

Routine Release Specification and Characterization Requirements, 3 mg



Summary Characterization and Specifications Document ZYN 3mg (all flavors)

Table 1 Final Product Chemical Constituents Characterization

Item	Parameter	Units	Characterization (dry basis)		
			Target	Upper Limit (Internal)	Upper Limit (External)
1	NNN+NNK	µg/g	---	0.03 (LOQ)	0.03 (LOQ)
2	NDMA	ng/g	---	0.6 (LOQ)	0.6 (LOQ)
3	Anabasine	% of nicotine	---	0.3	---
4	(b) (4)	% of nicotine	---	0.3	---
5	(b) (4)	% of nicotine	---	0.3	---
6	(b) (4)	% of nicotine	---	0.3	---
7	(b) (4)	% of nicotine	---	0.3	---
8	(b) (4)	% of nicotine	---	0.3	---
9	Nornicotine	% of nicotine	---	0.3	---
10	(b) (4)	% of nicotine	---	0.8	---
11	(b) (4)	µg/g	---	3.0	6.0
12	Benzo[a]pyrene	ng/g	---	0.6 (LOQ)	0.6 (LOQ)
13	Benzo[c]phenanthrene	ng/g	---	1.0 (LOQ)	---
14	Benzo[a]anthracene	ng/g	---	1.0 (LOQ)	---
15	Cyclopenta[c,d]pyrene	ng/g	---	1.0 (LOQ)	---
16	Chrysene	ng/g	---	1.0 (LOQ)	---
17	5-Methylchrysene	ng/g	---	5.0 (LOQ)	---
18	Benzo[b]fluoranthene	ng/g	---	1.0 (LOQ)	---
19	Benzo[k]fluoranthene	ng/g	---	1.0 (LOQ)	---
20	Benz[j]aceanthrylene	ng/g	---	0.6 (LOQ)	---
21	Dibenzo[a,h]anthracene	ng/g	---	0.6 (LOQ)	---
22	Indenol[1,2,3-cd]pyrene	ng/g	---	1.0 (LOQ)	---
23	Dibenzo[a,i]pyrene	ng/g	---	2.0 (LOQ)	---
24	Dibenzo[a,e]pyrene	ng/g	---	5.0 (LOQ)	---
25	Dibenzo[a,i]pyrene	ng/g	---	5.0 (LOQ)	---
26	Dibenzo[a,h]pyrene	ng/g	---	5.0 (LOQ)	---
27	Naphthalene	ng/g	---	20	---
28	Lead	µg/g	---	0.10 (LOQ)	0.20
29	Arsenic	µg/g	---	0.05 (LOQ)	0.10
30	Cadmium	µg/g	---	0.05 (LOQ)	0.10
31	Chromium	µg/g	---	0.15 (LOQ)	0.50
32	Nickel	µg/g	---	0.10 (LOQ)	0.50
33	Mercury	µg/g	---	0.02 (LOQ)	0.02 (LOQ)
34	Polonium 210	Bq/kg	---	10*	---
35	Uranium 235	Bq/kg	---	0.02 (LOQ)	---
36	Uranium 238	Bq/kg	---	0.25 (LOQ)	---
37	Formaldehyde	µg/g	---	10	14.5
38	Acetaldehyde	µg/g	---	10	20
39	Crotonaldehyde	µg/g	---	0.10 (LOQ)	0.10 (LOQ)
40	Aflatoxin B1	ng/g	---	0.1 (LOQ)	---
41	Aflatoxins (sum B1+B2+G1+G2)	ng/g	---	2.1 (LOQ)	2.1 (LOQ)
42	Ochratoxin A	ng/g	---	0.5 (LOQ)	0.5 (LOQ)
43	(b) (4)	%	---	0.4	---
44	Ethyl carbamate	ng/g	---	30 (LOQ)	---
45	Acrylamide	ng/g	---	60 (LOQ)	---
46	(b) (4)	%	---	1.5	---
47	(b) (4)	%	---	0.50	---
48	(b) (4)	%	---	1.0 (LOQ)	---

*Occasional analysis just above LOQ. LOQ=limit of quantification

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Table 2 Final Product Routine Release Specification

Item	Parameter	Units	Acceptance Criteria		
			Target	Lower Range Limit	Upper Range Limit
1	Moisture	% as is	(b) (4)	---	6.0
2	pH	---		7.7	8.7
3	Total Nicotine	% as is		0.682	0.818
4	Pouch Weight	g		0.36	0.44
5	Net Can Weight	g		5.4	6.6

Table 3 Final Product Shelf Life Specification

Item	Parameter	Units	Acceptance Criteria		
			Target	Lower Range Limit	Upper Range Limit
1	Moisture	% as is	---	---	6.0
2	pH	---	---	7.2	9.1
3	Total Nicotine	mg/g as is	---	6.21	8.62
4	Anabasine	% of nicotine	---	---	0.3
5	(b) (4)	% of nicotine	---	---	0.3
6	(b) (4)	% of nicotine	---	---	0.3
7	(b) (4)	% of nicotine	---	---	0.3
8	(b) (4)	% of nicotine	---	---	0.3
9	(b) (4)	% of nicotine	---	---	0.3
10	Nornicotine	% of nicotine	---	---	0.3
11	(b) (4)	% of nicotine	---	---	0.8
12	NNN+NNK	µg/g dry basis	---	---	0.03 (LOQ)
13	Total TSNA	µg/g dry basis	---	---	0.05 (LOQ)
14	(b) (4)	% dry basis	---	---	0.05 (LOQ)
15	(b) (4)	µg/g dry basis	---	---	6.0
16	Formaldehyde	µg/g dry basis	---	---	14.5
17	Acetaldehyde	µg/g dry basis	---	---	20
18	TAMC	lgcfu/g as is	---	---	3
19	TYMC	lgcfu/g as is	---	---	3

LOQ=limit of quantification

Table 4 Final Product Design Parameter Information

Item	Parameter	Units	Design Limits		
			Target	Lower Range Limit	Upper Range Limit
1	Moisture	% as is	(b) (4)	---	6.0
2	Portion length	mm		26.0	30.0
3	Portion width	mm		13.0	15.0
4	Portion thickness	mm		2.0	7.0
5	Portion mass	g		0.36	0.44
6	Pouches per can	#		14	16
7	Component: Finished Powder Granulate	---		---	---
7.1	Particle size distribution	---		---	---
7.1.2	d50	µm		175	350
7.1.3	d10	µm		50	200
7.1.4	d90	µm		300	600
7.2	Powder density	g/ml		0.35	0.55
8	Component: Pouch Wrapping Material	---	(b) (4)	---	---
8.1	Basis weight	g/m ²		26	41
8.2	Air permeability	L/m ² /s		1700	5100
8.3	Thickness	mm		0.15	0.39