.56	0.54	0.57
Carbon monoxide	B-48374			mg/stick	0.51	0.55	0.46	0.44	0.40	0.43	0.40	0.47	0.45
Carbon monoxide	B-48375			mg/stick	0.51	0.55	0.46	0.44	0.44	0.42	0.39	0.48	0.47



PARAMETER	BATCH	LSL	USL	UNIT	T0	T2	T4	T6	T9	T12	T16	T20	T24
Carbon monoxide	B-48376	(b) (4)		mg/stick	0.51	0.55	0.46	0.46	0.38	0.42	0.41	0.47	0.47
Formaldehyde	B-48374			µg/stick	4.663	4.056	5.166	3.396	4.090	3.804	3.364	4.011	4.224
Formaldehyde	B-48375			µg/stick	4.167	3.936	4.981	3.654	4.702	4.820	4.035	3.964	4.090
Formaldehyde	B-48376			µg/stick	4.105	4.022	4.755	3.804	4.993	4.859	3.932	3.999	4.508
Glycerin	B-48374			mg/stick	4.95	4.86	4.90	5.05	5.10	4.58	4.07	4.10	4.15
Glycerin	B-48375			mg/stick	5.14	5.02	4.65	5.07	5.08	4.63	4.14	4.64	4.39
Glycerin	B-48376			mg/stick	4.83	5.14	4.50	5.17	5.03	4.54	4.45	4.38	4.48
Menthol	B-48374			mg/stick	2.3	2.6	3.0	3.1	3.6	3.3	3.4	3.2	3.4
Menthol	B-48375			mg/stick	2.2	2.9	3.0	3.3	3.5	3.4	3.4	3.3	3.4
Menthol	B-48376			mg/stick	2.1	2.9	2.8	3.2	3.3	3.4	3.3	3.2	3.5
Nicotine	B-48374			mg/stick	1.19	1.15	1.18	1.20	1.17	1.19	1.16	1.05	1.17
Nicotine	B-48375			mg/stick	1.23	1.17	1.14	1.20	1.22	1.19	1.17	1.15	1.26
Nicotine	B-48376			mg/stick	1.21	1.23	1.16	1.26	1.20	1.21	1.22	1.12	1.27
Phenol	B-48374			µg/stick	0.87	1.02	1.15	0.84	0.97	0.77	0.81	0.92	0.96
Phenol	B-48375			µg/stick	1.05	1.09	1.05	0.94	1.29	0.87	0.83	1.06	1.15
Phenol	B-48376			µg/stick	0.99	1.28	1.12	0.96	1.08	0.84	1.00	1.01	1.23
Triacetin	B-48374			mg/stick	0.60	0.61	0.61	0.57	0.56	0.50	0.42	0.43	0.43
Triacetin	B-48375			mg/stick	0.60	0.60	0.55	0.56	0.56	0.49	0.41	0.43	0.43
Triacetin	B-48376			mg/stick	0.55	0.57	0.50	0.51	0.50	0.46	0.41	0.41	0.43

Table 6 Mean values for physical parameters and Water activity for 3 batches T0 – T24 for 22°C 60% RH

PARAMETER	BATCH	LSL	USL	UNIT	T0	T2	T4	T6	T9	T12	T16	T20	T24
(b) (4)				(b) (4)									
Tobacco stick weight	B-48374	(b) (4)		mg	819	841	822	838	824	838	843	813	826
Tobacco stick weight	B-48375			mg	830	819	823	821	816	832	824	816	824
Tobacco stick weight	B-48376			mg	817	824	820	822	817	823	822	812	825
Water activity	B-48374			N/A	0.43	0.50	0.51	0.54	0.56	0.56	0.57	0.59	0.58
Water activity	B-48375			N/A	0.44	0.49	0.51	0.54	0.56	0.56	0.57	0.58	0.57
Water activity	B-48376			N/A	0.42	0.49	0.51	0.53	0.56	0.56	0.57	0.59	0.58



7.3.1 Aerosol Constituents Evaluation for 22°C 60%RH

7.3.1.1 Nicotine for 22°C 60%RH

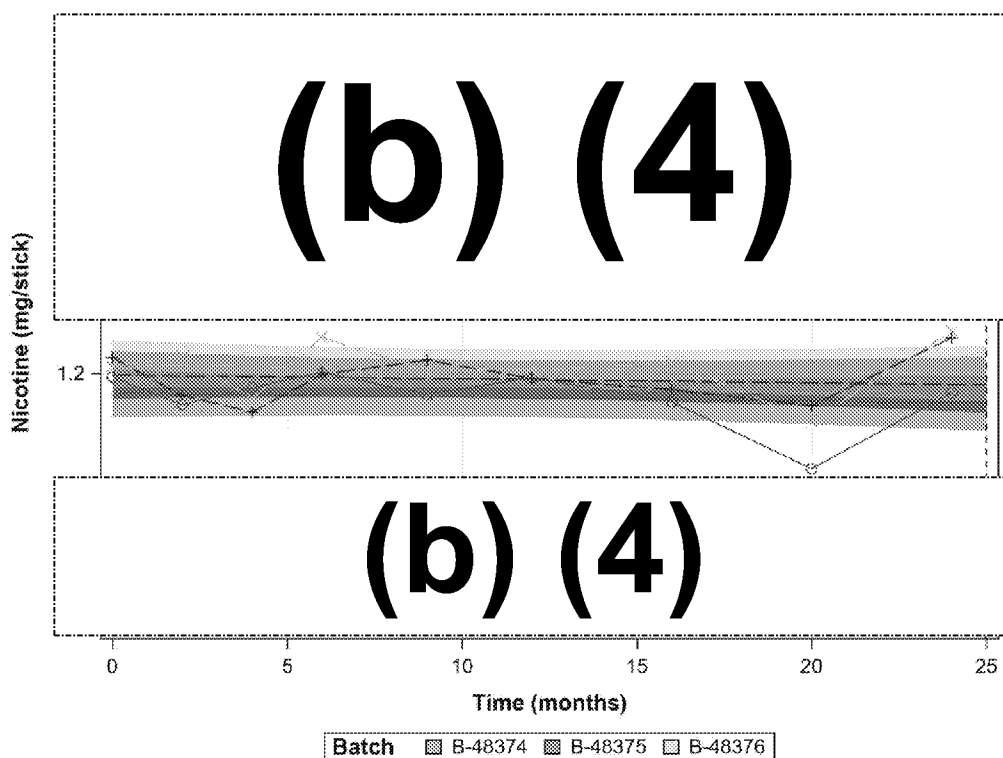


Figure 5 Evolution of Nicotine for the 3 batches together with the specification levels, the linear regression of the 3 batches and the 95% CI for the regression (CI shown as the shaded area - valid for all figures presented below)

The best model accepted at the significance level of 0.25 has Different intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.3.1.2 Glycerin for 22°C 60%RH

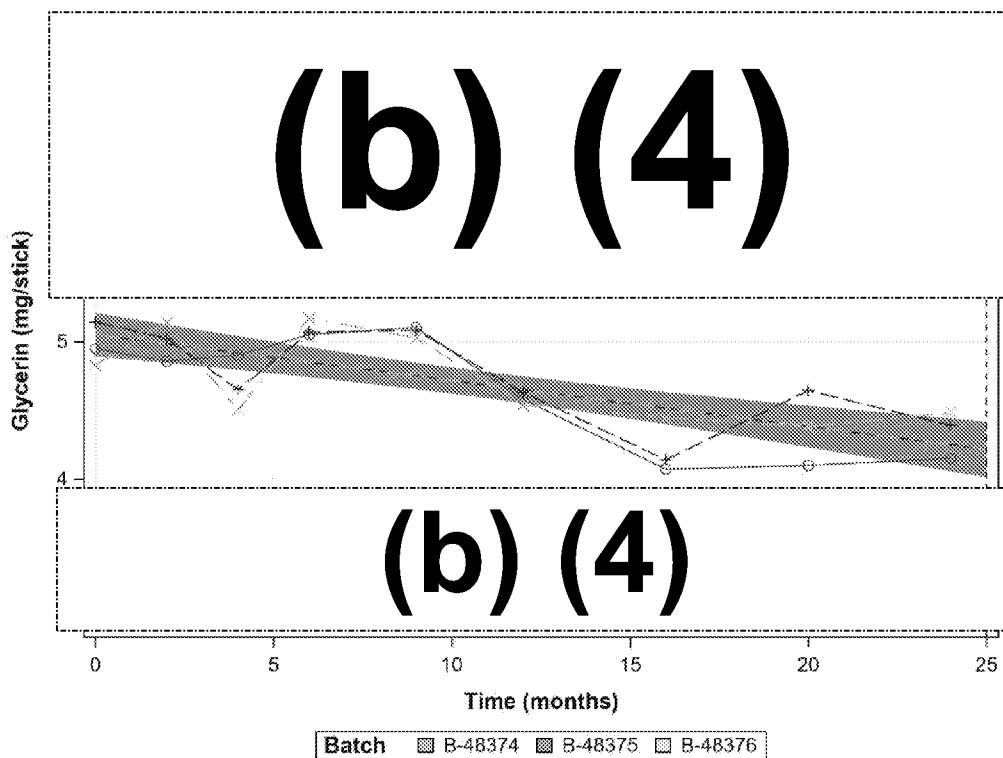


Figure 6 Evolution of Glycerin for the 3 batches together with the specification levels, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.3.1.3 Triacetin for 22°C 60%RH

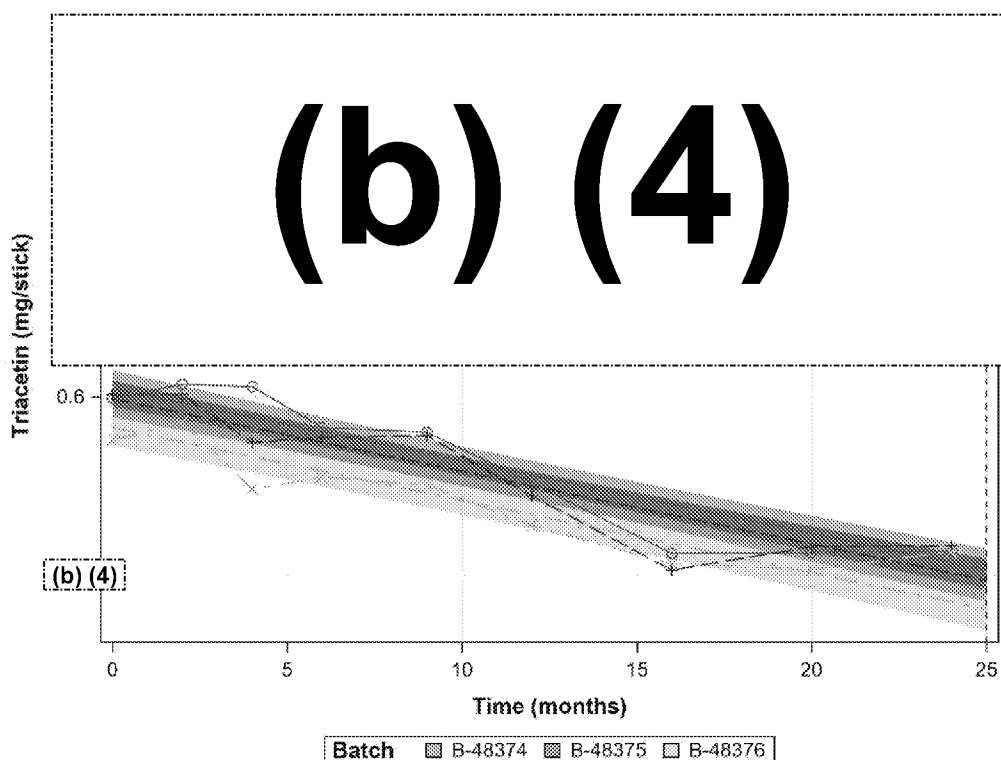


Figure 7 Evolution of Triacetin for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Different intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.3.1.4 Carbon monoxide for 22°C 60%RH

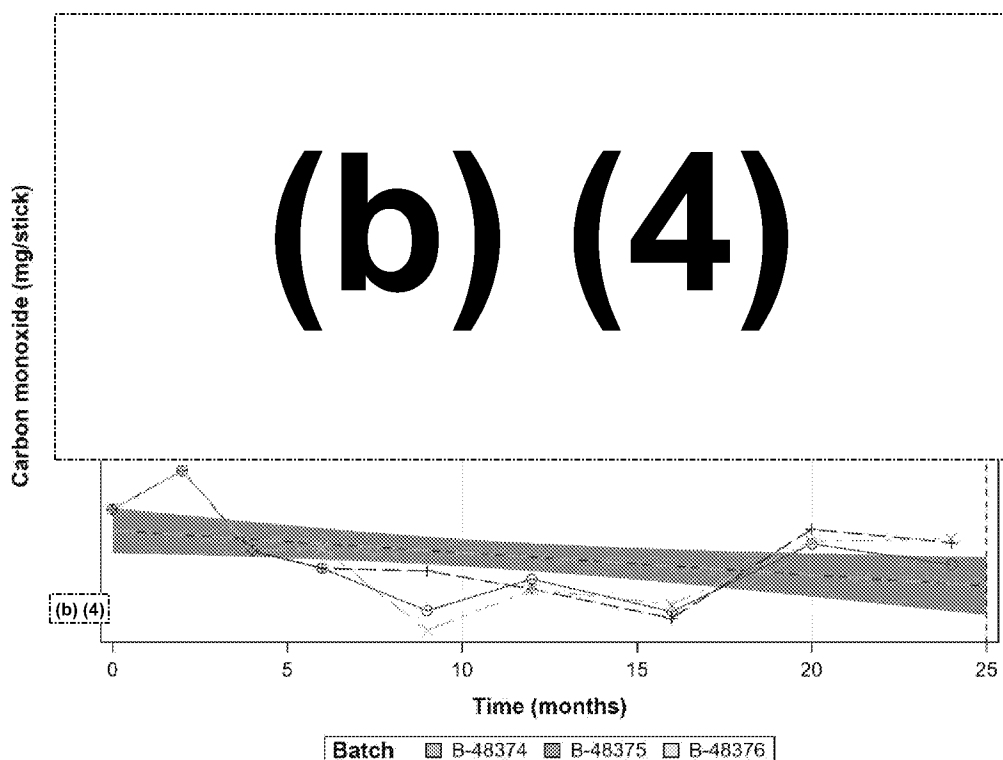


Figure 8 Evolution of Carbon monoxide for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.3.1.5 Phenol for 22°C 60%RH

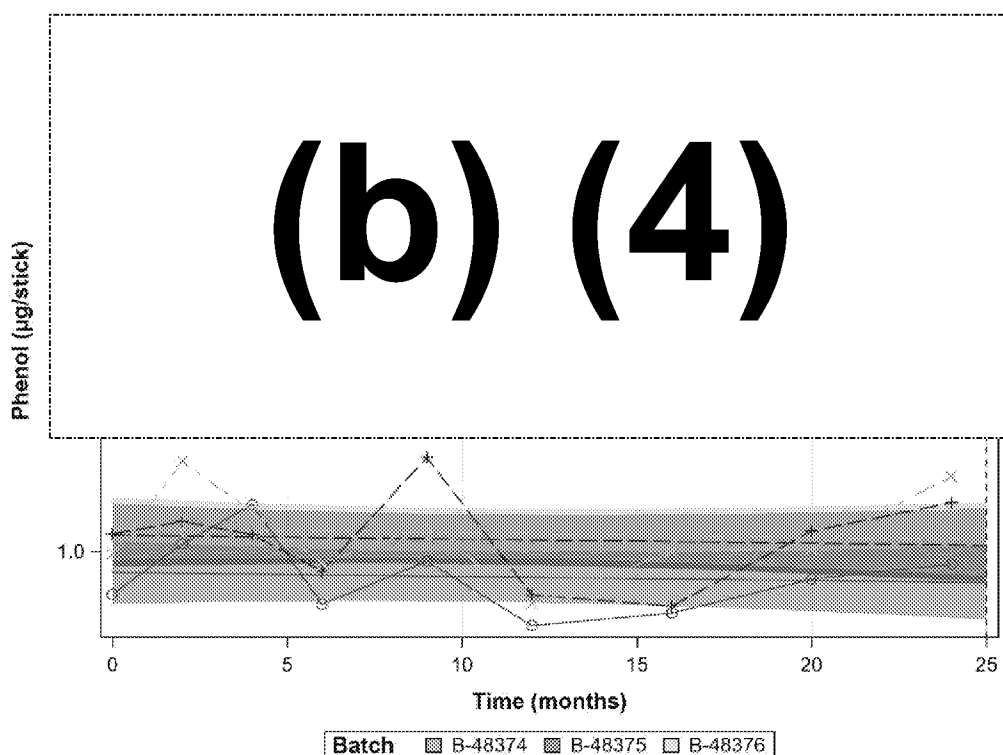


Figure 9 Evolution of Phenol for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Different intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.3.1.6 Acrylamide for 22°C 60%RH

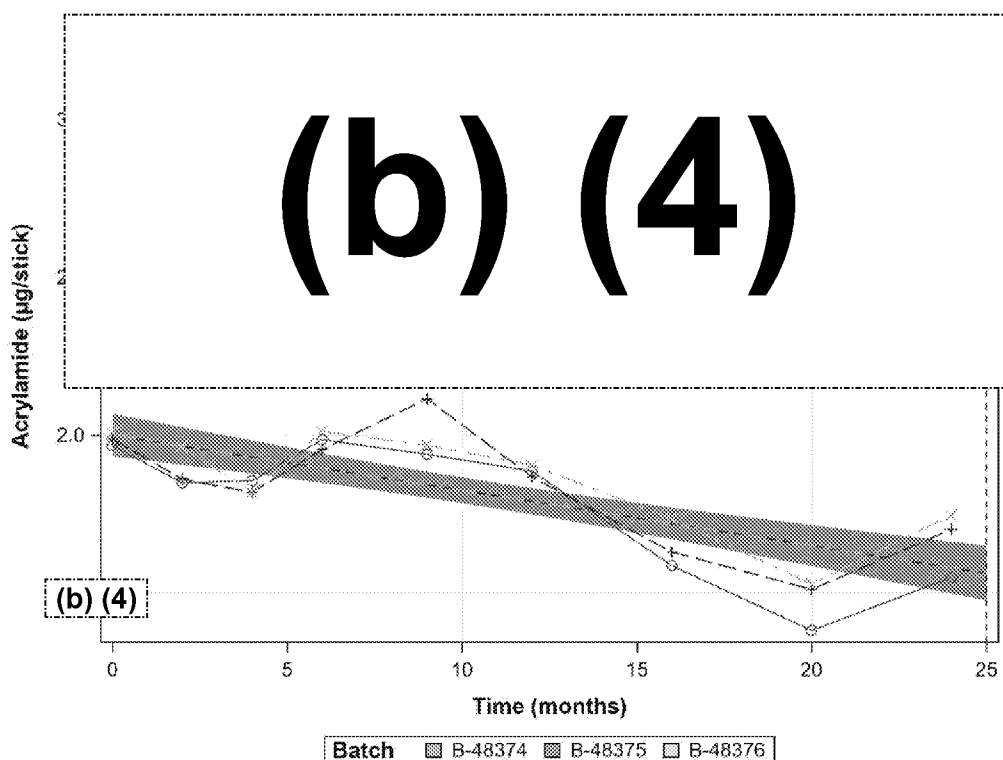


Figure 10 Evolution of Acrylamide for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.3.1.7 Menthol for 22°C 60%RH

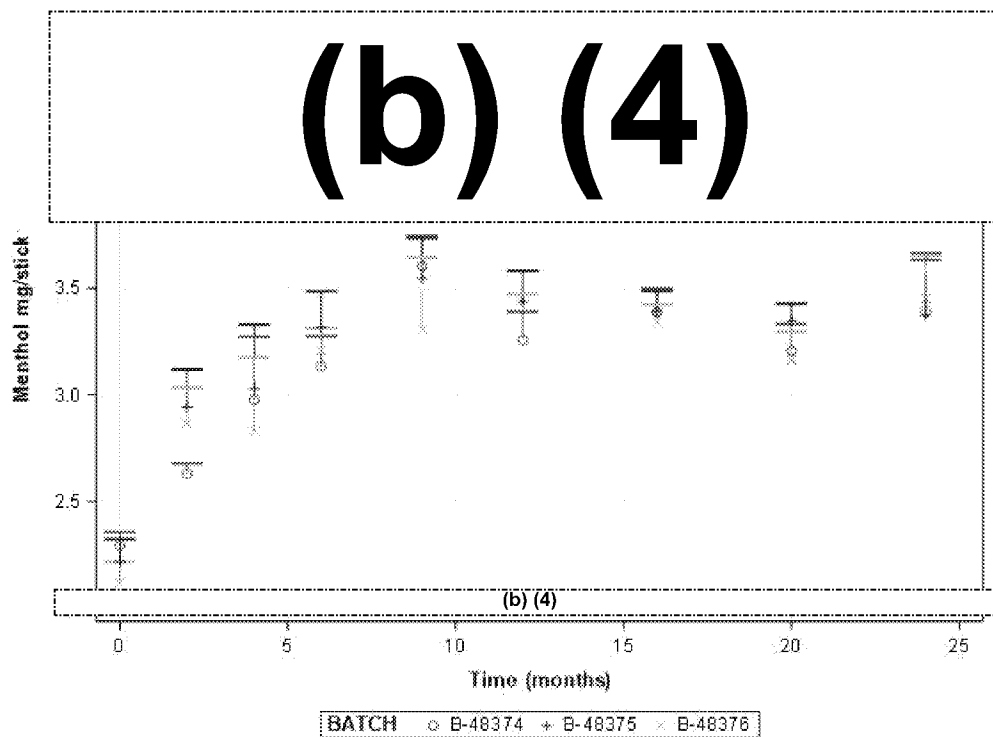


Figure 11 Evolution of Menthol for the 3 batches (mean value plus the one sided 95% CIs of the mean) together with the specification level

The mean values and their one sided upper 95% CIs are not exceeding the specification level for Menthol. Therefore, a shelf life of 24 months is acceptable.



