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1 MANUFACTURING

1.1 Manufacturing and Testing Sites

1.1.1 ZYN Manufacturing Sites

The manufacturing facilities and their function are listed in Table 1.

Table 1 ZYN Manufacturing Sites

Manufacturing Site	Function
Swedish Match USA, Inc Two James Center 1021 East Cary Street, Suite 1600 Richmond, VA 23219 Contact Person: Gerard J. Roerty, Jr. Vice President, General Counsel & Secretary Two James Center 1021 East Cary Street, Suite 1600 Richmond, VA 23219 Phone: 804-787-5100 Email: gerry.roerty@swedishmatch.com DUNS: (b) (4) FEI: (b) (4)	Sponsor/Applicant
Swedish Match North America LLC 1121 Industrial Drive Owensboro, KY 42301 Contact Person: Tony Martin Vice President, US Supply Chain 1121 Industrial Drive Owensboro, KY 42301 Phone: 334-712-7888 Email: tony.martin@swedishmatch.com DUNS: (b) (4) FEI: (b) (4)	Manufacturing and packaging Storage and distribution

Manufacturing Site	Function
Swedish Match North Europe AB Rollsbovägen 45 SE-442 40 Kungälv, Sweden Contact Person (Manufacturing and packaging): Cecilia Wiksfors Director Supply Chain Kungälv Phone: (b) (6) Email: (b) (6) Contact Person (Storage and distribution) Mikael Brunsten Manager Warehouse Phone: (b) (6) Email: (b) (6) DUNS: (b) (4)	Manufacturing and packaging Storage and distribution

Source: Section H.1.4.1.1 Swedish Match (Owensboro, KY) Facility Information
DUNS=Data Universal Numbering System; FEI=FDA Establishment Identifier.

1.1.2 Nicotine Manufacturer

The nicotine manufacturer is listed in Table 2. (b) (4) was inspected by the Food and Drug Administration (FDA) in June 2019 and received an inspection classification of "no action indicated." Refer to (b) (4) for the FDA inspection letter.

Table 2 Nicotine Manufacturer

Nicotine Manufacturer	Function
(b) (4), (b) (6)	Nicotine manufacture

Source: (b) (4)
DUNS=Data Universal Numbering System; FEI=FDA Establishment Identifier.

1.2 Flavor Suppliers

The manufacturers of the flavors used in the ZYN product are listed in Table 3.

Table 3 Flavor Manufacturers

Flavor Manufacturer	Flavor (Product Code)	Associated ZYN Products (Unique ID KY; SE)
(b) (4), (b) (6)		Cool Mint 3mg (900510; 8105) Cool Mint 6mg (900520; 8106)
		Peppermint 3 mg (901510; 8107) Peppermint 6 mg (901520; 8108)
		Spearmint 3 mg (902510; 8109) Spearmint 6 mg (902520; 8110)
		Wintergreen 3 mg (903510; 8111) Wintergreen 6 mg (903520; 8112)

Flavor Manufacturer	Flavor (Product Code)	Associated ZYN Products (Unique ID KY; SE)
(b) (4), (b) (6)		Coffee 3 mg (904510; 8124) Coffee 6 mg (904520; 8125)
		Cinnamon 3 mg (906510; 8128) Cinnamon 6 mg (906520; 8129)
		Citrus 3 mg (907510; 8122) Citrus 6 mg (907520; 8123)
		Fresh 3 mg (921510; 8140) Fresh 6 mg (921520; 8141)
		Chill 3 mg (920510; 8136) Chill 6 mg (920520; 8137)
		Peppermint 3 mg (901510; 8107) Peppermint 6 mg (901520; 8108)
		Spearmint 3 mg (902510; 8109) Spearmint 6 mg (902520; 8110)

Source: (b) (4)
DUNS=Data Universal Numbering System; FEI=FDA Establishment Identifier; ID=identifier.

1.3 Testing Facilities

The testing facilities and the type of testing performed at each facility are listed in Table 4.

Table 4 Testing Facilities Used for ZYN

Testing Facility	Function	Last Accreditation Assessment/Inspection and Outcome
(b) (4), (b) (6)		

Testing Facility	Function	Last Accreditation Assessment/Inspection and Outcome
(b) (4), (b) (6)		

DUNS=Data Universal Numbering System; FDA=Food and Drug Administration; FEI=FDA Establishment Identifier; HPHC=harmful and potentially harmful constituents; NA=not available.

1.4 ZYN Nicotine Pouch Formulations

The ZYN nicotine pouch product flavors, unique identifiers (IDs), and location of the product formulation tables are listed in Table 5. The formulation of each strength of ZYN across all flavors uses the same ingredients, with the exception of the flavor-specific components. The ingredients common to all flavors of the ZYN finished product (3 mg and 6 mg), their unique IDs, CAS Numbers, and the intended function of each ingredient is presented in Table 17. The amounts of ethanol and water listed in the formulation tables represent residual amounts after the fluid bed granulation and sieving operations.

Table 5 ZYN Finished Product Unique IDs and Formulation Locations

ZYN Product Flavor	Unique ID		Formulation Table
	US	SE	
Cool Mint 3 mg Cool Mint 6 mg	900510 900520	8105 8106	Table 6
Peppermint 3 mg Peppermint 6 mg	901510 901520	8107 8108	Table 7
Spearmint 3 mg Spearmint 6 mg	902510 902520	8109 8110	Table 8
Wintergreen 3 mg Wintergreen 6 mg	903510 903520	8111 8112	Table 9
Citrus 3 mg Citrus 6 mg	907510 907520	8122 8123	Table 10
Coffee 3 mg Coffee 6 mg	904510 904520	8124 8125	Table 11
Cinnamon 3 mg Cinnamon 6 mg	906510 906520	8128 8129	Table 12
Smooth 3 mg Smooth 6 mg	914510 914520	8134 8135	Table 13

ZYN Product Flavor	Unique ID		Formulation Table
	US	SE	
Chill 3 mg Chill 6 mg	920510 920520	8136 8137	Table 14
Fresh 3 mg Fresh 6 mg	921510 921520	8140 8141	Table 15

ID=identifier; SE=Kungälv, Sweden, manufacturing site; US=Owensboro, Kentucky, United States, manufacturing site.

Table 6 ZYN Cool Mint Formulation 3 mg (8105), 6 mg (8106)

Ingredient	Function	Milligrams/Pouch (Range)	
		3 mg	6 mg
Acesulfame K	Sweetener	(b) (4)	
Ethanol	Processing aid		
Hydroxypropyl cellulose[3]	Stabilizer		
Maltitol[1]	Filler		
Microcrystalline cellulose	Filler		
Nicotine bitartrate dihydrate[2]	Other (key ingredient)		
Pouch material	Fiber		
Sodium carbonate[3]	pH adjuster		
Sodium bicarbonate[3]	pH adjuster		
(b) (4)	Processing aid		
	Flavor		

Source: Section H.1.1.1.1 Cool Mint (8105), Section H.1.1.1.2 Cool Mint (8106)

1 The amount added is adjusted to achieve a target pouch weight of 0.4 g.

2 The amount of nicotine bitartrate dihydrate is designed to deliver the target amount (3.0 mg or 6.0 mg) nicotine per pouch.

3 The amount added is adjusted to achieve a target pH of (b) (4)

Table 7 ZYN Nicotine Pouch Peppermint Formulation 3 mg (8107), 6 mg (8108)

Ingredient	Function	Milligrams/Pouch (Range)	
		3 mg	6 mg
Acesulfame K	Sweetener	(b) (4)	
(b) (4)	Processing aid		
Hydroxypropyl cellulose[3]	Stabilizer		
Maltitol[1]	Filler		
Microcrystalline cellulose	Filler		
(b) (4)	Flavor		
Nicotine bitartrate dihydrate[2]	Other (key ingredient)		

Ingredient	Function	Milligrams/Pouch (Range)	
		3 mg	6 mg
Pouch material	Fiber	(b) (4)	
Sodium carbonate[3]	pH adjuster		
Sodium bicarbonate[3]	pH adjuster		
(b) (4)	Processing aid		
	Flavor		

Source: Section H.1.1.1.1 Peppermint (8107), Section H.1.1.1.2 Peppermint (8108)

1 The amount added is adjusted to achieve a target pouch weight of 0.4 g.

2 The amount of nicotine bitartrate dihydrate is designed to deliver the target amount (3.0 mg or 6.0 mg) nicotine per pouch.

3 The amount added is adjusted to achieve a target pH of (b) (4)

Table 8 ZYN Spearmint Formulations 3 mg (8109), 6 mg (8110)

Ingredient	Function	Milligrams/Pouch (Range)	
		3 mg	6 mg
Acesulfame K	Sweetener	(b) (4)	
(b) (4)	Processing aid		
Hydroxypropyl cellulose[3]	Stabilizer		
Maltitol[1]	Filler		
Microcrystalline cellulose	Filler		
(b) (4)	Flavor		
Nicotine bitartrate dihydrate[2]	Other (key ingredient)		
Pouch material	Fiber		
Sodium carbonate[3]	pH adjuster		
Sodium bicarbonate[3]	pH adjuster		
(b) (4)	Processing aid		
	Flavor		

Source: Section H.1.1.1.1 Spearmint (8109), Section H.1.1.1.2 Spearmint (8110)

1 The amount added is adjusted to achieve a target pouch weight of 0.4 g.

2 The amount of nicotine bitartrate dihydrate is designed to deliver the target amount (3.0 mg or 6.0 mg) nicotine per pouch.

3 The amount added is adjusted to achieve a target pH of (b) (4).

Table 9 ZYN Wintergreen Formulations 3 mg (8111), 6 mg (8112)

Ingredient	Function	Milligrams/Pouch (Range)	
		3 mg	6 mg
Acesulfame K	Sweetener	(b) (4)	
Ethanol	Processing aid		
Hydroxypropyl cellulose[3]	Stabilizer		

Ingredient	Function	Milligrams/Pouch (Range)	
		3 mg	6 mg
Maltitol[1]	Filler	(b) (4)	
Microcrystalline cellulose	Filler		
Nicotine bitartrate dihydrate[2]	Other (key ingredient)		
Pouch material	Fiber		
Sodium carbonate[3]	pH adjuster		
Sodium bicarbonate[3]	pH adjuster		
(b) (4)	Processing aid		
	Flavor		

Source: Section H.1.1.1.1 Wintergreen (8111), Section H.1.1.1.2 Wintergreen (8112)

1 The amount added is adjusted to achieve a target pouch weight of 0.4 g.

2 The amount of nicotine bitartrate dihydrate is designed to deliver the target amount (3.0 mg or 6.0 mg) nicotine per pouch.

3 The amount added is adjusted to achieve a target pH of (b) (4)

Table 10 ZYN Citrus Formulations 3 mg (8122), 6 mg (8123)

Ingredient	Function	Milligrams/Pouch (Range)	
		3 mg	6 mg
Acesulfame K	Sweetener	(b) (4)	
(b) (4)	Processing aid		
Hydroxypropyl cellulose[3]	Stabilizer		
Maltitol[1]	Filler		
Microcrystalline cellulose	Filler		
Nicotine bitartrate dihydrate[2]	Other (key ingredient)		
Pouch material	Fiber		
Sodium carbonate[3]	pH adjuster		
Sodium bicarbonate[3]	pH adjuster		
(b) (4)	Processing aid		
	Flavor		

Source: Section H.1.1.1.1 Citrus (8122), Section H.1.1.1.2 Citrus (8123)

1 The amount added is adjusted to achieve a target pouch weight of 0.40 g.

2 The amount of nicotine bitartrate dihydrate is designed to deliver the target amount (3.0 mg or 6.0 mg) of nicotine per pouch

3 The amount added is adjusted to achieve a target pH of (b) (4)

Table 11 ZYN Coffee Formulations 3 mg (8124), 6 mg (8125)

Ingredient	Function	Milligrams/Pouch (Range)	
		3 mg	6 mg
Acesulfame K	Sweetener	(b) (4)	
(b) (4)	Processing aid		
Hydroxypropyl cellulose[3]	Stabilizer		
Maltitol[1]	Filler		
Microcrystalline cellulose	Filler		
Nicotine bitartrate dihydrate[2]	Other (key ingredient)		
Pouch material	Fiber		
Sodium carbonate[3]	pH adjuster		
Sodium bicarbonate[3]	pH adjuster		
(b) (4)	Processing aid		
	Flavor		

Source: Section H.1.1.1.1 Coffee (8124), Section H.1.1.1.2 Coffee (8125)

1 The amount added is adjusted to achieve a target pouch weight of 0.4 g.

2 The amount of nicotine bitartrate dihydrate is designed to deliver the target amount (3.0 mg or 6.0 mg) nicotine per pouch.

3 The amount added is adjusted to achieve a target pH of (b) (4)

Table 12 ZYN Cinnamon Formulations 3 mg (8128), 6 mg (8129)

Ingredient	Function	Milligrams/Pouch (Range)	
		3 mg	6 mg
Acesulfame K	Sweetener	(b) (4)	
(b) (4)	Processing aid		
Hydroxypropyl cellulose[3]	Stabilizer		
Maltitol[1]	Filler		
Microcrystalline cellulose	Filler		
Nicotine bitartrate dihydrate[2]	Other (key ingredient)		
Pouch material	Fiber		
Sodium carbonate[3]	pH adjuster		
Sodium bicarbonate[3]	pH adjuster		
(b) (4)	Processing aid		
	Flavor		

Source: Section H.1.1.1.1 Cinnamon (8128), Section H.1.1.1.2 Cinnamon (8129)

1 The amount added is adjusted to achieve a target pouch weight of 0.4 g.

2 The amount of nicotine bitartrate dihydrate is designed to deliver the target amount (3.0 mg or 6.0 mg) nicotine per pouch.

3 The amount added is adjusted to achieve a target pH of (b) (4)

Table 13 ZYN Smooth Formulations 3 mg (8134), 6 mg (8135)

Ingredient	Function	Milligrams/Pouch (Range)	
		3 mg	6 mg
Acesulfame K	Sweetener	(b) (4)	
(b) (4)	Processing aid		
Hydroxypropyl cellulose[3]	Stabilizer		
Maltitol[1]	Filler		
Microcrystalline cellulose	Filler		
Nicotine bitartrate dihydrate[2]	Other (key ingredient)		
Pouch material	Fiber		
Sodium carbonate[3]	pH adjuster		
Sodium bicarbonate[3]	pH adjuster		
(b) (4)	Processing aid		

Source: Section H.1.1.1.1 Smooth (8134), Section H.1.1.1.2 Smooth (8135)

1 The amount added is adjusted to achieve a target pouch weight of 0.4 g.

2 The amount of nicotine bitartrate dihydrate is designed to deliver the target amount (3.0 mg or 6.0 mg) nicotine per pouch.

3 The amount added is adjusted to achieve a target pH of (b) (4)

Table 14 ZYN Chill Formulations 3 mg (8136), 6 mg (8137)

Ingredient	Function	Milligrams/Pouch (Range)	
		3 mg	6 mg
Acesulfame K	Sweetener	(b) (4)	
(b) (4)	Processing aid		
Hydroxypropyl cellulose[3]	Stabilizer		
Maltitol[1]	Filler		
Microcrystalline cellulose	Filler		
(b) (4)	Flavor		
Nicotine bitartrate dihydrate[2]	Other (key ingredient)		
Pouch material	Fiber		
Sodium carbonate[3]	pH adjuster		
Sodium bicarbonate[3]	pH adjuster		
(b) (4)	Processing aid		

Source: Section H.1.1.1.1 Chill (8136), Section H.1.1.1.2 Chill (8137)

1 The amount added is adjusted to achieve a target pouch weight of 0.4 g.

2 The amount of nicotine bitartrate dihydrate is designed to deliver the target amount (3.0 mg or 6.0 mg) nicotine per pouch.

3 The amount added is adjusted to achieve a target pH of (b) (4)

Table 15 ZYN Fresh Formulations 3 mg (8140), 6 mg (8141)

Ingredient	Function	Milligrams/Pouch (Range)	
		3 mg	6 mg
Acesulfame K	Sweetener	(b) (4)	
(b) (4)	Processing aid		
Hydroxypropyl cellulose[3]	Stabilizer		
Maltitol[1]	Filler		
Microcrystalline cellulose	Filler		
Nicotine bitartrate dihydrate[2]	Other (key ingredient)		
Pouch material	Fiber		
Sodium carbonate[3]	pH adjuster		
Sodium bicarbonate[3]	pH adjuster		
(b) (4)	Processing aid		
	Flavor		

Source: Section H.1.1.1.1 Fresh (8140), Section H.1.1.1.2 Fresh (8141)

1 The amount added is adjusted to achieve a target pouch weight of 0.4 g.

2 The amount of nicotine bitartrate dihydrate is designed to deliver the target amount (3.0 mg or 6.0 mg) nicotine per pouch.

3 The amount added is adjusted to achieve a target pH of (b) (4)

1.5 ZYN Nicotine Pouch Manufacturing

1.5.1 Manufacturing Process and Process Flow Diagram

The manufacturing process for the ZYN product is composed of two processing stages, namely finished powder granulate (FPG) (bulk) processing, and packing of finished product pouches. The same process is used for all flavors of ZYN, as the formulations are similar except for the flavoring components. The FPG production process is described in Section 1.5.1.1, and the pouch packing process is described in Section 1.5.1.1.3.

