

Product Data Sheet

Product	Empty Hard Bovine Gelatin Capsules		
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Specification No.: GSG-04	Specification Valid From:	2016-08-20	
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General Parameters

Description	Empty, two-piece, cylindrical hard gelatine capsules, typical in taste and odour.		
Manufacturer	Shanxi Guangsheng Medicinal Capsule Co., Ltd.		
Legal Status	EU legislation for food and pharmaceuticals	Country of Origin	China
Composition	Bovine gelatine (Ph. Eur.) and purified water (Ph. Eur.)		
Colour range	Clear transparent and opaque, with colours according to agreement		
Imprint	Test and colour according to agreement	Ink type	Edible
Organic Food Supplements	Hard capsules prepared from pure bovine gelatine and water are permitted for preparation of food supplements labelled as organic. (Source: Commissions Regulation No. 889/2008/EC, Article 28 and Annex IX)		
Shelf Life	4 years from date of manufacturing, when stored and handled as described in the storage and handling section (page 2).		

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

Size	000	00	0	1
Capsules/box	50 000	70 000	100 000	125 000
Lengths, 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	15.5 ±0.4
- Filled (closed)	25.7 ±0.5	23.4 ±0.5	21.7 ±0.5	19.3 ±0.5
Single Wall thickness, mm				
- Body	0.115 ±0.02	0.105 ±0.02	0.100 ±0.02	0.100 ±0.02
- Cap	0.115 ±0.02	0.105 ±0.02	0.100 ±0.02	0.095 ±0.02
Weight, mg	177 ±8	128 ±7	98 ±6	75 ±6
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
Body volume	1.35 cc	0.93 cc	0.68 cc	0.50 cc
Dose (mg/capsule) as function of powder density				
- 0.60 g/cc	810 mg	558 mg	408 mg	300 mg
- 0.80 g/cc	1080 mg	744 mg	544 mg	400 mg
- 1.0 g/cc	1350 mg	930 mg	680 mg	500 mg
- 1.2 g/cc	1620 mg	1116 mg	816 mg	600 mg

For elongated (size 00el, 0el, 1el) and small capsules (size 2, 3, 4, 5): please request our full dimensions table

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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 1.0 mg/kg	
Mercury (Hg)	NMT 0.1 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, clear trans.	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	≤ 1000 cfu/g	
Yeasts and moulds	≤ 100 cfu/g	
Enterobacteria	≤ 100 cfu/g	Ph. Eur. 2.4.12./13 or equivalent
E. coli	Negative in 1 g	
Salmonella	Negative in 10 g	

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.