7.3.1.8 Formaldehyde for 22°C 60%RH

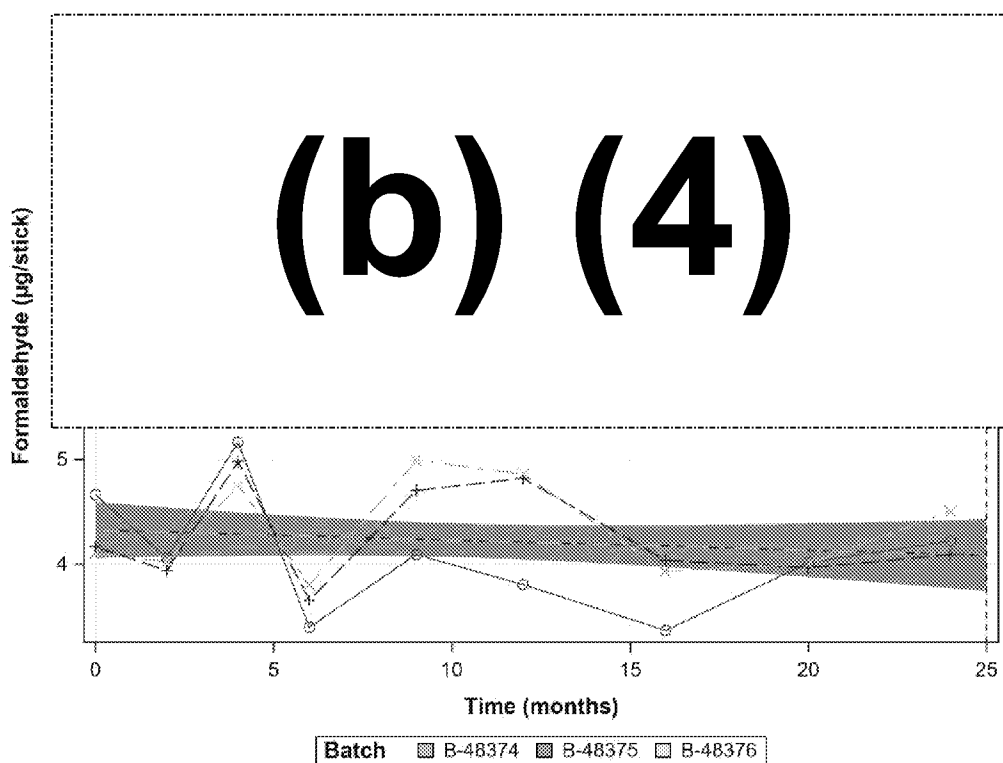


Figure 12 Evolution of Formaldehyde for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.3.1.9 1,3-Butadiene for 22°C 60%RH

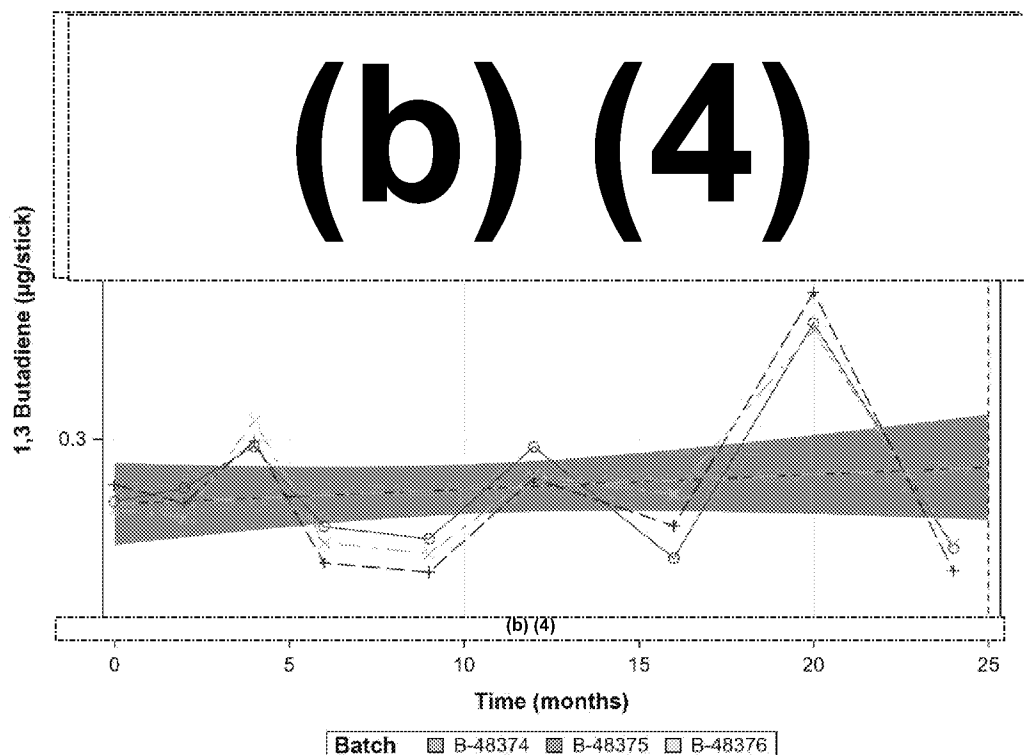


Figure 13 Evolution of 1,3-Butadiene for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.3.1.10 Benzene 22°C 60%RH

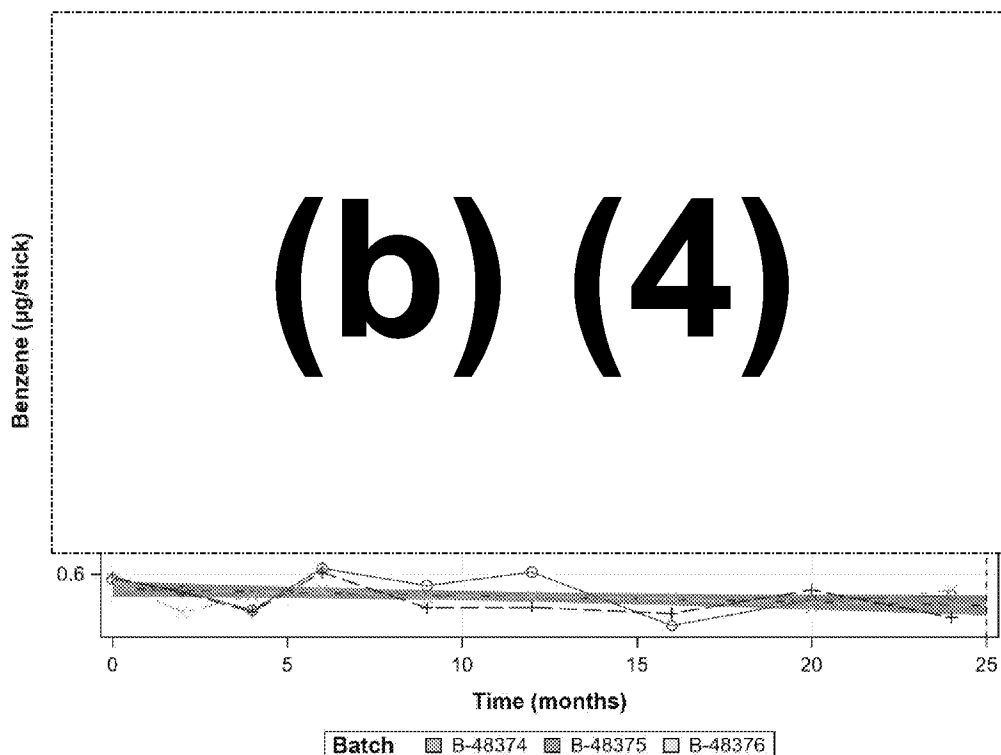


Figure 14 Evolution of Benzene for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.3.2 Physical Parameters Evaluation for 22°C 60%RH

(b) (4)

(b) (4)



7.3.2.2 Tobacco Stick Weight 22°C 60%RH

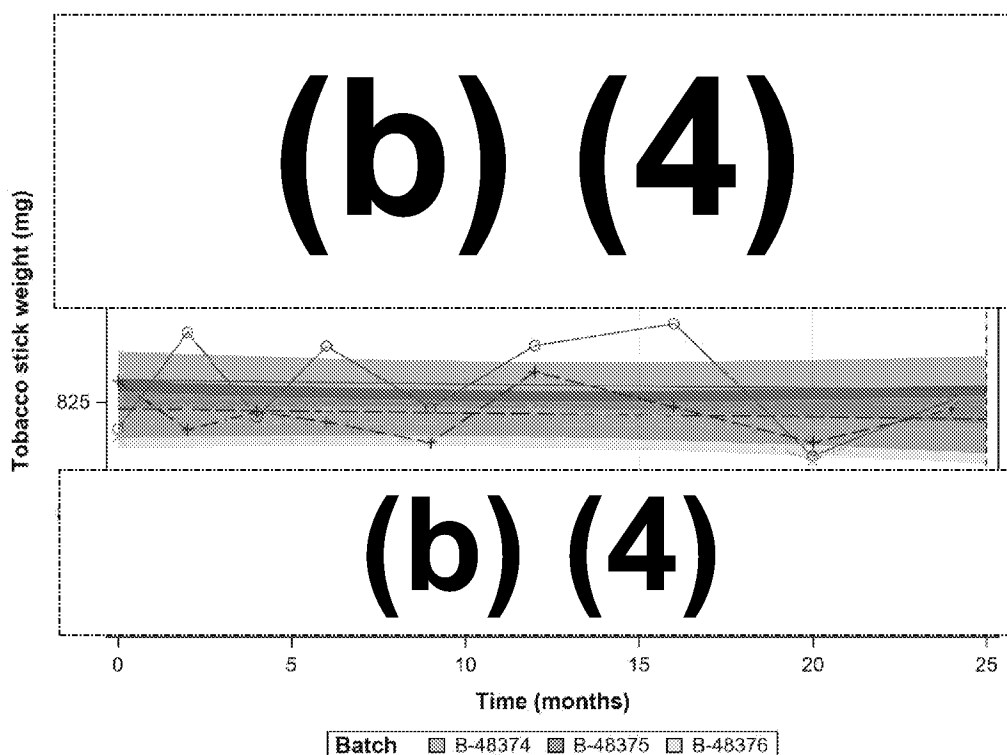


Figure 16 Evolution of Tobacco Stick weight for the 3 batches together with the specification levels, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Different intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.3.3 Water Activity Evaluation for 22°C 60%RH

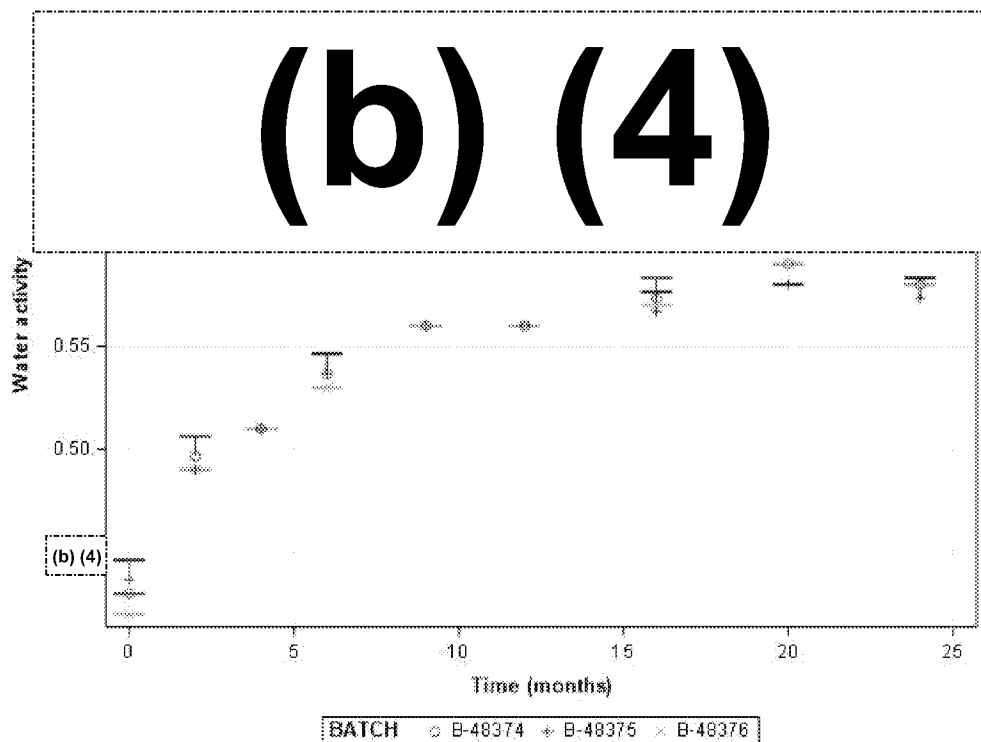


Figure 17 Evolution of Water activity for the 3 batches (mean value plus the one sided 95% CIs of the mean) together with the specification level

The mean values and the one sided upper 95% CIs limit did not exceed the (b) (4). Therefore, a shelf life of 24 months is acceptable.

7.3.4 Sensorial Evaluation for 22°C 60%RH

Sensorial evaluation results are described in details in a separate reports up to 12 months [9] and up to 24 months [10].

(b) (4)



(b) (4)

7.3.5 Visual Evaluation for 22°C 60%RH

(b) (4)



(b) (4)



(b) (4)



(b) (4)



7.4 Results for Storage Condition 30°C 65% RH

The Table 7 and Table 8 contain for each batch and each tested parameter per time point the reported value (mean value), together with the upper and/or lower specification levels.

Figure 23 to Figure 35 contain the reported value for the 3 batches together with the specification levels, the linear regression and the upper and lower 95% CI of the regression of the mean or the individual batches depending on the final model kept (model 1, model 2 or model 3). The CIs are illustrated on the figures by the shaded area.

For Menthol, Water activity and (b) (4) the reported value with the one sided 95% CI is shown over time for the 3 batches.

The dashed red lines represent the specification limits. Whereas, the dashed blue line shows the time when the 95% CI crosses the specification or is automatically drawn at 25 months if the 95% CI crosses the specification after the study length of 24 months.

The graphs were created with x-axes above the 24 months of study duration, however this has no extrapolation purpose.

Table 7 Mean values for aerosol constituents for 3 batches T0 – T24 for 30°C 65% RH

PARAMETER	BATCH	LSL	USL	UNITS	T0	T2	T4	T6	T9	T12	T16	T20	T24
1,3 Butadiene	B-48374	(b) (4)		µg/stick	0.267	0.260	0.370	0.239	0.261	0.260	0.390	0.332	0.270
1,3 Butadiene	B-48375			µg/stick	0.275	0.280	0.361	0.242	0.236	0.295	0.386	0.355	0.277
1,3 Butadiene	B-48376			µg/stick	0.262	0.302	0.367	0.269	0.271	0.299	0.408	0.344	0.278
Acrylamide	B-48374			µg/stick	1.97	1.70	1.43	1.75	1.60	1.46	1.01	0.89	0.91
Acrylamide	B-48375			µg/stick	1.99	1.89	1.47	1.86	1.68	1.31	1.10	0.99	0.98
Acrylamide	B-48376			µg/stick	2.01	1.77	1.47	1.89	1.79	1.50	1.08	0.89	1.06
Benzene	B-48374			µg/stick	0.59	0.54	0.65	0.56	0.56	0.50	0.55	0.51	0.54
Benzene	B-48375			µg/stick	0.59	0.56	0.65	0.58	0.54	0.53	0.55	0.55	0.55
Benzene	B-48376			µg/stick	0.59	0.60	0.67	0.60	0.61	0.57	0.58	0.53	0.55
Carbon monoxide	B-48374			mg/stick	0.51	0.61	0.50	0.49	0.40	0.43	0.39	0.47	0.47
Carbon monoxide	B-48375			mg/stick	0.51	0.61	0.46	0.49	0.38	0.41	0.41	0.50	0.45
Carbon monoxide	B-48376			mg/stick	0.51	0.57	0.46	0.51	0.40	0.45	0.41	0.50	0.47
Formaldehyde	B-48374			µg/stick	4.663	4.489	4.892	3.510	4.410	4.914	4.055	4.146	4.423
Formaldehyde	B-48375			µg/stick	4.167	3.953	4.444	3.663	4.152	4.157	4.037	4.313	4.293
Formaldehyde	B-48376			µg/stick	4.105	4.658	4.697	3.723	4.657	4.824	3.997	4.291	4.584



PARAMETER	BATCH	LSL	USL	UNITS	T0	T2	T4	T6	T9	T12	T16	T20	T24
Glycerin	B-48374	(b) (4)		mg/stick	4.95	4.77	4.00	4.86	4.33	3.82	3.27	3.07	2.85
Glycerin	B-48375			mg/stick	5.14	5.13	3.80	4.78	4.34	3.32	3.41	3.39	2.98
Glycerin	B-48376			mg/stick	4.83	4.49	3.81	4.89	4.47	4.01	3.40	3.21	3.11
Menthol	B-48374			mg/stick	2.3	3.4	3.2	3.3	3.4	3.1	2.7	2.7	2.7
Menthol	B-48375			mg/stick	2.2	3.5	3.2	3.5	3.2	3.1	2.9	2.8	2.7
Menthol	B-48376			mg/stick	2.1	3.3	3.2	3.4	3.2	3.0	2.9	2.7	2.6
Nicotine	B-48374			mg/stick	1.19	1.15	1.04	1.19	1.11	1.10	1.00	0.96	0.99
Nicotine	B-48375			mg/stick	1.23	1.21	0.96	1.22	1.12	1.04	1.08	1.03	1.03
Nicotine	B-48376			mg/stick	1.21	1.13	0.99	1.22	1.15	1.14	1.03	0.97	1.09
Phenol	B-48374			µg/stick	0.87	1.05	0.92	0.92	0.96	0.75	0.64	0.74	0.77
Phenol	B-48375			µg/stick	1.05	1.29	0.82	0.92	1.24	0.52	0.80	0.92	0.87
Phenol	B-48376			µg/stick	0.99	1.07	0.77	1.10	1.08	0.77	0.77	0.93	0.92
Triacetin	B-48374			mg/stick	0.60	0.53	0.42	0.44	0.46	0.38	0.32	0.31	0.31
Triacetin	B-48375			mg/stick	0.60	0.47	0.38	0.36	0.42	0.33	0.30	0.30	0.26
Triacetin	B-48376			mg/stick	0.55	0.45	0.36	0.39	0.40	0.34	0.29	0.29	0.27

Table 8 Mean values for physical parameters and Water activity for 3 batches T0 – T24 for 30°C 65% RH

PARAMETER	BATCH	LSL	USL	UNITS	T0	T2	T4	T6	T9	T12	T16	T20	T24
				b) (4)									
Tobacco stick weight	B-48374	(b) (4)		mg	819	822	817	823	815	834	816	807	815
Tobacco stick weight	B-48375			mg	830	826	822	825	821	830	824	818	826
Tobacco stick weight	B-48376			mg	817	829	826	830	833	829	820	793	826
Water activity	B-48374			N/A	0.43	0.57	0.60	0.63	0.64	0.63	0.65	0.66	0.65
Water activity	B-48375			N/A	0.44	0.56	0.60	0.62	0.64	0.63	0.65	0.65	0.65
Water activity	B-48376			N/A	0.42	0.57	0.60	0.63	0.64	0.63	0.64	0.66	0.65