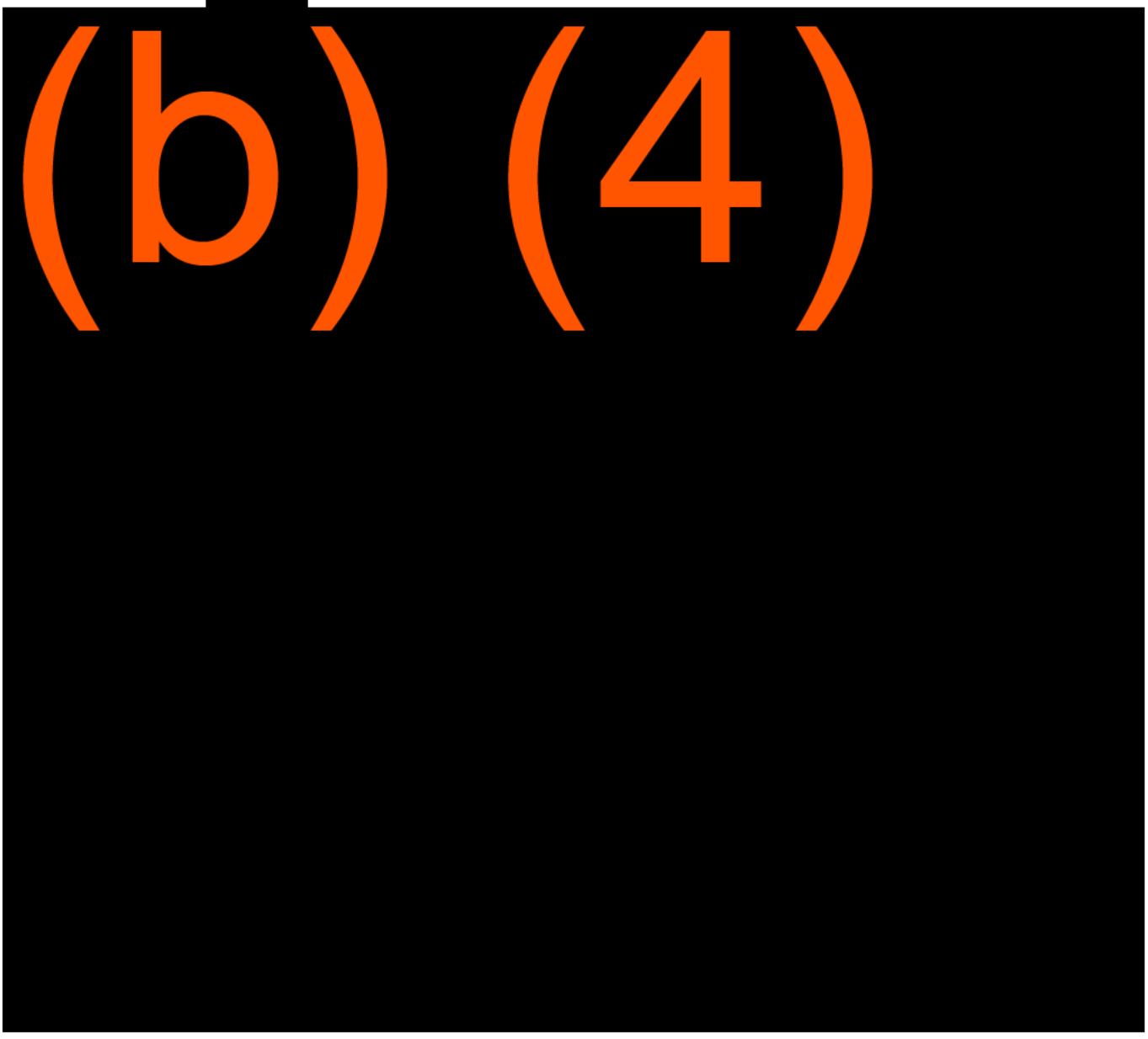
1.5.1.1 Finished Powder Granulate Production

The FPG is produced by batch processing controlled by a manufacturing system. The same FPG may be produced in different batch sizes based on the quantity of FPG needed to meet the requisite order quantity of finished product. Process recipes are formulated to result in an FPG of the same properties, irrespective of batch size. A typical finished batch size is (b) (4) kg.

(b) (4)

(b) (4) A flow diagram of the (b) (4) flow diagram is presented in Figure 1.

Figure 1 (b) (4)



Source: (b) (4)
ID=identification; SM=Swedish Match.

1.5.1.1.1 Granulation Liquid Preparation

(b) (4)

1.5.1.1.2 pH Regulator Preparation

(b) (4)

1.5.1.1.3 Granulation Dispersion Liquid Preparation

(b) (4)

1.5.1.1.4 Charging Powder Preparation

(b) (4)

The charging powder is utilized in the preparation of the FPG.

1.5.1.1.5 Finished Powder Granulate

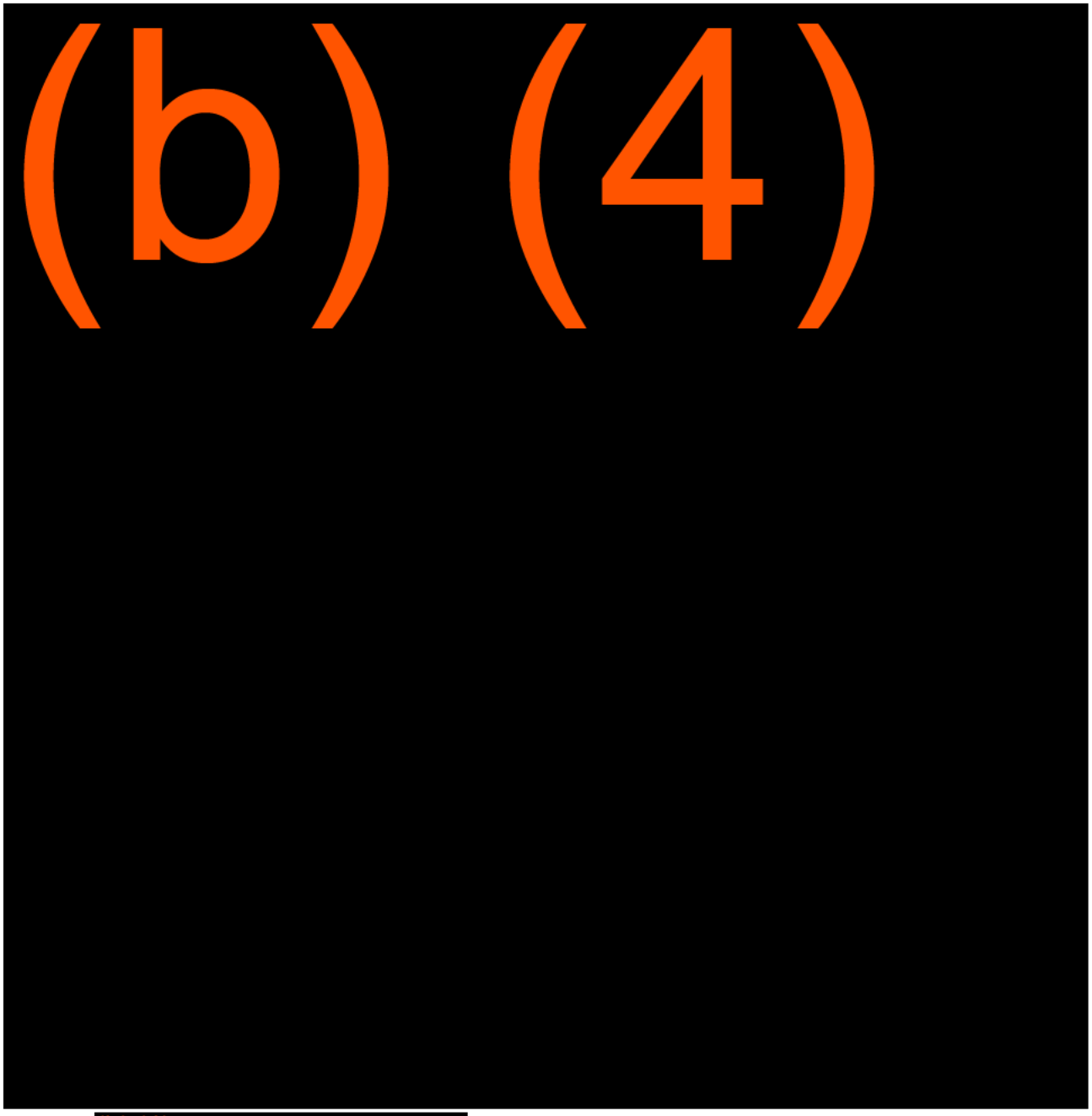
(b) (4)

(b) (4) The FPG is then stored until packaging into pouches.

1.5.1.2 Pouch Packing and Packaging Process

The packing of finished products includes packing of FPG into portion pouches that are packaged into cans, which are considered the primary container. The cans are shrink-wrapped into a five-unit roll as a retail unit, which is considered the secondary container. The rolls are packed into cardboard shipping cases, which are considered the tertiary container, and the cardboard cases are stacked on pallets and stored in a warehouse until shipping. Refer to Section G.4 Product Composition Summary, Section 1.3.1, Section 1.3.2, and Section 1.3.3, for a description of the primary, secondary, and tertiary packaging, respectively. A ZYN packaging final assembly process flow diagram is presented in Figure 2.

Figure 2 Pouch Packing and Packaging Final Assembly Process Flow Diagram



Source: (b) (4)

(b) (4) The filled pouches at this stage are referred to as dry weight pouches, which is the final appearance of ZYN pouch products.

During packing, samples of dry weight pouches are frequently collected and checked for weight, appearance, and seal integrity.

The finished pouches are counted and packed in cans. The cans pass over an in-line weight checker that rejects cans that do not meet the weight tolerances. The approved cans are sealed with a side label, and top and bottom labels are applied. Bottom labels are marked with the batch number and expiry date. The packed cans are wrapped with a plastic shrink wrap as rolls. A roll label is applied, and the rolls are packed in cardboard boxes. Cardboard boxes are stacked on a pallet and transported to a warehouse.

1.5.2 Master Batch Record

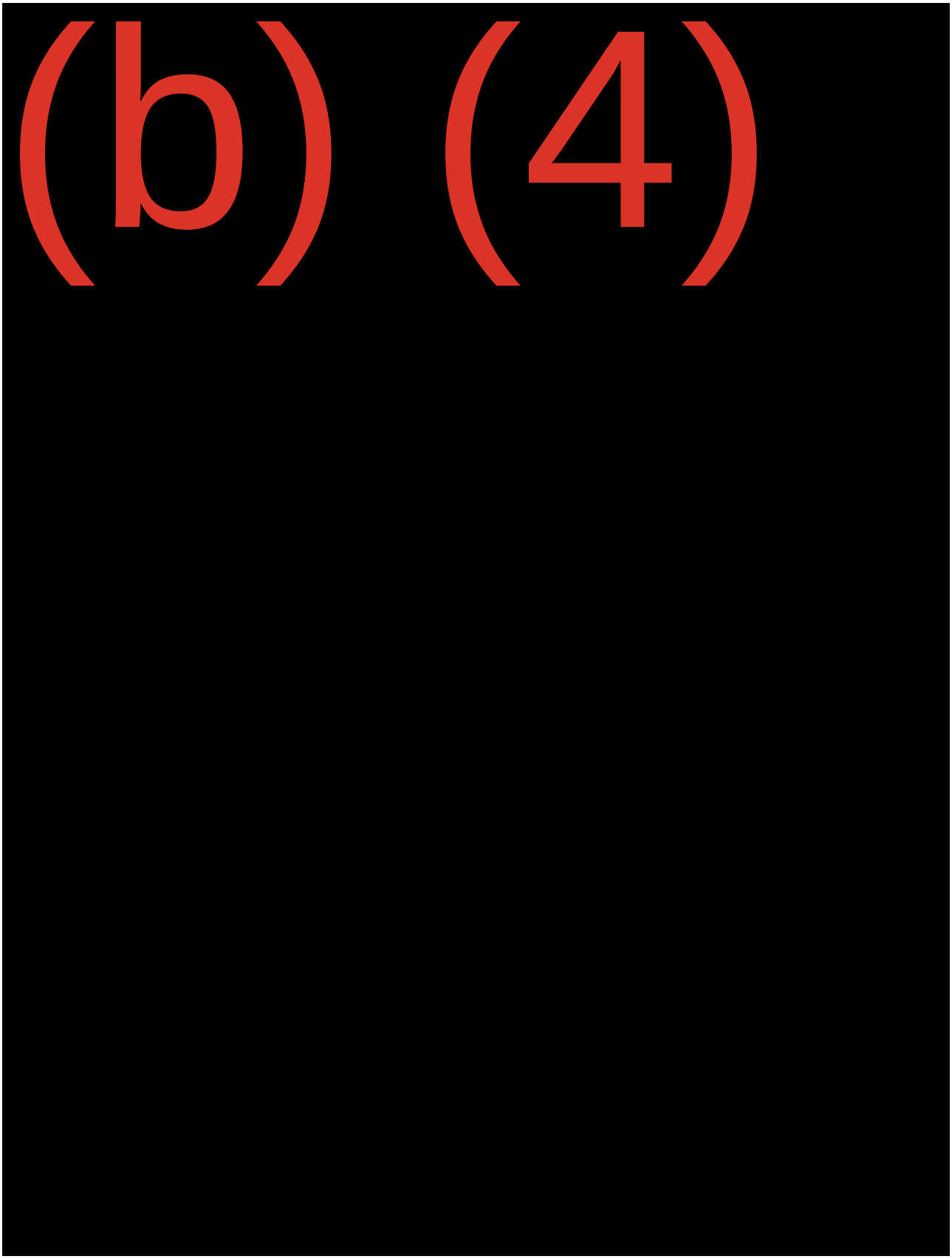
The master batch records for all ZYN products can be found in Section H.1.4.3 Swedish Match Corporate Applicable Procedures.

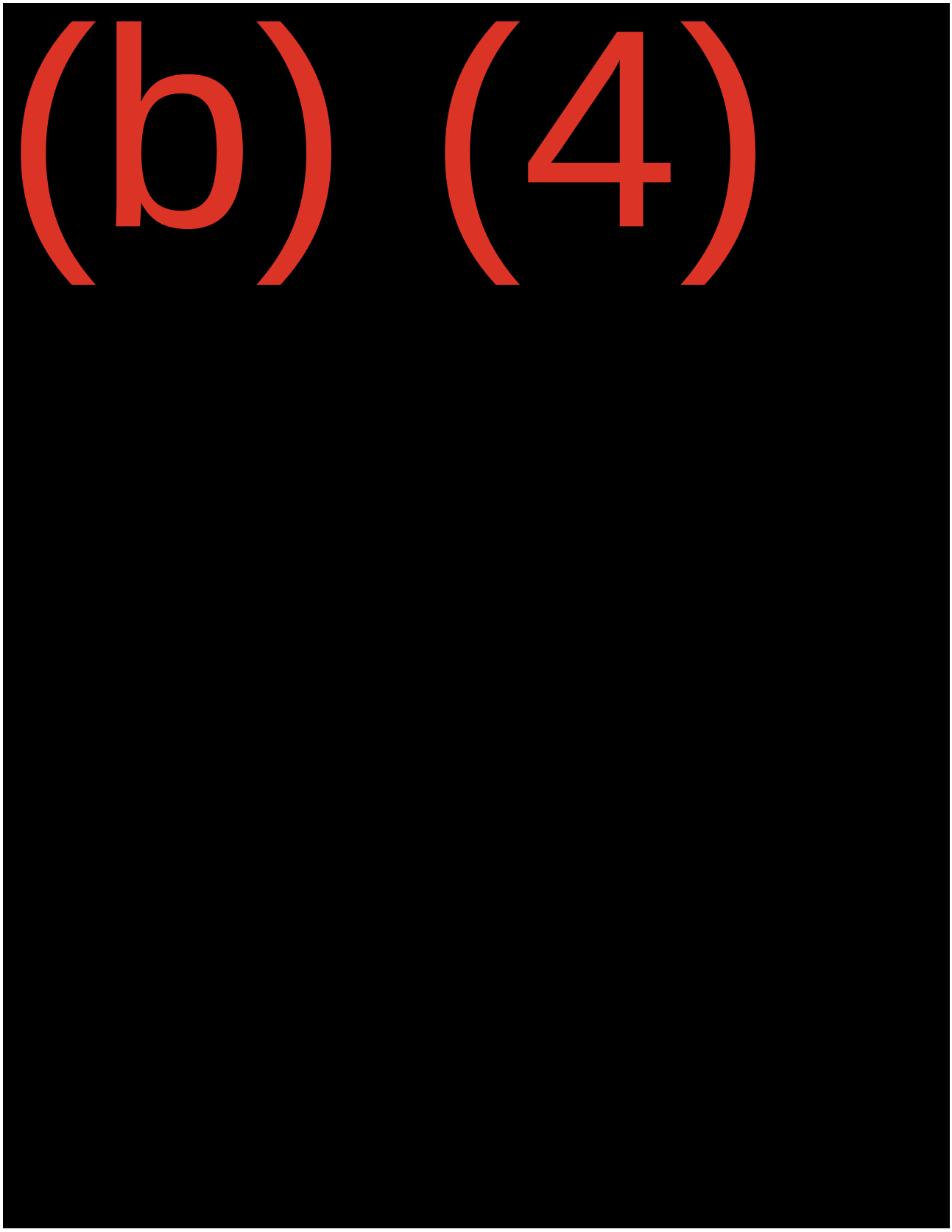
1.5.3 Standard Operating Procedures (Swedish Match)

A summary of key Swedish Match Quality Management System Standard Operating Procedures related to manufacturing and control of ZYN products is presented in Table 16.

Table 16 Summary of Key Swedish Match QMS SOPs

SOP Number	Title	Description
(b) (4)		


(b) (4)


(b) (4)

2 PROPERTIES

2.1 Nicotine Bitartrate Dihydrate

The nicotine bitartrate dihydrate used in all flavors of ZYN products is sourced from (b) (4) has filed a tobacco product master file (TPMF) with the FDA, which was assigned TPMF number (b) (4). A copy of the TPMF letter of authorization (LOA) is located in Section A5 Other, TPMF Letters of Authorization.

