

Product Data Sheet

Product

Bovine Gelatine Capsules

Specification No.: GSG-08

Specification valid from: 2021-01-04

General parameters

Description	Empty, two-piece, cylindrical hard gelatine capsules, typical in taste and odour		
Manufacturer	Shanxi Guangsheng Medicinal Capsule Co., Ltd.		
Manufacturer certifications	BRC, NSF-GMP, ISO9001, ISO14001, OHSAS18001, Halal, and Kosher		
Legal status	EU legislation for food and pharmaceuticals	Country of origin	China
Composition	Bovine gelatine (Ph. Eur.) and purified water (Ph. Eur.)		
Colour range	Transparent, semi-transparent and opaque, with colours according to agreement		
Imprint	Text and colour according to agreement	Ink type	Edible

Galenic properties (AQL-defect rate: Critical: 0.01 %, Major: 0.10 %, Minor: 0.40 %, on fully automatic testing machines)

Size	000	00	0	1
Weight, mg	177 ±8	128 ±7	98 ±6	75 ±6
Volume, cc	1.35	0.93	0.68	0.50
Dose (mg/capsule) as function of bulk density				
- 0.6 g/cc	810	558	408	300
- 0.8 g/cc	1080	744	544	400
- 1.0 g/cc	1350	930	680	500
- 1.2 g/cc	1620	1116	816	600
Length, mm				
- Cap	13.1 ±0.4	11.8 ±0.4	10.9 ±0.4	9.8 ±0.4
- Body	22.0 ±0.4	20.2 ±0.4	18.6 ±0.4	16.5 ±0.4
- Overall closed (filled)	25.7 ±0.5	23.4 ±0.5	21.7 ±0.5	19.3 ±0.5
External diameter, mm				
- Cap	9.85 ±0.05	8.55 ±0.05	7.66 ±0.05	6.95 ±0.05
- Body	9.49 ±0.05	8.20 ±0.05	7.35 ±0.05	6.65 ±0.04
Single wall thickness, mm				
- Cap	0.115 ±0.02	0.105 ±0.02	0.100 ±0.02	0.100 ±0.02
- Body	0.110 ±0.02	0.105 ±0.02	0.100 ±0.02	0.095 ±0.02

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Analytical parameters

Galenic properties

Disintegration time ≤ 15 min. (EP, 37°C, guided disc)

Chemical

Arsenic (As)	NMT 1.0 mg/kg	
Lead (Pb)	NMT 1.0 mg/kg	
Cadmium (Cd)	NMT 0.5 mg/kg	
Mercury (Hg)	NMT 0.1 mg/kg	
Heavy metals	NMT 10 mg/kg	
Chromium (Cr)	NMT 2.0 mg/kg	on gelatine raw material USP 2013
Sulphur Dioxide (SO ₂)	NMT 10 mg/kg	
Sulphated ash, transparent	NMT 2.0% w/w	
Sulphated ash, opaque	NMT 5.0% w/w	
Loss on drying	12.5 to 17.0 % w/w	105°C, 4 hours or constant weight

Microbiology

Total viable count	≤ 500 cfu/g	
Yeasts and moulds	≤ 100 cfu/g	
Enterobacteria	≤ 100 cfu/g	
E. coli	Negative in 1 g	Ph. Eur. 2.4.12./13 or equivalent
Salmonella	Negative in 10 g	
Staphylococcus aureus	Negative in 1 g	
Pseudomonas aeruginosa	Negative in 1 g	

Packaging

Size	000	00	0	1
Capsules/box	50 000	70 000	100 000	125 000
Packaging material	Double polyethylene food grade bag in sturdy cardboard-box			
Box dimensions	585 x 385 x 730 mm (length x width x height)			

Storage and handling

Storage	Store between 10°C and 25°C and relative humidity (RH) between 35% and 65%, in tightly closed packing, protected from direct light.
Pre-filling	Recommended storage between 20°C and 24°C and RH between 45% and 65% at least 12 hours before opening.
Handling and filling	Temperature between 20°C and 24°C and RH between 45% and 65% during usage. Use only stainless-steel scoops and spatulas. Do not leave capsules in a filling machine hopper for prolonged period, when not in use. Keep mouth of the bag closed when not in use.
Shelf life	5 years from date of manufacturing, when stored and handled as described.