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TECHNICAL DATA SHEET FOR EMPTY HARD CAPSULES OF VEGETABLE ORIGIN

- Empty HPMC CAPS are manufactured with Pharmaceutical grade HPMC.
- The empty hard capsules of vegetable origin are produced on our premises are odourless and tasteless and suitable for human consumption.
- Distributed on over all the world and are intended for use in pharmaceutical and food products.
- Colored empty HPMC CAPS are formulated using approved and officially certified dyes and pigments for Food, Drugs and Cosmetics (FD & C), and / or for Drugs and Cosmetics (D & C).
- The components of the printing inks are manufactured in compliance with 21 CFR.
- THE raw materials meet all requirements of the USP & EP.
- Soluble in water.
- Disintegrate in less than 15 minutes.
- Moisture content is kept between 4% and 8%
- Visual quality is based on the ANSI/ASQ-Z1.4, single sampling plan (General Inspection).
- The empty hard capsules of vegetable origin HPMC CAPS have an expiration date of five years from the manufacturing date, provided they are stored and handled in their original packaging, in places with temperatures between 59°F (15°C) and 86°F (30°C), and relative humidity levels between 35% and 70%.

TABLE N° 1 EMPTY CAPSULES WEIGHT

SIZE	CAPSULE WEIGHT (mg)
000	160.0 ± 12
00E	145.0 ± 6
00	139.0 ± 7
0E	121.0 ± 6
0	109.0 ± 6
1	80.0 ± 5
2	63.0 ± 4
3	50.0 ± 3
4	40.0 ± 3

The specifications limits are for the average capsule weight. Depending on the size, the body represents approximately 60% of the total capsule weight.

TABLE N° 2 INDIVIDUAL LENGTHS

SIZE	CAP		BODY	
	(mm)	(inches)	(mm)	(inches)
000	12.90 ± 0.35	0.508 ± 0.014	21.90 ± 0.35	0.862 ± 0.014
00E	13.00 ± 0.35	0.510 ± 0.014	22.35 ± 0.35	0.879 ± 0.014
00	11.80 ± 0.35	0.464 ± 0.014	20.10 ± 0.35	0.791 ± 0.014
0E	11.73 ± 0.35	0.461 ± 0.014	20.00 ± 0.35	0.860 ± 0.014
0	10.85 ± 0.35	0.427 ± 0.014	18.35 ± 0.35	0.722 ± 0.014
1	9.85 ± 0.35	0.388 ± 0.014	16.40 ± 0.35	0.645 ± 0.014
2	8.80 ± 0.35	0.346 ± 0.014	15.15 ± 0.35	0.596 ± 0.014
3	8.00 ± 0.35	0.315 ± 0.014	13.45 ± 0.35	0.529 ± 0.014
4	7.20 ± 0.35	0.283 ± 0.014	12.10 ± 0.35	0.476 ± 0.014

These parameters are only for in-process control purposes and are not acceptance/rejection criteria.

TABLE N° 3 JOINING LENGTHS OF THE LOCKED CAPSULES

SIZE	CLOSED CAPSULE	
	(mm)	(inches)
000	27.80 ± 0.50	1.094 ± 0.019
00E	25.30 ± 0.30	1.000 ± 0.012
00	23.40 ± 0.30	0.921 ± 0.012
0E	23.20 ± 0.30	0.913 ± 0.012
0	21.60 ± 0.30	0.850 ± 0.012
1	19.40 ± 0.30	0.764 ± 0.012
2	17.60 ± 0.30	0.693 ± 0.012
3	15.70 ± 0.30	0.618 ± 0.012
4	14.30 ± 0.30	0.563 ± 0.012

The joining lengths of the locked capsules can vary with fill material and filling machine adjustment. These parameters are only for in-process control purposes and are not acceptance/rejection criteria.