While there is no United States Pharmacopeia (USP) monograph for nicotine bitartrate dihydrate, the nicotine bitartrate dihydrate used in the manufacture of ZYN meets the purity criteria of the USP and European Pharmacopoeia. Refer to the TPMF for details regarding the characterization, analytical procedures, specifications, and batch analyses results for Nicotine bitartrate dihydrate used in the ZYN products.

2.2 Function of Nicotine Bitartrate Dihydrate Used in ZYN

The primary reason for using the bitartrate dihydrate salt of nicotine in ZYN is to protect nicotine from evaporation and oxidation during storage. Freebase nicotine is released from the product and then adsorbed by the mucosal membrane of the mouth when the ZYN pouch is wetted by saliva, thus allowing the neutralization reaction between the nicotine salt and the pH regulator.

In contrast, Electronic Nicotine Delivery System (ENDS) products using nicotine salts provide a more efficient transfer of nicotine to the lungs without accumulation in the mouth and throat, thus avoiding irritation. Once the nicotine salt of the ENDS product is delivered to the lungs, a rapid neutralization to freebase nicotine occurs from contact with the pulmonary extravascular space or fluid, which possesses a slightly alkaline pH (ie, higher pH). Refer to Section H.1.2.1 Nicotine Salt Function for complete details regarding the selection of nicotine bitartrate dihydrate salt.

2.3 Ingredients

The common ingredients used in ZYN products (all flavors and strengths) are either food-grade or pharmaceutical grade materials (Table 17) that comply with Swedish Match requirements and compendial requirements, where applicable. Certificates of analysis for the common ingredients will be available upon request.

Table 17 ZYN Finished Product Common Ingredients

Ingredient	Grade	Unique ID	CAS Number	Function
Acesulfame K	Food grade	(b) (4)	(b) (4)	Sweetener
(b) (4)	(b) (4)			Processing aid
Hydroxypropyl cellulose	USP			Stabilizer
Maltitol	Food grade			Filler
Microcrystalline cellulose	(b) (4)			Filler
Nicotine bitartrate dihydrate	USP[a]			Other (key ingredient)

Ingredient	Grade	Unique ID	CAS Number	Function
Pouch material	NA	NA	NA	Fiber
Sodium bicarbonate	Food grade	4108150	144-55-8	pH adjuster
Sodium carbonate	Food grade	4108200	497-19-8	pH adjuster
(b) (4)	(b) (4)	[redacted]	[redacted]	Processing aid

Source: Section H.1.1.1 Pouch Contents
CAS=Chemical Abstracts Service; EP=European Pharmacopoeia; FCC=Food Chemicals Codex; ID=identifier; JP=Japanese Pharmacopoeia; NF=National Formulary; USP=United States Pharmacopeia.
[a] Meets the purity criteria in the nicotine USP monograph.

2.4 Flavor Components

The flavor compounds used in all flavors of ZYN product are food-grade ingredients and comply with Swedish Match requirements and compendial requirements, where applicable. Certificates of analysis for the flavoring compounds will be available upon request.

2.5 ZYN Pouch Material

ZYN pouch material consists of (b) (4) [redacted], and (b) (4) [redacted]. The routine release specifications and analytical procedures used for testing the pouch material are presented in Table 18. Details of the analytical procedures and the testing results are provided in Section 2.5.2 and Section 2.5.3, respectively.

2.5.1 Routine Release Specification and Characterization Requirements

The routine release specifications for the pouch material are presented in Table 18.

Table 18 Pouch Material Characterization

Test Parameter	Unit of Measure	Acceptance Criteria	Analytical Procedure
Basis weight	g/m^2	(b) (4) [redacted]	
Sheet thickness	mm		
Air permeability	$L/m^2/sec$		

Source: Section H.1.2.3.5 Justification of Release Specification and Characterization Testing

2.5.2 Analytical Procedures

2.5.2.1 Summary of Analytical Procedure for Measurement of Pouch Material Basis Weight (b) (4) [redacted]

This test method originated from the European Disposables and Nonwovens Association (EDANA) and measures the mass per unit area of a nonwoven material expressed in grams per square meter (g/m^2). Rolls of the nonwoven material are randomly selected from a lot for lot sampling (Table 19). From each roll or portion of material taken from the lot sample, at least one laboratory sample is cut from the full width of the fabric and 1 m (1 yard) in the machine direction.

Table 19 Lot Sampling for Basis Weight Measurement

Number of Units in the Lot	Number of Units for Lot Sample
1 to 5	All
6 to 99	5
100 to 400	15
Over 400	20

Source: Section H.1.2.3.2 Pouch Material Thickness and Basis Weight

Note: An adequate specification or other agreement between the purchaser and supplier requires taking into account the variability between rolls of nonwoven fabric and between specimens from a swatch from a roll of material to provide a sampling plan with meaningful producer's risk, consumer's risk, acceptable quality level, and limiting quality level.

(b) (4) The mass of each test sample is determined using a balance to an accuracy of at least 0.1% of the mass. The mass per unit area of each sample, the mean value in g/m^2, and the coefficient of variation is calculated and reported, as required. Refer to Section H.1.2.3.2 Pouch Material Thickness and Basis Weight for complete details of this analytical procedure.

2.5.2.2 Summary of Analytical Procedure for Measurement of Pouch Material Thickness (b) (4)

This test method originated from EDANA and measures the distance between the face and back surfaces of the material when under specific pressure. The method is applicable for normal and bulky (thickness >20 mm) nonwovens. The apparent thickness varies inversely with the applied pressure, hence the pressure is specified when reporting any thickness value.

Rolls of the nonwoven material are randomly selected from a lot for lot sampling. Refer to Table 19 for the lot sampling for thickness measurement.

(b) (4) Refer to Section H.1.2.3.2 Pouch Material Thickness and Basis Weight for complete details of this analytical procedure.

2.5.2.3 Summary of Analytical Procedure for Measurement of Pouch Material Air Permeability (b) (4)

This test method originated from EDANA and covers the measurement of the air permeability of nonwoven materials.

Rolls of the nonwoven material are randomly selected from a lot for lot sampling. Refer to Table 19 for lot sampling for pouch material air permeability measurement.

(b) (4)

The air permeability of individual specimens is calculated using values read directly from the test instrument in SI units or any other appropriate unit rounded off to three significant digits. Refer to Section H.1.2.3.2 Pouch Material Air Permeability for complete details of this analytical procedure.

2.5.3 Pouch Material Characterization Results

Three batches of the incoming pouch material were tested using the analytical procedures presented in Table 18. Testing was performed on 10 replicate samples of each batch. The mean and standard deviation of the batch results are presented in Table 20. All batches met the specified acceptance criteria.

Table 20 ZYN Pouch Material Characterization Results

Batch	Basis Weight (g/m^2) (n=10)		Sheet Thickness (mm) (n=10)		Air Permeability (L/m^2/sec) (n=10)	
	Mean	SD	Mean	SD	Mean	SD
(b) (4)						

Source: Section H.1.2.3.4 Pouch Material Characterization
n=number of samples tested per batch; SD=standard deviation.

2.6 ZYN Finished Product

2.6.1 Routine Release Specifications

The finished product specifications for ZYN products are listed in Table 21.

Table 21 Swedish Match ZYN Finished Product Release Specification

Test Parameter	Unit of Measure	Acceptance Criteria Target (Range) 3 mg	Acceptance Criteria Target (Range) 6 mg
(b) (4)			

Source: Section H.1.2.3.1 3 mg, Section H.1.2.3.1 6 mg
NA=not applicable.

2.6.2 Analytical Procedures and Validation Parameters for Finished Product Routine Batch Release

The analytical procedures used for the routine release of the ZYN finished product at the Kungälv and Owensboro testing facilities are presented in Table 22 and Table 23, respectively. The analytical procedures have been fully validated and found to be suitable for the routine release testing of the ZYN products. A brief summary of each analytical procedure and their validation results follows in Section 2.6.2.1 to Section 2.6.2.8.

Table 22 Finished Product Analytical Procedures for Routine Release (Kungälv)

Test	Analytical Procedure
Nicotine content (UHPLC-UV)	(b) (4)
pH (potentiometric method using pH electrode)	
Moisture content (loss on drying)	
Individual pouch weight	
Can content weight	

Source: Section H.1.2.3.5 Justification of Release Specification and Characterization Testing
UHPLC=ultra-high performance liquid chromatography; UV=ultraviolet.

Table 23 Finished Product Analytical Procedures for Routine Release (Owensboro)

Test	Analytical Procedure
Nicotine content	(b) (4)
pH	
Moisture content (halogen)	
Individual pouch weight	
Can content weight	

Source: Section H.1.2.3.5 Justification of Release Specification and Characterization Testing

2.6.2.1 Summary of Analytical Procedure and Validation Parameters - Determination of Nicotine Content in Tobacco-Derived Products by UHPLC-UV (b) (4)

The quantitation of nicotine in Swedish Match ZYN finished products (all flavors and strengths) is accomplished using analytical procedure (b) (4). This analytical procedure employs an

ultra-high performance liquid chromatography (UHPLC) coupled to an ultraviolet (UV) light detector system.

(b) (4) A summary of the key validation results is presented in Table 24. Refer to Section H.1.2.3.2 Nicotine Granulat for complete details of the analytical procedure and its validation.

Table 24 Validation Results - Determination of Nicotine Content in Tobacco-Derived Products by UHPLC-UV (b) (4)

Analyte	Measurement Range (mg/g)	LOQ (mg/g)	RSD_r (%)	RSD_R (%)	Total Relative Measurement Uncertainty (%)[1]
Nicotine	(b) (4)				

Source: Section H.1.2.3.2 Summary of Methods

LOQ=limit of quantification; RSD_r=relative standard deviation under repeatability condition; RSD_R=relative standard deviation under laboratory reproducibility condition; UHPLC=ultra-high performance liquid chromatography; UV=ultraviolet.

[1] A coverage factor of two was used.

2.6.2.2 Summary of Analytical Procedure and Validation Parameters - Determination of Nicotine Content in ZYN Products by UHPLC-DAD (b) (4)

The quantitation of nicotine in Swedish Match ZYN finished products (all flavors and strengths) at the Owensboro facility is accomplished using analytical procedure (b) (4)

The analytical procedure has been fully validated to demonstrate specificity, precision repeatability, precision reproducibility, accuracy, LOD, LOQ, linearity, robustness, and measurement range and uncertainty. A summary of the key validation results is presented in Table 25. Refer to Section H.1.2.3.2 Nicotine (Owensboro) for complete details of the analytical procedure and its validation.

Table 25 Validation Results - Determination of Nicotine Content in ZYN Products by UHPLC-DAD (b) (4)

Analyte	Measurement Range (mg/g)	LOQ (mg/g)	RSD_r (%)	RSD_R (%)	Total Relative Measurement Uncertainty (%)[1]
Nicotine	(b) (4)				

Source: Section H.1.2.3.2 Summary of Methods
DAD=diode array detector; LOQ=limit of quantification; RSD_r=relative standard deviation under repeatability condition; RSD_R=relative standard deviation under laboratory reproducibility condition; UHPLC=ultra high-performance liquid chromatography.
[1] A coverage factor of two was used.

2.6.2.3 Summary of Analytical Procedure and Validation Parameters - Measurement of pH (b) (4)

The pH of Swedish Match ZYN finished products (all flavors and strengths) is measured using a potentiometric method (ie, with a pH electrode) described in analytical procedure (b) (4).

The analytical procedure has been fully validated to demonstrate specificity, precision repeatability, precision reproducibility, robustness, and measurement range and uncertainty. A summary of the key validation results is presented in Table 26. Refer to Section H.1.2.3.2 pH for complete details of the analytical procedure and its validation.

Table 26 Validation Results - Measurement of pH (b) (4)

Test Sample	Measurement Range	LOQ	RSD_r (%)	RSD_R (%)	Total Relative Measurement Uncertainty (%)[1]
Aqueous extract of pouch or loose snus	(b) (4)				

Source: Section H.1.2.3.2 Summary of Methods
LOQ=limit of quantification; NA=not applicable; RSD_r=relative standard deviation under repeatability condition; RSD_R=relative standard deviation under laboratory reproducibility condition.
[1] A coverage factor of two was used.

2.6.2.4 Summary of Analytical Procedure and Validation Parameters - Measurement of pH (b) (4)

The pH of Swedish Match ZYN finished products (all flavors and strengths) is measured using a robotic pH meter. The robot is able to self-calibrate, dilute multiple pre-weighed samples with deionized water, stir, and record pH measurements at prescribed time intervals. The pH robot is outfitted with a glass electrode with a built-in temperature sensor for measurement. A specific amount of sample is mixed with deionized water and the pH is determined through immersion of a pH probe into the sample.

The analytical procedure has been fully validated to demonstrate specificity, precision repeatability, precision reproducibility, robustness, and measurement range and uncertainty. A summary of the key validation results is presented in Table 27. Refer to Section H.1.2.3.2 pH for complete details of the analytical procedure and its validation.

Table 27 Validation Results – Measurement of pH (b) (4)

Test Sample	Measurement Range	LOQ	RSD_r (%)	RSD_R (%)	Total Relative Measurement Uncertainty (%)[1]
Aqueous extract of pouch or loose snus	(b) (4)				

Source: Section H.1.2.3.2 Summary of Methods
LOQ=limit of quantification; RSD_r=relative standard deviation under repeatability condition; RSD_R=relative standard deviation under laboratory reproducibility condition.
[1] A coverage factor of two was used.

2.6.2.5 Summary of Analytical Procedure and Validation Parameters - Moisture Content Measurement (b) (4)

The quantitative determination of dry matter (moisture content) in Swedish Match ZYN finished products (all flavors and strengths) is performed according to analytical procedure (b) (4). This is a method for the determination of moisture content by loss on drying at 105°C±1°C. The total mass loss is taken as the moisture content and is reported as a percentage.

Instructions for using the moisture meters (Halogen Moisture) are provided in (b) (4).

(b) (4)

The analytical procedure has been fully validated to demonstrate specificity, precision repeatability, precision reproducibility, robustness, and measurement uncertainty. A summary of the key validation results is presented in Table 28. Refer to Section H.1.2.3.2 Determination of Dry Matter (Moisture Content) for complete details of the analytical procedure and its validation.

Table 28 Validation Results - Moisture Content Measurement (b) (4)

Test Sample	Measurement Range (%)	LOQ (%)	RSD_r (%)	RSD_R (%)	Total Relative Measurement Uncertainty (%)[1]
Ambient pouch or loose snus	(b) (4)				

Source: Section H.1.2.3.2 Summary of Methods
LOQ=limit of quantification; RSD_r=relative standard deviation under repeatability condition; RSD_R=relative standard deviation under laboratory reproducibility condition.
[1] A coverage factor of two was used.

2.6.2.6 Summary of Analytical Procedure and Validation Parameters - Determination of Moisture by Halogen Moisture Analyzer (b) (4)

The quantitative determination of moisture content in Swedish Match ZYN finished products (all flavors and strengths) is performed according to analytical procedure (b) (4) using a

halogen moisture analyzer. The sample is heated through thermal radiation to quantify the amount of moisture present in the tobacco sample through loss on drying.

(b) (4)

The analytical procedure has been fully validated to demonstrate specificity, precision repeatability, precision reproducibility, robustness, and measurement range and uncertainty. A summary of the key validation results is presented in Table 29. Refer to Section H.1.2.3.2 Moisture by Halogen Moisture Analyzer for complete details of the analytical procedure and its validation.

Table 29 Validation Results - Determination of Moisture by Halogen Moisture Analyzer (b) (4)

Test Sample	Measurement Range (%)	LOQ	RSD_r (%)	RSD_R (%)	Total Relative Measurement Uncertainty (%)[1]
Ambient pouch or loose snus	(b) (4)				

Source: Section H.1.2.3.2 Summary of Methods
LOQ=limit of quantification; RSD_r=relative standard deviation under repeatability condition; RSD_R=relative standard deviation under laboratory reproducibility condition.
[1] A coverage factor of two was used.

2.6.2.7 Summary of Analytical Procedure for Determination of Pouch Weight (b) (4)

The quantitative determination of the pouch weight of the Swedish Match ZYN finished products (all flavors and strengths) is performed according to analytical procedure (b) (4). A set number of pouches is weighed individually, and then the average of this number is calculated. Refer to Section H.1.2.3.2 Pouch Weight (Kungalv) for complete details of the analytical procedure.

2.6.2.8 Summary of Analytical Procedure for Determination of Pouch Weight (b) (4)

The quantitative determination of the pouch weight of the Swedish Match ZYN finished products (all flavors and strengths) is performed according to analytical procedure (b) (4). Determination of the weight of individual ZYN pouches is accomplished by utilization of a Mettler Toledo XS4002S balance (or equivalent). Refer to Section H.1.2.3.2 Pouch Weight (Owensboro) for complete details of the analytical procedure.

2.6.3 Analytical Procedures and Validation Parameters for Finished Product Characterization and Stability

The analytical procedures used for the characterization and stability studies of the Swedish Match ZYN finished products are presented in Table 30 and Table 31. The analytical procedures have been fully validated and found to be suitable for the characterization and stability studies of the ZYN products. A brief summary of the analytical procedures and their validation follows in Section 2.6.3.1 to Section 2.6.3.23, except for analytical procedure (b) (4), which is summarized in Section 2.6.2.5.

