



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 suitable for human consumption.
- Hard gelatin capsules meet all established requirements of the current USP and EP.
- Hard gelatin capsules are distributed all over the world and are intended for use in pharmaceutical and food products.
- Hard gelatin capsule sections separate freely prior to being filled, and the edges of the separated cap and body are cleanly and evenly cut without visible roughness.
- 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 Military Standard 105E, using simple sampling with level III of General Inspection.
- The empty hard gelatin capsules 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 77°F (25°C), and relative humidity levels between 35% and 65%.
- Hard gelatin capsules are made in Colombia, South America.

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 specifications limits are established taking into account the average capsule weight. Depending on the size, the body represents approximately 60% of the total capsule weight.



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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 lengths of the locked capsules can vary with regard to filling content 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, (In 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	Long join	Bubble
Oil hole	Double cap	Collect pinch (minor)
Scrape hole	Loose piece	Particle inside the capsule
Closed capsule	Bad dipping	Rough cut (minor)
Cracked	Long cap or body	Star end
Sticking capsule	Chipped cap or body (major)	String (minor)
Trim	Dirty capsule	Inside dirty end
Double dip	Punched ends (major)	Black speck
Short body	Thin spot	Scraping
Uncut	Lateral corrugation (major)	Spot
Mashed	Collect pinch (major)	Punched end (minor)
Lateral corrugation (critical)	Short cap	Chipped cap or body (minor)
Bad join	String (major)	Wrinkle
Telescoped	Rough cut (major)	Gelatin speck
Split		Gelatin clot
		Uneven cut



TABLE No. 8 PRINT DEFECTS

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

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

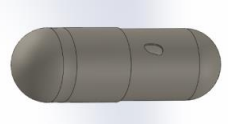
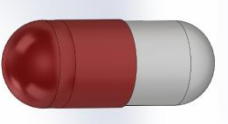
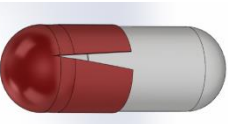
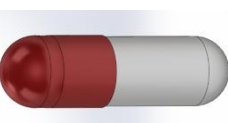
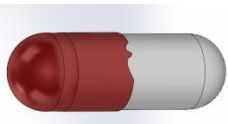
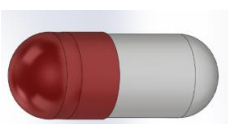

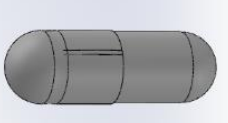
TYPE OF DEFECT	SIZE OF SAMPLE (No. Capsules)	UNPRINTED CAPSULES		PRINTED CAPSULES	
		# Acceptance	# Rejection	# Acceptance	# Rejection
CRITICAL	1250	0	1	0	1
MAJOR	1250	1	2	2	3
MINOR	1250	7	8	21	22

- Hard gelatin capsules visual quality is based on Military Standard 105E, using simple sampling with level III of General Inspection.



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TABLE N° 11: CLASIFICATION 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 sinuosities (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>



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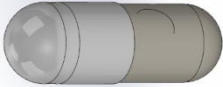



 A grey, cylindrical capsule with a textured surface showing several irregular wrinkles or folds, particularly around the central ring and the cap.	<p>Wrinkles: Wrinkles greater than 3 x 2 mm on the capsule ring or along the cap or body.</p>
 A white and grey capsule with a thin, fibrous string or thread protruding from the cap area.	<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>
 A grey capsule with a dome-shaped end that has a star-shaped or stellated wrinkle pattern on its surface.	<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>
 A white capsule with a small, clear, spherical bubble or air space on its surface.	<p>Bubble: Air spaces considered as a minor defect when having a diameter of 1 mm or more.</p>
 A green capsule with a small, dark, circular speck or stain on its surface.	<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-xxxx
Black	3-xxxx
Blue	4-xxxx
Brown	5-xxxx
Buff	6-xxxx
Caramel	7-xxxx
Flesh	8-xxxx
Grey	9-xxxx
Green	10-xxxx
Orange	14-xxxx
Pink	15-xxxx
Purple	16-xxxx
Red	17-xxxx
Scarlet	18-xxxx
Yellow	19-xxxx
White	20-xxxx
Silver	21-xxxx
Gold	22-xxxx

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

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: **Jan 1st, 2018**

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

Signature: _____

The signature is a handwritten mark in black ink, appearing to be the initials "LDH" with a stylized flourish. It is positioned above a horizontal line that serves as a baseline for the signature.

Certificate code: G016-10