7.4.1 Aerosol Constituents Evaluation for 30°C 65%RH

7.4.1.1 Nicotine for 30°C 65%RH

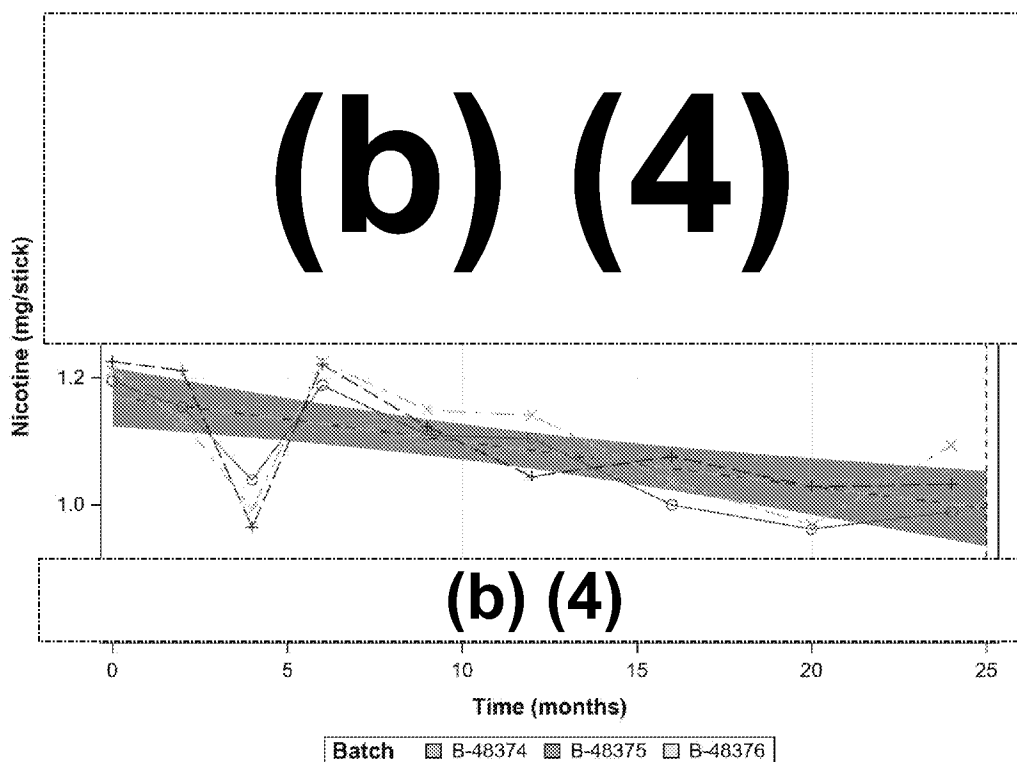


Figure 23 Evolution of Nicotine for the 3 batches together with the specification levels, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.4.1.2 Glycerin for 30°C 65%RH

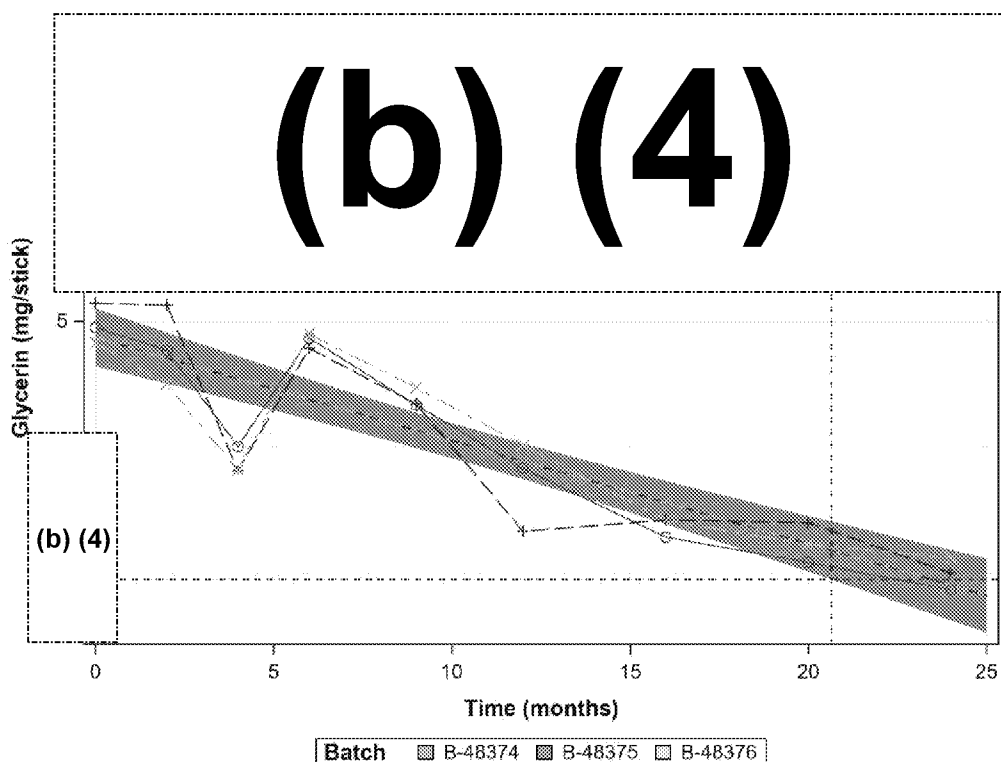


Figure 24 Evolution of Glycerin for the 3 batches together with the specification levels, the linear regression of the 3 batches and the 95% CI for the regression (Dashed blue line shows the time when 95% CI crosses the lower specification)

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 20 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 20 months have been met.



7.4.1.3 Triacetin for 30°C 65%RH

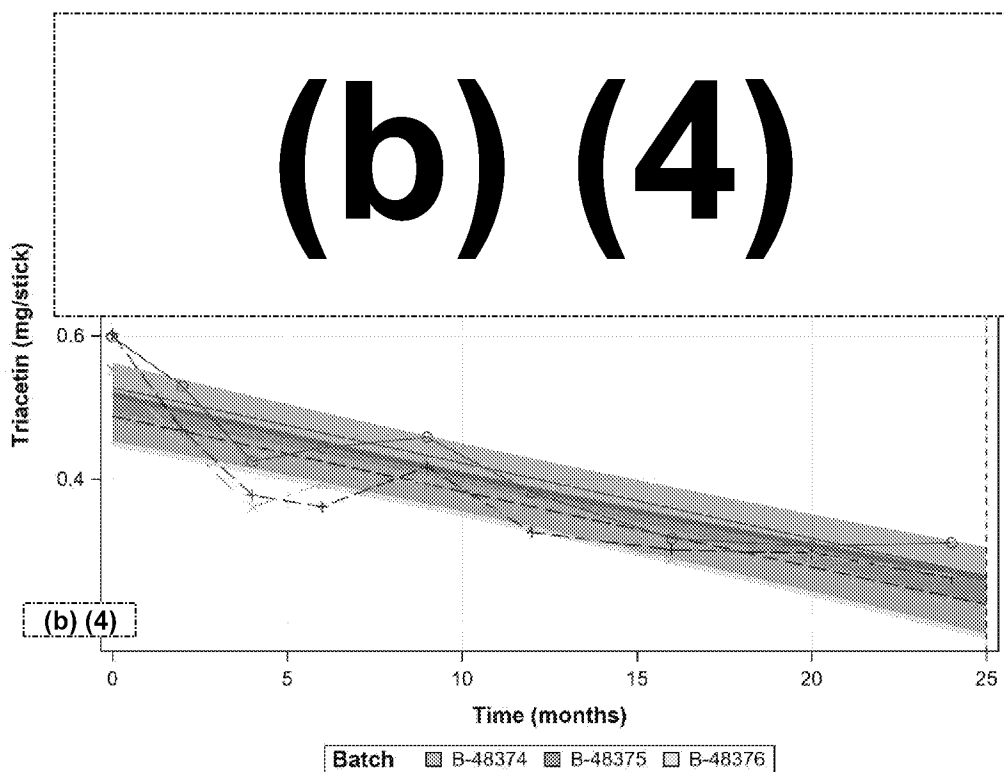


Figure 25 Evolution of Triacetin for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Different intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.4.1.4 Carbon monoxide for 30°C 65%RH

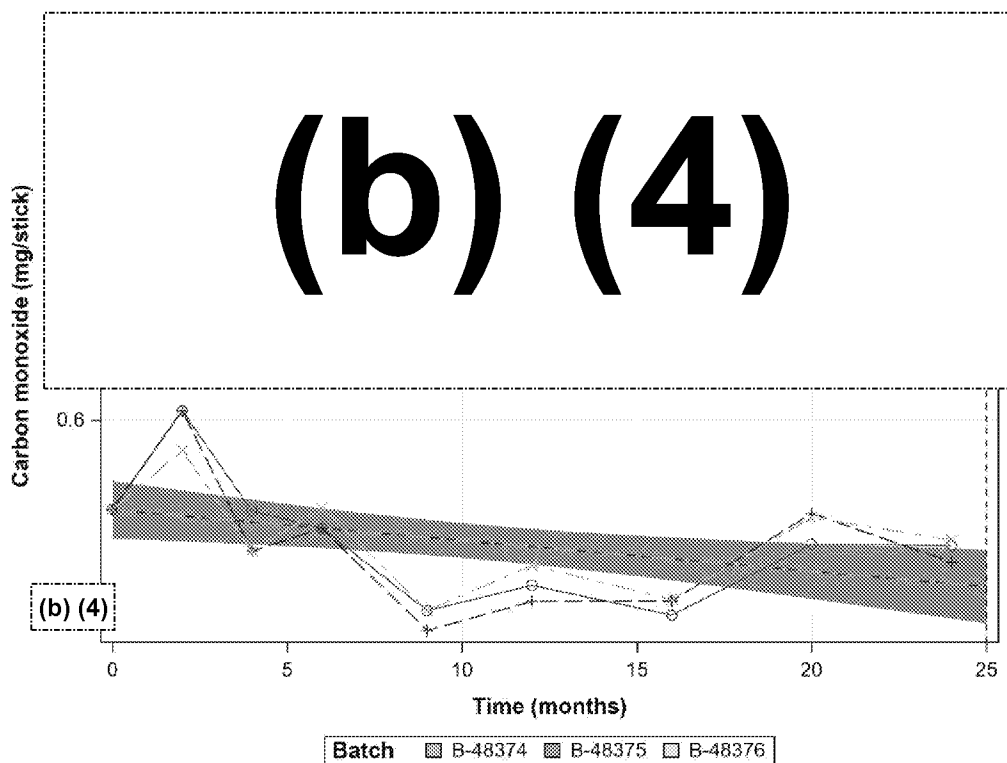


Figure 26 Evolution of Carbon monoxide for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.4.1.5 Phenol for 30°C 65%RH

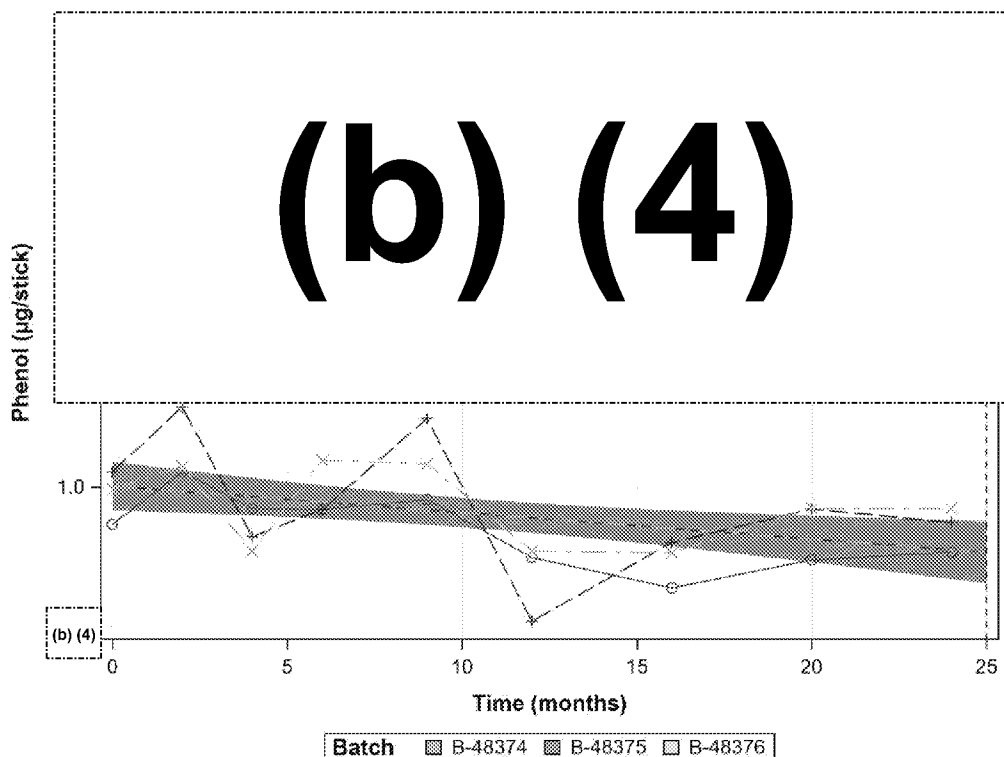


Figure 27 Evolution of Phenol for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.4.1.6 Acrylamide for 30°C 65%RH

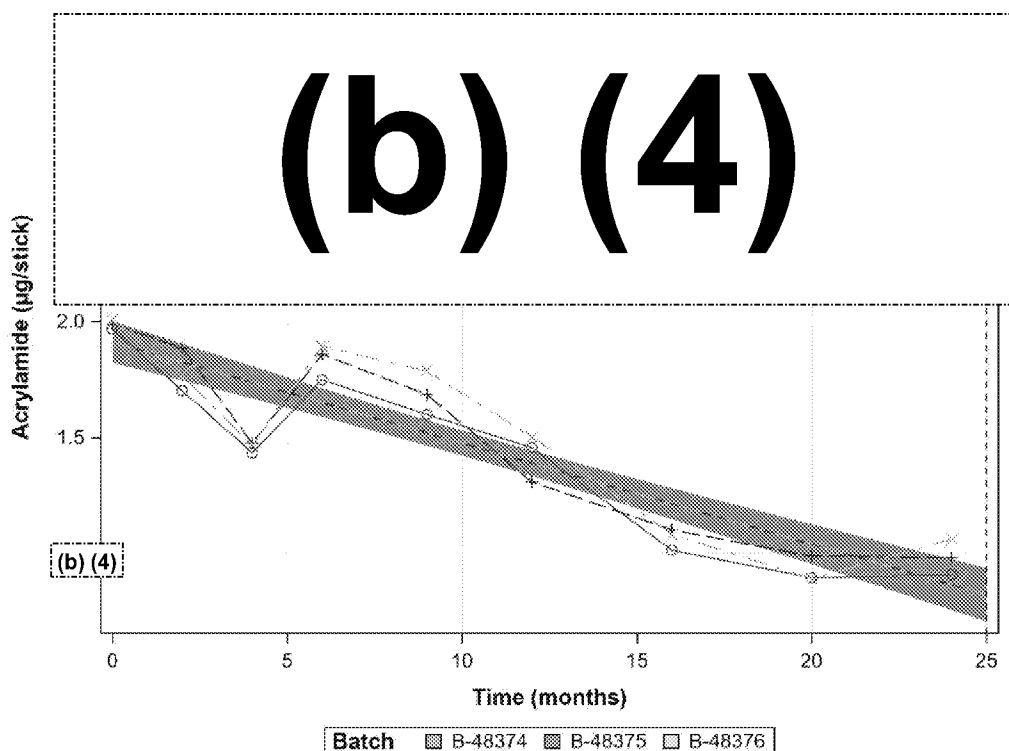


Figure 28 Evolution of Acrylamide for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.4.1.7 Menthol for 30°C 65%RH

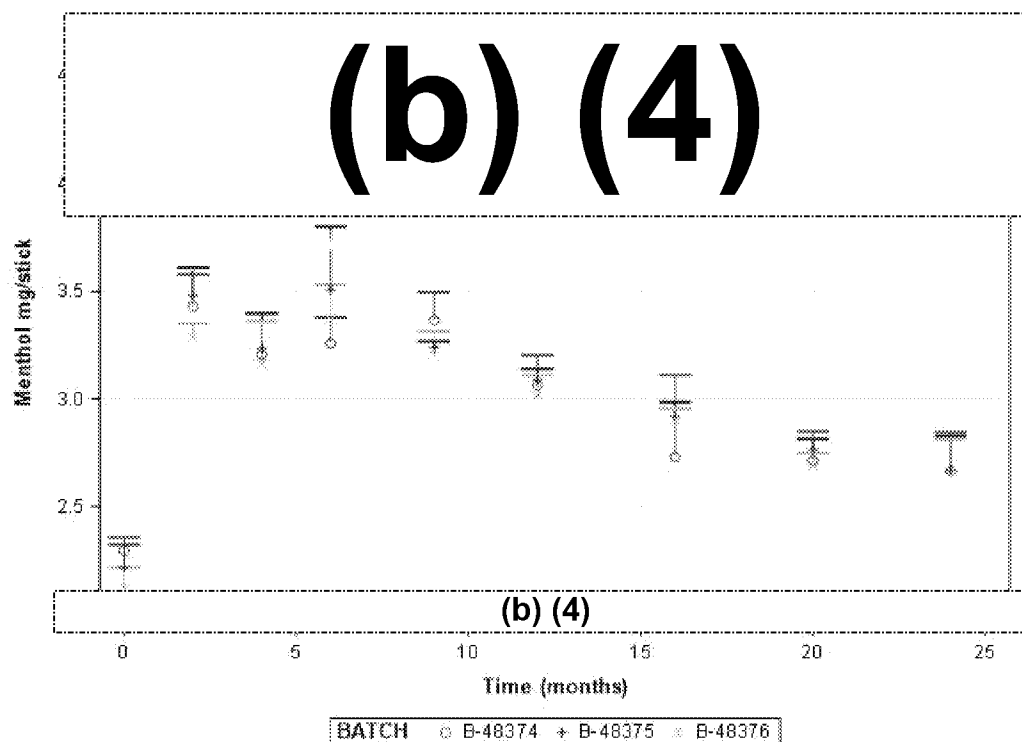


Figure 29 Evolution of Menthol for the 3 batches (mean value plus the one sided 95% CIs of the mean) together with the specification level

The mean values and their one sided upper 95% CIs are not exceeding the specification level for Menthol. Therefore, a shelf life of 24 months is acceptable.