Table 30 Finished Product Characterization and Stability Analytical Procedures

Test	Analytical Procedure
Acrylamide (UHPLC-MS/MS)	(b) (4)
Volatile aldehydes (UHPLC-MS/MS)[a]	
Alkaloids (GC-FID)[a]	
Ammonium (DFA)	
Benzo[a]pyrene (UHPLC-FLD)	
Chloride (DFA)	
Coumarin (UHPLC-MS/MS)	
Elements (ICP-MS)	
Ethanol (DFA)	
Ethyl carbamate (UHPLC-MS/MS)	
Humectants and sugars (HPLC-RID)	
Moisture by CORESTA Method 76	
Moisture content (loss on drying)[a]	
Mycotoxins (UHPLC-MS/MS)	
N-nitrosodimethylamine (UHPLC-MS/MS)	
Nicotine related compounds (UHPLC-MS/MS)[a]	
Nitrite/nitrate (SCFA-PD)[a]	
pH (potentiometric method using pH electrode)[a]	
Polyaromatic hydrocarbons and naphthalene (HS-GC-MS/MS)	
Tobacco-specific nitrosamines (UHPLC-MS/MS)[a]	
Water activity (Tunable Diode Laser or Dewpoint)	
TAMC/Total bacterial count (SPC)[a]	
TYMC[a]	
Particle size distribution	

Source: Section H.1.2.3.2 Summary of Methods

DFA=discrete photometric analyzer; GC=gas chromatography; FID=flame ionization detector; FLD=fluorescence detector; HPLC=high-performance liquid chromatography; HS=headspace; ICP=inductively coupled plasma; MS=mass spectrometry; PD=photometric detector; RID=refractive index detector; SCFA=segmented continuous flow analysis; SPC=standard plate count; TAMC=total aerobic microbial count; TYMC=total yeasts and molds count; UHPLC=ultra-high-performance liquid chromatography.

[a] Analytical procedure used for analysis of stability study samples

Table 31 Chemical Analyses Performed by Contract Laboratories

Test	Contract Laboratory
Polonium-210	(b) (4)
Starch and sugars	

Source: Section H.1.2.3.2 Summary of Methods

2.6.3.1 Summary of Analytical Procedure and Validation Parameters - Quantitative Analysis of Acrylamide (b) (4)

The quantitation of acrylamide in Swedish Match ZYN (all flavors and strengths) is accomplished using analytical procedure (b) (4)

Acrylamide is extracted from (b) (4)

The analytical procedure has been fully validated to demonstrate specificity, cross talk, carry over, precision repeatability, precision reproducibility, accuracy, matrix effect, yield (recovery), process efficiency, LOD, LOQ, linearity, robustness, stability, and measurement range and uncertainty. A summary of the key validation results is presented in Table 32. Refer to Section H.1.2.3.2 Acrylamide for complete details of the analytical procedure and its validation.

Table 32 Validation Results - Quantitative Analysis of Acrylamide (b) (4)

Analyte	Measurement Range (ng/g)	LOQ (ng/g)	RSD_r (%)	RSD_R (%)	Total Relative Measurement Uncertainty (%)[1]
Acrylamide	(b) (4)				

Source: Section H.1.2.3.2 Summary of Methods
LOQ=limit of quantification; RSD_r=relative standard deviation under repeatability condition; RSD_R=relative standard deviation under laboratory reproducibility condition.
[1] A coverage factor of two was used.

2.6.3.2 Summary of Analytical Procedure and Validation Parameters - Quantitative Analysis of Volatile Aldehydes (b) (4)

The quantitation of the volatile aldehydes; formaldehyde, acetaldehyde, acrolein, and crotonaldehyde; in Swedish Match ZYN (all flavors and strengths) is accomplished using analytical procedure (b) (4), which is based on CORESTA recommended method number 86 (CRM No. 86), but differs in some aspects (Table 33).

The volatile aldehydes (b) (4)

(b) (4)

Table 33 Differences Between CRM No. 86 and Analytical Procedure (b) (4)

Parameter	CRM No. 86	(b) (4)
Analytes	(b) (4)	
Measurement range		
DNF solution		
Internal standard for crotonaldehyde		

Source: Section H.1.2.3.2 Summary of Methods
CRM No.=CORESTA recommended method number; DNF=2,4-dinitrophenylhydrazine.

The analytical procedure has been fully validated to demonstrate selectivity, cross talk, carry-over, precision repeatability, precision reproducibility, accuracy, LOD, LOQ, linearity, matrix effect, robustness, cross validation, and measurement range and uncertainty. A summary of the key validation results is presented in Table 34. Refer to Section H.1.2.3.2 Aldehydes for complete details of the analytical procedures and their validations.

Table 34 Validation Results - Quantitative Analysis of Aldehydes (b) (4)

Analyte	Measurement Range (µg/g)	LOQ (µg/g)	RSD_r (%)	RSD_R (%)	Total Relative Measurement Uncertainty (%)[1]
Formaldehyde	(b) (4)				
Acetaldehyde					
Crotonaldehyde					
Acrolein					

Source: Section H.1.2.3.2 Summary of Methods
LOQ=limit of quantification; RSD_r=relative standard deviation under repeatability condition; RSD_R=relative standard deviation under laboratory reproducibility condition.
1 A coverage factor of two was used.

2.6.3.3 Summary of Analytical Procedure and Validation Parameters - Quantitative Analysis of Alkaloids (b) (4)

Analytical procedure (b) (4) was developed for the analysis of nicotine, nornicotine, myosmine, anabasine, and anatabine in tobacco, tobacco products, and tobacco-derived products (also called purified products), as well as for determining the level of alkaloids/nicotine in used portion snus. However, in this Premarket Tobacco Application (PMTA) the method was only used for the determination of nicotine. Analytical procedure (b) (4) - Quantitative

Analysis of 7 Nicotine Degradation Products and Alkaloids in Tobacco, Tobacco products, and Tobacco Derived Products with UHPLC-MS/MS, was used for the determination of nornicotine, myosmine, anabasine, and anatabine (Section 2.6.3.16).

(b) (4) is modified from the Federal Register Method and CORESTA Recommended Method No. 62 (CRM No. 62). The differences between CRM No. 62 and (b) (4) are presented in Table 35. The separation and quantitation of each individual alkaloid is accomplished with a gas chromatograph (GC) instrument fitted with a capillary column and flame ionization detector. After the addition of sodium hydroxide to the sample, the alkaloids are extracted using extraction solution of methyl tert-butyl ether containing quinoline as an internal standard.

Table 35 Difference Between CRM No. 62 and (b) (4)

Parameter	CRM No. 62	(b) (4)
Analyte	(b) (4)	
Sample amount		
Sodium hydroxide		
Injection method		
GC column		

Source: Section H.1.2.3.2 Summary of Methods
CRM No.=CORESTA recommended method number; GC=gas chromatography.

The analytical procedure has been fully validated to demonstrate selectivity, precision repeatability, precision reproducibility, accuracy, extraction yield (recovery), LOD, LOQ, linearity, robustness, and measurement range and uncertainty. A summary of the key validation results is presented in Table 36. Refer to Section H.1.2.3.2 Alkaloids for complete details of the analytical procedure and its validation.

Table 36 Validation Results - Quantitative Analysis of Alkaloids (b) (4)

Analyte	Measurement Range (%)	LOQ (%)	RSD_r (%)	RSD_R (%)	Total Relative Measurement Uncertainty (%)[1]
Nicotine	(b) (4)				

Source: Section H.1.2.3.2 Summary of Methods
LOQ=limit of quantification; RSD_r=relative standard deviation under repeatability condition; RSD_R=relative standard deviation under laboratory reproducibility condition.
[1] A coverage factor of two was used.

2.6.3.4 Summary of Analytical Procedure and Validation Parameters - Quantitative Analysis of Ammonium Ions (b) (4)

The quantitative analysis of ammonium ions in Swedish Match ZYN (all flavors and strengths) is accomplished using analytical procedure (b) (4) which uses a discrete photometric analyzer (DFA) for the analysis.

(b) (4)

(b) (4) Refer to (b) (4) for general instructions for analysis using DFA. The analytical procedure has been fully validated to demonstrate specificity, precision repeatability, precision reproducibility, accuracy, recovery, LOD, LOQ, linearity, robustness, and measurement range and uncertainty. A summary of the key validation results is presented in Table 37. Refer to Section H.1.2.3.2 Ammonia for complete details of the analytical procedure and its validation.

Table 37 Validation Results - Quantitative Analysis of Ammonium Ions (b) (4)

Analyte	Measurement Range (mg/g)	LOQ (mg/g)	RSD_r (%)	RSD_R (%)	Total Relative Measurement Uncertainty (%)[1]
Ammonium	(b) (4)				

Source: Section H

LOQ=limit of quantification; RSD_r=relative standard deviation under repeatability condition; RSD_R=relative standard deviation under laboratory reproducibility condition.

[1] A coverage factor of two was used.

2.6.3.5 Summary of Analytical Procedure and Validation Parameters - Quantitative Analysis of Benzo[a]pyrene (b) (4)

The quantitative analysis of benzo[a]pyrene (B[a]P) in Swedish Match ZYN (all flavors and strengths) is accomplished using analytical procedure (b) (4).

(b) (4)

The analytical procedure has been fully validated to demonstrate specificity, precision repeatability, precision reproducibility, accuracy, extraction yield (recovery), LOD, LOQ, linearity, range, robustness, stability, carry-over, and measurement uncertainty. A summary of the key validation results is presented in Table 38. Refer to Section H.1.2.3.2 BaP for complete details of the analytical procedure and its validation.

Table 38 Validation Results - Quantitative Analysis of Benzo[a]pyrene (b) (4)

Analyte	Measurement Range (ng/g)	LOQ (ng/g)	RSD_r (%)	RSD_R (%)	Total Relative Measurement Uncertainty (%)[1]
Benzo[a]pyrene	(b) (4)				

Source: Section H.1.2.3.2 Summary of Methods
LOQ=limit of quantification; RSD_r=relative standard deviation under repeatability condition; RSD_R=relative standard deviation under laboratory reproducibility condition.
[1] A coverage factor of two was used.

2.6.3.6 Summary of Analytical Procedure and Validation Parameters - Quantitative Analysis of Chloride (b) (4)

The quantitative analysis of chloride ions in Swedish Match ZYN (all flavors and strengths) is accomplished using a DFA analytical procedure (b) (4).

(b) (4)

The analytical procedure has been fully validated to demonstrate specificity, precision repeatability, precision reproducibility, accuracy, recovery, LOD, LOQ, linearity, robustness, and measurement range and uncertainty. A summary of the key validation results is presented in Table 39. Refer to Section H.1.2.3.2 Chloride for complete details of the analytical procedure and its validation.

Table 39 Validation Results - Quantitative Analysis of Chloride (b) (4)

Analyte	Measurement Range (mg/g)	LOQ (mg/g)	RSD_r (%)	RSD_R (%)	Total Relative Measurement Uncertainty (%)[1]
Chloride	(b) (4)				

Source: Section H.1.2.3.2 Summary of Methods
LOQ=limit of quantification; RSD_r=relative standard deviation under repeatability condition; RSD_R=relative standard deviation under laboratory reproducibility condition.
[1] A coverage factor of two was used.

2.6.3.7 Summary of Analytical Procedure and Validation Parameters - Quantitative Analysis of Coumarin (b) (4)

The quantitation of coumarin in Swedish Match ZYN (all flavors and strengths) is accomplished using analytical procedure (b) (4) which uses an UHPLC-MS/MS system for analysis.

(b) (4) The analytical procedure has been fully validated to demonstrate specificity/selectivity, cross talk, carry-over, precision repeatability, precision reproducibility, accuracy, matrix effect/process efficiency, recovery, LOD, LOQ, linearity, robustness, and measurement range and uncertainty. A summary of the key validation results is presented in Table 40. Refer to Section H.1.2.3.2 Coumarin for complete details of the analytical procedure and its validation.

Table 40 Validation Results - Quantitative Analysis of Coumarin (b) (4)

Analyte	Measurement Range (µg/g)	LOQ (µg/g)	RSD_r (%)	RSD_R (%)	Total Relative Measurement Uncertainty (%)[1]
Coumarin	(b) (4)				

Source: Section H.1.2.3.2 Summary of Methods
LOQ=limit of quantification; RSD_r=relative standard deviation under repeatability condition; RSD_R=relative standard deviation under laboratory reproducibility condition.
[1] A coverage factor of two was used.

2.6.3.8 Summary of Analytical Procedure and Validation Parameters - Quantitative Analysis of Elements (b) (4)

An inductively coupled plasma mass spectrometry (ICP-MS) method is used to quantitatively determine the concentrations of beryllium (Be), chromium (Cr), nickel (Ni), arsenic (As), selenium (Se), cadmium (Cd), mercury (Hg), lead (Pb), uranium 235 (U-235), and uranium 238 (U-238) in Swedish Match ZYN (all flavors and strengths) (b) (4). This method was developed by Swedish Match and is, in large part, similar to the FDA method: Analysis of Foods for As, Cd, Cr, Hg, and Pb by Inductively Coupled Plasma Mass Spectrometry.

(b) (4) Differences between the FDA method and the in-house method are presented in Table 41.

Table 41 Differences Between FDA Method and (b) (4)

Parameter	FDA Method	(b) (4)
Elements analyzed	Cr, As, Cd, Hg, Pb	Be, Cr, Ni, As, Se, Cd, Hg, Pb, U-235, U-238
Volumes of acid and water during digestion: $H_2O/HNO_3/H_2O_2$	(b) (4)	
Microwave oven program: Ramp time/temperature/digestion time		

Parameter	FDA Method	(b) (4)
Added amount of HCl following digestion/final volume of sample solution	(b) (4)	
Approximate concentration of acid in the finished sample solution: HNO_3/HCl		
Blanks/batch		
Check samples/batch		
Certified reference samples		
Spiked sample (fortified analytical portion)		
Mode of analysis		
Integration times		
Standard curve concentration		
The addition of a carbon effect minimizer to the internal standard		
Internal standard variation limit (in operation) during analysis		

Source: Section H.1.2.3.2 Summary of Methods
Be=beryllium; Cr=chromium; Ni=nickel; As=arsenic; Se=selenium; Cd=cadmium; FDA=Food and Drug Administration; He=helium; Hg=mercury; NA=not applicable; Pb=lead; ppb=parts per billion; U-235=uranium 235; U-238=uranium 238.

The analytical procedure has been fully validated to demonstrate specificity/selectivity, precision repeatability, precision reproducibility, accuracy, recovery, LOD, LOQ, linearity, robustness, and measurement range and uncertainty. A summary of the key validation results is presented in Table 42. Refer to Section H.1.2.3.2 Elements for complete details of the analytical procedure and its validation.

Table 42 Validation Results - Quantitative Analysis of Elements (b) (4)

Analyte	Measurement Range (µg/g)	LOQ (µg/g)	RSD_r (%)	RSD_R (%)	Total Relative Measurement Uncertainty (%)[a]
Arsenic	(b) (4)				
Beryllium					
Cadmium					
Chromium					
Mercury					
Lead					
Nickel					
Selenium					
Uranium-235					
Uranium-238					

Source: Section H.1.2.3.2 Summary of Methods
LOQ=limit of quantification; RSD_r=relative standard deviation under repeatability condition; RSD_R=relative standard deviation under laboratory reproducibility condition.
[a] A coverage factor of two was used.

2.6.3.9 Summary of Analytical Procedure and Validation Parameters - Quantitative Analysis of Ethanol (b) (4)

The quantitative analysis of ethanol in Swedish Match ZYN (all flavors and strengths) is accomplished using a DFA analytical procedure (b) (4).

DFA performs a quick analysis by creating chemical reactions at a microscale level during incubation and then using spectrophotometric detection. Ethanol is extracted from samples using Milli-Q quality water. In the DFA instrument, a NAD^+ solution is added to the extract and a reaction is performed enzymatically using alcohol dehydrogenase (ADH) at 37°C where a reduction of the NAD^+ is achieved.

The absorbance of reduced nicotinamide adenine dinucleotide (NADH) is measured spectrophotometrically at the wavelength of 340 nm and is linear to the ethanol concentration.

$$\text{Ethanol} + NAD^+ \quad \leftarrow \quad \text{ADH} \quad \rightarrow \quad \text{Acetaldehyde} + \text{NADH} + H^+$$

Refer to (b) (4) for general instructions for analysis using DFA.

The analytical procedure has been fully validated to demonstrate specificity, precision repeatability, precision reproducibility, accuracy, recovery, LOD, LOQ, linearity, robustness,

and measurement range and uncertainty. A summary of the key validation results is presented in Table 43. Refer to Section H.1.2.3.2 Ethanol for complete details of the analytical procedure and its validation.

Table 43 Validation Results - Quantitative Analysis of Ethanol (b) (4)

Analyte	Measurement Range (wt%)	LOQ (wt%)	RSD_r (%)	RSD_R (%)	Total Relative Measurement Uncertainty (%)[1]
Ethanol	(b) (4)				

Source: Section H.1.2.3.2 Summary of Methods
LOQ=limit of quantification; RSD_r=relative standard deviation under repeatability condition; RSD_R=relative standard deviation under laboratory reproducibility condition.
[1] A coverage factor of two was used.

2.6.3.10 Summary of Analytical Procedure and Validation Parameters - Quantitative Analysis of Ethyl Carbamate (b) (4)

The quantitation of ethyl carbamate in Swedish Match ZYN (all flavors and strengths) is accomplished using analytical procedure (b) (4)

(b) (4)

The analytical procedure has been fully validated to demonstrate specificity, precision repeatability, precision reproducibility, accuracy, assessment of matrix effects, extraction yield (recovery), LOD, LOQ, linearity, robustness, cross-validation, and measurement range and uncertainty. A summary of the key validation results is presented in Table 44. Refer to Section H.1.2.3.2 Ethyl Carbamate for complete details of the analytical procedures and their validation.

