



TECHNICAL DATA SHEET FOR EMPTY HARD GELATIN CAPSULES

- Hard Gelatin Capsules are manufactured with Pharmaceutical Grade Gelatin (derived from bovine hide raw material).
- Hard Gelatin Capsules produced on our premises are odourless and tasteless and are suitable for human consumption.
- Hard Gelatin Capsules raw materials meet all requirements of the current USP.
- Hard Gelatin Capsules are distributed globally and are intended for use in pharmaceutical and food products.
- Hard Gelatin Capsules are soluble in hot water at $98.6^{\circ}\text{F} \pm 1.8^{\circ}\text{F}$ ($37^{\circ}\text{C} \pm 1^{\circ}\text{C}$).
- Hard Gelatin Capsules disintegrate in no more than 15 minutes.
- Hard Gelatin Capsules moisture content is kept between 13 % and 16%.
- Hard Gelatin Capsules visual quality is based on the ANSI/ASQ-Z1.4 Single Sampling Plan (General Inspection).
- Hard Gelatin Capsules have an expiration date of five years, provided they are stored and handled in their original packaging, in places with temperatures between 59°F (15°C) and 77°F (25°C), and relative humidity levels between 35 % and 65 %.
- Hard Gelatin Capsules are made in Colombia and Canada.

TABLE No. 1 EMPTY CAPSULE WEIGHT

SIZE	CAPSULE WEIGHT (mg)
000	163.0 ± 10
00E	130.0 ± 10
00	123.0 ± 7
0E	107.0 ± 7
0	99.0 ± 6
1	76.0 ± 5
2	61.0 ± 4
3	48.0 ± 3
4	38.0 ± 3

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

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CALLE 79B 78C-21 BARRANQUILLA – COLOMBIA
TELEPHONE / TELEFONO (57-60-5) 330-4100 FAX (57-60-5) 330-4105

TABLE No. 2 INDIVIDUAL LENGTH

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	12.94 ± 0.35	0.509 ± 0.014	22.38 ± 0.35	0.881 ± 0.014
00	11.80 ± 0.35	0.464 ± 0.014	20.10 ± 0.35	0.791 ± 0.014
0E	11.90 ± 0.35	0.468 ± 0.014	20.00 ± 0.35	0.787 ± 0.014
0	10.85 ± 0.35	0.427 ± 0.014	18.45 ± 0.35	0.726 ± 0.014
1	9.85 ± 0.35	0.388 ± 0.014	16.40 ± 0.35	0.646 ± 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 No. 3 JOINING LENGTH OF THE LOCKED CAPSULE

SIZE	(mm)	(inches)
000	26.00 ± 0.30	1.024 ± 0.012
00E	25.40 ± 0.30	1.000 ± 0.012
00	23.40 ± 0.30	0.921 ± 0.012
0E	23.40 ± 0.30	0.921 ± 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 length 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 No. 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	7.66	0.302	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

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TABLE No. 5 APPROXIMATE CONTENT OF THE FILLED CAPSULE, (mg)

DENSITY SIZE	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 No. 6 MICROBIOLOGICAL QUALITY OF THE CAPSULE

PARAMETER	SPECIFICATION
Total aerobic microbial count	NMT 1000 CFU / g
Salmonella Species	Absence /10 g
Escherichia coli	Absence/1 g
Pseudomonas Aeruginosa	Absence /1 g
Staphylococcus Aureus	Absence /1 g
Total Combined Yeast and Molds Count	NMT 100 CFU /g



TABLE No. 7 VISIBLE DEFECTS

CRITICAL	MAJOR	MINOR
Foreign material	Short / long join	Bubble
Hole	Loose piece	Collet pinch (minor)
Bad dip/Wrinkle	Loose cuttings	Undissolved gelatin
Locked capsule	Chipped cap or body (major)	Rough cut (minor)
Torn/Bad cut	Grease spot	Star end
Capsules stuck together	Punched ends (major)	String (minor)
Double dip	Thin spot	Grease spot
Short body	Rough cut	Scratches
Short body	Collet pinch (major)	Chipped cap or body
Uncut cap/body	Long / short cap	Wrinkle
Mashed	String	Specks
Corrugation (critical)	Corrugation(major)	Rough cut (minor)
Telescoped	Bad join	Uneven cut
Split		Punched ends (minor)
Cutting inside		

TABLE No. 8 PRINT DEFECTS

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

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TABLE No. 9 ACCEPTABLE QUALITY LEVELS (AQL)



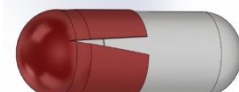




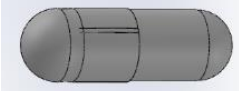
TYPE OF DEFECT	UNPRINTED CAPSULES % AQL	PRINTED CAPSULES % AQL
CRITICAL	0.010	0.010
MAJOR	0.040	0.065
MINOR	0.250	1.500

TABLE No. 10 ACCEPTANCE – REJECTION LEVELS

TYPE OF DEFECT	SIZE OF SAMPLE (No. Capsules)	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

Hard Gelatin Capsule visual quality is based on the ANSI/ASQ-Z1.4 Single Sampling Plan (General Inspection).

TABLE N° 11: CLASIFICACION OF VISIBLE DEFECTS

	<p>Hole: Perforation on the capsule surface</p>
	<p>Short body: Length of body is 1.5 mm shorter than the specified</p>
	<p>Split: Pronounced fissure greater than 1.0 mm</p>
	<p>Long body: Length of body is 1.0 mm greater than the specified length.</p>
	<p>Rough cut: Irregular cut in a dented form or pronounced sinuosity (greater than 1 mm) on the edges of cap and body.</p>
	<p>Short cap: Length of cap is 1.0 mm shorter than the specified length.</p>
	<p>Punched end major: Flat dome. It compromises the shoulder of the cap or body Punched end minor: Flat dome without affection of the cap or body shoulder.</p>
	<p>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”.</p>

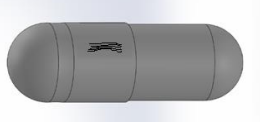
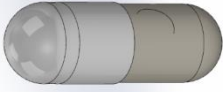


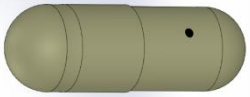
	<p>Wrinkles: Wrinkles greater than 3 x 2 mm on the capsule ring or along the cap or body.</p>
	<p>String: Small threads appearing as a result of an inadequate cutting, greater than 3.0 mm of length in capsules of sizes “000”-“1” and greater than 2.0 mm of diameter in capsules “2”-“4”</p>
	<p>Star end: 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”.</p>
	<p>Bubble: Air spaces considered as a minor defect when having a diameter of 1 mm or more.</p>
	<p>Specks: Stain or dot of a different color on the surface of the capsule.</p>



TABLE No. 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.

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TABLE No. 13 PACKAGING STANDARDS FOR EMPTY HARD GELATIN CAPSULES


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 protection barrier against moisture and corrugated cartons for the secure storage and transportation of the capsule. This packaging material allows the protection of the physic chemical and microbiological characteristics of the product provided the storage under the specified conditions of temperature and relative humidity.

Issued: **January 1st, 2023**

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

Signature: 

Certificate code: G016-10

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