7.4.1.8 Formaldehyde for 30°C 65%RH

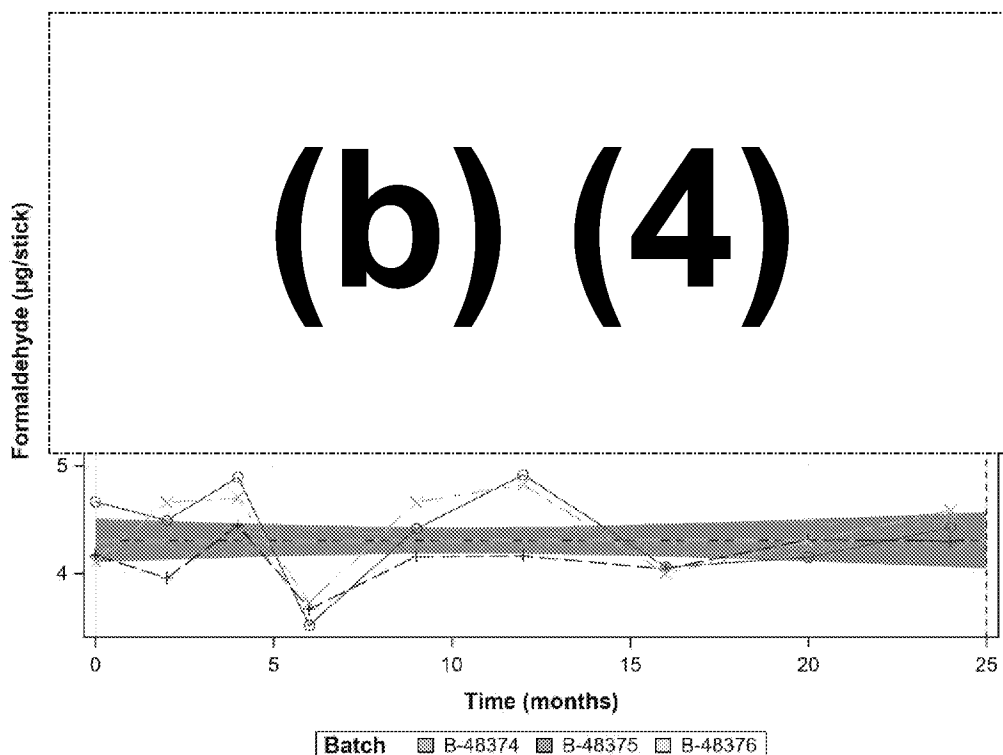


Figure 30 Evolution of Formaldehyde for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.4.1.9 1,3-Butadiene for 30°C 65%RH

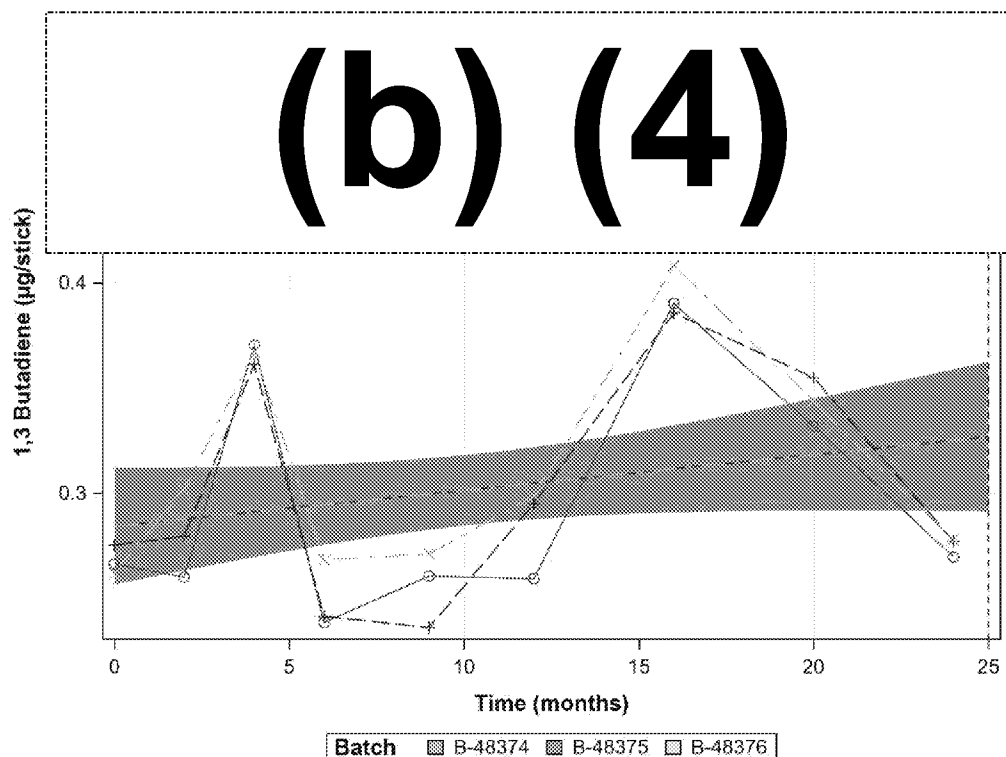


Figure 31 Evolution of 1,3-Butadiene for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.4.1.10 Benzene for 30°C 65%RH

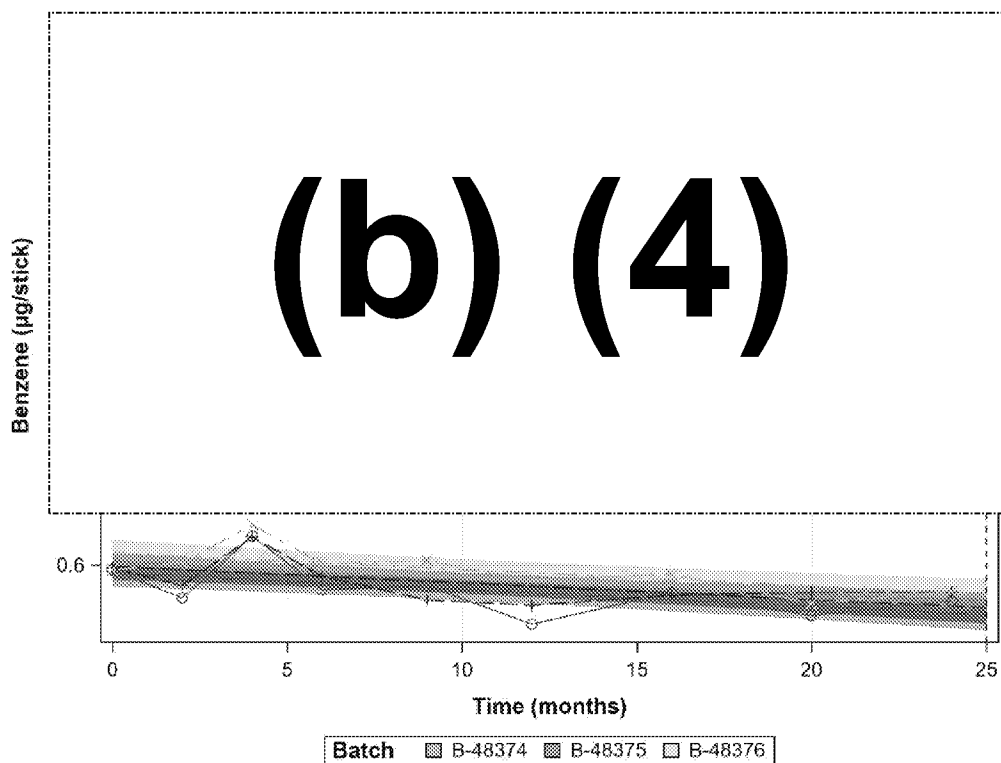


Figure 32 Evolution of Benzene for the 3 batches together with the specification level, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Different intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.4.2 Physical Parameters Evaluation for 30°C 65%RH

(b) (4)



7.4.2.2 Tobacco Stick Weight for 30°C 65%RH

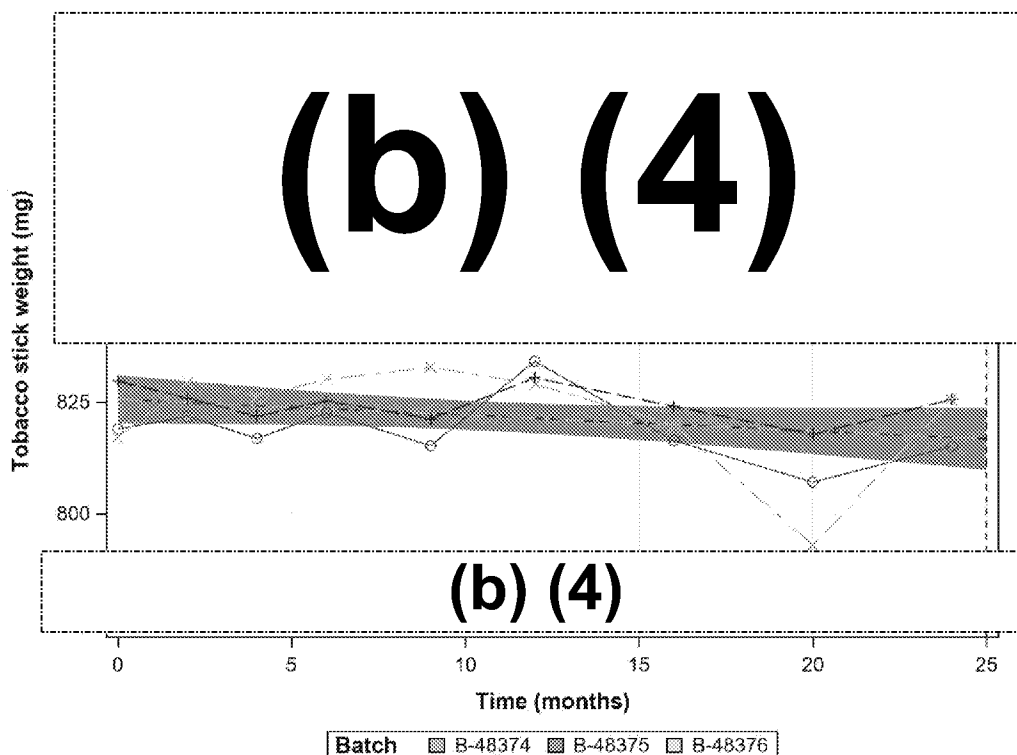


Figure 34 Evolution of Tobacco Stick weight for the 3 batches together with the specification levels, the linear regression of the 3 batches and the 95% CI for the regression

The best model accepted at the significance level of 0.25 has Common intercepts and Common slopes. The model suggests the earliest crossing time over 24 months with 95% confidence.

Based on the ICH Guidelines the requirements for a shelf life of 24 months have been met.



7.4.3 Water Activity Evaluation for 30°C 65%RH

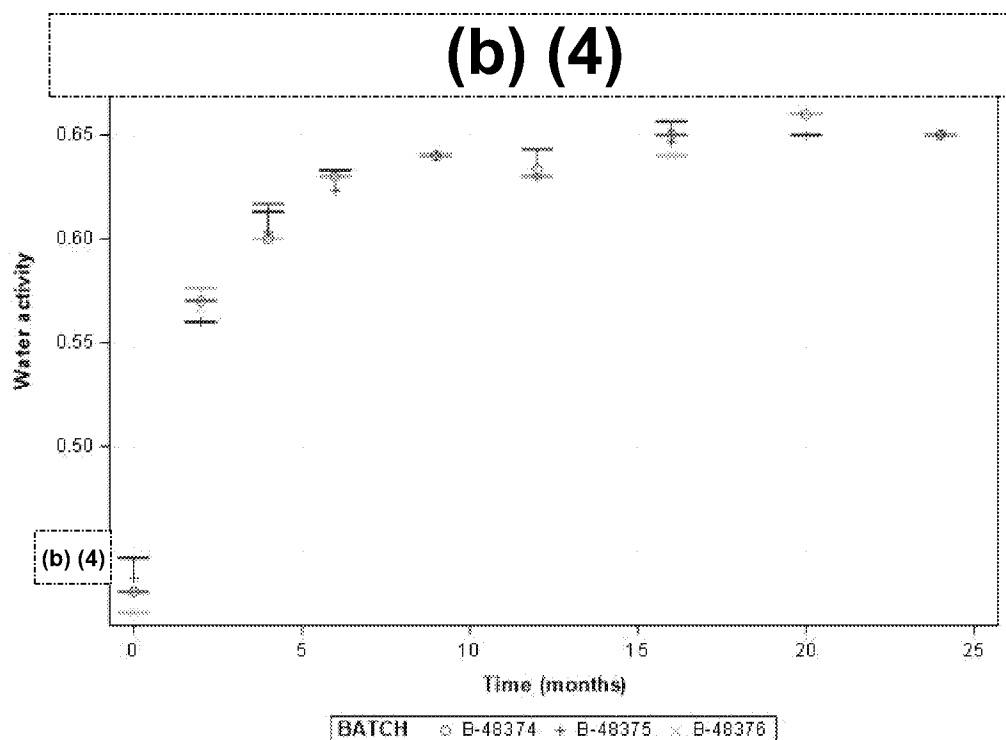


Figure 35 Evolution of Water activity for the 3 batches (mean value plus the 95% CIs of the mean) together with the specification level

The mean values and the one sided upper 95% CIs limit did not exceed the (b) (4). Therefore, a shelf life of 24 months is acceptable.



7.4.4 Sensorial Evaluation for 30°C 65%RH

Sensorial evaluation results are described in details in a separate reports up to 12 months [9] and up to 24 months [10].

Overall, the sensory profile of the three tested batches did not undergo major sensory changes at condition 30°C 65%RH over the 24 months.

(b) (4)

(b) (4)

For more details see final sensorial reports.



7.4.5 Visual Evaluation for 30°C 65%RH

(b) (4)



(b) (4)



(b) (4)



(b) (4)



8 Stability Assessment

Storage condition 22°C 60%RH

All tested aerosol constituents, Water activity and the Tobacco stick weight remained within the acceptance criteria for 24 months.

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Storage condition 30°C 65%RH

In hot and humid condition, Water activity, Tobacco stick weight and all tested aerosol constituents

(b) (4)

(b) (4)



(b) (4)

Table 9 Summary of the shelf life met per parameters for the storage conditions 22°C 60%RH and 30°C 65%RH

	22°C 60%RH	30°C 65%RH
PARAMETER	CRITERIA MET FOR SHELF LIFE OF: (months)	CRITERIA MET FOR SHELF LIFE OF: (months)
Nicotine	24	24
Glycerin	24	20
Triacetin	24	24
Carbon monoxide	24	24
Phenol	24	24
Acrylamide	24	24
Menthol	24	24
Formaldehyde	24	24
1,3-butadiene	24	24
Benzene	24	24
(b) (4)		
Tobacco stick weight	24	24
Water activity	24	24
Visual quality	see observations in Chapter 7.3.5	see observations in Chapter 7.4.5
Sensory (QDP)	see observations in Chapter 7.3.4	see observations in Chapter 7.4.4

9 Impact Assessment of Specification Change

The specifications used for the assessment of the aerosol results, excluding Menthol, were revised from Version 3.0 of 11-Oct-2017 [5] to Version 5.0 of 09-Jul-2019 [16] during the follow-up stability study (see Table 10). The stability study was evaluated versus the specifications used in the study protocol. However, the impact of those changes on the estimated shelf life period were assessed and are reported in Table 10.

The change in the specifications has minor impact on the estimated shelf life period for the aerosol constituents. With the new specifications Glycerin under 30°C 65%RH storage condition support shelf life of 24 months, instead of 20 months.



Table 10 Summary of Equivalence Specifications and Corresponding Shelf Life Period

		Equivalence specifications Version 3.0, 11-Oct-2017 (Old)				Equivalence specifications Version 5.0, 09-Jul-2019 (New)			
		Limits		Criteria met for Shelf life of: (months)		Limits		Criteria met for Shelf life of: (months)	
Parameter	Unit	Lower	Upper	22°C 60%RH	30°C 65%RH	Lower	Upper	22°C 60%RH	30°C 65%RH
Nicotine	mg/stick	(b) (4)		24	24	(b) (4)		24	24
Glycerin	mg/stick			24	20			24	24
CO	mg/stick			24	24			24	24
Acrylamide	µg/stick			24	24			24	24
Phenol	µg/stick			24	24			24	24
Triacetin	mg/stick			24	24			24	24
1,3-butadiene	µg/stick			24	24			24	24
Benzene	µg/stick			24	24			24	24
Formaldehyde	µg/stick			24	24			24	24
Water activity	N/A			24	24			24	24



10 Related Documents

- [1] P1 THS 2 2 STABILITY STUDY REPORT DI HM STAB-2017_P1_M_3_signed.pdf

(b) (4)

- [2] PMI Stability Study Program THS2.2.docx, V1, 06-Oct-2017

(b) (4)

- [3] P1 THS 2 2 STABILITY STUDY PROTOCOL STAB-2017_P1_R_1 STAB-2017_P1_M_2 STAB-2017_P1_M_3_signed.pdf

(b) (4)

- [4] P1 THS 2 2 STABILITY STUDY FOLLOW UP PROTOCOL STAB-2017_P1_R_1 STAB-2017_P1_M_2 STAB-2017_P1_M_3_signed.pdf

(b) (4)

- [5] Platform 1 Equivalence Specification for Aerosol Endpoints Generated under Health Canada Intense Regime, Donatien Tabin Djoko, V3.0, 11-Oct-2017

(b) (4)

- [6] Menthol Threshold Levels in PMI Products, Florence Vonmoos, V1.0, 05-Oct-2017

(b) (4)

- [7] P1 Product specifications report, Pedro Campelos, V1.0, 16-Mar-2016

- [8] DI High C3.2 Performance Specification Report, V2.0, Mirko Minzoni, 24-Oct-2016

- [9] P1 - THS / THD 2.4 - A02 / SEN / P1_PDev_EXPR_SS_068_2018_P1 MRTP US High T12

(b) (4)

- [10] P1 - THS / THD 2.4 - A02 / SEN / P1_Pdev_EXPR_SS_070_2019_P1 MRTP US High Menthol T24

(b) (4)



- [11] PMI-RRP-FOR-111546_STAB-2017_P1_M_3_OOT (b)(4) T6_signed.pdf
(b)(4)
- [12] PMI-RRP-FOR-111546_STAB-2017_P1_M_3_OOT Menthol_T9_signed.pdf
(b)(4)
- [13] PMI-RRP-FOR-111546_STAB-2017_P1_M_3_OOS (b)(4) T9_signed.pdf
(b)(4)
- [14] PMI-RRP-FOR-111546_STAB-2017_P1_M_3_OOS (b)(4) T12_signed.pdf
(b)(4)
- [15] PMI-RRP-FOR-114236_STAB-2017_P1_M_3_OOL Glycerin_T24_signed.pdf
(b)(4)
- [16] Platform 1 equivalence specification for aerosol endpoints generated under health
canada intense regime, Donatien Tabin Djoko, V5.0, 09-Jul-2019
(b)(4)

11 Reference Documents

- [17] ISO 3402:1999 Tobacco and tobacco products -- Atmosphere for conditioning and testing
- [18] WHO Stability testing of active pharmaceutical ingredients and finished pharmaceutical products
- [19] ICH Q1(E) Evaluation of Stability Data
- [20] ISO 20778:2018 Cigarettes -- Routine analytical cigarette smoking machine -- Definitions and standard conditions with an intense smoking regime

12 Change Management Log

Version N°	Detailed Description of change (including reason for change)
3.0	Minor changes to correct typo error in the V2.0. (Header and page 1)
2.0	Images' format changed for the Figures listed below to make them readable in pdf format in R3:



Version N°	Detailed Description of change (including reason for change)
	Menthol: Figure 11 and 29 Water Activity: Figure 17 and 35 (b) (4)
1.0	Original Issue

13 Review and Approval

This document has been approved using electronic signatures. Refer to the signature page and/or approval workflow for the signatory names, dates and functions.

14 Definitions and Abbreviations

Abbreviation	Definition
AVG	Average
CAPA	Corrective Action Preventive Action
CI	Confidence Interval
CO	Carbon Monoxide
CV	Coefficient of Variation
CSVQI	Client Sensitive Visual Quality Index
CVQA	Central Visual Quality Audit
DCR	Design Change Request
EDMS	Electronic Document Management System
FOR	Form
HAT	Hollow Acetate Tube



Abbreviation	Definition
ICH	International Council for Harmonisation
ID number	Identification number
ISO	International Organization for Standardization
(b) (4)	
GC-MS	Gas Chromatography Mass Spectrometry
LSL	Lower Shelf Life specification limit
n	Number of Determinations
N	Newton
N/A	Not Applicable
NC	Non-conformity
OOS	Out of Specification
OOT	Out of Trend
P1	Platform 1
PMI	Philip Morris International
PDIMS	Product Development Information Management System
PMMTB	Philip Morris Manufacturing & Technology Bologna (Training Center)
PMPSA	Philip Morris Products Société Anonyme.
PO	Purchase Order
QA	Quality Audit
QDP	Quantitative Descriptive Profile



Abbreviation	Definition
QSS	Quality System Suite
RDLIMS	Research Development Laboratory Information Management System
R&D	Research and Development
RH	Relative Humidity
RRP	Reduced Risk Products
RTD	Resistance to Draw
SAS	Statistical Analysis System
SDMS	Scientific Data Management System
SEC	Sensory Evaluation Center
SOP	Standard Operating Procedure
STDEV	Standard Deviation
THS	Tobacco Heating System
TO	Testing Order
USL	Upper Shelf Life specification limit
UPLC-MS/MS	Ultra Performance Liquid Chromatography tandem Mass Spectrometry
WHO	World Health Organization
WKI	Work Instruction



15 Appendices

15.1 Storage Locations

Storage condition: 22°C 60%RH		Storage condition: 30°C 65%RH	
PMI ID storage location	Period	PMI ID storage location	Period
T1381	From 20-Nov-2017 until 30-Nov-2019	13018	From 20-Nov-2017 until 11-Dec-2017
		13017	From 11-Dec-2017 until 12-Nov-2018
		6323	From 12-Nov-2018 until 16-Nov-2018
		13017	From 16-Nov-2018 until 30-Nov-2019