Table 44 Validation Results - Quantitative Analysis of Ethyl Carbamate (b) (4)

Analyte	Measurement Range (ng/g)	LOQ (ng/g)	RSD_r (%)	RSD_R (%)	Total Relative Measurement Uncertainty (%)[1]
Ethyl carbamate	(b) (4)				

Source: Section H.1.2.3.2 Summary of Methods
LOQ=limit of quantification; RSD_r=relative standard deviation under repeatability condition; RSD_R=relative standard deviation under laboratory reproducibility condition.
[1] A coverage factor of two was used.

2.6.3.11 Summary of Analytical Procedure and Validation Parameters - Quantitative Analysis of Humectants and Sugars (b) (4)

The quantification of humectants (glycerol and 1,2-propylene glycol), disaccharides (as the sum of sucrose and maltose), individual monosaccharides (glucose and fructose) and the sugar

alcohol xylitol in Swedish Match ZYN finished product (all flavors and strengths) is accomplished using analytical procedure (b) (4) .

In this PMTA, the method was only used for determination of humectants. An external laboratory, (b) (4), was used to conduct testing for the determination of individual sugars (Section 2.6.3.12).

(b) (4) . The method is a modified CRM No. 61 for humectants. A comparison of the two methods is presented in Table 45.

Table 45 Differences Between CRM 61 and (b) (4)

Parameter	CRM No. 61	(b) (4)
Constituent analytes	Glycerol, 1,2-propylene glycol, sorbitol	Glycerol, 1,2-propylene glycol, disaccharides, glucose, fructose, and xylitol
Measurement range	(b) (4)	
Amount of sample		
Amount of extraction solution		

Source: Section H.1.2.3.2 Summary of Methods
CRM No.=CORESTA recommended method number.

The analytical procedure has been fully validated to demonstrate specificity, precision repeatability, precision reproducibility, accuracy, recovery, LOD, LOQ, linearity, robustness, and measurement uncertainty. A summary of the key validation results is presented in Table 46. Refer to Section H.1.2.3.2 Humectants and Sugar for complete details of the analytical procedure and its validation.

Table 46 Validation Results - Quantitative Analysis of Humectants and Sugars (b) (4)

Analyte	Measurement Range (%)	LOQ (%)	RSD_r (%)	RSD_R (%)	Total Relative Measurement Uncertainty (%)[1]
Glycerol	(b) (4)				
Propylene glycol					

Source: Section H.1.2.3.2 Summary of Methods
LOQ=limit of quantification; RSD_r=relative standard deviation under repeatability condition; RSD_R=relative standard deviation under laboratory reproducibility condition.
[1] A coverage factor of two was used.

2.6.3.12 Summary of Analytical Procedure and Validation Parameters - Determination of Moisture by CORESTA Method 76 (b) (4)

This is a method for the determination of moisture content by loss on drying, and it was only used for the characterization of the comparator products (Section G.5 Nonclinical Evaluation Summary). The analytical procedure determines the moisture in the range of 5% to 60% and is therefore not suitable and not used for the determination of moisture content of the very dry Swedish Match ZYN finished products.

This method is based on the CRM No. 76 and the "Total Moisture Determination" method prescribed by Federal Register (Federal Register volume 74, No. 4). Moisture is determined gravimetrically by taking a given sample quantity and drying at 99°C for three hours. The moisture content is calculated by measuring the weight prior to evaporation of moisture and after drying is complete. This is a non-specific method and what evaporates consists of water and volatile compounds. The differences between the Federal Register Method, CRM No. 76 and (b) (4) are presented in Table 47.

Table 47 Differences Between Federal Register Method, CRM No. 76, and (b) (4)

Equipment/Procedure	Federal Register Method	CRM No. 76	(b) (4)
Sample quantity for analysis	5 g	2 g to 10 g	5 g
Dimensions of sample cups	(b) (4)		

Equipment/Procedure	Federal Register Method	CRM No. 76	(b) (4)
Handling of sample	(b) (4)		

Source: Section H.1.2.3.2 Summary of Methods
CRM No.=CORESTA recommended method number.

The analytical procedure has been fully validated to demonstrate specificity, precision repeatability, precision reproducibility, and measurement range and uncertainty. A summary of the key validation results is presented in Table 48. Refer to Section H.1.2.3.2 Moisture CORESTA (Kungalv) for complete details of the analytical procedure and its validation.

Table 48 Validation Results - Determination of Moisture by CORESTA Method 76 (b) (4)

Test Sample	Measurement Range (%)	LOQ (%)	RSD_r (%)	RSD_R (%)	Total Relative Measurement Uncertainty (%)[1]
Ambient pouch	(b) (4)				

Source: Section H.1.2.3.2 Summary of Methods
LOQ=limit of quantification; RSD_r=relative standard deviation under repeatability condition; RSD_R=relative standard deviation under laboratory reproducibility condition.
[1] A coverage factor of two was used.

2.6.3.13 Summary of Analytical Procedure and Validation Parameters - Quantitative Analysis of Starch and Sugars (b) (4)

An in-house method was developed by (b) (4) for the quantitative analysis of starch and sugars in Swedish Match ZYN finished products (all flavors and strengths). (b) (4)

The analytical procedure has been fully validated to demonstrate specificity, precision repeatability, precision reproducibility, accuracy, recovery, LOD, LOQ, linearity, robustness, and measurement uncertainty. A summary of the key validation results is presented in Table 49. Refer to Section H.1.2.3.2 Humectants and Sugar for complete details of the analytical procedure and its validation.

Table 49 Validation Results – Quantitative Analysis of Starch and Sugars

Analyte	Measurement Range	LOQ	RSD_r (%)	RSD_R (%)	Total Relative Measurement Uncertainty (%)[1]
Starch/sugars	(b) (4)				

					(b) (4)

Source: Section H.1.2.3.2 Summary of Methods
LOQ=limit of quantification; RSD_r=relative standard deviation under repeatability condition; RSD_R=relative standard deviation under laboratory reproducibility condition.
[1] A coverage factor of two was used.

2.6.3.14 Summary of Analytical Procedure and Validation Parameters - Quantitative Analysis of Mycotoxins (b) (4)

The quantitation of the mycotoxins (ochratoxin A, aflatoxin B1, aflatoxin B2, aflatoxin G1, and aflatoxin G2) in Swedish Match ZYN finished product (all flavors and strengths) is accomplished using analytical procedure (b) (4) .

(b) (4)

The analytical procedure has been fully validated to demonstrate specificity/selectivity, cross talk, carry-over, precision repeatability, precision reproducibility, accuracy, recovery, LOD, LOQ, linearity, robustness, assessment of matrix effects, process efficiency, cross-validation, and measurement range and uncertainty. A summary of the key validation results is presented in Table 50. Refer to Section H.1.2.3.2 Mycotoxins for complete details of the analytical procedure.

Table 50 Validation Results - Quantitative Analysis of Mycotoxins (b) (4)

Analyte	Measurement Range (ng/g)	LOQ (ng/g)	RSD_r (%)	RSD_R (%)	Total Relative Measurement Uncertainty (%)[1]
Ochratoxin A	(b) (4)				
Aflatoxin B1					
Aflatoxin B2					
Aflatoxin G1					

Analyte	Measurement Range (ng/g)	LOQ (ng/g)	RSD_r (%)	RSD_R (%)	Total Relative Measurement Uncertainty (%)[1]
Aflatoxin G2	(b) (4)				

Source: Section H.1.2.3.2 Summary of Methods
LOQ=limit of quantification; RSD_r=relative standard deviation under repeatability condition; RSD_R=relative standard deviation under laboratory reproducibility condition.
[1] A coverage factor of two was used.

2.6.3.15 Summary of Analytical Procedure and Validation Parameters - Quantitative Analysis of N-Nitrosodimethylamine (b) (4)

The quantitation of N-nitrosodimethylamine (NDMA) in Swedish Match ZYN finished product (all flavors and strengths) is accomplished using analytical procedure (b) (4).

(b) (4)

The analytical procedure has been fully validated to demonstrate selectivity, cross talk, carry-over, precision repeatability, precision reproducibility, accuracy, LOD, LOQ, linearity, robustness, recovery, stability, matrix effects, process efficiency, cross-validation, and measurement range and uncertainty. A summary of the key validation results is presented in Table 51. Refer to Section H.1.2.3.2 NDMA for complete details of the analytical procedure and their validation.

Table 51 Validation Results - Quantitative Analysis of N-Nitrosodimethylamine (QEMS-7-6862)

Analyte	Measurement Range (ng/g)	LOQ (ng/g)	RSD_r (%)	RSD_R (%)	Total Relative Measurement Uncertainty (%)[1]
NDMA	(b) (4)				

Source: Section H.1.2.3.2 Summary of Methods
LOQ=limit of quantification; NDMA=N-nitrosodimethylamine; RSD_r=relative standard deviation under repeatability condition; RSD_R=relative standard deviation under laboratory reproducibility condition.
[1] A coverage factor of two was used.

2.6.3.16 Summary of Analytical Procedure and Validation Parameters - Quantitative Analysis of Nicotine Degradation Products and Alkaloids (b) (4)

The quantitation of seven alkaloids and nicotine degradation products in Swedish Match ZYN finished product (all flavors and strengths) is accomplished using analytical procedure (b) (4) (b) (4) This is an in-house method designed by Swedish Match for the analysis of three alkaloids

(anabasine, anatabine, and myosmine) and four nicotine degradation products (cotinine, nicotine-N-oxide, nornicotine, and β-nicotyrine).

(b) (4)

he analytical procedures have been fully validated to demonstrate specificity/selectivity, cross talk, carry-over, precision repeatability, precision reproducibility, accuracy, matrix effect, recovery, process efficiency, LOD, LOQ, linearity, robustness, and measurement range and uncertainty. A summary of the key validation results is presented in Table 52. Refer to Section H.1.2.3.2 Nicotine Degradation for complete details of the analytical procedure and its validation.

Table 52 Validation Results - Quantitative Analysis of Nicotine Degradation Products and Alkaloids (b) (4)

Analyte	Measurement Range (µg/g)	LOQ (µg/g)	RSD_r (%)	RSD_R (%)	Total Relative Measurement Uncertainty (%)[1]
Nicotine-N-oxide	(b) (4)				
Nornicotine					
Cotinine					
Anabasine					
Anatabine					
Myosmine					
β-Nicotyrine					

Source: Section H.1.2.3.2 Summary of Methods

LOQ=limit of quantification; RSD_r=relative standard deviation under repeatability condition; RSD_R=relative standard deviation under laboratory reproducibility condition.

[1] A coverage factor of two was used.

2.6.3.17 Summary of Analytical Procedure and Validation Parameters - Quantitative Analysis of Nitrite/Nitrate Ions (b) (4)

The concentration of nitrate and nitrite in Swedish Match ZYN finished product (all flavors and strengths) is determined using segmented continuous flow analysis and photometric detection (b) (4) Nitrite and nitrate are extracted using water. The method has been modified in compliance with ISO standard 13395 (15 July 1996) and CRM No. 36 (January 2015) as presented in Table 53.

Table 53 Differences Between ISO Standard 13395, CRM No. No. 36, and (b) (4)

Parameter	ISO Standard 13395 (15/07/1996)	CRM No. 36 (January 2015)	(b) (4)
Analyte	Nitrite, nitrate	Nitrate	Nitrite, nitrate
Reduction of nitrate to nitrite	Cadmium column	Hydrazinium sulphate	(b) (4)
Buffer solution nitrate	Imidazole pH 7.2-7.4	0.2 M sodium hydroxide	
Gas for segmentation	Nitrogen	Air	
Wavelength detector	520-560 nm	520 nm	
Calibration solution	Sodium nitrite, Potassium nitrate	Potassium nitrate	

Source: Section H.1.2.3.2 Summary of Methods
CRM No.=CORESTA recommended method number; ISO=International Organization for Standardization.

The analytical procedure has been fully validated to demonstrate specificity, precision repeatability, precision reproducibility, accuracy, recovery, LOD, LOQ, linearity, robustness, and measurement range and uncertainty. A summary of the key validation results is presented in Table 54. Refer to Section H.1.2.3.2 Nitrite/Nitrate for complete details of the analytical procedure and its validation.

Table 54 Validation Results – Quantitative Analysis of Nitrite/Nitrate Ions (b) (4)

Analyte	Measurement Range (µg/g)	LOQ (µg/g)	RSD_r (%)	RSD_R (%)	Total Relative Measurement Uncertainty (%)[1]
Nitrite ion	(b) (4)				
Nitrate ion					

Source: Section H.1.2.3.2 Summary of Methods
LOQ=limit of quantification; RSD_r=relative standard deviation under repeatability condition; RSD_R=relative standard deviation under laboratory reproducibility condition.
[1] A coverage factor of two was used.

2.6.3.18 Summary of Analytical Procedure and Validation Parameters - Measurement of pH (b) (4)

The pH of Swedish Match ZYN finished products (all flavors and strengths) is measured using a potentiometric method (ie, with a pH electrode), described in analytical procedure (b) (4) The method is slightly modified from the CRM No. 69 and FDA method (Federal Register, volume 74, No. 4, section 712-719) (Table 55).

A measuring electrode sensitive to hydrogen ions and a reference electrode is immersed in the solution whose pH must be measured. For this method, a combination electrode is used where

the reference electrode is integrated into the measuring electrode. The potential difference between the electrodes is a Nernst function of the hydrogen ion activity in the solution.

Table 55 Difference Between FDA Method, CRM No. 69, and Analytical Procedure (b) (4)

Parameter	FDA Method	CRM No. 69	QEMS-7-7356
Sample amount	2.00 g	2.0±0.1 g	(b) (4)
Stirring	5, 15, 30 minutes depending on whether there is systematic variation	5-30 minutes	
Calibration	2-point	2-point	

Source: Section H.1.2.3.2 Summary of Methods
CRM No.=CORESTA recommended method number; FDA=Food and Drug Administration.

The analytical procedure has been fully validated to demonstrate specificity, precision repeatability, precision reproducibility, robustness, and measurement range and uncertainty. A summary of the key validation results is presented in Table 56. Refer to Section H.1.2.3.2 pH for complete details of the analytical procedure and its validation.

Table 56 Validation Results – Measurement of pH (b) (4)

Test Sample	Measurement Range	LOQ	RSD_r (%)	RSD_R (%)	Total Relative Measurement Uncertainty (%)[1]
Aqueous extract of pouch or loose snus	(b) (4)				

Source: Section H.1.2.3.2 Summary of Methods
LOQ=limit of quantification; NA=not applicable; RSD_r=relative standard deviation under repeatability condition; RSD_R=relative standard deviation under laboratory reproducibility condition.
[1] A coverage factor of two was used.

2.6.3.19 Summary of Analytical Procedure and Validation Parameters - Quantitative Analysis of Polyaromatic Hydrocarbons and Naphthalene (b) (4)

The concentration of 18 polyaromatic hydrocarbons (PAHs) and naphthalene in Swedish Match ZYN finished product (all flavors and strengths) is determined using analytical procedure (b) (4).

This analytical procedure uses GC-MS/MS, headspace gas chromatography coupled to tandem mass spectrometers (HS-GC-MS/MS) for the determination of PAHs. For the single analysis of only B[a]P, a GC-MS is used. It is based on the CRM No. 82. The differences between the two methods are presented in Table 57.

(b) (4)

Table 57 Difference Between CRM No. 82 and (b) (4)

Parameter	CRM No. 82	(b) (4)
Sample	1 g	
Internal standard	50 µL (0.3 ng/mL)	
Extraction	10 mL MeOH; shake for 30 min	
Filtration Centrifugation	0.45 µm filter NA	
SPE	Conditioning 3 mL MeOH Load sample (7-8 mL) Wash 2 mL MeOH:H_2O Wash 2 mL Isopropanol Wash 0.3 mL hexane Elute 3 mL toluene:iso-octane	
Evaporation	3 mL to >300 µL (~20 min)	
GC column	17-MS column	
Injection volume	1 µL	
Use of APs	No	

Source: Section H.1.2.3.2 Summary of Methods
AP=active protectants; CRM No.=CORESTA recommended method number; GC=gas chromatography; H_2O=water; MeOH=methanol; NA=not applicable; SPE=solid phase extraction.

The analytical procedures have been fully validated to demonstrate specificity, precision repeatability, precision reproducibility, accuracy, LOQ, linearity, robustness, and measurement range and uncertainty. A summary of the key validation results is presented in Table 58. Refer to Section H.1.2.3.2 PAHs and Naphthalene for complete details of the analytical procedure and its validation.

Table 58 Validation Results – Quantitative Analysis of Polyaromatic Hydrocarbons and Naphthalene (b) (4)

Analyte	Measurement Range (ng/g)	LOQ (ng/g)	RSD_r (%)	RSD_R (%)	Total Relative Measurement Uncertainty (%)[1]
Benz[j]aceanthrylene	(b) (4)				

Analyte	Measurement Range (ng/g)	LOQ (ng/g)	RSD_r (%)	RSD_R (%)	Total Relative Measurement Uncertainty (%)[1]
Benzo[a]anthracene	(b) (4)				
Benzo[a]pyrene (GC-MS)					
Benzo[a]pyrene (GC-MS/MS)					
Benzo[b]fluoranthene					
Benzo[c]phenanthrene					
Benzo[k]fluoranthene					
Chrysene					
Cyclopenta[c,d]pyrene					
Dibenzo[a,e]pyrene					
Dibenzo[a,h]anthracene					
Dibenzo[a,h]pyrene					
Dibenzo[a,i]pyrene					
Dibenzo[a,l]pyrene					
Indeno[1,2,3-c,d]pyrene					
5-Methylchrysene					
Naphthalene					

Source: Section H.1.2.3.2 Summary of Methods
GC=gas chromatography; LOQ=limit of quantification; MS=mass spectrometry; RSD_r=relative standard deviation under repeatability condition; RSD_R=relative standard deviation under laboratory reproducibility condition.
[1] A coverage factor of 2 was used.

