

GS Capsule

Empty Hard Gelatin Capsules Specification (EU)

Create value for customers partners and employees around the world with reliable quality and service and optimize dosage form solutions continuously.

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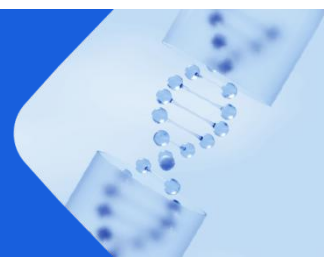
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1. Capsule Specification

1.1 Dimensions

Size	—	Length ±0.4 (mm)	Outside Diameter (mm)	Weight Range (mg)	Locked Length ±0.5 (mm)
000#	Cap	13.10	9.86±0.07	161-185	25.7
	Body	22.10	9.46±0.07		
00#el	Cap	12.80	8.53±0.07	122-140	25.6
	Body	22.10	8.16±0.07		
00#	Cap	11.80	8.53±0.07	121-137	23.6
	Body	20.20	8.16±0.07		
0#el+	Cap	10.90	7.65±0.06	106-118	24.4
	Body	21.40	7.30±0.06		
0#el	Cap	11.80	7.65±0.06	102-114	23.3
	Body	20.20	7.30±0.06		
0#	Cap	10.90	7.65±0.06	92-104	21.5
	Body	18.60	7.30±0.06		
A#	Cap	14.40	8.55±0.06	110-122	17.9
	Body	14.80	8.20±0.06		
B#	Cap	11.00	8.55±0.06	82-94	14.6
	Body	11.30	8.25±0.06		
B#-	Cap	11.00	8.55±0.06	82-94	14.1
	Body	11.00	8.25±0.06		
1#el	Cap	9.90	6.92±0.06	76-86	20.2
	Body	17.50	6.60±0.06		
1#	Cap	9.80	6.92±0.06	71-81	19.4
	Body	16.50	6.60±0.06		
2#	Cap	9.00	6.35±0.06	57-65	17.7
	Body	15.30	6.03±0.06		
3#	Cap	8.10	5.82±0.06	46-54	15.8
	Body	13.60	5.52±0.06		
4#	Cap	7.20	5.32±0.06	35-41	14.3
	Body	12.20	5.02±0.06		
5#	Cap	6.40	4.91±0.06	25-31	11.0
	Body	9.20	4.63±0.06		



- ① Length is measured by the electronic digital caliper with the accuracy of 0.01mm.
- ② The weight is measured by the analytical balance with the accuracy of 0.001g.
- ③ Outside diameter is measured by the KEYENCE 2D MICROMETER with the accuracy of 0.01mm, this data is for reference only, cannot be used as the final acceptance standard, it can be used as a reference for packaging material dimensions.
- ④ Locked Length is measured by the electronic digital caliper with the accuracy of 0.1mm, this data is for reference only, cannot be used as the final acceptance standard.
- ⑤ Other sizes can be produced according to customer requirements.

1.2 Capsules Dimensions AQL

Technical Requirements	Inspection Items	Sampling Quantity (pcs)	AQL	
			Ac	Re
Dimensions	Length	20	1	2
	Weight	100	3	4

Remarks: Ac is short for acceptable quantity, Re is short for rejectable quantity.

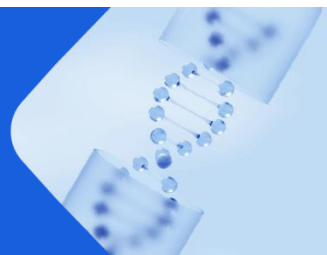
2. Capsule Appearance








2.1 Manufacturing defects

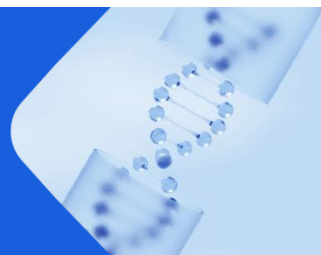
Critical: It refers to the defect that causes the capsule to lose the container characteristic, or the filling quantity is too low, or causes the filling machine to stop seriously, or delays the filling production, etc.