15.2 Analyses Dates per Time Point

Time Point	Analysis Type	Beginning of the Study (T0) / Sample Pull Out Day from the Storage Location (T2-T24) (1)	Conditioning Start Date (2)	Analyses Start Date (3)	Analysis End Date (4)
0	Aerosol chemistry	20-Nov-2017	20-Nov-2017	23-Nov-2017	30-Nov-2017
	Physical		23-Nov-2017	29-Nov-2017	04-Dec-2017
	Sensory		22-Nov-2017	22-Nov-2017	27-Nov-2017
	Visual inspection		N/A	21-Nov-2017	04-Dec-2017
	Water activity		20-Nov-2017	24-Nov-2017	29-Nov-2017
2	Aerosol chemistry	22-Jan-2018	22-Jan-2018	26-Jan-2018	02-Feb-2018
	Physical	22-Jan-2018	30-Jan-2018	31-Jan-2018	21-Feb-2017
	Sensory	22-Jan-2018	24-Jan-2018	05-Feb-2018	09-Feb-2018
	Visual inspection	22-Jan-2018	N/A	29-Jan-2017	31-Jan-2017
	Water activity	25-Jan-2018	25-Jan-2018	29-Jan-2018	30-Jan-2017
4	Aerosol chemistry	23-Mar-2018	23-Mar-2018	26-Mar-2018	11-Apr-2018
	Physical	23-Mar-2018	26-Mar-2018	28-Mar-2018	09-Apr-2018
	Sensory	23-Mar-2018	23-Mar-2018	03-Apr-2018	09-Apr-2018
	Visual inspection	23-Mar-2018	N/A	23-Mar-2018	26-Mar-2018
	Water activity	26-Mar-2018	26-Mar-2018	29-Mar-2018	04-Apr-2018
6	Aerosol chemistry	22-May-2018	22-May-2018	25-May-2018	13-Jun-2018
	Physical	22-May-2018	29-May-2018	31-May-2018	05-Jun-2018
	Sensory	22-May-2018	07-Jun-2018	19-Jun-2018	25-Jun-2018
	Visual inspection	22-May-2018	N/A	24-May-2018	24-May-2018
	Water activity	22-May-2018	23-May-2018	25-May-2018	07-Jun-2018
9	Aerosol chemistry	20-Aug-2018	20-Aug-2018	23-Aug-2018	07-Sep-2018
	Physical	20-Aug-2018	24-Aug-2018	27-Aug-2018	29-Aug-2018
	Sensory	20-Aug-2018	31-Aug-2018	11-Sep-2018	20-Sep-2018
	Visual inspection	20-Aug-2018	N/A	22-Aug-2018	28-Aug-2018
	Water activity	21-Aug-2018	22-Aug-2018	24-Aug-2018	27-Aug-2018
12	Aerosol chemistry	20-Nov-2018	20-Nov-2018	04-Apr-2019	10-Dec-2018
	Physical	20-Nov-2018	21-Nov-2018	22-Nov-2018	23-Nov-2018
	Sensory	20-Nov-2018	05-Dec-2018	12-Dec-2018	21-Dec-2018
	Visual inspection	20-Nov-2018	N/A	27-Nov-2018	27-Nov-2018
	Water activity	23-Nov-2018	23-Nov-2018	26-Nov-2018	28-Nov-2018
16	Aerosol chemistry	21-Mar-2019	22-Mar-2019	04-Apr-2019	24-Apr-2019



Time Point	Analysis Type	Beginning of the Study (T0) / Sample Pull Out Day from the Storage Location (T2-T24) (1)	Conditioning Start Date (2)	Analyses Start Date (3)	Analysis End Date (4)
16	Physical	21-Mar-2019	12-Apr-2019	15-Apr-2019	18-Apr-2019
	Sensory	21-Mar-2019	27-Mar-2019	28-Mar-2019	04-Apr-2019
	Visual inspection	21-Mar-2019	N/A	27-Mar-2019	27-Mar-2019
	Water activity	22-Mar-2019	22-Mar-2019	25-Mar-2019	27-Mar-2019
20	Aerosol chemistry	22-Jul-2019	22-Jul-2019	30-Jul-2019	12-Aug-2019
	Physical	22-Jul-2019	25-Jul-2019	30-Jul-2019	31-Jul-2019
	Sensory	22-Jul-2019	21-Aug-2019	26-Aug-2019	02-Sep-2019
	Visual inspection	22-Jul-2019	N/A	24-Jul-2019	25-Jul-2019
	Water activity	23-Jul-2019	23-Jul-2019	26-Jul-2019	28-Jul-2019
24	Aerosol chemistry	21-Nov-2019	21-Nov-2019	27-Nov-2019	06-Dec-2019
	Physical	21-Nov-2019	22-Nov-2019	26-Nov-2019	11-Dec-2019
	Sensory	21-Nov-2019	03-Dec-2019	16-Dec-2019	20-Dec-2019
	Visual inspection	21-Nov-2019	N/A	27-Nov-2019	28-Nov-2019
	Water activity	22-Nov-2019	22-Nov-2019	25-Nov-2019	27-Nov-2019

(1) – Beginning of the study for T0: date when samples were placed in the conditioning room and the climatic chamber for the one year storage. Samples for T0 were kept in conditioning room (22°C 60%RH) for the analyses. Sample Pull Out Day from the Storage Location for T2-T24: dates when samples were taken out from the storage location for analyses.

(2) - Date of beginning of conditioning. For Water activity date of reception.

(3) - First day of analyses

(4) - Date when results were released by the laboratory or last day of the sensorial evaluation

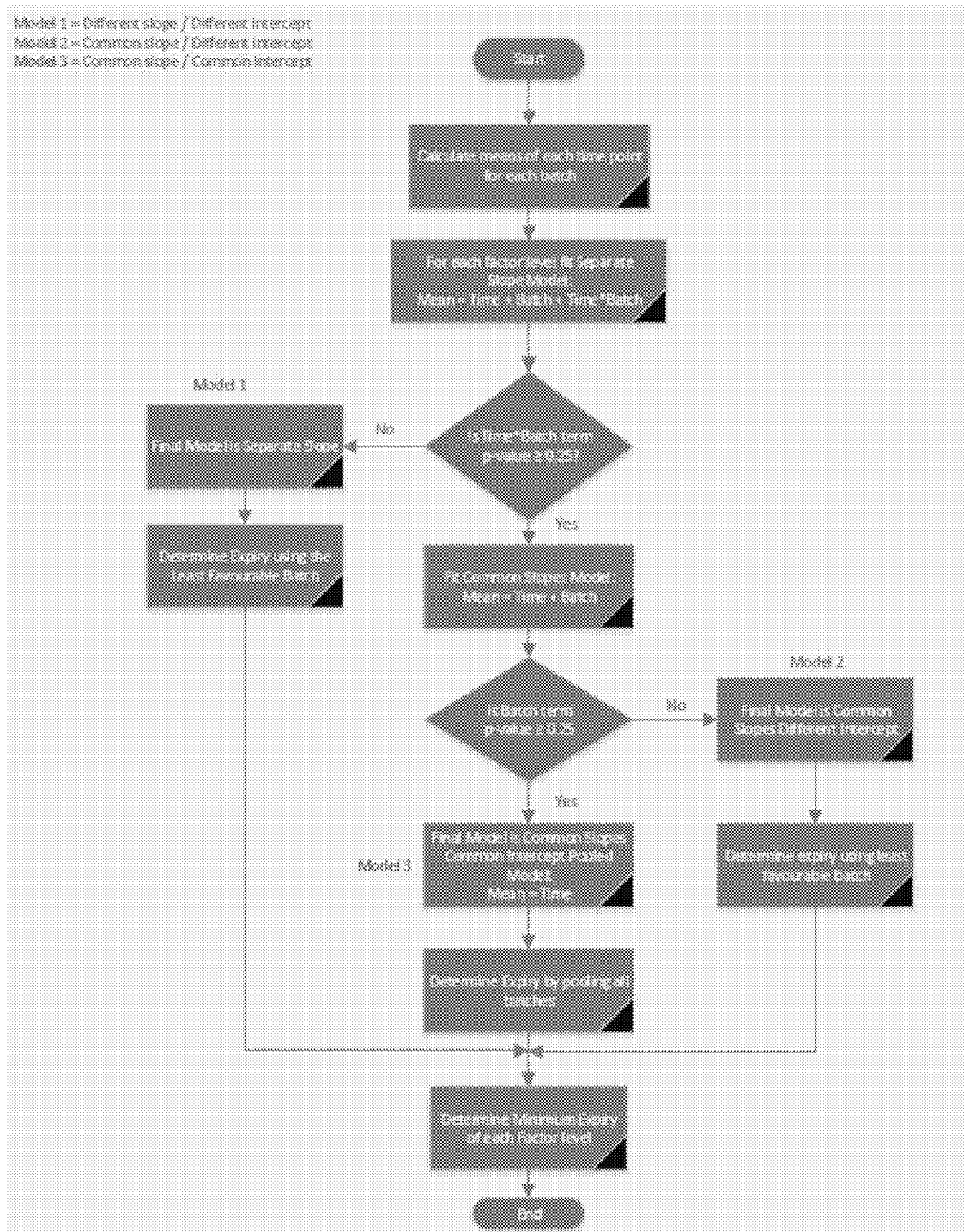


15.3 Sample Traceability Matrix

Time Point	Testing Order	RDLIMS Project Number	(b) (4) report number for Water activity
T0	TO-16488, TO-16760	RLS-ZRH-2017-1251	17-25232
T2	TO-16670, TO-16649	RLS-ZRH-2018-69	18-01850
T4	TO-17733, TO-17736	RLS-ZRH-2018-320	18-06421
T6	TO-18277, TO-18280	RLS-ZRH-2018-490	18-10464
T9	TO-19189, TO-19307	RLS-ZRH-2018-721	18-17887
T12	TO-20214, TO-20336	RLS-ZRH-2018-875	18-26274
T16	TO-21261, TO-21355	RLS-ZRH-2019-118	19-06397
T20	TO-22344, TO-22436	RLS-ZRH-2019-318	19-15089
T24	TO-23288, TO-23422	RLS-ZRH-2019-477	19-25162



15.4 Statistical Analyses Flowchart





15.5 Tabulated Results and Summary Statistics for 22°C 60%RH

CONDITION	VARIABLE	BATCH	Time point	LSI	USI	UNIT	N	Mean	Std	CV	Lower 95%CI	Upper 95%CI
22°C 60%RH	1,3 Butadiene	B-48374	T0			µg/stick	6	0.267	0.029	10.728		
22°C 60%RH	1,3 Butadiene	B-48374	T2			µg/stick	4	0.274	0.014	5.291		
22°C 60%RH	1,3 Butadiene	B-48374	T4			µg/stick	4	0.296	0.033	11.133		
22°C 60%RH	1,3 Butadiene	B-48374	T6			µg/stick	4	0.253	0.014	5.505		
22°C 60%RH	1,3 Butadiene	B-48374	T9			µg/stick	4	0.246	0.019	7.708		
22°C 60%RH	1,3 Butadiene	B-48374	T12			µg/stick	6	0.296	0.016	5.527		
22°C 60%RH	1,3 Butadiene	B-48374	T16			µg/stick	6	0.236	0.017	7.316		
22°C 60%RH	1,3 Butadiene	B-48374	T20			µg/stick	6	0.362	0.011	2.989		
22°C 60%RH	1,3 Butadiene	B-48374	T24			µg/stick	6	0.241	0.014	5.602		
22°C 60%RH	1,3 Butadiene	B-48375	T0			µg/stick	6	0.275	0.030	11.061		
22°C 60%RH	1,3 Butadiene	B-48375	T2			µg/stick	4	0.266	0.022	8.178		
22°C 60%RH	1,3 Butadiene	B-48375	T4			µg/stick	4	0.299	0.025	8.254		
22°C 60%RH	1,3 Butadiene	B-48375	T6			µg/stick	4	0.234	0.016	6.891		
22°C 60%RH	1,3 Butadiene	B-48375	T9			µg/stick	4	0.229	0.027	11.873		
22°C 60%RH	1,3 Butadiene	B-48375	T12			µg/stick	6	0.279	0.036	12.835		
22°C 60%RH	1,3 Butadiene	B-48375	T16			µg/stick	6	0.253	0.027	10.512		
22°C 60%RH	1,3 Butadiene	B-48375	T20			µg/stick	6	0.379	0.022	5.922		
22°C 60%RH	1,3 Butadiene	B-48375	T24			µg/stick	6	0.229	0.024	10.427		
22°C 60%RH	1,3 Butadiene	B-48376	T0			µg/stick	6	0.262	0.007	2.700		
22°C 60%RH	1,3 Butadiene	B-48376	T2			µg/stick	4	0.258	0.016	6.121		
22°C 60%RH	1,3 Butadiene	B-48376	T4			µg/stick	4	0.310	0.020	6.307		
22°C 60%RH	1,3 Butadiene	B-48376	T6			µg/stick	4	0.244	0.021	8.757		
22°C 60%RH	1,3 Butadiene	B-48376	T9			µg/stick	4	0.239	0.027	11.164		
22°C 60%RH	1,3 Butadiene	B-48376	T12			µg/stick	6	0.280	0.029	10.172		
22°C 60%RH	1,3 Butadiene	B-48376	T16			µg/stick	6	0.270	0.023	8.535		
22°C 60%RH	1,3 Butadiene	B-48376	T20			µg/stick	6	0.358	0.014	3.846		
22°C 60%RH	1,3 Butadiene	B-48376	T24			µg/stick	6	0.244	0.011	4.474		
22°C 60%RH	Acrylamide	B-48374	T0			µg/stick	6	1.968	0.062	3.140		
22°C 60%RH	Acrylamide	B-48374	T2			µg/stick	4	1.850	0.044	2.358		
22°C 60%RH	Acrylamide	B-48374	T4			µg/stick	4	1.857	0.149	8.005		
22°C 60%RH	Acrylamide	B-48374	T6			µg/stick	4	1.987	0.169	8.486		
22°C 60%RH	Acrylamide	B-48374	T9			µg/stick	4	1.940	0.105	5.410		
22°C 60%RH	Acrylamide	B-48374	T12			µg/stick	6	1.887	0.189	10.031		
22°C 60%RH	Acrylamide	B-48374	T16			µg/stick	6	1.588	0.147	9.235		

(b) (4)

(b) (4)

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CONDITION	VARIABLE	BATCH	Time point	LSE	USL	UNIT	N	Mean	Std	CV	Lower 95%CI	Upper 95%CI
22°C 60%RH	Acrylamide	B-48374	T20			µg/stick	6	1.382	0.131	9.452		
22°C 60%RH	Acrylamide	B-48374	T24			µg/stick	6	1.550	0.161	10.391		
22°C 60%RH	Acrylamide	B-48375	T0			µg/stick	6	1.989	0.162	8.128		
22°C 60%RH	Acrylamide	B-48375	T2			µg/stick	4	1.862	0.191	10.236		
22°C 60%RH	Acrylamide	B-48375	T4			µg/stick	4	1.820	0.115	6.340		
22°C 60%RH	Acrylamide	B-48375	T6			µg/stick	4	1.956	0.216	11.053		
22°C 60%RH	Acrylamide	B-48375	T9			µg/stick	4	2.116	0.220	10.389		
22°C 60%RH	Acrylamide	B-48375	T12			µg/stick	6	1.869	0.141	7.555		
22°C 60%RH	Acrylamide	B-48375	T16			µg/stick	6	1.631	0.230	14.121		
22°C 60%RH	Acrylamide	B-48375	T20			µg/stick	6	1.512	0.167	11.025		
22°C 60%RH	Acrylamide	B-48375	T24			µg/stick	6	1.702	0.136	7.966		
22°C 60%RH	Acrylamide	B-48376	T0			µg/stick	6	2.008	0.105	5.228		
22°C 60%RH	Acrylamide	B-48376	T2			µg/stick	4	1.964	0.235	11.953		
22°C 60%RH	Acrylamide	B-48376	T4			µg/stick	4	1.820	0.098	5.386		
22°C 60%RH	Acrylamide	B-48376	T6			µg/stick	4	2.013	0.106	5.262		
22°C 60%RH	Acrylamide	B-48376	T9			µg/stick	4	1.969	0.277	14.078		
22°C 60%RH	Acrylamide	B-48376	T12			µg/stick	6	1.906	0.189	9.910		
22°C 60%RH	Acrylamide	B-48376	T16	(b) (4)		µg/stick	6	1.735	0.181	10.446		(b) (4)
22°C 60%RH	Acrylamide	B-48376	T20			µg/stick	6	1.529	0.115	7.526		
22°C 60%RH	Acrylamide	B-48376	T24			µg/stick	6	1.748	0.077	4.398		
22°C 60%RH	Benzene	B-48374	T0			µg/stick	6	0.592	0.058	9.800		
22°C 60%RH	Benzene	B-48374	T2			µg/stick	4	0.572	0.006	1.094		
22°C 60%RH	Benzene	B-48374	T4			µg/stick	4	0.539	0.035	6.489		
22°C 60%RH	Benzene	B-48374	T6			µg/stick	4	0.610	0.042	6.829		
22°C 60%RH	Benzene	B-48374	T9			µg/stick	4	0.581	0.054	9.373		
22°C 60%RH	Benzene	B-48374	T12			µg/stick	6	0.604	0.073	12.081		
22°C 60%RH	Benzene	B-48374	T16			µg/stick	6	0.513	0.033	6.456		
22°C 60%RH	Benzene	B-48374	T20			µg/stick	6	0.556	0.018	3.294		
22°C 60%RH	Benzene	B-48374	T24			µg/stick	6	0.564	0.035	6.276		
22°C 60%RH	Benzene	B-48375	T0			µg/stick	6	0.595	0.053	8.941		
22°C 60%RH	Benzene	B-48375	T2			µg/stick	4	0.569	0.041	7.279		
22°C 60%RH	Benzene	B-48375	T4			µg/stick	4	0.536	0.017	3.170		
22°C 60%RH	Benzene	B-48375	T6			µg/stick	4	0.604	0.057	9.482		
22°C 60%RH	Benzene	B-48375	T9			µg/stick	4	0.543	0.038	7.082		
22°C 60%RH	Benzene	B-48375	T12			µg/stick	6	0.544	0.045	8.232		

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CONDITION	VARIABLE	BATCH	Time point	LSE	USL	UNIT	N	Mean	Std	CV	Lower 95%CI	Upper 95%CI
22°C 60%RH	Benzene	B-48375	T16			µg/stick	6	0.533	0.045	8.384		
22°C 60%RH	Benzene	B-48375	T20			µg/stick	6	0.574	0.022	3.765		
22°C 60%RH	Benzene	B-48375	T24			µg/stick	6	0.527	0.034	6.404		
22°C 60%RH	Benzene	B-48376	T0			µg/stick	6	0.592	0.029	4.840		
22°C 60%RH	Benzene	B-48376	T2			µg/stick	4	0.535	0.041	7.610		
22°C 60%RH	Benzene	B-48376	T4			µg/stick	4	0.564	0.015	2.644		
22°C 60%RH	Benzene	B-48376	T6			µg/stick	4	0.574	0.061	10.681		
22°C 60%RH	Benzene	B-48376	T9			µg/stick	4	0.559	0.049	8.796		
22°C 60%RH	Benzene	B-48376	T12			µg/stick	6	0.562	0.049	8.680		
22°C 60%RH	Benzene	B-48376	T16			µg/stick	6	0.559	0.036	6.451		
22°C 60%RH	Benzene	B-48376	T20			µg/stick	6	0.544	0.017	3.082		
22°C 60%RH	Benzene	B-48376	T24			µg/stick	6	0.573	0.019	3.275		
22°C 60%RH	Carbon monoxide	B-48374	T0			mg/stick	6	0.506	0.053	10.541		
22°C 60%RH	Carbon monoxide	B-48374	T2			mg/stick	4	0.547	0.049	8.882		
22°C 60%RH	Carbon monoxide	B-48374	T4			mg/stick	4	0.462	0.048	10.497		
22°C 60%RH	Carbon monoxide	B-48374	T6			mg/stick	4	0.443	0.042	9.524		
22°C 60%RH	Carbon monoxide	B-48374	T9	(b) (4)		mg/stick	4	0.399	0.042	10.526	(b) (4)	
22°C 60%RH	Carbon monoxide	B-48374	T12			mg/stick	6	0.432	0.032	7.436		
22°C 60%RH	Carbon monoxide	B-48374	T16			mg/stick	6	0.398	0.018	4.489		
22°C 60%RH	Carbon monoxide	B-48374	T20			mg/stick	6	0.469	0.032	6.759		
22°C 60%RH	Carbon monoxide	B-48374	T24			mg/stick	6	0.447	0.029	6.543		
22°C 60%RH	Carbon monoxide	B-48375	T0			mg/stick	6	0.506	0.075	14.907		
22°C 60%RH	Carbon monoxide	B-48375	T2			mg/stick	4	0.547	0.049	8.882		
22°C 60%RH	Carbon monoxide	B-48375	T4			mg/stick	4	0.462	0.048	10.497		
22°C 60%RH	Carbon monoxide	B-48375	T6			mg/stick	4	0.443	0.042	9.524		
22°C 60%RH	Carbon monoxide	B-48375	T9			mg/stick	4	0.441	0.106	23.968		
22°C 60%RH	Carbon monoxide	B-48375	T12			mg/stick	6	0.421	0.011	2.561		
22°C 60%RH	Carbon monoxide	B-48375	T16			mg/stick	6	0.391	0.032	8.084		
22°C 60%RH	Carbon monoxide	B-48375	T20			mg/stick	6	0.485	0.039	7.972		
22°C 60%RH	Carbon monoxide	B-48375	T24			mg/stick	6	0.470	0.036	7.667		
22°C 60%RH	Carbon monoxide	B-48376	T0			mg/stick	6	0.506	0.053	10.541		