2.6.3.20 Summary of Analytical Procedure and Validation Parameters - Quantitative Analysis of Tobacco-Specific Nitrosamines (b) (4)

The quantitation of tobacco-specific N-nitrosamines (TSNAs), including N-nitrosonornicotine (NNN), N-nitrosoanatabine (NAT), N-nitrosoanabasine (NAB), and 4-(methylnitrosamino)-1-(3-(pyridyl)-1-butanone (NNK) in Swedish Match ZYN finished product (all flavors and strengths) is accomplished using analytical procedure (b) (4). This analytical procedure is based on

the CORESTA Recommended Method No. 72 (CRM No. 72)(b) (4)

Table 59 Difference Between CRM No. 72 and (b) (4)

Parameter	CRM No. 72	(b) (4)
Column	C_{18} 2.1 mm × 50 mm, 2.5 µm particle size	
IS solution	0.300 mL; 2000 ng/mL (manual)	
Extraction	Shaker, 40±5 min	
Filtration	Spray filter, 0.45 µm, PTFE	
LC flow	0.22 mL/min	
Mobile Phase A	Water	
Mobile Phase B	0.1% acetic acid in methanol	
Injection volume	10 µL	
Reporting unit	ng/g	

Source: Section H.1.2.3.2 Summary of Methods
CRM No.=CORESTA recommended method number; IS=internal standard; LC=liquid chromatography; PTFE=polytetrafluoroethylene; rpm=revolutions per minute.

The analytical procedures have been fully validated to demonstrate specificity, cross talk, carry-over, precision repeatability, precision reproducibility, accuracy, assessment of matrix effects, extraction yield (recovery), LOD, LOQ, linearity, robustness, and measurement range and uncertainty. A summary of the key validation results is presented in Table 60. Refer to Section H.1.2.3.2 TSNA for complete details of the analytical procedures and their validations.

Table 60 Validation Results - Quantitative Analysis of Tobacco-specific Nitrosamines (b) (4)

Analyte	Measurement Range (µg/g)	LOQ (µg/g)	RSD_r (%)	RSD_R (%)	Total Relative Measurement Uncertainty (%)[1]
N-nitrosonornicotine	(b) (4)				
N-nitrosoanatabine					
N-nitrosoanabasine					
4-(methylnitrosamino)-1-(3-(pyridyl)-1-butanone					

Analyte	Measurement Range (µg/g)	LOQ (µg/g)	RSD_r (%)	RSD_R (%)	Total Relative Measurement Uncertainty (%)[1]
Total TSNA	(b) (4)				

Source: Section H.1.2.3.2 Summary of Methods
LOQ=limit of quantification; RSD_r=relative standard deviation under repeatability condition; RSD_R=relative standard deviation under laboratory reproducibility condition; TSNA=tobacco-specific N-nitrosamines.
[1] A coverage factor of two was used.

2.6.3.21 Summary of Analytical Procedure and Validation Parameters - Measurement of Water Activity (b) (4)

The water activity (a_w) determination in Swedish Match ZYN finished product (all flavors and strengths) is accomplished using analytical procedure (b) (4). This analytical procedure utilizes either a tunable diode laser instrument or dewpoint instrument to measure the a_w.

(b) (4)

The analytical procedure has been fully validated to demonstrate specificity, precision repeatability, precision reproducibility, accuracy, robustness, and measurement range and uncertainty. A summary of the validation results is presented in Table 61. Refer to Section H.1.2.3.2 Water Activity for complete details of the analytical procedure and its validation.

Table 61 Validation Results - Determination of Water Activity (b) (4)

Analyte	Measurement Range (a_w)	LOQ	RSD_r (%)	RSD_R (%)	Total Relative Measurement Uncertainty (%)[1]
Water activity	(b) (4)				

Source: Section H.1.2.3.2 Summary of Methods
a_w=water activity; LOQ=limit of quantification; NA=not applicable; RSD_r=relative standard deviation under repeatability condition; RSD_R=relative standard deviation under laboratory reproducibility condition.
[1] A coverage factor of two was used.

2.6.3.22 Summary of Analytical Procedure and Validation Parameters - Determination of Total Aerobic Microbial Count/Total Bacterial Count (b) (4)

The Standard Plate Count method is used for determination of total bacterial count in ZYN finished product (all flavors and strengths) using analytical procedure (b) (4).

(b) (4)

Refer to Section H.1.2.3.2 Total Bacteria Count for complete details of the analytical procedure.

2.6.3.23 Summary of Analytical Procedure and Validation Parameters – Determination of Total Yeasts and Molds Count (b) (4)

This is a method to assess growth on a predetermined surface with dipslide.

(b) (4)

2.6.3.24 Summary of Analytical Procedure and Validation Parameters - Determination of Particle Size Distribution (b) (4)

(b) (4)

The method has been validated and the key validation results are presented in Table 62.

Table 62 Validation Results - Particle Size Distribution (b) (4)

Parameters	Results
Relative standard deviation under repeatability conditions	(b) (4)
Relative standard deviation under repeatability conditions	
Relative standard deviation under repeatability conditions	

Source: Section H.1.2.3.2 Summary of Methods

2.6.4 ZYN Batch Analysis

2.6.4.1 ZYN Routine Release Batch Analysis Results

The finished product batch analyses of the Swedish Match ZYN products were performed on samples from batches manufactured over a period. A summary of the batches used for testing for each flavor and strength of the ZYN products is provided in Table 63.

Summaries of the finished product routine batch analysis results for the data set tested for each flavor and strength of the ZYN products, are presented in Table 64 to Table 83.

Table 63 Batch Release Testing Results for Swedish Match ZYN Products

ZYN Product	Unique Product Identification Number	Manufacturing Date Range	Batch Release Data Table[a]
Cool Mint 3 mg	8105	07OCT2019-09OCT2019	Table 64
Cool Mint 6 mg	8106	01OCT2019-16OCT2019	Table 65
Peppermint 3 mg	8107	24SEP2019-13DEC2019	Table 66
Peppermint 6 mg	8108	07OCT2019-15OCT2019	Table 67
Spearmint 3 mg	8109	04SEP2019-21OCT2019	Table 68
Spearmint 6 mg	8110	10SEP2019-22OCT2019	Table 69
Wintergreen 3 mg	8111	(05SEP2019-30DEC2019	Table 70
Wintergreen 6 mg	8112	13SEP2019-30OCT2019	Table 71
Citrus 3 mg	8122	16SEP2019-20DEC2019	Table 72
Citrus 6 mg	8123	18SEP2019-20DEC2019	Table 73
Coffee 3 mg	8124	16OCT2019-17DEC2019	Table 74
Coffee 6 mg	8125	01JUL2019-20DEC2019	Table 75
Cinnamon 3 mg	8128	01JUL2019-07OCT2019	Table 76
Cinnamon 6 mg	8129	02JUL2019-07OCT2019	Table 77
Smooth 3 mg	8134	11JUL2019-26DEC2019	Table 78
Smooth 6 mg	8135	26AUG2019-26DEC2019	Table 79
Chill 3 mg	8136	28AUG2019-30SEP2019	Table 80
Chill 6 mg	8137	29AUG2019-30SEP2019	Table 81
Fresh 3 mg	8140	11OCT2019-21OCT2019	Table 82
Fresh 6 mg	8141	11OCT2019-21OCT2019	Table 83

[a] Data set summary of three batches.

Table 64 ZYN Cool Mint 3 mg (8105) Routine Release Results

Test	Acceptance Criteria Target (Range)	Batch Average (Standard Deviation)
Moisture (%; n=4/batch)	(b) (4)	(b) (4)
pH (n=4/batch)		
Nicotine (% as is; n=4/batch)		
Pouch weight (g; n=20/batch)		
Net can weight (g)		

Source: Section H.1.2.3.4.1 Cool Mint (8105) Routine Release Results, Certificate of Analysis
n=number of samples.

Table 65 ZYN Cool Mint 6 mg (8106) Routine Release Results

Test	Acceptance Criteria Target (Range)	Batch Average (Standard Deviation) (b) (4) [redacted] [redacted]
Moisture (%; n=4/batch)	(b) (4)	
pH (n=4/batch)		
Nicotine (% as is; n=4/batch)		
Pouch weight (g; n=20/batch)		
Net can weight (g)		

Source: Section H.1.2.3.4.2 Cool Mint (8106) Routine Release Results, Certificate of Analysis
n=number of samples.

Table 66 ZYN Peppermint 3 mg (8107) Routine Release Results

Test	Acceptance Criteria Target (Range)	Batch Average (Standard Deviation) (b) (4) [redacted] [redacted]
Moisture (%; n=4/batch)	(b) (4)	
pH (n=4/batch)		
Nicotine (% as is; n=4/batch)		
Pouch weight (g; n=20/batch)		
Net can weight (g)		

Source: Section H.1.2.3.4.1 Peppermint (8107) Routine Release Results, Certificate of Analysis
n=number of samples.

Table 67 ZYN Peppermint 6 mg (8108) Routine Release Results

Test	Acceptance Criteria Target (Range)	Batch Average (Standard Deviation) (b) (4) [redacted] [redacted]
Moisture (%; n=4/batch)	(b) (4)	
pH (n=4/batch)		
Nicotine (% as is; n=4/batch)		
Pouch weight (g; n=20/batch)		
Net can weight (g)		

Source: Section H.1.2.3.4.2 Peppermint (8108) Routine Release Results, Certificate of Analysis
n=number of samples.

Table 68 ZYN Spearmint 3 mg (8109) Routine Release Results

Test	Acceptance Criteria Target (Range)	Batch Average (Standard Deviation) (b) (4) [redacted] [redacted]
Moisture (%; n=4/batch)	(b) (4)	
pH (n=4/batch)		
Nicotine (% as is; n=4/batch)		
Pouch weight (g; n=20/batch)		

Test	Acceptance Criteria Target (Range)	Batch Average (Standard Deviation)
		(b) (4)
Net can weight (g)	(b) (4)	

Source: Section H.1.2.3.4.1 Spearmint (8109) Routine Release Results, Certificate of Analysis
n=number of samples.

Table 69 ZYN Spearmint 6 mg (8110) Routine Release Results

Test	Acceptance Criteria Target (Range)	Batch Average (Standard Deviation)
		(b) (4)
Moisture (%; n=4/batch)	(b) (4)	
pH (n=4/batch)		
Nicotine (% as is; n=4/batch)		
Pouch weight (g; n=20/batch)		
Net can weight (g)		

Source: Section H.1.2.3.4.2 Spearmint (8110) Routine Release Results, Certificate of Analysis
n=number of samples.

Table 70 ZYN Wintergreen 3 mg (8111) Routine Release Results

Test	Acceptance Criteria Target (Range)	Batch Average (Standard Deviation)
		(b) (4)
Moisture (%; n=4/batch)	(b) (4)	
pH (n=4/batch)		
Nicotine (% as is; n=4/batch)		
Pouch weight (g; n=20/batch)		
Net can weight (g)		

Source: Section H.1.2.3.4.1 Wintergreen (8111) Routine Release Results, Certificate of Analysis
n=number of samples.

Table 71 ZYN Wintergreen 6 mg (8112) Routine Release Results

Test	Acceptance Criteria Target (Range)	Batch Average (Standard Deviation)
		(b) (4)
Moisture (%; n=4/batch)	(b) (4)	
pH (n=4/batch)		
Nicotine (% as is; n=4/batch)		
Pouch weight (g; n=20/batch)		
Net can weight (g)		

Source: Section H.1.2.3.4.2 Wintergreen (8112) Routine Release Results, Certificate of Analysis
n=number of samples.

Table 72 ZYN Citrus 3 mg (8122) Routine Release Results

Test	Acceptance Criteria Target (Range)	Batch Average (Standard Deviation)
Moisture (%; n=4/batch)	(b) (4)	[redacted]
pH (n=4/batch)		
Nicotine (% as is; n=4/batch)		
Pouch weight (g; n=20/batch)		
Net can weight (g)		

Source: Section H.1.2.3.4.1 Citrus (8122) Routine Release Results, Certificate of Analysis
n=number of samples.

Table 73 ZYN Citrus 6 mg (8123) Routine Release Results

Test	Acceptance Criteria Target (Range)	Batch Average (Standard Deviation)
Moisture (%; n=4/batch)	(b) (4)	[redacted]
pH (n=4/batch)		
Nicotine (% as is; n=4/batch)		
Pouch weight (g; n=20/batch)		
Net can weight (g)		

Source: Section H.1.2.3.4.2 Citrus (8123) Routine Release Results Certificate of Analysis
n=number of samples.

Table 74 ZYN Coffee 3 mg (8124) Routine Release Results

Test	Acceptance Criteria Target (Range)	Batch Average (Standard Deviation)
Moisture (%; n=4/batch)	(b) (4)	[redacted]
pH (n=4/batch)		
Nicotine (% as is; n=4/batch)		
Pouch weight (g; n=20/batch)		
Net can weight (g)		

Source: Section H.1.2.3.4.1 Coffee (8124) Routine Release Results, Certificate of Analysis
n=number of samples.

Table 75 ZYN Coffee 6 mg (8125) Routine Release Results

Test	Acceptance Criteria Target (Range)	Batch Average (Standard Deviation)
Moisture (%; n=4/batch)	(b) (4)	[redacted]
pH (n=4/batch)		
Nicotine (% as is; n=4/batch)		
Pouch weight (g; n=20/batch)		

Test	Acceptance Criteria Target (Range)	Batch Average (Standard Deviation)		
		(b) (4)		
Net can weight (g)	(b) (4)			

Source: Section H.1.2.3.4.2 Coffee (8125) Routine Release Results, Certificate of Analysis
n=number of samples.

Table 76 ZYN Cinnamon 3 mg (8128) Routine Release Results

Test	Acceptance Criteria Target (Range)	Batch Average (Standard Deviation)		
		(b) (4)		
Moisture (%; n=4/batch)	(b) (4)			
pH (n=4/batch)				
Nicotine (% as is; n=4/batch)				
Pouch weight (g; n=20/batch)				
Net can weight (g)				

Source: Section H.1.2.3.4.1 Cinnamon (8128) Routine Release Results, Certificate of Analysis
n=number of samples.

Table 77 ZYN Cinnamon 6 mg (8129) Routine Release Results

Test	Acceptance Criteria Target (Range)	Batch Average (Standard Deviation)		
		(b) (4)		
Moisture (%; n=4/batch)	(b) (4)			
pH (n=4/batch)				
Nicotine (% as is; n=4/batch)				
Pouch weight (g; n=20/batch)				
Net can weight (g)				

Source: Section H.1.2.3.4.2 Cinnamon (8129) Routine Release Results, Certificate of Analysis
n=number of samples.

Table 78 ZYN Smooth 3 mg (8134) Routine Release Results

Test	Acceptance Criteria Target (Range)	Batch Average (Standard Deviation)		
		(b) (4)		
Moisture (%; n=4/batch)	(b) (4)			
pH (n=4/batch)				
Nicotine (% as is; n=4/batch)				
Pouch weight (g; n=20/batch)				
Net can weight (g)				

Source: Section H.1.2.3.4.1 Smooth (8134) Routine Release Results, Certificate of Analysis
n=number of samples.

Table 79 ZYN Smooth 6 mg (8135) Routine Release Results

Test	Acceptance Criteria Target (Range)	Batch Average (Standard Deviation)
		(b) (4)
Moisture (%; n=4/batch)	(b) (4)	
pH (n=4/batch)		
Nicotine (% as is; n=4/batch)		
Pouch weight (g; n=20/batch)		
Net can weight (g)		

Source: Section H.1.2.3.4.2 Smooth (8135) Routine Release Results, Certificate of Analysis
n=number of samples.

Table 80 ZYN Chill 3 mg (8136) Routine Release Results

Test	Acceptance Criteria Target (Range)	Batch Average (Standard Deviation)
		(b) (4)
Moisture (%; n=4/batch)	(b) (4)	
pH (n=4/batch)		
Nicotine (% as is; n=4/batch)		
Pouch weight (g; n=20/batch)		
Net can weight (g)		

Source: Section H.1.2.3.4.1 Chill (8136) Routine Release Results, Certificate of Analysis
n=number of samples.

Table 81 ZYN Chill 6 mg (8137) Routine Release Results

Test	Acceptance Criteria Target (Range)	Batch Average (Standard Deviation)
		(b) (4)
Moisture (%; n=4/batch)	(b) (4)	
pH (n=4/batch)		
Nicotine (% as is; n=4/batch)		
Pouch weight (g; n=20/batch)		
Net can weight (g)		

Source: Section H.1.2.3.4.2 Chill (8137) Routine Release Results, Certificate of Analysis
n=number of samples.

Table 82 ZYN Fresh 3 mg (8140) Routine Release Results

Test	Acceptance Criteria Target (Range)	Batch Average (Standard Deviation)
		(b) (4)
Moisture (%; n=4/batch)	(b) (4)	
pH (n=4/batch)		
Nicotine (% as is; n=4/batch)		
Pouch weight (g; n=20/batch)		

Test	Acceptance Criteria Target (Range)	Batch Average (Standard Deviation)
		(b) (4)
Net can weight (g)	(b) (4)	

Source: Section H.1.2.3.4.1 Fresh (8140) Routine Release Results, Certificate of Analysis
n=number of samples.

Table 83 ZYN Fresh 6 mg (8141) Routine Release Results

Test	Acceptance Criteria Target (Range)	Batch Average (Standard Deviation)
		(b) (4)
Moisture (%; n=4/batch)	(b) (4)	
pH (n=4/batch)		
Nicotine (% as is; n=4/batch)		
Pouch weight (g; n=20/batch)		
Net can weight (g)		

Source: Section H.1.2.3.4.2 Fresh (8141) Routine Release Results, Certificate of Analysis
n=number of samples.