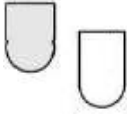





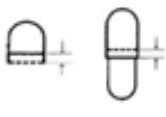

Major: It refers to the defect that leads to filling operation problems. For example, capsules can't be separated, adjusted, or locked properly, etc.

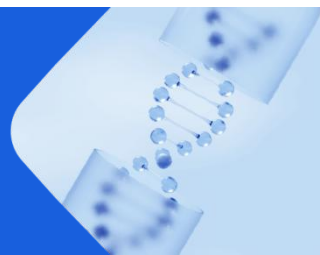
Minor: It refers to the defect that does not affect the filling operation but affects the appearance of the capsule.












Classification	Defect Name	Defect Picture	Description
Critical defect	Holes		Holes caused by various reasons
	Uncut/Inner cut residue		Capsule with uncut cap / body connected or remain inside
	Cracks/Gap		Cutting edge cracks greater than 2mm/gaps greater than 2mm
	Short body		The length of the capsule is more than 1mm shorter than the specified length
	Dented capsules		The body or cap is flattened or twisted
	Telescoped		When the capsule is combined, the overlapping parts of the cap are interlaced with each other
	Trimmings		Any cut part left after the body or cap is cut



Major defect	Cracks/Gap		Cutting edge cracks greater than 1mm/gaps greater than 1mm
	Single section		Separated body or cap
	Crease		The length of a single longitudinal fold on the capsule is greater than 5mm, and the concavity or convexity is greater than 1mm
	Locked		The combination of capsule cap and body has reached the final locking position
	Double cap		There is an additional cap on the capsule body
	Dented end		The diameter of the top depression is greater than 4.0mm
	Thin point		The single wall thickness of the thin part on the cap or body is less than or equal to 0.03mm
	Short/long caps		The length of the cap is more than 1mm shorter or longer than the specified length
	Long body		The length of the body is more than 1mm longer than the specified length



Minor defect	Cracks/Gap		Cutting edge cracks greater than 1mm/gaps less than or equal to 1mm
	Bubble		There are bubbles with a diameter greater than 0.3mm on the capsule
	Collet pinches		The longitudinal fold length on the capsule is greater than 3mm
	Dented End		The diameter of the top depression is greater than 2.0mm
	Black dot/Heterochromatic dot		Black spots with a diameter greater than 0.3mm on the capsule or spots of a color different from the capsule
	Star end		Top star shaped fold with a diameter greater than 4.0mm
	Scrapes		The outer surface of the capsule is scratched with a length greater than or equal to 2mm
	Corrugation		The folds on the capsule wall are greater than 5mm × 3mm
	Strings		Cutting edge with hanging wire greater than 2.0mm



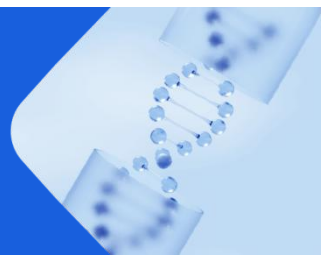
2.2 Printing defects

Critical: Unable to distinguish printed designs(including words and letters).

Major: Able to distinguish printed designs but the designs are unclear or upside down.

Minor: Clear printing content but meanwhile there are printing defects that only affect the appearance.

Classification	Defect Name	Description
Critical defect	Unprint	No designated pattern on the capsule
	Repetitive printing	Repetitive printing of patterns on capsules
	Serious incompleteness	The important strokes (important parts) of the pattern are incomplete, resulting in inability to confirm or incorrect confirmation
Major defect	Reverse	The pattern on the cap and body is opposite to the specified direction
	Rubbing	The handwriting on the pattern is blurry, resulting in unclear patterns
	Bias	More than a quarter of the pattern is covered by a cap or the pattern on the cap is missing after final locking
	Ink dots	The ink dots on the capsule are greater than 0.5mm
	Ink mark	The ink mark on the capsule is greater than or equal to 3mm
Minor defect	Incomplete	The text (letters) on the pattern is missing, and the pattern can be recognized (except for missing printing on the lock point)
	Rubbing	Part of the handwriting on the pattern is blurry, but the pattern is recognizable
	Bias	Less than a quarter of the pattern is covered by a cap or the pattern on the cap is missing after final locking
	Ink dots	Ink dots on the capsule range from 0.3mm to 0.5mm
	Ink mark	The ink on the capsule is greater than or equal to 1mm and less than 3mm