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CONDITION	VARIABLE	BATCH	Time point	LSE	USL	UNIT	N	Mean	Std	CV	Lower 95%CI	Upper 95%CI
22°C 60%RH	Carbon monoxide	B-48376	T2			mg/stick	4	0.547	0.049	8.882		
22°C 60%RH	Carbon monoxide	B-48376	T4			mg/stick	4	0.462	0.048	10.497		
22°C 60%RH	Carbon monoxide	B-48376	T6			mg/stick	4	0.465	0.049	10.497		
22°C 60%RH	Carbon monoxide	B-48376	T9			mg/stick	4	0.378	0.048	12.830		
22°C 60%RH	Carbon monoxide	B-48376	T12			mg/stick	6	0.421	0.016	3.711		
22°C 60%RH	Carbon monoxide	B-48376	T16			mg/stick	6	0.405	0.021	5.079		
22°C 60%RH	Carbon monoxide	B-48376	T20			mg/stick	6	0.472	0.029	6.137		
22°C 60%RH	Carbon monoxide	B-48376	T24			mg/stick	6	0.475	0.031	6.520		
22°C 60%RH	Formaldehyde	B-48374	T0			µg/stick	6	4.663	0.615	13.198		
22°C 60%RH	Formaldehyde	B-48374	T2			µg/stick	4	4.056	0.334	8.223		
22°C 60%RH	Formaldehyde	B-48374	T4			µg/stick	4	5.166	0.439	8.496		
22°C 60%RH	Formaldehyde	B-48374	T6			µg/stick	4	3.396	0.381	11.234		
22°C 60%RH	Formaldehyde	B-48374	T9			µg/stick	4	4.090	0.865	21.153		
22°C 60%RH	Formaldehyde	B-48374	T12			µg/stick	6	3.804	0.278	7.303		
22°C 60%RH	Formaldehyde	B-48374	T16			µg/stick	6	3.364	0.813	24.179		
22°C 60%RH	Formaldehyde	B-48374	T20	(b) (4)		µg/stick	6	4.011	1.121	27.936	(b) (4)	
22°C 60%RH	Formaldehyde	B-48374	T24			µg/stick	6	4.224	0.584	13.826		
22°C 60%RH	Formaldehyde	B-48375	T0			µg/stick	6	4.167	0.345	8.285		
22°C 60%RH	Formaldehyde	B-48375	T2			µg/stick	4	3.936	0.268	6.818		
22°C 60%RH	Formaldehyde	B-48375	T4			µg/stick	4	4.981	0.390	7.831		
22°C 60%RH	Formaldehyde	B-48375	T6			µg/stick	4	3.654	0.204	5.587		
22°C 60%RH	Formaldehyde	B-48375	T9			µg/stick	4	4.702	0.564	11.986		
22°C 60%RH	Formaldehyde	B-48375	T12			µg/stick	6	4.820	1.160	24.075		
22°C 60%RH	Formaldehyde	B-48375	T16			µg/stick	6	4.035	0.236	5.838		
22°C 60%RH	Formaldehyde	B-48375	T20			µg/stick	6	3.964	0.720	18.167		
22°C 60%RH	Formaldehyde	B-48375	T24			µg/stick	6	4.090	0.457	11.170		
22°C 60%RH	Formaldehyde	B-48376	T0			µg/stick	6	4.105	0.520	12.677		
22°C 60%RH	Formaldehyde	B-48376	T2			µg/stick	4	4.022	0.870	21.619		
22°C 60%RH	Formaldehyde	B-48376	T4			µg/stick	4	4.755	0.487	10.241		
22°C 60%RH	Formaldehyde	B-48376	T6			µg/stick	4	3.804	0.592	15.565		
22°C 60%RH	Formaldehyde	B-48376	T9			µg/stick	4	4.993	0.815	16.324		
22°C 60%RH	Formaldehyde	B-48376	T12			µg/stick	6	4.859	0.315	6.475		
22°C 60%RH	Formaldehyde	B-48376	T16			µg/stick	6	3.932	0.423	10.770		

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CONDITION	VARIABLE	BATCH	Time point	LSE	USL	UNIT	N	Mean	Std	CV	Lower 95%CI	Upper 95%CI
22°C 60%RH	Formaldehyde	B-48376	T20			µg/stick	6	3.999	0.600	15.013		
22°C 60%RH	Formaldehyde	B-48376	T24			µg/stick	6	4.508	0.894	19.832		
22°C 60%RH	Glycerin	B-48374	T0			mg/stick	6	4.949	0.266	5.375		
22°C 60%RH	Glycerin	B-48374	T2			mg/stick	4	4.857	0.287	5.905		
22°C 60%RH	Glycerin	B-48374	T4			mg/stick	4	4.902	0.394	8.028		
22°C 60%RH	Glycerin	B-48374	T6			mg/stick	4	5.052	0.335	6.632		
22°C 60%RH	Glycerin	B-48374	T9			mg/stick	4	5.104	0.269	5.263		
22°C 60%RH	Glycerin	B-48374	T12			mg/stick	6	4.580	0.383	8.370		
22°C 60%RH	Glycerin	B-48374	T16			mg/stick	6	4.070	0.421	10.351		
22°C 60%RH	Glycerin	B-48374	T20			mg/stick	6	4.098	0.351	8.577		
22°C 60%RH	Glycerin	B-48374	T24			mg/stick	6	4.150	0.307	7.393		
22°C 60%RH	Glycerin	B-48375	T0			mg/stick	6	5.144	0.368	7.164		
22°C 60%RH	Glycerin	B-48375	T2			mg/stick	4	5.025	0.182	3.626		
22°C 60%RH	Glycerin	B-48375	T4			mg/stick	4	4.651	0.281	6.040		
22°C 60%RH	Glycerin	B-48375	T6			mg/stick	4	5.069	0.548	10.815		
22°C 60%RH	Glycerin	B-48375	T9			mg/stick	4	5.084	0.244	4.791		
22°C 60%RH	Glycerin	B-48375	T12			mg/stick	6	4.632	0.247	5.341		
22°C 60%RH	Glycerin	B-48375	T16			mg/stick	6	4.138	0.539	13.018		
22°C 60%RH	Glycerin	B-48375	T20			mg/stick	6	4.644	0.316	6.806		
22°C 60%RH	Glycerin	B-48375	T24			mg/stick	6	4.390	0.410	9.342		
22°C 60%RH	Glycerin	B-48376	T0			mg/stick	6	4.830	0.213	4.408		
22°C 60%RH	Glycerin	B-48376	T2			mg/stick	4	5.139	0.493	9.600		
22°C 60%RH	Glycerin	B-48376	T4			mg/stick	4	4.499	0.382	8.498		
22°C 60%RH	Glycerin	B-48376	T6			mg/stick	4	5.172	0.525	10.159		
22°C 60%RH	Glycerin	B-48376	T9			mg/stick	4	5.027	0.360	7.157		
22°C 60%RH	Glycerin	B-48376	T12			mg/stick	6	4.537	0.269	5.937		
22°C 60%RH	Glycerin	B-48376	T16			mg/stick	6	4.446	0.278	6.245		
22°C 60%RH	Glycerin	B-48376	T20			mg/stick	6	4.381	0.251	5.737		
22°C 60%RH	Glycerin	B-48376	T24			mg/stick	6	4.483	0.154	3.433		
22°C 60%RH	Menthol	B-48374	T0			mg/stick	6	2.296	0.077	3.335		
22°C 60%RH	Menthol	B-48374	T2			mg/stick	4	2.632	0.040	1.523		
22°C 60%RH	Menthol	B-48374	T4			mg/stick	4	2.977	0.251	8.442		
22°C 60%RH	Menthol	B-48374	T6			mg/stick	4	3.134	0.119	3.812		
22°C 60%RH	Menthol	B-48374	T9			mg/stick	4	3.602	0.120	3.324		
22°C 60%RH	Menthol	B-48374	T12			mg/stick	6	3.255	0.164	5.035		

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CONDITION	VARIABLE	BATCH	Time point	LSE	USL	UNIT	N	Mean	Std	CV	Lower 95%CI	Upper 95%CI
22°C 60%RH	Menthol	B-48374	T16			mg/stick	6	3.389	0.132	3.902		
22°C 60%RH	Menthol	B-48374	T20			mg/stick	6	3.209	0.150	4.677		
22°C 60%RH	Menthol	B-48374	T24			mg/stick	6	3.395	0.290	8.534		
22°C 60%RH	Menthol	B-48375	T0			mg/stick	6	2.220	0.126	5.653		
22°C 60%RH	Menthol	B-48375	T2			mg/stick	4	2.943	0.150	5.095		
22°C 60%RH	Menthol	B-48375	T4			mg/stick	4	3.029	0.255	8.407		
22°C 60%RH	Menthol	B-48375	T6			mg/stick	4	3.316	0.143	4.325		
22°C 60%RH	Menthol	B-48375	T9			mg/stick	4	3.543	0.163	4.608		
22°C 60%RH	Menthol	B-48375	T12			mg/stick	6	3.436	0.174	5.068		
22°C 60%RH	Menthol	B-48375	T16			mg/stick	6	3.392	0.116	3.407		
22°C 60%RH	Menthol	B-48375	T20			mg/stick	6	3.346	0.097	2.913		
22°C 60%RH	Menthol	B-48375	T24			mg/stick	6	3.372	0.355	10.518		
22°C 60%RH	Menthol	B-48376	T0			mg/stick	6	2.121	0.117	5.497		
22°C 60%RH	Menthol	B-48376	T2			mg/stick	4	2.865	0.144	5.022		
22°C 60%RH	Menthol	B-48376	T4			mg/stick	4	2.831	0.293	10.336		
22°C 60%RH	Menthol	B-48376	T6			mg/stick	4	3.206	0.090	2.815		
22°C 60%RH	Menthol	B-48376	T9			mg/stick	4	3.308	0.285	8.611		
22°C 60%RH	Menthol	B-48376	T12			mg/stick	6	3.411	0.073	2.129		
22°C 60%RH	Menthol	B-48376	T16			mg/stick	6	3.338	0.105	3.144		
22°C 60%RH	Menthol	B-48376	T20			mg/stick	6	3.161	0.165	5.213		
22°C 60%RH	Menthol	B-48376	T24			mg/stick	6	3.452	0.246	7.140		
22°C 60%RH	Nicotine	B-48374	T0			mg/stick	6	1.194	0.032	2.661		
22°C 60%RH	Nicotine	B-48374	T2			mg/stick	4	1.151	0.032	2.799		
22°C 60%RH	Nicotine	B-48374	T4			mg/stick	4	1.178	0.064	5.412		
22°C 60%RH	Nicotine	B-48374	T6			mg/stick	4	1.202	0.071	5.921		
22°C 60%RH	Nicotine	B-48374	T9			mg/stick	4	1.167	0.036	3.108		
22°C 60%RH	Nicotine	B-48374	T12			mg/stick	6	1.193	0.079	6.584		
22°C 60%RH	Nicotine	B-48374	T16			mg/stick	6	1.155	0.064	5.554		
22°C 60%RH	Nicotine	B-48374	T20			mg/stick	6	1.050	0.045	4.246		
22°C 60%RH	Nicotine	B-48374	T24			mg/stick	6	1.170	0.086	7.347		
22°C 60%RH	Nicotine	B-48375	T0			mg/stick	6	1.225	0.042	3.409		
22°C 60%RH	Nicotine	B-48375	T2			mg/stick	4	1.165	0.051	4.366		
22°C 60%RH	Nicotine	B-48375	T4			mg/stick	4	1.139	0.076	6.671		
22°C 60%RH	Nicotine	B-48375	T6			mg/stick	4	1.199	0.077	6.458		
22°C 60%RH	Nicotine	B-48375	T9			mg/stick	4	1.221	0.031	2.549		

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CONDITION	VARIABLE	BATCH	Time point	LSL	USL	UNIT	N	Mean	Std	CV	Lower 95%CI	Upper 95%CI
22°C 60%RH	Nicotine	B-48375	T12			mg/stick	6	1.192	0.052	4.386		
22°C 60%RH	Nicotine	B-48375	T16			mg/stick	6	1.175	0.111	9.472		
22°C 60%RH	Nicotine	B-48375	T20			mg/stick	6	1.149	0.049	4.267		
22°C 60%RH	Nicotine	B-48375	T24			mg/stick	6	1.256	0.069	5.463		
22°C 60%RH	Nicotine	B-48376	T0			mg/stick	6	1.211	0.036	2.935		
22°C 60%RH	Nicotine	B-48376	T2			mg/stick	4	1.228	0.072	5.840		
22°C 60%RH	Nicotine	B-48376	T4			mg/stick	4	1.160	0.031	2.668		
22°C 60%RH	Nicotine	B-48376	T6			mg/stick	4	1.257	0.077	6.112		
22°C 60%RH	Nicotine	B-48376	T9			mg/stick	4	1.205	0.058	4.774		
22°C 60%RH	Nicotine	B-48376	T12			mg/stick	6	1.206	0.052	4.295		
22°C 60%RH	Nicotine	B-48376	T16			mg/stick	6	1.217	0.040	3.294		
22°C 60%RH	Nicotine	B-48376	T20			mg/stick	6	1.125	0.044	3.912		
22°C 60%RH	Nicotine	B-48376	T24			mg/stick	6	1.267	0.039	3.063		
22°C 60%RH	Phenol	B-48374	T0			µg/stick	6	0.868	0.119	13.690		
22°C 60%RH	Phenol	B-48374	T2			µg/stick	4	1.024	0.109	10.683		
22°C 60%RH	Phenol	B-48374	T4			µg/stick	4	1.146	0.062	5.398		
22°C 60%RH	Phenol	B-48374	T6			µg/stick	4	0.836	0.166	19.888		
22°C 60%RH	Phenol	B-48374	T9			µg/stick	4	0.971	0.135	13.866		
22°C 60%RH	Phenol	B-48374	T12			µg/stick	6	0.771	0.298	38.618		
22°C 60%RH	Phenol	B-48374	T16			µg/stick	6	0.810	0.181	22.405		
22°C 60%RH	Phenol	B-48374	T20			µg/stick	6	0.915	0.067	7.357		
22°C 60%RH	Phenol	B-48374	T24			µg/stick	6	0.962	0.150	15.553		
22°C 60%RH	Phenol	B-48375	T0			µg/stick	6	1.054	0.201	19.062		
22°C 60%RH	Phenol	B-48375	T2			µg/stick	4	1.094	0.104	9.513		
22°C 60%RH	Phenol	B-48375	T4			µg/stick	4	1.052	0.101	9.612		
22°C 60%RH	Phenol	B-48375	T6			µg/stick	4	0.940	0.256	27.267		
22°C 60%RH	Phenol	B-48375	T9			µg/stick	4	1.292	0.301	23.304		
22°C 60%RH	Phenol	B-48375	T12			µg/stick	6	0.866	0.091	10.519		
22°C 60%RH	Phenol	B-48375	T16			µg/stick	6	0.831	0.221	26.608		
22°C 60%RH	Phenol	B-48375	T20			µg/stick	6	1.064	0.192	18.082		
22°C 60%RH	Phenol	B-48375	T24			µg/stick	6	1.152	0.199	17.311		
22°C 60%RH	Phenol	B-48376	T0			µg/stick	6	0.993	0.137	13.778		
22°C 60%RH	Phenol	B-48376	T2			µg/stick	4	1.279	0.263	20.580		
22°C 60%RH	Phenol	B-48376	T4			µg/stick	4	1.124	0.056	4.991		
22°C 60%RH	Phenol	B-48376	T6			µg/stick	4	0.964	0.031	3.248		

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CONDITION	VARIABLE	BATCH	Time point	LSL	USL	UNIT	N	Mean	Std	CV	Lower 95%CI	Upper 95%CI
22°C 60%RH	Phenol	B-48376	T9			µg/stick	4	1.081	0.235	21.714		
22°C 60%RH	Phenol	B-48376	T12			µg/stick	6	0.837	0.225	26.827		
22°C 60%RH	Phenol	B-48376	T16			µg/stick	6	1.000	0.144	14.399		
22°C 60%RH	Phenol	B-48376	T20			µg/stick	6	1.007	0.065	6.466		
22°C 60%RH	Phenol	B-48376	T24			µg/stick	6	1.234	0.245	19.837		
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CONDITION	VARIABLE	BATCH	Time point	LSE	USL	UNIT	N	Mean	Std	CV	Lower 95%CI	Upper 95%CI
(4)												
22°C 60%RH	Tobacco stick weight	B-48374	T0			mg	50	819.0	11.7	1.43		
22°C 60%RH	Tobacco stick weight	B-48374	T2			mg	50	840.6	11.3	1.34		
22°C 60%RH	Tobacco stick weight	B-48374	T4			mg	50	821.7	9.7	1.18		
22°C 60%RH	Tobacco stick weight	B-48374	T6			mg	50	837.5	12.6	1.51		
22°C 60%RH	Tobacco stick weight	B-48374	T9			mg	50	823.7	11.9	1.45		
22°C 60%RH	Tobacco stick weight	B-48374	T12			mg	50	837.7	12.0	1.43		
22°C 60%RH	Tobacco stick weight	B-48374	T16			mg	50	842.6	13.0	1.54		
22°C 60%RH	Tobacco stick weight	B-48374	T20			mg	50	813.0	9.7	1.19		
22°C 60%RH	Tobacco stick weight	B-48374	T24			mg	50	825.5	13.1	1.59		
22°C 60%RH	Tobacco stick weight	B-48375	T0			mg	50	829.7	8.2	0.99		
22°C 60%RH	Tobacco stick weight	B-48375	T2			mg	50	818.8	12.6	1.53		
22°C 60%RH	Tobacco stick weight	B-48375	T4			mg	50	822.9	12.5	1.52		
22°C 60%RH	Tobacco stick weight	B-48375	T6			mg	50	820.6	13.2	1.61		
22°C 60%RH	Tobacco stick weight	B-48375	T9			mg	50	815.9	10.0	1.23		
22°C 60%RH	Tobacco stick weight	B-48375	T12			mg	50	831.8	14.8	1.77		
22°C 60%RH	Tobacco stick weight	B-48375	T16			mg	50	823.9	14.0	1.70		
22°C 60%RH	Tobacco stick weight	B-48375	T20			mg	50	815.9	12.4	1.52		
22°C 60%RH	Tobacco stick weight	B-48375	T24			mg	50	823.5	13.2	1.60		
22°C 60%RH	Tobacco stick weight	B-48376	T0			mg	50	817.2	12.2	1.49		
22°C 60%RH	Tobacco stick weight	B-48376	T2			mg	50	823.7	11.6	1.40		
22°C 60%RH	Tobacco stick weight	B-48376	T4			mg	50	819.5	13.7	1.67		
22°C 60%RH	Tobacco stick weight	B-48376	T6			mg	50	822.4	11.3	1.37		
22°C 60%RH	Tobacco stick weight	B-48376	T9			mg	50	817.2	10.3	1.26		
22°C 60%RH	Tobacco stick weight	B-48376	T12			mg	50	822.9	11.0	1.33		
22°C 60%RH	Tobacco stick weight	B-48376	T16			mg	50	821.8	11.7	1.43		
22°C 60%RH	Tobacco stick weight	B-48376	T20			mg	50	812.0	9.4	1.15		
22°C 60%RH	Tobacco stick weight	B-48376	T24			mg	50	824.5	12.0	1.46		