2.6.4.2 ZYN Characterization Results

The characterization testing was performed on at least three different batches of each ZYN product following the analytical procedures described in Section 2.6.3. Characterization results for each ZYN product are summarized in the appendix of Section G.5 Nonclinical Evaluation Summary.

2.6.5 ZYN Products Justification of Specifications

2.6.5.1 ZYN Product Release Specification

Justification of specifications for ZYN product release is summarized in Table 84 and fully described in Section H.1.2.3.5 Justification of Release Specification and Characterization Testing.

Table 84 ZYN Product Release – Justification of Specification

Test Parameter [Analytical Procedure No.]	Unit	Target	Acceptance Criteria	Justification of Product Release Specifications
Nicotine (ZYN 3 mg/pouch) (b) (4)	mg/g as is	(b) (4)		
Nicotine (ZYN 6 mg/pouch) (b) (4)	mg/g as is			
pH (b) (4)	NA			
Moisture content (b) (4) (b) (4)	% as is			
Can content weight	g/can			
Pouch weight (b) (4)	g/pouch			

Source: Section H.1.2.3.5 Justification of Release Specification and Characterization Testing
NA=not applicable.

2.6.5.2 ZYN Product Characterization Specification

The justification of specification for ZYN product characterization parameters subject to annual analysis, precursory ZYN product characterization parameters, and ZYN component parameters are summarized in Table 85 and Table 86, and fully described in Section H.1.2.3.5 Justification of Release Specification and Characterization Testing. External limits are set for analytes that are included in the GOTHIATEK quality standard used for General Snus to facilitate bridging to General Snus and characterize the product throughout the shelf life of the product at recommended storage conditions. The internal limits are used for monitoring and to guide continued improvements of the product.

Table 85 ZYN Product Characterization Parameters Subject to Annual Analysis – Justification of Specification

Test Parameter [Analytical Procedure No.]	Unit[1]	Target	Internal Limit	External Limit	Justification of Product Characterization Specification
Nicotine (ZYN 3 mg/pouch) (b) (4)	mg/g as is	(b) (4)			
Nicotine (ZYN 6 mg/pouch) (b) (4)	mg/g as is				
pH (b) (4)	NA				
Moisture content (b) (4)	% as is				
Tobacco-specific Nitrosamines (b) (4) NNN+NNK Total TSNA	 µg/g µg/g				
Nitrite (b) (4)	µg/g				

Test Parameter [Analytical Procedure No.]	Unit[1]	Target	Internal Limit	External Limit	Justification of Product Characterization Specification
Aldehydes (b) (4) Acetaldehyde Crotonaldehyde Formaldehyde	 µg/g µg/g µg/g	 NA NA NA	(b) (4)		
Water activity (a_w) (b) (4)	NA	NA			
Microbial content TAMC TYMC (b) (4)	 lgcfu/g lgcfu/g	 NA NA			
Nicotine related compounds (b) (4) Anabasine Anatabine Cotinine Myosmine Nicotine-N-oxide β-Nicotyrine Nornicotine Total nicotine related compounds	 % of nicotine % of nicotine % of nicotine % of nicotine % of nicotine % of nicotine % of nicotine % of nicotine	 NA NA NA NA NA NA NA NA			
N-Nitrosodimethylamine (b) (4)	ng/g	NA			

Test Parameter [Analytical Procedure No.]	Unit[1]	Target	Internal Limit	External Limit	Justification of Product Characterization Specification
Benzo[a]pyrene and PAHs (b) (4) and (b) (4)			(b) (4)		
Benzo[a]pyrene	ng/g	NA			
Benzo[c]phenanthrene	ng/g	NA			
Benzo[a]anthracene	ng/g	NA			
Cyclopenta[c,d]pyrene	ng/g	NA			
Chrysene	ng/g	NA			
5-Methylchrysene	ng/g	NA			
Benzo[b]fluoranthene	ng/g	NA			
Benzo[k]fluoranthene	ng/g	NA			
Benz[j]aceanthrylene	ng/g	NA			
Dibenzo[a,h]anthracene	ng/g	NA			
Indenol[1,2,3-cd]pyrene	ng/g	NA			
Dibenzo[a,l]pyrene	ng/g	NA			
Dibenzo[a,e]pyrene	ng/g	NA			
Dibenzo[a,i]pyrene	ng/g	NA			
Dibenzo[a,h]pyrene	ng/g	NA			
Naphthalene	ng/g	NA			
Heavy metals (b) (4)					
Lead	µg/g	NA			
Arsenic	µg/g	NA			
Cadmium	µg/g	NA			
Chromium	µg/g	NA			
Nickel	µg/g	NA			
Mercury	µg/g	NA			

Test Parameter [Analytical Procedure No.]	Unit[1]	Target	Internal Limit	External Limit	Justification of Product Characterization Specification
Propylene glycol (b) (4)	%	(b) (4)			
Ethanol (b) (4)	%				
Pouches per can	NA				
Pouch dimensions Length Width Height	 mm mm mm				

Source: Section H.1.2.3.5 Justification of Release Specification and Characterization Testing

a_w=water activity; B[a]P=Benzo[a]pyrene; FDA=Food and Drug Administration; lgcfu=log colony forming units; HPHC=Harmful and Potentially Harmful Constituents; LOQ=limit of quantification; NA=not applicable; NNK=nicotine-derived nitrosamine ketone; NNN=N-nitrosonornicotine; PAH=polyaromatic hydrocarbon; TAMC=total aerobic microbial count; TSNA= tobacco-specific nitrosamine; TYMC=total yeast and mold count; USP=United States Pharmacopeia.

1 All chemical data are presented on a dry weight basis when not otherwise indicated.

2 Food and Drug Administration, 21 CFR Part 1132 [Docket No. FDA-2016-N-2527]; Tobacco Product Standard for N-Nitrosonornicotine Level in Finished Smokeless Tobacco Products; Federal Register Volume 82, No.13, January 23, 2017.

3 WHO Study Group on Tobacco Product Regulation. Report on the scientific basis of tobacco product regulation: third report of a WHO study group (WHO Technical Report Series, No. 955). Geneva: World Health Organization; 2009.

Table 86 ZYN Product Characterization Parameters Subject to Precursory Analysis – Justification of Specification

Test Parameter [Analytical Procedure No.]	Unit	Target	Internal Limit	Justification of Product Release Specifications
Mycotoxins (b) (4)			(b) (4)	
Aflatoxin B_1	ng/g	NA		
Aflatoxins B_1, B_2, G_1, and G_2 (sum)	ng/g	NA		
Ochratoxin A	ng/g	NA		
Ethyl carbamate (b) (4)	ng/g	NA		
Acrylamide (b) (4)	ng/g	NA		
Radioisotopes (b) (4) and (b) (4)				
Polonium 210	Bq/kg	NA		
Uranium 235	Bq/kg	NA		
Uranium 238	Bq/kg	NA		
Agrochemicals (b) (4)	NA	NA		

Test Parameter [Analytical Procedure No.]	Unit	Target	Internal Limit	Justification of Product Release Specifications
Fermentable sugars and polysaccharides (b) (4) Sugars Sugars and starch	 % %	 NA NA	(b) (4)	

Source: Section H.1.2.3.5 Justification of Release Specification and Characterization Testing
Bq=Becquerel; FDA=Food and Drug Administration; HPHC= Harmful and Potentially Harmful Constituents; LOQ=limit of quantification; NA=not applicable.

2.6.5.3 ZYN Product Component Characterization Specification

The justification of specification for ZYN product component characterization parameters are summarized in Table 87, and fully described in Section H.1.2.3.5 Justification of Release Specification and Characterization Testing.

Table 87 Characterization Parameters of ZYN Components – Justification of Specification

Test Parameter [Analytical Procedure No.]	Unit	Target	Internal Limit	Justification of Product Release Specifications
ZYN particle size distribution (b) (4) d50 d10 d90	 µm µm µm	(b) (4)		
ZYN powder density	g/mL			
Pouch wrapping material dimensions Thickness (b) (4) Basis weight (b) (4) Air permeability (b) (4)	 mm g/m^2 $L/m^2/s$			

Source: Section H.1.2.3.5 Justification of Release Specification and Characterization Testing
NA=not applicable; SKU=stock keeping unit.

2.6.5.4 ZYN Product Shelf Life Specification

The justification of specification for ZYN product shelf life parameters are summarized in Table 88 and fully described in Section H.1.2.3.5 Justification of Release Specification and Characterization Testing.

Table 88 ZYN Product Shelf Life Parameters – Justification of Specification

Test Parameter [Analytical Procedure No.]	Unit	Target	Acceptance Criteria	Justification of Shelf-Life Specification
Nicotine (ZYN 3 mg/pouch) (b) (4)	mg/g as is	(b) (4)		
Nicotine (ZYN 6 mg/pouch) (b) (4)	mg/g as is			
pH (b) (4)	NA			
Moisture content (b) (4) and (b) (4)	% as is			
NNK+NNN (b) (4)	µg			
Total TSNA (b) (4)	µg/g			
Nitrate (b) (4)	%			
Nitrite (b) (4)	µg/g			

Test Parameter [Analytical Procedure No.]	Unit	Target	Acceptance Criteria	Justification of Shelf-Life Specification
TAMC (b) (4)	lgcfu/g	NA	(b) (4)	
TYMC (b) (4)	lgcfu/g	NA		
Nicotine related compounds (b) (4)				
Anabasine	% of nicotine	NA		
Anatabine	% of nicotine	NA		
Cotinine	% of nicotine	NA		
Myosmine	% of nicotine	NA		
Nicotine N-oxide	% of nicotine	NA		
β-Nicotyrine	% of nicotine	NA		
Nornicotine	% of nicotine	NA		
Total nicotine related compounds	% of nicotine	NA		
Acetaldehyde (b) (4)	µg/g	NA		
Formaldehyde (b) (4)	µg/g	NA		

Source: Section H.1.2.3.5 Justification of Release Specification and Characterization Testing

FDA=Food and Drug Administration; HPHC=harmful and potentially harmful constituent; lgcfu/g=$\log_{10}$ colony forming units per gram; LOQ=limit of quantitation; NA=not applicable; NNK=nicotine-derived nitrosamine ketone; NNN=N-nitrosonornicotine; TAMC=total aerobic microbial count; TSNA=tobacco-specific nitrosamine; TYMC=total yeast and mold count

2.7 Stability

2.7.1 Nicotine

The nicotine bitartrate dihydrate used in all flavors of ZYN products is sourced from (b) (4) has filed a tobacco product master file (TPMF) with the Food and Drug Administration (FDA), which was assigned TPMF number (b) (4). A copy of the TPMF letter of authorization (LOA) is located in Section A5 Other, TPMF Letters of Authorization.

Refer to the TPMF number (b) (4) for details regarding the stability protocol, stability data, and the established shelf-life for Nicotine bitartrate dihydrate used in the ZYN products.

2.7.2 ZYN Product Stability

2.7.2.1 Stability Protocol

A stability study was performed to establish the shelf life of ZYN products intended for the PMTA-regulated market. The ZYN finished products subjected to shelf-life stability testing are listed in Table 89.

Table 89 Swedish Match ZYN Products

ZYN Product	Unique Product Identification Number	Batch Number	Stability Data Table
Cool Mint 3 mg	8105	(b) (4)	Table 91
Cool Mint 6 mg	8106		Table 92
Peppermint 3 mg	8107		Table 93
Peppermint 6 mg	8108		Table 94
Spearmint 3 mg	8109		Table 95
Spearmint 6 mg	8110		Table 96
Wintergreen 3 mg	8111		Table 97
Wintergreen 6 mg	8112		Table 98
Citrus 3 mg	8122		Table 99
Citrus 6 mg	8123		Table 100
Coffee 3 mg	8124		Table 101
Coffee 6 mg	8125		Table 102
Cinnamon 3 mg	8128		Table 103
Cinnamon 6 mg	8129		Table 104
Smooth 3 mg	8134		Table 105
Smooth 6 mg	8135		Table 106
Chill 3 mg	8136		Table 107
Chill 6 mg	8137		Table 108
Fresh 3 mg	8140		Table 109
Fresh 6 mg	8141		Table 110

Source: Section H.1.2.4.2.1 Stability Protocol

A single batch of each ZYN finished product was placed on stability to determine the product shelf life. The stability testing storage conditions and schedule are described in Table 90.

Table 90 Storage Conditions and Sampling Time Points for the Long-term Stability Studies

Storage Conditions: (b) (4) RH	**Sampling Time Point (Weeks)**
Sample withdrawal	(b) (4)
Sample withdrawal window (days)	

Source: Section H.1.2.4.2.1 Stability Protocol
NA=not applicable; RH=relative humidity.

The analytical procedures used for the shelf life stability testing were the same as those used for finished product release testing and characterization testing. For summaries of the referenced analytical procedures, refer to Section 2.6.2 and Section 2.6.3. For full details of the ZYN finished product shelf life stability protocol, refer to Section H.1.2.4.2.1 Stability Protocol.

2.8 Finished Product Stability

All TSNAs, total yeasts and molds count, and nitrate were below their respective LOQs at all time points. The results for total aerobic microbial count were consistently below the LOQ, with the exception of a single sample that gave a result at the LOQ. For some products, minor increases in nitrite were observed; however, the largest measured content (b) (4) µg/g) was well below the acceptance criterion ((b) (4) µg/g).

Table 91 ZYN Cool Mint 3 mg (8105) Long-term Stability Data (Batch No. (b) (4) Relative Humidity)

Test (b) (4)	**Acceptance Criteria**	**Storage Time (Weeks)**						
		0	**4**	**12**	**24**	**36**	**52**	**56**
Moisture content (%)[a] (b) (4)	(b) (4)							
pH[a] (b) (4)								
Nicotine (mg/g as is)[a] (b) (4)								
Nicotine related compound in greatest quantity (% of nicotine)[a] (b) (4)								

Test (b) (4)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Total nicotine related compounds (% of nicotine)[a] (b) (4)		
Acetaldehyde (µg/g)[a] (b) (4)		
Formaldehyde (µg/g)[a] (b) (4)		

Source: Section H.1.2.4.2.2 Cool Mint (8105)
QEMS=quality and environmental management system.
[a] Average values for triplicate measurements reported here.
[b] β-Nicotyrine

Table 92 ZYN Cool Mint 6 mg (8106) Long-term Stability Data (Batch No. (b) (4) Relative Humidity)

Test (b) (4)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Moisture content (%)[a] (b) (4)		
pH[a] (b) (4)		
Nicotine (mg/g as is)[a] (b) (4)		
Nicotine related compounds in greatest quantity (% of nicotine)[a] (b) (4)		
Total nicotine related compounds (% of nicotine)[a] (b) (4)		

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Acetaldehyde (µg/g)[a] (b) (4)		
Formaldehyde (µg/g)[a] (b) (4)		

Source: Section H.1.2.4.2.3 Cool Mint (810

QEMS=quality and environmental management system.

[a] Average values for triplicate measurements reported here.
[b] Average value for duplicate measurements reported here.
[c] Nicotine N-oxide
[d] β-Nicotyrine

Table 93 ZYN Peppermint 3 mg (8107) Long-term Stability Data (Batch No. (b) (4) Relative Humidity)

Test (b) (4)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Moisture content (%)[a] (b) (4)		
pH[a] (b) (4)		
Nicotine (mg/g as is)[a] (b) (4)		
Nicotine related compounds in greatest quantity (% of nicotine)[a] (b) (4)		
Total nicotine related compounds (% of nicotine)[a] (b) (4)		

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Acetaldehyde (µg/g)[a] (b) (4)	(b) (4)	
Formaldehyde (µg/g)[a] (b) (4)		

Source: Section H.1.2.4.2.2 Peppermint (8107)
QEMS=quality and environmental management system.
[a] Average values for triplicate measurements ((b) (4)) and decuplicate (ie, (b) (4) replicates) measurements (b) (4)) are reported here.
[b] β-Nicotyrine
[c] Nicotine N-oxide
[d] Measurement is suspect due to extended time between sample preparation and instrumental analysis.

Table 94 ZYN Peppermint 6 mg (8108) Long-term Stability Data (Batch No. (b) (4) Relative Humidity)

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Moisture content (%)[a] (b) (4)	(b) (4)	
pH[a] (b) (4)		
Nicotine (mg/g as is)[a] (b) (4)		
Nicotine related compounds in greatest quantity (% of nicotine)[a] (b) (4)		
Total nicotine related compounds (% of nicotine)[a] (b) (4)		

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Acetaldehyde (µg/g)[a] (b) (4)	(b) (4)	
Formaldehyde (µg/g)[a] (b) (4)		

Source: Section H.1.2.4.2.3 Peppermint (8108)
QEMS=quality and environmental management system.
[a] Average values for triplicate measurements ((b) (4) weeks) and decuplicate (ie, (b) (4) replicates) measurements ((b) (4)) are reported here.
[b] Nicotine N-oxide
[c] Measurement is suspect due to extended time between sample preparation and instrumental analysis.