TABLE N° 4 EXTERNAL DIAMETER

SIZE	CAP		BODY	
	(mm)	(inches)	(mm)	(inches)
000	9.94	0.391	9.55	0.376
00E	8.58	0.338	8.25	0.325
00	8.56	0.337	8.23	0.324
0E	7.65	0.301	7.35	0.289
0	7.65	0.301	7.35	0.289
1	6.96	0.274	6.63	0.261
2	6.39	0.252	6.12	0.241
3	5.85	0.230	5.60	0.220
4	5.33	0.210	5.08	0.200

These parameters are only for in-process control purposes and are not acceptance/rejection criteria.

TABLE N° 5 APPROXIMATE CONTENT OF THE FILLED CAPSULE (mg)

SIZE	DENSITY			
	0.6 g/ml	0.8 g/ml	1.0 g/ml	1.2 g/ml
000	822	1,096	1,370	1,644
00E	612	816	1.020	1.224
00	570	760	950	1.140
0E	462	616	770	924
0	408	544	680	816
1	288	384	480	576
2	216	288	360	432
3	162	216	270	324
4	120	160	200	240

TABLE N° 6 MICROBIOLOGICAL QUALITY OF THE CAPSULE

PARAMETER	SPECIFICATION
Total aerobic microbial count	NMT 1000 CFU/g
Salmonella Spp	Absence /10 g
Escherichia Coli	Absence / g
Pseudomonas Aeruginosa	Absence / g
Staphylococcus Aureus	Absence / g
Yeast and Mold	NMT 100 CFU /g

TABLE N° 7 VISIBLE DEFECTS

CRITICAL	MAJOR	MINOR
Foreign capsule	Grease spot	Bubbles
Hole	Punched ends	Specks
Locked capsule	Chipped cap or body (major)	Chipped cap or body (minor)
Cracked	Thin spot	Wrinkle
Sticking capsule	String (major)	Star end
Cutting	Double cap	String (minor)
Double dip	Loose piece	Line in end
Short body	Bad dip	Undissolved particle inside
Uncut	Rough cut (major)	Scraped
Mashed capsule	Bad joining	Collect pinch
Long cap or body	Lateral corrugation	Particle in the capsule
	Short cap	Grease spot (minor)
	Long joining	Uneven cut
		Rough cut (minor)

TABLE N° 8. VISIBLE DEFECTS ON PRINTED CAPSULES

CRITICAL	MAJOR	MINOR
Foreign material	Partial Imprint (missing or cut off)	Ink spot (minor)
Unprinted	Off-center (misplaced printing)	Off-center misplaced (minor)
	Smeared/Multiple Imprint (not legible)	Partial imprint (minor)
		Roller mark
		Poor ink cover-up
		Print line
		Multiple print (Legible)
		Light and Dark imprint
		Smeared/Multiple Imprint (legible)

TABLE N° 9 ACCEPTABLE QUALITY LEVELS (AQL)

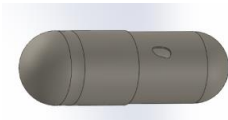

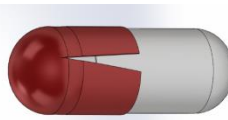
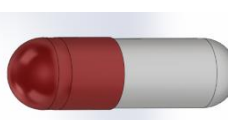
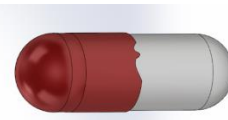
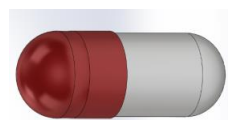
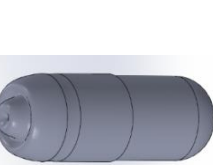
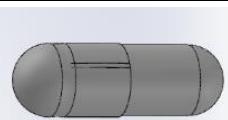
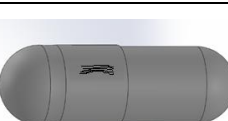
TYPE OF DEFECT	UNPRINTED CAPSULES (AQL)	PRINTED CAPSULES (AQL)
CRITICAL	0.010 %	0.010 %
MAJOR	0.040 %	0.065 %
MINOR	0.250 %	1.500 %