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CONDITION	VARIABLE	BATCH	Time point	LSE	USL	UNIT	N	Mean	Std	CV	Lower 95%CI	Upper 95%CI
22°C 60%RH	Triacetin	B-48374	T0			mg/stick	6	0.599	0.026	4.266		
22°C 60%RH	Triacetin	B-48374	T2			mg/stick	4	0.614	0.009	1.429		
22°C 60%RH	Triacetin	B-48374	T4			mg/stick	4	0.612	0.032	5.268		
22°C 60%RH	Triacetin	B-48374	T6			mg/stick	4	0.566	0.025	4.460		
22°C 60%RH	Triacetin	B-48374	T9			mg/stick	4	0.561	0.013	2.233		
22°C 60%RH	Triacetin	B-48374	T12			mg/stick	6	0.504	0.022	4.347		
22°C 60%RH	Triacetin	B-48374	T16			mg/stick	6	0.425	0.035	8.357		
22°C 60%RH	Triacetin	B-48374	T20			mg/stick	6	0.425	0.024	5.557		
22°C 60%RH	Triacetin	B-48374	T24			mg/stick	6	0.427	0.047	11.013		
22°C 60%RH	Triacetin	B-48375	T0			mg/stick	6	0.603	0.022	3.586		
22°C 60%RH	Triacetin	B-48375	T2			mg/stick	4	0.603	0.009	1.442		
22°C 60%RH	Triacetin	B-48375	T4			mg/stick	4	0.549	0.016	2.859		
22°C 60%RH	Triacetin	B-48375	T6			mg/stick	4	0.555	0.023	4.221		
22°C 60%RH	Triacetin	B-48375	T9			mg/stick	4	0.557	0.049	8.767		
22°C 60%RH	Triacetin	B-48375	T12			mg/stick	6	0.489	0.015	3.157		
22°C 60%RH	Triacetin	B-48375	T16			mg/stick	6	0.406	0.028	6.888		
22°C 60%RH	Triacetin	B-48375	T20			mg/stick	6	0.432	0.032	7.522		
22°C 60%RH	Triacetin	B-48375	T24	(b) (4)		mg/stick	6	0.433	0.034	7.853	(b) (4)	
22°C 60%RH	Triacetin	B-48376	T0			mg/stick	6	0.552	0.015	2.660		
22°C 60%RH	Triacetin	B-48376	T2			mg/stick	4	0.572	0.032	5.669		
22°C 60%RH	Triacetin	B-48376	T4			mg/stick	4	0.496	0.033	6.705		
22°C 60%RH	Triacetin	B-48376	T6			mg/stick	4	0.510	0.020	3.992		
22°C 60%RH	Triacetin	B-48376	T9			mg/stick	4	0.501	0.034	6.698		
22°C 60%RH	Triacetin	B-48376	T12			mg/stick	6	0.456	0.019	4.236		
22°C 60%RH	Triacetin	B-48376	T16			mg/stick	6	0.413	0.025	6.053		
22°C 60%RH	Triacetin	B-48376	T20			mg/stick	6	0.406	0.020	4.855		
22°C 60%RH	Triacetin	B-48376	T24			mg/stick	6	0.426	0.039	9.067		
22°C 60%RH	Water activity	B-48374	T0			N/A	3	0.430	0.000	0.000		
22°C 60%RH	Water activity	B-48374	T2			N/A	3	0.497	0.006	1.162		
22°C 60%RH	Water activity	B-48374	T4			N/A	3	0.510	0.000	0.000		
22°C 60%RH	Water activity	B-48374	T6			N/A	3	0.537	0.006	1.076		
22°C 60%RH	Water activity	B-48374	T9			N/A	3	0.560	0.000	0.000		
22°C 60%RH	Water activity	B-48374	T12			N/A	3	0.560	0.000	0.000		
22°C 60%RH	Water activity	B-48374	T16			N/A	3	0.573	0.006	1.007		
22°C 60%RH	Water activity	B-48374	T20			N/A	3	0.590	0.000	0.000		

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CONDITION	VARIABLE	BATCH	Time point	LSL	USL	UNIT	N	Mean	Std	CV	Lower 95%CI	Upper 95%CI
22°C 60%RH	Water activity	B-48374	T24			N/A	3	0.580	0.000	0.000		
22°C 60%RH	Water activity	B-48375	T0			N/A	3	0.437	0.006	1.322		
22°C 60%RH	Water activity	B-48375	T2			N/A	3	0.490	0.000	0.000		
22°C 60%RH	Water activity	B-48375	T4			N/A	3	0.510	0.000	0.000		
22°C 60%RH	Water activity	B-48375	T6			N/A	3	0.537	0.006	1.076		
22°C 60%RH	Water activity	B-48375	T9			N/A	3	0.560	0.000	0.000		
22°C 60%RH	Water activity	B-48375	T12			N/A	3	0.560	0.000	0.000		
22°C 60%RH	Water activity	B-48375	T16			N/A	3	0.567	0.006	1.019		
22°C 60%RH	Water activity	B-48375	T20			N/A	3	0.580	0.000	0.000		
22°C 60%RH	Water activity	B-48375	T24			N/A	3	0.573	0.006	1.007		
22°C 60%RH	Water activity	B-48376	T0			N/A	3	0.420	0.000	0.000		
22°C 60%RH	Water activity	B-48376	T2			N/A	3	0.490	0.000	0.000		
22°C 60%RH	Water activity	B-48376	T4			N/A	3	0.510	0.000	0.000		
22°C 60%RH	Water activity	B-48376	T6			N/A	3	0.530	0.000	0.000		
22°C 60%RH	Water activity	B-48376	T9			N/A	3	0.560	0.000	0.000		
22°C 60%RH	Water activity	B-48376	T12			N/A	3	0.560	0.000	0.000		
22°C 60%RH	Water activity	B-48376	T16			N/A	3	0.570	0.000	0.000		
22°C 60%RH	Water activity	B-48376	T20			N/A	3	0.590	0.000	0.000		
22°C 60%RH	Water activity	B-48376	T24			N/A	3	0.580	0.000	0.000		

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15.6 Tabulated Results and Summary Statistics for 30°C 65%RH

CONDITION	VARIABLE	BATCH	Time point	LSL	USL	UNIT	N	Mean	Std	CV	Lower 95% CI	Upper 95% CI
30°C 65%RH	1,3 Butadiene	B-48374	T0			µg/stick	6	0.267	0.029	10.728		
30°C 65%RH	1,3 Butadiene	B-48374	T2			µg/stick	4	0.260	0.019	7.233		
30°C 65%RH	1,3 Butadiene	B-48374	T4			µg/stick	4	0.370	0.042	11.342		
30°C 65%RH	1,3 Butadiene	B-48374	T6			µg/stick	4	0.239	0.020	8.339		
30°C 65%RH	1,3 Butadiene	B-48374	T9			µg/stick	4	0.261	0.019	7.189		
30°C 65%RH	1,3 Butadiene	B-48374	T12			µg/stick	6	0.260	0.010	3.900		
30°C 65%RH	1,3 Butadiene	B-48374	T16			µg/stick	6	0.390	0.046	11.793		
30°C 65%RH	1,3 Butadiene	B-48374	T20			µg/stick	6	0.332	0.018	5.491		
30°C 65%RH	1,3 Butadiene	B-48374	T24			µg/stick	6	0.270	0.029	10.662		
30°C 65%RH	1,3 Butadiene	B-48375	T0			µg/stick	6	0.275	0.030	11.061		
30°C 65%RH	1,3 Butadiene	B-48375	T2			µg/stick	4	0.280	0.018	6.401		
30°C 65%RH	1,3 Butadiene	B-48375	T4			µg/stick	4	0.361	0.025	6.960		
30°C 65%RH	1,3 Butadiene	B-48375	T6			µg/stick	4	0.242	0.019	8.036		
30°C 65%RH	1,3 Butadiene	B-48375	T9			µg/stick	4	0.236	0.013	5.393		
30°C 65%RH	1,3 Butadiene	B-48375	T12			µg/stick	6	0.295	0.020	6.802		
30°C 65%RH	1,3 Butadiene	B-48375	T16			µg/stick	6	0.386	0.030	7.772		
30°C 65%RH	1,3 Butadiene	B-48375	T20			µg/stick	6	0.355	0.018	4.985		
30°C 65%RH	1,3 Butadiene	B-48375	T24			µg/stick	6	0.277	0.021	7.539		
30°C 65%RH	1,3 Butadiene	B-48376	T0			µg/stick	6	0.262	0.007	2.700		
30°C 65%RH	1,3 Butadiene	B-48376	T2			µg/stick	4	0.302	0.016	5.197		
30°C 65%RH	1,3 Butadiene	B-48376	T4			µg/stick	4	0.367	0.011	3.118		
30°C 65%RH	1,3 Butadiene	B-48376	T6			µg/stick	4	0.269	0.020	7.476		
30°C 65%RH	1,3 Butadiene	B-48376	T9			µg/stick	4	0.271	0.020	7.528		
30°C 65%RH	1,3 Butadiene	B-48376	T12			µg/stick	6	0.299	0.018	5.978		
30°C 65%RH	1,3 Butadiene	B-48376	T16			µg/stick	6	0.408	0.035	8.631		
30°C 65%RH	1,3 Butadiene	B-48376	T20			µg/stick	6	0.344	0.030	8.769		
30°C 65%RH	1,3 Butadiene	B-48376	T24			µg/stick	6	0.278	0.025	8.837		
30°C 65%RH	Acrylamide	B-48374	T0			µg/stick	6	1.968	0.062	3.140		
30°C 65%RH	Acrylamide	B-48374	T2			µg/stick	4	1.701	0.085	5.018		
30°C 65%RH	Acrylamide	B-48374	T4			µg/stick	4	1.433	0.215	15.033		
30°C 65%RH	Acrylamide	B-48374	T6			µg/stick	4	1.748	0.092	5.248		
30°C 65%RH	Acrylamide	B-48374	T9			µg/stick	4	1.598	0.233	14.608		
30°C 65%RH	Acrylamide	B-48374	T12			µg/stick	6	1.456	0.136	9.372		
30°C 65%RH	Acrylamide	B-48374	T16			µg/stick	6	1.013	0.214	21.101		

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CONDITION	VARIABLE	BATCH	Time point	LSL	USL	UNIT	N	Mean	Std	CV	Lower 95%CI	Upper 95%CI
30°C 65%RH	Acrylamide	B-48374	T20			µg/stick	6	0.894	0.095	10.666		
30°C 65%RH	Acrylamide	B-48374	T24			µg/stick	6	0.907	0.111	12.245		
30°C 65%RH	Acrylamide	B-48375	T0			µg/stick	6	1.989	0.162	8.128		
30°C 65%RH	Acrylamide	B-48375	T2			µg/stick	4	1.886	0.143	7.565		
30°C 65%RH	Acrylamide	B-48375	T4			µg/stick	4	1.474	0.164	11.138		
30°C 65%RH	Acrylamide	B-48375	T6			µg/stick	4	1.858	0.114	6.113		
30°C 65%RH	Acrylamide	B-48375	T9			µg/stick	4	1.685	0.161	9.575		
30°C 65%RH	Acrylamide	B-48375	T12			µg/stick	6	1.308	0.117	8.973		
30°C 65%RH	Acrylamide	B-48375	T16			µg/stick	6	1.101	0.101	9.157		
30°C 65%RH	Acrylamide	B-48375	T20			µg/stick	6	0.987	0.038	3.877		
30°C 65%RH	Acrylamide	B-48375	T24			µg/stick	6	0.980	0.093	9.482		
30°C 65%RH	Acrylamide	B-48376	T0			µg/stick	6	2.008	0.105	5.228		
30°C 65%RH	Acrylamide	B-48376	T2			µg/stick	4	1.770	0.051	2.888		
30°C 65%RH	Acrylamide	B-48376	T4			µg/stick	4	1.467	0.220	15.000		
30°C 65%RH	Acrylamide	B-48376	T6			µg/stick	4	1.894	0.114	6.001		
30°C 65%RH	Acrylamide	B-48376	T9			µg/stick	4	1.786	0.122	6.831		
30°C 65%RH	Acrylamide	B-48376	T12			µg/stick	6	1.502	0.066	4.413		
30°C 65%RH	Acrylamide	B-48376	T16			µg/stick	6	1.081	0.193	17.893		
30°C 65%RH	Acrylamide	B-48376	T20			µg/stick	6	0.890	0.060	6.733		
30°C 65%RH	Acrylamide	B-48376	T24			µg/stick	6	1.059	0.045	4.245		
30°C 65%RH	Benzene	B-48374	T0			µg/stick	6	0.592	0.058	9.800		
30°C 65%RH	Benzene	B-48374	T2			µg/stick	4	0.543	0.028	5.176		
30°C 65%RH	Benzene	B-48374	T4			µg/stick	4	0.651	0.093	14.264		
30°C 65%RH	Benzene	B-48374	T6			µg/stick	4	0.557	0.029	5.295		
30°C 65%RH	Benzene	B-48374	T9			µg/stick	4	0.564	0.047	8.252		
30°C 65%RH	Benzene	B-48374	T12			µg/stick	6	0.497	0.039	7.761		
30°C 65%RH	Benzene	B-48374	T16			µg/stick	6	0.552	0.059	10.652		
30°C 65%RH	Benzene	B-48374	T20			µg/stick	6	0.512	0.019	3.622		
30°C 65%RH	Benzene	B-48374	T24			µg/stick	6	0.537	0.043	8.079		
30°C 65%RH	Benzene	B-48375	T0			µg/stick	6	0.595	0.053	8.941		
30°C 65%RH	Benzene	B-48375	T2			µg/stick	4	0.565	0.034	6.102		
30°C 65%RH	Benzene	B-48375	T4			µg/stick	4	0.650	0.055	8.435		
30°C 65%RH	Benzene	B-48375	T6			µg/stick	4	0.581	0.051	8.849		
30°C 65%RH	Benzene	B-48375	T9			µg/stick	4	0.539	0.023	4.274		
30°C 65%RH	Benzene	B-48375	T12			µg/stick	6	0.530	0.026	4.902		

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CONDITION	VARIABLE	BATCH	Time point	LSL	USL	UNIT	N	Mean	Std	CV	Lower 95%CI	Upper 95%CI
30°C 65%RH	Benzene	B-48375	T16			µg/stick	6	0.547	0.037	6.676		
30°C 65%RH	Benzene	B-48375	T20			µg/stick	6	0.552	0.013	2.333		
30°C 65%RH	Benzene	B-48375	T24			µg/stick	6	0.553	0.038	6.877		
30°C 65%RH	Benzene	B-48376	T0			µg/stick	6	0.592	0.029	4.840		
30°C 65%RH	Benzene	B-48376	T2			µg/stick	4	0.604	0.042	6.993		
30°C 65%RH	Benzene	B-48376	T4			µg/stick	4	0.671	0.054	8.118		
30°C 65%RH	Benzene	B-48376	T6			µg/stick	4	0.603	0.043	7.113		
30°C 65%RH	Benzene	B-48376	T9			µg/stick	4	0.608	0.055	8.983		
30°C 65%RH	Benzene	B-48376	T12			µg/stick	6	0.574	0.027	4.768		
30°C 65%RH	Benzene	B-48376	T16			µg/stick	6	0.584	0.039	6.728		
30°C 65%RH	Benzene	B-48376	T20			µg/stick	6	0.533	0.030	5.617		
30°C 65%RH	Benzene	B-48376	T24			µg/stick	6	0.554	0.030	5.445		
30°C 65%RH	Carbon monoxide	B-48374	T0			mg/stick	6	0.506	0.053	10.541		
30°C 65%RH	Carbon monoxide	B-48374	T2			mg/stick	4	0.610	0.042	6.897		
30°C 65%RH	Carbon monoxide	B-48374	T4			mg/stick	4	0.504	0.000	0.000		
30°C 65%RH	Carbon monoxide	B-48374	T6			mg/stick	4	0.486	0.042	8.696		
30°C 65%RH	Carbon monoxide	B-48374	T9	(b) (4)		mg/stick	4	0.399	0.042	10.526	(b) (4)	
30°C 65%RH	Carbon monoxide	B-48374	T12			mg/stick	6	0.425	0.019	4.443		
30°C 65%RH	Carbon monoxide	B-48374	T16			mg/stick	6	0.394	0.012	2.963		
30°C 65%RH	Carbon monoxide	B-48374	T20			mg/stick	6	0.469	0.027	5.748		
30°C 65%RH	Carbon monoxide	B-48374	T24			mg/stick	6	0.468	0.033	7.150		
30°C 65%RH	Carbon monoxide	B-48375	T0			mg/stick	6	0.506	0.075	14.907		
30°C 65%RH	Carbon monoxide	B-48375	T2			mg/stick	4	0.610	0.042	6.897		
30°C 65%RH	Carbon monoxide	B-48375	T4			mg/stick	4	0.462	0.048	10.497		
30°C 65%RH	Carbon monoxide	B-48375	T6			mg/stick	4	0.486	0.042	8.696		
30°C 65%RH	Carbon monoxide	B-48375	T9			mg/stick	4	0.378	0.048	12.830		
30°C 65%RH	Carbon monoxide	B-48375	T12			mg/stick	6	0.408	0.009	2.179		
30°C 65%RH	Carbon monoxide	B-48375	T16			mg/stick	6	0.409	0.007	1.740		
30°C 65%RH	Carbon monoxide	B-48375	T20			mg/stick	6	0.501	0.045	8.961		
30°C 65%RH	Carbon monoxide	B-48375	T24			mg/stick	6	0.450	0.042	9.399		
30°C 65%RH	Carbon monoxide	B-48376	T0			mg/stick	6	0.506	0.053	10.541		

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CONDITION	VARIABLE	BATCH	Time point	LSL	USL	UNIT	N	Mean	Std	CV	Lower 95%CI	Upper 95%CI
30°C 65%RH	Carbon monoxide	B-48376	T2			mg/stick	4	0.568	0.042	7.407		
30°C 65%RH	Carbon monoxide	B-48376	T4			mg/stick	4	0.462	0.048	10.497		
30°C 65%RH	Carbon monoxide	B-48376	T6			mg/stick	4	0.507	0.000	0.000		
30°C 65%RH	Carbon monoxide	B-48376	T9			mg/stick	4	0.399	0.042	10.526		
30°C 65%RH	Carbon monoxide	B-48376	T12			mg/stick	6	0.446	0.018	4.081		
30°C 65%RH	Carbon monoxide	B-48376	T16			mg/stick	6	0.411	0.014	3.515		
30°C 65%RH	Carbon monoxide	B-48376	T20			mg/stick	6	0.497	0.040	8.079		
30°C 65%RH	Carbon monoxide	B-48376	T24			mg/stick	6	0.473	0.010	2.189		
30°C 65%RH	Formaldehyde	B-48374	T0			µg/stick	6	4.663	0.615	13.198		
30°C 65%RH	Formaldehyde	B-48374	T2			µg/stick	4	4.489	0.384	8.565		
30°C 65%RH	Formaldehyde	B-48374	T4			µg/stick	4	4.892	0.923	18.861		
30°C 65%RH	Formaldehyde	B-48374	T6			µg/stick	4	3.510	0.582	16.592		
30°C 65%RH	Formaldehyde	B-48374	T9			µg/stick	4	4.410	0.667	15.113		
30°C 65%RH	Formaldehyde	B-48374	T12			µg/stick	6	4.914	0.338	6.872		
30°C 65%RH	Formaldehyde	B-48374	T16			µg/stick	6	4.055	0.492	12.122		
30°C 65%RH	Formaldehyde	B-48374	T20			µg/stick	6	4.146	0.322	7.776		
30°C 65%RH	Formaldehyde	B-48374	T24			µg/stick	6	4.423	0.634	14.325		
30°C 65%RH	Formaldehyde	B-48375	T0			µg/stick	6	4.167	0.345	8.285		
30°C 65%RH	Formaldehyde	B-48375	T2			µg/stick	4	3.953	0.709	17.940		
30°C 65%RH	Formaldehyde	B-48375	T4			µg/stick	4	4.444	0.419	9.424		
30°C 65%RH	Formaldehyde	B-48375	T6			µg/stick	4	3.663	0.339	9.264		
30°C 65%RH	Formaldehyde	B-48375	T9			µg/stick	4	4.152	0.608	14.635		
30°C 65%RH	Formaldehyde	B-48375	T12			µg/stick	6	4.157	0.659	15.842		
30°C 65%RH	Formaldehyde	B-48375	T16			µg/stick	6	4.037	0.503	12.464		
30°C 65%RH	Formaldehyde	B-48375	T20			µg/stick	6	4.313	0.560	12.985		
30°C 65%RH	Formaldehyde	B-48375	T24			µg/stick	6	4.293	0.587	13.679		
30°C 65%RH	Formaldehyde	B-48376	T0			µg/stick	6	4.105	0.520	12.677		
30°C 65%RH	Formaldehyde	B-48376	T2			µg/stick	4	4.658	0.405	8.703		
30°C 65%RH	Formaldehyde	B-48376	T4			µg/stick	4	4.697	0.590	12.569		
30°C 65%RH	Formaldehyde	B-48376	T6			µg/stick	4	3.723	0.341	9.151		
30°C 65%RH	Formaldehyde	B-48376	T9			µg/stick	4	4.657	0.684	14.686		
30°C 65%RH	Formaldehyde	B-48376	T12			µg/stick	6	4.824	0.429	8.886		
30°C 65%RH	Formaldehyde	B-48376	T16			µg/stick	6	3.997	0.593	14.824		