Table 95 ZYN Spearmint 3 mg (8109) Long-term Stability Data (Batch No. (b) (4) Relative Humidity)

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Moisture content (%)[a] (b) (4)	(b) (4)	
pH[a] (b) (4)		
Nicotine (mg/g as is)[a] (b) (4)		
Nicotine related compounds in greatest quantity (% of nicotine)[a] (b) (4)		
Total nicotine related compounds (% of nicotine)[a] (b) (4)		

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Acetaldehyde (µg/g)[a] (b) (4)		(b) (4)
Formaldehyde (µg/g)[a] (b) (4)		

Source: Section H.1.2.4.2.2 Spearmint (8109)
QEMS=quality and environmental management system.
[a] Average values for triplicate measurements reported here.
[b] β-Nicotyrine
[c] Nicotine N-oxide

Table 96 ZYN Spearmint 6 mg (8110) Long-term Stability Data (Batch No. (b) (4) Relative Humidity)

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Moisture content (%)[a] (b) (4)		(b) (4)
pH[a] (b) (4)		
Nicotine (mg/g as is)[a] (b) (4)		
Nicotine related compounds in greatest quantity (% of nicotine)[a] (b) (4)		
Total nicotine related compounds (% of nicotine)[a] (b) (4)		

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Acetaldehyde (µg/g)[a] (b) (4)		
Formaldehyde (µg/g)[a] (b) (4)		

Source: Section H.1.2.4.2.3 Spearmint (8110)
QEMS=quality and environmental management system.
[a] Average values for triplicate measurements reported here.
[b] β-Nicotyrine
[c] Nicotine N-oxide

Table 97 ZYN Wintergreen 3 mg (8111) Long-term Stability Data (Batch No. (b) (4) Relative Humidity)

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Moisture content (%)[a] (b) (4)		
pH[a] (b) (4)		
Nicotine (mg/g as is)[a] (b) (4)		
Nicotine related compound in greatest quantity (% of nicotine)[a] (b) (4)		
Total nicotine related compounds (% of nicotine)[a] (b) (4)		

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Acetaldehyde (µg/g)[a] (b) (4)	(b) (4)	
Formaldehyde (µg/g)[a] (b) (4)		

Source: Section H.1.2.4.2.2 Wintergreen (8111)
QEMS=quality and environmental management system.
[a] Average values for triplicate measurements ((b) (4)) and decuplicate (ie, (b) (4) replicates) measurements (b) (4)) are reported here.
[b] β-Nicotyrine

Table 98 ZYN Wintergreen 6 mg (8112) Long-term Stability Data (Batch No. (b) (4) Relative Humidity)

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Moisture content (%)[a] (b) (4)	(b) (4)	
pH[a] (b) (4))		
Nicotine (mg/g as is)[a] (b) (4)		
Nicotine related compounds in greatest quantity (% of nicotine)[a] (b) (4)		
Total nicotine related compounds (% of nicotine)[a] (b) (4)		

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Acetaldehyde (µg/g)[a] (b) (4)		
Formaldehyde (µg/g)[a] (b) (4)		

Source: Section H.1.2.4.2.3 Wintergreen (8112)
QEMS=quality and environmental management system.
[a] Average values for triplicate measurements ((b) (4)) and decuplicate (ie, (b) (4) replicates) measurements ((b) (4)) are reported here.
[b] β-Nicotyrine
[c] Nicotine N-oxide

Table 99 ZYN Citrus 3 mg (8122) Long-term Stability Data (Batch No. (b) (4) Relative Humidity)

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Moisture content (%)[a] (b) (4)		
pH[a] (b) (4)		
Nicotine (mg/g as is)[a] (b) (4)		
Nicotine related compounds in greatest quantity (% of nicotine)[a] (b) (4)		
Total nicotine related compounds (% of nicotine)[a] (b) (4)		

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Acetaldehyde (µg/g)[a] (b) (4)		
Formaldehyde (µg/g)[a] (b) (4)		

Source: Section H.1.2.4.2.2 Citrus (8122)
QEMS=quality and environmental management system.
[a] Average values for triplicate measurements reported here.
[b] β-Nicotyrine
[c] Nicotine N-oxide

Table 100 ZYN Citrus 6 mg (8123) Long-term Stability Data (Batch No. (b) (4) Relative Humidity)

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Moisture content (%)[a] (b) (4)		
pH[a] (b) (4)		
Nicotine (mg/g as is)[a] (b) (4)		
Nicotine related compounds in greatest quantity (% of nicotine)[a] (b) (4)		
Total nicotine related compounds (% of nicotine)[a] (b) (4)		

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Acetaldehyde (µg/g)[a] (b) (4)		(b) (4)
Formaldehyde (µg/g)[a] (b) (4)		

Source: Section H.1.2.4.2.3 Citrus (8123)
QEMS=quality and environmental management system.
[a] Average values for triplicate measurements reported here.
[b] Nicotine N-oxide
[c] Nornicotine

Table 101 ZYN Coffee 3 mg (8124) Long-term Stability Data (Batch No. (b) (4) Relative Humidity)

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Moisture content (%)[a] (b) (4)		(b) (4)
pH[a] (b) (4)		
Nicotine (mg/g as is)[a] (b) (4))		
Nicotine related compounds in greatest quantity (% of nicotine)[a] (b) (4)		
Total nicotine related compounds (% of nicotine)[a] (b) (4)		

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Acetaldehyde (µg/g)[a] (b) (4)		(b) (4)
Formaldehyde (µg/g)[a] (b) (4))		

Source: Section H.1.2.4.2.2 Coffee (8124)
QEMS=quality and environmental management system.
[a] Average values for triplicate measurements reported here.
[b] β-Nicotyrine
[c] Nicotine N-oxide

Table 102 ZYN Coffee 6 mg (8125) Long-term Stability Data (Batch No. (b) (4) Relative Humidity)

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Moisture content (%)[a] (b) (4)		(b) (4)
pH[a] (b) (4)		
Nicotine (mg/g as is)[a] (b) (4)		
Nicotine related compounds in greatest quantity (% of nicotine)[a] (b) (4)		
Total nicotine related compounds (% of nicotine)[a] (b) (4)		

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Acetaldehyde (µg/g)[a] (b) (4)		
Formaldehyde (µg/g)[a] (b) (4)		

Source: Section H.1.2.4.2.3 Coffee (8125)
QEMS=quality and environmental management system.
[a] Average values for triplicate measurements reported here.
[b] β-Nicotyrine
[c] Nicotine N-oxide

Table 103 ZYN Cinnamon 3 mg (8128) Long-term Stability Data (Batch No. (b) (4) Relative Humidity)

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Moisture content (%)[a] (b) (4)		
pH[a] (b) (4)		
Nicotine (mg/g as is)[a] (b) (4)		
Nicotine related compound in greatest quantity (% of nicotine)[a] (b) (4)		
Total nicotine related compounds (% of nicotine)[a] (b) (4)		

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Acetaldehyde (µg/g)[a] (b) (4)		
Formaldehyde (µg/g)[a] (b) (4))		

Source: Section H.1.2.4.2.2 Cinnamon (8128)
QEMS=quality and environmental management system.
[a] Average values for triplicate measurements reported here.
[b] Nicotine N-oxide

Table 104 ZYN Cinnamon 6 mg (8129) Long-term Stability Data (Batch No. (b) (4) Relative Humidity)

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Moisture content (%)[a] (b) (4)		
pH[a] (b) (4)		
Nicotine (mg/g as is)[a] (b) (4)		
Nicotine related compounds in greatest quantity (% of nicotine)[a] (b) (4)		
Total nicotine related compounds (% of nicotine)[a] (b) (4)		

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks)
Acetaldehyde (µg/g)[a] (b) (4)	(b) (4)	(b) (4)
Formaldehyde (µg/g)[a] (b) (4)		

Source: Section H.1.2.4.2.3 Cinnamon (8129)
QEMS=quality and environmental management system.
[a] Average values for triplicate measurements reported here.
[b] Nicotine N-oxide

Table 105 ZYN Smooth 3 mg (8134) Long-term Stability Data (Batch No. (b) (4) Relative Humidity)

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks)
Moisture content (%)[a] (b) (4)	(b) (4)	(b) (4)
pH[a] (b) (4)		
Nicotine (mg/g as is)[a] (b) (4)		
Nicotine related compounds in greatest quantity (% of nicotine)[a] (b) (4)		
Total nicotine related compounds (% of nicotine)[a] (b) (4)		

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks)
Acetaldehyde (µg/g)[a] (b) (4)		(b) (4)
Formaldehyde (µg/g)[a] ((b) (4)		

Source: Section H.1.2.4.2.2 Smooth (8134)
QEMS=quality and environmental management system.
[a] Average values for triplicate measurements ((b) (4)) and decuplicate (ie, (b) (4) replicates) measurements (b) (4)) are reported here.
[b] Nornicotine

Table 106 ZYN Smooth 6 mg (8135) Long-term Stability Data (Batch No. (b) (4) Relative Humidity)

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks)						
		0	4	12	24	36	52	56
Moisture content (%)[a] (b) (4)		(b) (4)						
pH[a] (b) (4)								
Nicotine (mg/g as is)[a] (b) (4)								
Nicotine related compound in greatest quantity (% of nicotine)[a] (b) (4)								
Total nicotine related compounds (% of nicotine)[a] (b) (4)								

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Acetaldehyde (µg/g)[a] (b) (4)		
Formaldehyde (µg/g)[a] (b) (4)		

Source: Section H.1.2.4.2.3 Smooth (8135)
QEMS=quality and environmental management system.
[a] Average values for triplicate measurements ((b) (4)) and decuplicate (ie, (b) (4) replicates) measurements (b) (4)) are reported here.
[b] Nicotine N-oxide

Table 107 ZYN Chill 3 mg (8136) Long-term Stability Data ((b) (4) Relative Humidity)

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Moisture content (%)[a] (b) (4)		
pH[a] (b) (4)		
Nicotine (mg/g as is)[a] (b) (4)		
Nicotine related compounds in greatest quantity (% of nicotine)[a] (b) (4)		
Total nicotine related compounds (% of nicotine)[a] (b) (4)		

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Acetaldehyde (µg/g)[a] (b) (4)		
Formaldehyde (µg/g)[a] (b) (4)		

Source: Section H.1.2.4.2.2 Chill (8136)
QEMS=quality and environmental management system.
[a] Average values for triplicate measurements reported here.
[b] Nornicotine
[c] Nicotine N-oxide

Table 108 ZYN Chill 6 mg (8137) Long-term Stability Data (Batch No. (b) (4) Relative Humidity)

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Moisture content (%)[a] (b) (4)		
pH[a] (b) (4)		
Nicotine (mg/g as is)[a] (b) (4)		
Nicotine related compound in greatest quantity (% of nicotine)[a] (b) (4)		
Total nicotine related compounds (% of nicotine)[a] (b) (4)		

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Acetaldehyde (µg/g)[a] (b) (4)		
Formaldehyde (µg/g)[a] (b) (4)		

Source: Section H.1.2.4.2.3 Chill (8137)
QEMS=quality and environmental management system.
[a] Average values for triplicate measurements reported here.
[b] Nicotine N-oxide

Table 109 ZYN Fresh 3 mg (8140) Long-term Stability Data (Batch No. (b) (4) Relative Humidity)

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Moisture content (%)[a] (b) (4)		
pH[a] (b) (4)		
Nicotine (mg/g as is)[a] (b) (4)		
Nicotine related compounds in greatest quantity (% of nicotine)[a] (b) (4)		
Total nicotine related compounds (% of nicotine)[a] (b) (4)		

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Acetaldehyde (µg/g)[a] (b) (4)		
Formaldehyde (µg/g)[a] (b) (4)		

Source: Section H.1.2.4.2.2 Fresh (8140)
QEMS=quality and environmental management system.
[a] Average values for triplicate measurements reported here.
[b] Nornicotine
[c] Nicotine N-oxide
[d] Measurement is suspect due to extended time between sample preparation and instrumental analysis.

Table 110 ZYN Fresh 6 mg (8141) Long-term Stability Data (Batch No. (b) (4) Relative Humidity)

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Moisture content (%)[a] (b) (4)		
pH[a] (b) (4)		
Nicotine (mg/g as is)[a] (b) (4)		
Nicotine related compounds in greatest quantity (% of nicotine)[a] (b) (4)		
Total nicotine related compounds (% of nicotine)[a] (b) (4)		

Test (QEMS No.)	Acceptance Criteria	Storage Time (Weeks) (b) (4)
Acetaldehyde (µg/g)[a] (b) (4)	(b) (4)	
Formaldehyde (µg/g)[a] (b) (4)		

Source: Section H.1.2.4.2.3 Fresh (8141)
QEMS=quality and environmental management system.
[a] Average values for triplicate measurements reported here.
[b] Nicotine N-oxide
[c] Measurement is suspect due to extended time between sample preparation and instrumental analysis.

2.8.1.1 Stability Discussion and Conclusions

Summaries of the finished product shelf-life stability studies for ZYN under the long-term ([redacted] RH) storage conditions are provided in Table 91 through Table 110; the proposed shelf life for all ZYN products is [redacted]. The measured nicotine content for the 3 mg and 6 mg ZYN products does not change substantially and remains within the acceptance criteria during the entire [redacted] of storage. In addition, the moisture content, pH, nicotine-related compound in greatest quantity, and the total nicotine-related compounds were measured within each respective acceptance criteria. All TSNAs, TYMC, and nitrate were below their respective LOQs at all time points. The results for TAMC were consistently below the LOQ, with the exception of a single sample that gave a result at the LOQ. For some products, minor increases in nitrite were observed; however, the largest measured content ([redacted] µg/g) was well below the acceptance criterion ([redacted] µg/g). Only two HPHCs, acetaldehyde and formaldehyde, gave measurements above the LOQ and the corresponding data are included in the summarized stability data tables. Note that these two aldehydes decreased rather rapidly with storage. For full details of all Swedish Match ZYN product stability data, refer to [redacted]

2.9 Assessment of Child Resistant Packaging

2.9.1 Child-Resistant Packaging Specifications

Child-resistant packaging for ZYN products must conform with the Poison Prevention Packaging Act of 1970, US Title 16 Code of Federal Regulations Section 1700.20 (US 16 CFR §1700.20), which provides the requirements listed in Table 111.

Table 111 Child-Resistant Packaging Specifications per US 16 CFR §1700.20

Cumulative Number of Children	Package Openings					
	First 5 Minutes			Full 10 Minutes		
	Pass	Continue	Fail	Pass	Continue	Fail
50	0-3	4-10	11+	0-5	6-14	15+
100	4-10	11-18	19+	6-15	16-24	25+
150	11-18	19-25	26+	16-25	26-34	35+
200	19-30	NA	31+	26-40	NA	41+

Source: United States Title 16 Code of Federal Regulations Section 1700.20
NA=not applicable.

2.9.2 Child-Resistant Packaging Methods

2.9.2.1 Package Opening Test for Children

An assessment of recloseable child-resistant packaging [redacted] used for Swedish Match ZYN was performed on nursery school-age children in accordance with US

Title 16 Code of Federal Regulations Section 1700.20 (US 16 CFR §1700.20) and is described in Section H.1.2.5 Child-Resistant Packaging Report. The assessment test involved [redacted] children aged [redacted]. The participating children represented the full span of socio-demographics (ie, lower, middle, and upper classes). The children were tested in pairs; each was provided with a sample child-resistant container and given five minutes to open the container without a prior demonstration. The children who were unable to open the container during the first five minutes received a demonstration by the testers of how to open the container. The children were then given an additional five minutes to try to open the package.

2.9.2.2 Package Opening Test for Senior Adults

An assessment of recloseable child-resistant packaging [redacted] used for Swedish Match ZYN was performed on senior adults in accordance with US 16 CFR §1700.20 and is described in Section H.1.2.5 Child-Resistant Packaging Report. The assessment test involved [redacted] senior adults aged 50 to 70 years with 25% aged 50 to 54 years, 25% aged 55 to 59 years, and 50% aged 60 to 70 years. Ninety-nine percent of the senior adult participants successfully opened and reclosed child-resistant packaging during five minutes of training; one female was unable to open the [redacted]. During the one minute main test, [redacted] of [redacted] (93%) senior adult participants were successful in opening and reclosing the child-resistant packaging. The [redacted] adults who were unable to open and reclose the packaging experienced problems in finding and aligning the arrow markings quickly enough or in exerting sufficient pressure on the embossed areas to allow the lid to separate from the bottom portion of the [redacted]. These results clearly show that the child-resistant packaging is sufficiently designed to prevent the large majority of children from gaining access to the ZYN product contents while allowing convenient, easy access to adult consumers.

2.9.3 Child-Resistant Packaging Results

2.9.3.1 Package Opening Test for Children

Of the [redacted] children participating in the child-resistant packaging assessment test, only [redacted] were able to open the package during the first five minutes and without the aid of a visual demonstration. Following a largely non-verbal demonstration of how to open the container/lid system by the testers, the [redacted] children who failed to open the package during the first five minutes were given an additional five minutes to try again. Of these children, [redacted] more were able to open the child-resistant package for a total of [redacted] children or 12%, which passes the acceptance criteria (Table 111) for the test method described in US 16 CFR §1700.20. The package opening results for nursery school aged children are summarized in Table 112 and described fully in Section H.1.2.5 Child-Resistant Packaging Report.

Table 112 Child-Resistant Package-Opening Test Results for Children

Child Test	n	N	n/N (%)	Result
Successful package opening (package failure) (first 5 min attempt)	(b) (4)			
Successful package opening (package failure) (first 5 min attempt, brief demonstration, followed by second 5 min attempt)				

Source: Section H.1.2.5 Child-Resistant Packaging Report
n=number of children successfully opening the package; N=total number of children involved in the child-resistant package opening test.

2.9.3.2 Package Opening Test for Senior Adults

The child-resistant packaging used for Swedish Match ZYN product did not impede senior adults aged from 50 to 70 years from opening the containers, based on the test method described in US 16 CFR §1700.20. The package opening results for senior adults are summarized in Table 113 and described in Section H.1.2.5 Child-Resistant Packaging Report.

Table 113 Child-Resistant Package-Opening Test Results for Senior Adults

Senior (Adult) Test	n	N	n/N (%)
Package opened in 5 min	(b) (4)		
Failed to open package in 5 min			
Package opened in 1 min			
Failed to open package in 1 min			

Source: Section H.1.2.5 Child-Resistant Packaging Report
n=number of senior adults either succeeding or failing to opening the package; N=total number of senior adults involved in the child-resistant package opening test.