

QUANTITATIVE ANALYSIS OF NICOTINE IN TOBACCO DERIVED PRODUCTS WITH (b) (4)

TABLE OF CONTENTS

Purpose	3
Applies to	3
General information	3
Principle of the method	3
Method's calibration range, measurement range, and combined measurement uncertainty ..	3
Internal reference documents (available upon request).....	4
Risk assessment and safety instructions	4
Summarized risk assessment	4
Equipment	4
Apparatus	4
(b) (4)-parameters	5
Other equipment and laboratory utensils	6
Chemicals and solvents	6
Check samples	7
Preparation of stock and calibration solutions	7
Preparation of other solutions	8
Sample handling	9
Sample storage and Sample preparation	9
Sample amount	9

Analysis.....	10
Calibration and verification of instrument	10
Sample stability	10
Analysis procedure	10
Documentation	11
Measurement data	11
Collection and storage of measurement data.....	11
Calculations.....	11
Quality assurance	11
If the response in a sample is higher than the highest standard	12
Reporting of analysis results	12
Revision history.....	12
Person responsible.....	13
Validation report	14
Specificity.....	14
Carry-Over	15
Repeatability.....	15
Precision within the laboratory (Kungälv)	15
Accuracy.....	16
Bias from accuracy.....	16
Extraction yield	16
Limit of detection (LOD) and Limit of quantification (LOQ)	16
Linearity	17
Robustness.....	17
Additional validation - (b) (4) analysis	17
Reproducibility.....	18
(b) (4)	18
Measurement range and measurement uncertainty	19
Conclusion.....	19

Purpose

To determine the concentration of nicotine in granulate of tobacco derived products (also referred to as purified products e.g. (b) (4)) with (b) (4)

Applies to

APS and Q-lab Kungälv

General information

Principle of the method

After weighing the sample, the nicotine is extracted into a (b) (4). The extract is then filtered into vials, whereupon the sample preparation is complete. Separation and quantification is performed using (b) (4). The concentration calculations are performed using (b) (4). The capacity of the method and analyst is (b) (4) samples per week. The chemical structure for nicotine is shown in Figure 1.

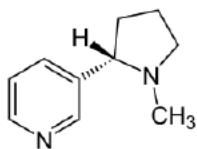


Figure 1. Chemical structural formula for nicotine.

Note: All reference documents and additional information stated “available upon request” are in Swedish. They are available upon request but need to be translated into English first.

Method's calibration range, measurement range, and combined measurement uncertainty

(b) (4)

Table 1. (b) (4)

Analyte	Single sample (%)	Duplicate samples (%)
(b) (4)		

The most significant contributions to measurement uncertainty are from precision within laboratory, calibration curve linearity, and bias from accuracy.

Internal reference documents (available upon request)

(b) (4)

Risk assessment and safety instructions**Summarized risk assessment**

(b) (4)

Equipment**Apparatus**

(b) (4)

Swedish Match.

Quality and
Environmental
Management System

Document Title

**Quantitative Analysis of Nicotine
with (b) (4)**

Owned by Process

Contract Analysis APS

Document Type

Method Description

Valid From

05/07/2017

Page

5(19)

Approved By

(b) (6)

Document Publisher

(b) (6)

(b) (4)

(b) (4)

Other equipment and laboratory utensils

(b) (4)

Chemicals and solvents

(b) (4)

(b) (4)

Check samples

(b) (4)

Preparation of stock and calibration solutions

(b) (4)

Table 3. (b) (4)

(b) (4)

(b) (4)

Preparation of other solutions

(b) (4)

(b) (4)

Sample handling

Sample storage and Sample preparation

(b) (4)

Sample amount

(b) (4)

Analysis

Calibration and verification of instrument

(b) (4)

Sample stability

(b) (4)

Analysis procedure

(b) (4)

(b) (4)

Documentation

(b) (4)

Measurement data

Collection and storage of measurement data

(b) (4)

Calculations

(b) (4)

Quality assurance

(b) (4)

(b) (4)

If the response in a sample is higher than the highest standard

(b) (4)

Reporting of analysis results

(b) (4)

Revision history

06/07/2017

(b) (4)

31/08/2017

(b) (4)

Swedish Match.

Quality and
Environmental
Management System

Document Title

**Quantitative Analysis of Nicotine
with (b) (4)**

Owned by Process

Contract Analysis APS

Document Type

Method Description

Valid From

05/07/2017

Page

13(19)

Approved By

(b) (6)

Document Publisher

(b) (6)

27/09/2017

(b) (4)

10/01/2018

(b) (4)

23/01/2018

(b) (4)

Person responsible

Director APS

Validation report

(b) (4)

Table 4. (b) (4)

(b) (4)

Specificity

(b) (4)

Figure 2. (b) (4)



Figure 3. (b) (4)

Carry-Over

(b) (4)

Repeatability

(b) (4)

Table 5. (b) (4)

The content of Table 5 is entirely redacted with a solid black background. The text "(b) (4)" is printed in large, bold, orange font across the center of the table area.

Precision within the laboratory (Kungälv)

(b) (4)

Accuracy

(b) (4)

Bias from accuracy

(b) (4)

Extraction yield

(b) (4)

Limit of detection (LOD) and Limit of quantification (LOQ)

(b) (4)

Linearity

(b) (4)

Robustness

(b) (4)

Additional validation - (b) (4)

(b) (4)

Swedish Match.

Quality and
Environmental
Management System

Document Title

**Quantitative Analysis of Nicotine
with (b) (4)**

Owned by Process

Contract Analysis APS

Document Type

Method Description

Valid From

05/07/2017

Page

18(19)

Approved By

(b) (6)

Document Publisher

(b) (6)

(b) (4)

Reproducibility

(b) (4)

Additional validation of new (b) (4)

(b) (4)

Swedish Match.

Quality and
Environmental
Management System

Document Title

**Quantitative Analysis of Nicotine
with (b) (4)**

Owned by Process

Contract Analysis APS

Document Type

Method Description

Valid From

05/07/2017

Page

19(19)

Approved By

(b) (6)

Document Publisher

(b) (6)

(b) (4)

Measurement range and measurement uncertainty

(b) (4)

Table 8. (b) (4)

(b) (4)

Conclusion

(b) (4)