TABLE N° 10 ACCEPTANCE-REJECTION LEVELS (AQL)

TYPE OF DEFECT	SIZE OF THE CAPSULE SAMPLE	UNPRINTED CAPSULES		PRINTED CAPSULES	
		# Acceptance	#Rejection	# Acceptance	#Rejection
CRITICAL	1250	0	1	0	1
MAJOR	1250	1	2	2	3
MINOR	1250	7	8	21	22

Visual quality is based on ANSI/ASQ-Z1.4, Single Sampling Plan (General Inspection).

TABLE N° 11: CLASIFICACION OF VISIBLE DEFECTS

	Hole: Perforation on the capsule surface
	Short body: Length of body is 1.5 mm shorter than the specified
	Split: Pronounced fissure greater than 1.0 mm
	Long body: Length of body is 1.0 mm greater than the specified length.
	Rough cut: Irregular cut in a dented form or pronounced sinuosity (greater than 1 mm) on the edges of cap and body.
	Short cap: Length of cap is 1.0 mm shorter than the specified length.
	Punched end major: Flat dome. It compromises the shoulder of the cap or body Punched end minor: Flat dome without affectioning the cap or body shoulder.
	Collect pinches: pronounced nips or folds greater than 3.0 mm of length in capsules of sizes “000”- “1” and greater than 2.0 mm of length in capsules of sizes “2”- “4”.
	Wrinkles: Wrinkles greater than 3 x 2 mm on the capsule ring or along the cap or body.

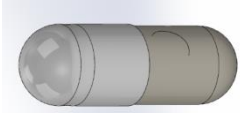



	String: Small threads appearing as a result of an inadequate cutting, greater than 3.0 mm in length in capsules of sizes “000”- “1” and greater than 2.0 mm in length in capsules “2”- “4”
	Star end: Stellated wrinkles on the dome in a slight or pronounced way greater than 4.0 mm of diameter in capsules of sizes “000”-“1” and greater than 3.0 mm of diameter in capsules “2”-“4”.
	Bubble: Air spaces considered as a minor defect when having a diameter of 1 mm or more.
	Specks: Stains or dots of a different color on the surface of the capsule.

TABLE N° 12 COLOR CODING OF CAPSULES

COLOR	CODE
Natural	1-0
Amethyst	2-XXX
Black	3-XXX
Blue	4-XXX
Brown	5-XXX
Buff	6-XXX
Caramel	7-XXX
Flesh	8-XXX
Grey	9-XXX
Green	10-XXX
Orange	14-XXX
Pink	15-XXX
Purple	16-XXX
Red	17-XXX
Scarlet	18-XXX
Yellow	19-XXX
White	20-XXX
Silver	21-XXX
Gold	22-XXX

Code: The first number corresponds to the color of the capsules and XXX is a consecutive number.

**TABLE N° 13 PACKAGING STANDARDS FOR EMPTY
HARD CAPSULES OF VEGETABLE ORIGIN**

SIZE	QUANTITY (CAPSULES / BOX)
000	50.000
00E	65.000
00	75.000
0E	90.000
0	100.000
1	125.000
2	175.000
3	200.000
4	250.000

Note: As specifications are under continuous review, be sure to contact your sales representative for the most up-to-date technical information.

The capsules are packaged in anti-static plastic bags which provide a protective barrier against moisture, and corrugated cartons for the secure storage and transportation of the capsules. This packaging material allows the protection of the physicochemical and microbiological characteristics of the product, provided they are stored under the specified conditions of temperature and relative humidity.

Issued: **April 4th, 2020**

Name / Position: **Leonardo De la Hoz P. / Quality Assurance Manager**

Signature:



Certificate code: V016-18