2.3 Capsules Appearance AQL

Technical Requirements		Inspection Items	Test Level	Sampling Quantity (pcs)	AQL		
					AQL(%)	Ac	Re
Capsules Appearance	Manufacturing defects	Critical	II	1250	0.01	0	1
		Major			0.04	1	2
		Minor			0.25	7	8
	Printing defects	Critical			0.01	0	1
		Major			0.065	2	3
		Minor			0.65	14	15

Remarks: Ac is short for acceptable quantity, Re is short for rejectable quantity.

Sampling Quantity (pcs) To be selected from $(\sqrt{n} + 1)$ cartons, where n =number of cartons in the lot

3. Packaging

The inner layer is packed in medicinal low density polyethylene bags and the outer layer is packed in corrugated cartons.

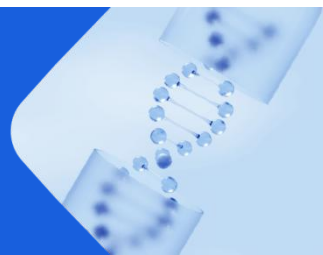
Size	000#	00#el	00#	0#el+	0#el	0#	A#
Packaging Unit (pcs /ctn)	50,000	70,000	75,000	80,000	90,000	100,000	100,000
Size	B#/B#-	1#el	1#	2#	3#	4#	5#
Packaging Unit (pcs /ctn)	100,000	130,000	140,000	180,000	220,000	300,000	300,000



4. Test

The gelatin capsules are tested according to ChP and comply with the USP, EP and JP standards.

	Test		Specification
Identification	Description		Unlocked cylindrical capsules
	Capsule colour		As per approved colour shade
	Identification of gelatin		Positive for gelatin
	Identification of opacifier		Conforms to approved composition
	Identification of colourants		Conforms to approved composition
Performance	Disintegration time		≤15min
	Loss on drying		13.0%~16.0%
	Weight range		According to dimension table 1.1
Purity	Odour		No foreign odour
Safety	Sulphated ash	Transparent	≤2.0%
		Translucent	≤3.0%
		Opaque	≤7.0%
		Calcium carbonate	≤15.0%
	Lubricant content		≤0.5%
	Sulphur dioxide		≤10ppm
	Chromium		≤2.0ppm
	Arsenic		≤1.0ppm
	Lead		≤1.0ppm
	Cadmium		≤0.5ppm
	Mercury		≤0.1ppm
Microbial Limits	Total Aerobic Microbial Count		≤500cfu/g
	Total Yeasts and Molds Count		≤100cfu/g
	Escherichia coli		Absent in 1g
	Salmonella		Absent in 10g
	Staphylococcus aureus		Absent in 1g
	Pseudomonas aeruginosa		Absent in 1g



5. Transport and Storage Conditions

The means of transport must be clean, sanitary and dry. The product should be protected from pressure, drop, moisture, sun, heat and freezing during transportation, which should not be combined with toxic or unclean goods in shipment. The product is stored in tightly closed under the condition of temperature 15°C~30°C and relative humidity 35%~65%, and the validity period is 5 years.

6. Declaration

GMO: No genetically modified ingredients or from the other raw materials derived from genetic modification.

Nano: No nano materials.

Radiation exposure: Not treated with radiation exposure.

Production process: Ethylene oxide is not used for sterilization.

TSE/BSE: The capsules are guaranteed to be made from Mad Cow Disease free gelatin.

