



TECHNICAL DATA SHEET FOR EMPTY HARD GELATIN CAPSULES

- Hard gelatin capsules are manufactured by HGCapsule.
- Hard gelatin capsules are manufactured with pharmaceutical gelatin, derived from bovine hide raw material.
- Colored hard gelatin capsules are formulated using dyes or pigments approved and officially certified for Food, Drugs and Cosmetics (FD&C grade), and/or for Drugs and Cosmetics (D&C grade).
- The flavors used in the formulations of the gelatin solution are classified as food grade. All of its ingredients are Generally Recognized As Safe (GRAS).
- Hard gelatin capsules have uniform dimensions within the specified tolerances.
- 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 less than 15 minutes.
- Hard gelatin capsules' moisture content is kept between 13% and 16%.
- Hard gelatin capsules have an expiration date of three years, provided they are stored and handled in their original packing, in places with temperatures between 59°F (15°C) and 77°F (25°C), and relative humidity levels between 35% and 65%.

TABLE No.1 EMPTY CAPSULE WEIGHT

SIZE	CAPSULE WEIGHT(mg)
000	165 ± 14
00	122 ± 11
0E	108 ± 10
0	97 ± 9
1	77 ± 7
2	63 ± 6
3	49 ± 5
4	39 ± 4
5	27 ± 4



TABLE No.2 INDIVIDUAL LENGTH

SIZE	CAP		BODY	
	(mm)	(inches)	(mm)	(inches)
000	12.9±0.3	0.508±0.012	22.3±0.3	0.878±0.012
00	11.8±0.3	0.464±0.012	20.2±0.3	0.795±0.012
0E	11.7±0.3	0.461±0.012	20.2±0.3	0.795±0.012
0	10.8±0.3	0.425±0.012	18.4±0.3	0.724±0.012
1	9.8±0.3	0.386±0.012	16.5±0.3	0.650±0.012
2	9.0±0.3	0.354±0.012	15.4±0.3	0.606±0.012
3	8.1±0.3	0.319±0.012	13.5±0.3	0.531±0.012
4	7.2±0.3	0.283±0.012	12.2±0.3	0.480±0.012
5	6.3±0.3	0.248±0.012	9.3±0.3	0.366±0.012

TABLE No.3 JOINING LENGTH OF THE LOCKED CAPSULE

SIZE	(mm)	(inches)
000	26.2±0.5	1.032±0.020
00	23.5±0.5	0.925±0.020
0E	23.4±0.5	0.921±0.020
0	21.4±0.5	0.843±0.020
1	19.1±0.5	0.752±0.020
2	17.5±0.5	0.689±0.020
3	15.5±0.5	0.610±0.020
4	14.0±0.5	0.551±0.020
5	11.0±0.5	0.433±0.020

TABLE No.4 EXTERNAL DIAMETER

SIZE	CAP		BODY	
	(mm)	(inches)	(mm)	(inches)
000	9.94	0.391	9.56	0.376
00	8.54	0.336	8.2	0.323
0E	7.68	0.302	7.36	0.290
0	7.68	0.302	7.36	0.290
1	6.96	0.274	6.65	0.262
2	6.37	0.251	6.08	0.240
3	5.83	0.230	5.56	0.219
4	5.32	0.209	5.05	0.199
5	4.9	0.193	4.64	0.183



TABLE No.5 APPROXIMATE CONTENT OF THE FILED CAPSULE,IN mg

DENISTY SIZE	0.6 g/ml	0.8 g/ml	1.0 g/ml	1.2 g/ml
000	828	1,104	1,380	1,656
00	570	760	950	1,140
0E	462	616	770	924
0	408	544	680	816
1	300	400	500	600
2	222	296	370	444
3	180	240	300	360
4	126	168	210	252
5	78	104	130	156

TABLE No.6 MICROBIOLOGICAL QUALITY OF THE CAPSULE

PARAMETER	SPECIFICATION
Total Aerobic bacteria	<1000 CFU/g
Yeast and mould	<100 CFU/g
Escherichia coli	Absent
Pseudomonas Aeruginosa	Absent
Staphylococcus Aureus	Absent
Salmonella	Absent
Total Coliforms	Absent

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	Imprint smeared (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)
		Poor ink cover-up
		Print line
		Multiple print (legible)
		Light & dark imprint

TABLE No.9 ACCEPTABLE QUALITY LEVELS (AQL)

TYPE OF DEGECT	UNPRINTED CAPSULES % AQL	PRINTED CAPSULES % AQL
CRITICAL	0.010	0.010
MAJOR	0.040	0.065
MINOR	0.250	0.650

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	14	15



TABLE No.11 SHIPMENT STADARDS FOR EMPTY HARD GELATIN CAPSULES

SIZE	QUANTITY (Capsules/Box)
000	50,000
00	75,000
0E	90,000
0	100,000
1	140,000
2	180,000
3	240,000
4	300,000
5	400,000

Name/Position : Cai Xianju / Quality Assurance Manage.