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CONDITION	VARIABLE	BATCH	Time point	LSL	USL	UNIT	N	Mean	Std	CV	Lower 95%CI	Upper 95%CI
30°C 65%RH	Formaldehyde	B-48376	T20			µg/stick	6	4.291	0.186	4.337		
30°C 65%RH	Formaldehyde	B-48376	T24			µg/stick	6	4.584	0.195	4.249		
30°C 65%RH	Glycerin	B-48374	T0			mg/stick	6	4.949	0.266	5.375		
30°C 65%RH	Glycerin	B-48374	T2			mg/stick	4	4.768	0.442	9.261		
30°C 65%RH	Glycerin	B-48374	T4			mg/stick	4	3.996	0.635	15.889		
30°C 65%RH	Glycerin	B-48374	T6			mg/stick	4	4.863	0.371	7.629		
30°C 65%RH	Glycerin	B-48374	T9			mg/stick	4	4.328	0.588	13.596		
30°C 65%RH	Glycerin	B-48374	T12			mg/stick	6	3.819	0.413	10.818		
30°C 65%RH	Glycerin	B-48374	T16			mg/stick	6	3.269	0.545	16.684		
30°C 65%RH	Glycerin	B-48374	T20			mg/stick	6	3.067	0.287	9.373		
30°C 65%RH	Glycerin	B-48374	T24			mg/stick	6	2.846	0.232	8.140		
30°C 65%RH	Glycerin	B-48375	T0			mg/stick	6	5.144	0.368	7.164		
30°C 65%RH	Glycerin	B-48375	T2			mg/stick	4	5.130	0.334	6.520		
30°C 65%RH	Glycerin	B-48375	T4			mg/stick	4	3.800	0.309	8.123		
30°C 65%RH	Glycerin	B-48375	T6			mg/stick	4	4.782	0.473	9.881		
30°C 65%RH	Glycerin	B-48375	T9			mg/stick	4	4.336	0.132	3.045		
30°C 65%RH	Glycerin	B-48375	T12			mg/stick	6	3.316	0.303	9.128		
30°C 65%RH	Glycerin	B-48375	T16			mg/stick	6	3.406	0.256	7.526		
30°C 65%RH	Glycerin	B-48375	T20			mg/stick	6	3.386	0.157	4.638		
30°C 65%RH	Glycerin	B-48375	T24			mg/stick	6	2.982	0.272	9.132		
30°C 65%RH	Glycerin	B-48376	T0			mg/stick	6	4.830	0.213	4.408		
30°C 65%RH	Glycerin	B-48376	T2			mg/stick	4	4.492	0.265	5.898		
30°C 65%RH	Glycerin	B-48376	T4			mg/stick	4	3.807	0.515	13.536		
30°C 65%RH	Glycerin	B-48376	T6			mg/stick	4	4.895	0.322	6.578		
30°C 65%RH	Glycerin	B-48376	T9			mg/stick	4	4.467	0.239	5.354		
30°C 65%RH	Glycerin	B-48376	T12			mg/stick	6	4.007	0.180	4.483		
30°C 65%RH	Glycerin	B-48376	T16			mg/stick	6	3.403	0.413	12.136		
30°C 65%RH	Glycerin	B-48376	T20			mg/stick	6	3.211	0.218	6.786		
30°C 65%RH	Glycerin	B-48376	T24			mg/stick	6	3.106	0.175	5.622		
30°C 65%RH	Menthol	B-48374	T0			mg/stick	6	2.296	0.077	3.335		
30°C 65%RH	Menthol	B-48374	T2			mg/stick	4	3.429	0.125	3.652		
30°C 65%RH	Menthol	B-48374	T4			mg/stick	4	3.208	0.162	5.055		
30°C 65%RH	Menthol	B-48374	T6			mg/stick	4	3.258	0.103	3.172		
30°C 65%RH	Menthol	B-48374	T9			mg/stick	4	3.364	0.112	3.330		
30°C 65%RH	Menthol	B-48374	T12			mg/stick	6	3.063	0.169	5.532		

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CONDITION	VARIABLE	BATCH	Time point	LSL	USL	UNIT	N	Mean	Std	CV	Lower 95% CI	Upper 95% CI
30°C 65%RH	Menthol	B-48374	T16			mg/stick	6	2.731	0.461	16.871		
30°C 65%RH	Menthol	B-48374	T20			mg/stick	6	2.711	0.168	6.194		
30°C 65%RH	Menthol	B-48374	T24			mg/stick	6	2.667	0.216	8.094		
30°C 65%RH	Menthol	B-48375	T0			mg/stick	6	2.220	0.126	5.653		
30°C 65%RH	Menthol	B-48375	T2			mg/stick	4	3.479	0.110	3.170		
30°C 65%RH	Menthol	B-48375	T4			mg/stick	4	3.234	0.138	4.269		
30°C 65%RH	Menthol	B-48375	T6			mg/stick	4	3.507	0.249	7.087		
30°C 65%RH	Menthol	B-48375	T9			mg/stick	4	3.240	0.024	0.728		
30°C 65%RH	Menthol	B-48375	T12			mg/stick	6	3.089	0.062	1.991		
30°C 65%RH	Menthol	B-48375	T16			mg/stick	6	2.918	0.082	2.812		
30°C 65%RH	Menthol	B-48375	T20			mg/stick	6	2.766	0.059	2.125		
30°C 65%RH	Menthol	B-48375	T24			mg/stick	6	2.668	0.194	7.278		
30°C 65%RH	Menthol	B-48376	T0			mg/stick	6	2.121	0.117	5.497		
30°C 65%RH	Menthol	B-48376	T2			mg/stick	4	3.285	0.055	1.683		
30°C 65%RH	Menthol	B-48376	T4			mg/stick	4	3.162	0.170	5.360		
30°C 65%RH	Menthol	B-48376	T6			mg/stick	4	3.370	0.137	4.051		
30°C 65%RH	Menthol	B-48376	T9			mg/stick	4	3.205	0.094	2.942		
30°C 65%RH	Menthol	B-48376	T12			mg/stick	6	3.014	0.117	3.881		
30°C 65%RH	Menthol	B-48376	T16			mg/stick	6	2.899	0.069	2.381		
30°C 65%RH	Menthol	B-48376	T20			mg/stick	6	2.691	0.071	2.634		
30°C 65%RH	Menthol	B-48376	T24			mg/stick	6	2.647	0.203	7.687		
30°C 65%RH	Nicotine	B-48374	T0			mg/stick	6	1.194	0.032	2.661		
30°C 65%RH	Nicotine	B-48374	T2			mg/stick	4	1.153	0.053	4.554		
30°C 65%RH	Nicotine	B-48374	T4			mg/stick	4	1.039	0.124	11.906		
30°C 65%RH	Nicotine	B-48374	T6			mg/stick	4	1.188	0.055	4.612		
30°C 65%RH	Nicotine	B-48374	T9			mg/stick	4	1.109	0.074	6.630		
30°C 65%RH	Nicotine	B-48374	T12			mg/stick	6	1.104	0.076	6.848		
30°C 65%RH	Nicotine	B-48374	T16			mg/stick	6	0.999	0.137	13.689		
30°C 65%RH	Nicotine	B-48374	T20			mg/stick	6	0.961	0.055	5.713		
30°C 65%RH	Nicotine	B-48374	T24			mg/stick	6	0.988	0.067	6.822		
30°C 65%RH	Nicotine	B-48375	T0			mg/stick	6	1.225	0.042	3.409		
30°C 65%RH	Nicotine	B-48375	T2			mg/stick	4	1.211	0.035	2.891		
30°C 65%RH	Nicotine	B-48375	T4			mg/stick	4	0.964	0.065	6.705		
30°C 65%RH	Nicotine	B-48375	T6			mg/stick	4	1.221	0.065	5.295		
30°C 65%RH	Nicotine	B-48375	T9			mg/stick	4	1.123	0.007	0.619		

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CONDITION	VARIABLE	BATCH	Time point	LSL	USL	UNIT	N	Mean	Std	CV	Lower 95%CI	Upper 95%CI
30°C 65%RH	Nicotine	B-48375	T12			mg/stick	6	1.044	0.018	1.732		
30°C 65%RH	Nicotine	B-48375	T16			mg/stick	6	1.075	0.048	4.419		
30°C 65%RH	Nicotine	B-48375	T20			mg/stick	6	1.028	0.030	2.889		
30°C 65%RH	Nicotine	B-48375	T24			mg/stick	6	1.032	0.065	6.296		
30°C 65%RH	Nicotine	B-48376	T0			mg/stick	6	1.211	0.036	2.935		
30°C 65%RH	Nicotine	B-48376	T2			mg/stick	4	1.133	0.032	2.793		
30°C 65%RH	Nicotine	B-48376	T4			mg/stick	4	0.992	0.149	14.980		
30°C 65%RH	Nicotine	B-48376	T6			mg/stick	4	1.225	0.072	5.841		
30°C 65%RH	Nicotine	B-48376	T9			mg/stick	4	1.149	0.033	2.866		
30°C 65%RH	Nicotine	B-48376	T12			mg/stick	6	1.140	0.033	2.937		
30°C 65%RH	Nicotine	B-48376	T16			mg/stick	6	1.035	0.129	12.508		
30°C 65%RH	Nicotine	B-48376	T20			mg/stick	6	0.967	0.030	3.136		
30°C 65%RH	Nicotine	B-48376	T24			mg/stick	6	1.093	0.024	2.204		
30°C 65%RH	Phenol	B-48374	T0			µg/stick	6	0.868	0.119	13.690		
30°C 65%RH	Phenol	B-48374	T2			µg/stick	4	1.055	0.057	5.380		
30°C 65%RH	Phenol	B-48374	T4			µg/stick	4	0.924	0.195	21.130		
30°C 65%RH	Phenol	B-48374	T6			µg/stick	4	0.920	0.069	7.494		
30°C 65%RH	Phenol	B-48374	T9			µg/stick	4	0.956	0.302	31.648		
30°C 65%RH	Phenol	B-48374	T12			µg/stick	6	0.749	0.160	21.290		
30°C 65%RH	Phenol	B-48374	T16			µg/stick	6	0.641	0.146	22.719		
30°C 65%RH	Phenol	B-48374	T20			µg/stick	6	0.741	0.160	21.584		
30°C 65%RH	Phenol	B-48374	T24			µg/stick	6	0.768	0.144	18.796		
30°C 65%RH	Phenol	B-48375	T0			µg/stick	6	1.054	0.201	19.062		
30°C 65%RH	Phenol	B-48375	T2			µg/stick	4	1.285	0.119	9.250		
30°C 65%RH	Phenol	B-48375	T4			µg/stick	4	0.823	0.145	17.588		
30°C 65%RH	Phenol	B-48375	T6			µg/stick	4	0.920	0.137	14.922		
30°C 65%RH	Phenol	B-48375	T9			µg/stick	4	1.244	0.131	10.499		
30°C 65%RH	Phenol	B-48375	T12			µg/stick	6	0.522	0.079	15.027		
30°C 65%RH	Phenol	B-48375	T16			µg/stick	6	0.803	0.131	16.335		
30°C 65%RH	Phenol	B-48375	T20			µg/stick	6	0.922	0.203	21.999		
30°C 65%RH	Phenol	B-48375	T24			µg/stick	6	0.874	0.128	14.671		
30°C 65%RH	Phenol	B-48376	T0			µg/stick	6	0.993	0.137	13.778		
30°C 65%RH	Phenol	B-48376	T2			µg/stick	4	1.074	0.118	10.942		
30°C 65%RH	Phenol	B-48376	T4			µg/stick	4	0.771	0.166	21.483		
30°C 65%RH	Phenol	B-48376	T6			µg/stick	4	1.096	0.231	21.089		

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CONDITION	VARIABLE	BATCH	Time point	LSL	USL	UNIT	N	Mean	Std	CV	Lower 95% CI	Upper 95% CI
30°C 65%RH	Phenol	B-48376	T9			µg/stick	4	1.084	0.152	14.011		
30°C 65%RH	Phenol	B-48376	T12			µg/stick	6	0.772	0.095	12.292		
30°C 65%RH	Phenol	B-48376	T16			µg/stick	6	0.766	0.160	20.961		
30°C 65%RH	Phenol	B-48376	T20			µg/stick	6	0.925	0.145	15.724		
30°C 65%RH	Phenol	B-48376	T24			µg/stick	6	0.925	0.105	11.380		

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CONDITION	VARIABLE	BATCH	Time point	LSL	USL	USMT	N	Mean	Std	CV	Lower 95%CI	Upper 95%CI
(4)												
30°C 65%RH	Tobacco stick weight	B-48374	T0				mg 50	819.0	11.7	1.43		
30°C 65%RH	Tobacco stick weight	B-48374	T2				mg 50	821.8	10.3	1.25		
30°C 65%RH	Tobacco stick weight	B-48374	T4				mg 50	816.9	8.8	1.08		
30°C 65%RH	Tobacco stick weight	B-48374	T6				mg 50	822.6	10.6	1.29		
30°C 65%RH	Tobacco stick weight	B-48374	T9				mg 50	815.3	9.5	1.17		
30°C 65%RH	Tobacco stick weight	B-48374	T12				mg 50	834.2	13.8	1.66		
30°C 65%RH	Tobacco stick weight	B-48374	T16				mg 50	816.4	12.1	1.48		
30°C 65%RH	Tobacco stick weight	B-48374	T20				mg 50	807.1	9.7	1.20		
30°C 65%RH	Tobacco stick weight	B-48374	T24				mg 50	815.1	11.7	1.44		
30°C 65%RH	Tobacco stick weight	B-48375	T0				mg 50	829.7	8.2	0.99		
30°C 65%RH	Tobacco stick weight	B-48375	T2				mg 50	825.9	17.7	2.14		
30°C 65%RH	Tobacco stick weight	B-48375	T4				mg 50	821.9	10.7	1.31		
30°C 65%RH	Tobacco stick weight	B-48375	T6	(b) (4)			mg 50	825.3	12.1	1.46		(b) (4)
30°C 65%RH	Tobacco stick weight	B-48375	T9				mg 50	821.3	9.5	1.15		
30°C 65%RH	Tobacco stick weight	B-48375	T12				mg 50	830.5	10.3	1.24		
30°C 65%RH	Tobacco stick weight	B-48375	T16				mg 50	824.1	14.5	1.77		
30°C 65%RH	Tobacco stick weight	B-48375	T20				mg 50	817.8	10.6	1.29		
30°C 65%RH	Tobacco stick weight	B-48375	T24				mg 50	825.6	8.3	1.01		
30°C 65%RH	Tobacco stick weight	B-48376	T0				mg 50	817.2	12.2	1.49		
30°C 65%RH	Tobacco stick weight	B-48376	T2				mg 50	829.3	11.1	1.34		
30°C 65%RH	Tobacco stick weight	B-48376	T4				mg 50	826.4	12.0	1.45		
30°C 65%RH	Tobacco stick weight	B-48376	T6				mg 50	830.1	11.5	1.38		
30°C 65%RH	Tobacco stick weight	B-48376	T9				mg 50	832.8	8.1	0.98		
30°C 65%RH	Tobacco stick weight	B-48376	T12				mg 50	829.0	10.2	1.23		
30°C 65%RH	Tobacco stick weight	B-48376	T16				mg 50	820.0	12.0	1.46		
30°C 65%RH	Tobacco stick weight	B-48376	T20				mg 50	793.0	10.2	1.28		
30°C 65%RH	Tobacco stick weight	B-48376	T24				mg 50	825.6	8.3	1.01		

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CONDITION	VARIABLE	BATCH	Time point	LSL	USL	UNIT	N	Mean	Std	CV	Lower 95%CI	Upper 95%CI
30°C 65%RH	Triacetin	B-48374	T0			mg/stick	6	0.599	0.026	4.266		
30°C 65%RH	Triacetin	B-48374	T2			mg/stick	4	0.530	0.020	3.821		
30°C 65%RH	Triacetin	B-48374	T4			mg/stick	4	0.424	0.050	11.688		
30°C 65%RH	Triacetin	B-48374	T6			mg/stick	4	0.444	0.020	4.577		
30°C 65%RH	Triacetin	B-48374	T9			mg/stick	4	0.458	0.039	8.538		
30°C 65%RH	Triacetin	B-48374	T12			mg/stick	6	0.381	0.019	5.018		
30°C 65%RH	Triacetin	B-48374	T16			mg/stick	6	0.317	0.044	13.769		
30°C 65%RH	Triacetin	B-48374	T20			mg/stick	6	0.306	0.015	4.881		
30°C 65%RH	Triacetin	B-48374	T24			mg/stick	6	0.311	0.030	9.642		
30°C 65%RH	Triacetin	B-48375	T0			mg/stick	6	0.603	0.022	3.586		
30°C 65%RH	Triacetin	B-48375	T2			mg/stick	4	0.469	0.019	4.122		
30°C 65%RH	Triacetin	B-48375	T4			mg/stick	4	0.377	0.034	8.882		
30°C 65%RH	Triacetin	B-48375	T6			mg/stick	4	0.361	0.025	6.945		
30°C 65%RH	Triacetin	B-48375	T9			mg/stick	4	0.417	0.024	5.731		
30°C 65%RH	Triacetin	B-48375	T12			mg/stick	6	0.325	0.027	8.251		
30°C 65%RH	Triacetin	B-48375	T16			mg/stick	6	0.301	0.016	5.233		
30°C 65%RH	Triacetin	B-48375	T20			mg/stick	6	0.297	0.015	5.104		
30°C 65%RH	Triacetin	B-48375	T24			mg/stick	6	0.261	0.037	14.027		
30°C 65%RH	Triacetin	B-48376	T0			mg/stick	6	0.552	0.015	2.660		
30°C 65%RH	Triacetin	B-48376	T2			mg/stick	4	0.451	0.007	1.496		
30°C 65%RH	Triacetin	B-48376	T4			mg/stick	4	0.361	0.038	10.529		
30°C 65%RH	Triacetin	B-48376	T6			mg/stick	4	0.394	0.012	3.047		
30°C 65%RH	Triacetin	B-48376	T9			mg/stick	4	0.398	0.022	5.579		
30°C 65%RH	Triacetin	B-48376	T12			mg/stick	6	0.335	0.013	3.875		
30°C 65%RH	Triacetin	B-48376	T16			mg/stick	6	0.288	0.036	12.366		
30°C 65%RH	Triacetin	B-48376	T20			mg/stick	6	0.294	0.011	3.770		
30°C 65%RH	Triacetin	B-48376	T24			mg/stick	6	0.266	0.018	6.600		
30°C 65%RH	Water activity	B-48374	T0			N/A	3	0.430	0.000	0.000		
30°C 65%RH	Water activity	B-48374	T2			N/A	3	0.570	0.000	0.000		
30°C 65%RH	Water activity	B-48374	T4			N/A	3	0.600	0.010	1.667		
30°C 65%RH	Water activity	B-48374	T6			N/A	3	0.630	0.000	0.000		
30°C 65%RH	Water activity	B-48374	T9			N/A	3	0.640	0.000	0.000		
30°C 65%RH	Water activity	B-48374	T12			N/A	3	0.633	0.006	0.912		
30°C 65%RH	Water activity	B-48374	T16			N/A	3	0.650	0.000	0.000		
30°C 65%RH	Water activity	B-48374	T20			N/A	3	0.660	0.000	0.000		

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CONDITION	VARIABLE	BATCH	Time point	LSL	USL	CMT	N	Mean	Std	CV	Lower 95% CI	Upper 95% CI
30°C 65%RH	Water activity	B-48374	T24	(b) (4)	(b) (4)	N/A	3	0.650	0.000	0.000	(b) (4)	(b) (4)
30°C 65%RH	Water activity	B-48375	T0			N/A	3	0.437	0.006	1.322		
30°C 65%RH	Water activity	B-48375	T2			N/A	3	0.560	0.000	0.000		
30°C 65%RH	Water activity	B-48375	T4			N/A	3	0.603	0.006	0.957		
30°C 65%RH	Water activity	B-48375	T6			N/A	3	0.623	0.006	0.926		
30°C 65%RH	Water activity	B-48375	T9			N/A	3	0.640	0.000	0.000		
30°C 65%RH	Water activity	B-48375	T12			N/A	3	0.630	0.000	0.000		
30°C 65%RH	Water activity	B-48375	T16			N/A	3	0.647	0.006	0.893		
30°C 65%RH	Water activity	B-48375	T20			N/A	3	0.650	0.000	0.000		
30°C 65%RH	Water activity	B-48375	T24			N/A	3	0.650	0.000	0.000		
30°C 65%RH	Water activity	B-48376	T0			N/A	3	0.420	0.000	0.000		
30°C 65%RH	Water activity	B-48376	T2			N/A	3	0.567	0.006	1.019		
30°C 65%RH	Water activity	B-48376	T4			N/A	3	0.600	0.000	0.000		
30°C 65%RH	Water activity	B-48376	T6			N/A	3	0.630	0.000	0.000		
30°C 65%RH	Water activity	B-48376	T9			N/A	3	0.640	0.000	0.000		
30°C 65%RH	Water activity	B-48376	T12			N/A	3	0.630	0.000	0.000		
30°C 65%RH	Water activity	B-48376	T16			N/A	3	0.640	0.000	0.000		
30°C 65%RH	Water activity	B-48376	T20			N/A	3	0.660	0.000	0.000		
30°C 65%RH	Water activity	B-48376	T24			N/A	3	0.650	0.000	0.000		

(b) (4)



(b) (4)



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