

Product Data Sheet

Product

Empty Hard Natural Capsules (Pullulan)

Specification No.: GSP-03

Specification Valid From

2016-08-30

General Parameters

Description	Empty, two-piece, cylindrical hard natural capsules, typical in taste and odour.		
Manufacturer	Shanxi Guangsheng Medicinal Capsule Co., Ltd.		
Legal Status	EU legislation for food supplements	Country of Origin	China
Composition	Pullulan (FCC & E-1204) 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
Excipients	Gellan gum, xanthan gum, carrageenan, and potassium chloride. <small>¹ The excipients are suitably controlled by the rules laid down by Commission Regulation 1333/2008/EC on food additives; however they are not required to be included in the list of ingredients as they serve no technological function in the finished capsules (Commission Regulation 1169/2011/EU, Article 20 (b)(i)).</small>		
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	00	0	1
Capsules/box	70 000	100 000	125 000
Lengths, mm			
- Cap	11.80 ±0.40	10.90 ±0.40	9.80 ±0.40
- Body	20.20 ±0.40	18.60 ±0.40	15.50 ±0.40
- Filled (closed)	23.40 ±0.50	21.70 ±0.50	19.30 ±0.50
Single Wall thickness, mm			
- Body	0.105 ±0.02	0.100 ±0.02	0.100 ±0.02
- Cap	0.105 ±0.02	0.100 ±0.02	0.095 ±0.02
Weight, mg	148 ±8	108 ±8	78 ±7
External Diameter, mm			
- Cap	8.55 ±0.05	7.66 ±0.05	6.95 ±0.05
- Body	8.55 ±0.05	7.66 ±0.05	6.95 ±0.05
Body volume	0.95 cc	0.68 cc	0.50 cc
Dose (mg/capsule) as function of powder density			
- 0.60 g/cc	570 mg	408 mg	300 mg
- 0.80 g/cc	760 mg	544 mg	400 mg
- 1.0 g/cc	950 mg	680 mg	500 mg
- 1.2 g/cc	1140 mg	816 mg	600 mg

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Analytical Parameters

Galenic properties

Disintegration time ≤ 30 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	
Sulphated ash, clear trans.	NMT 2.0% w/w	
Sulphated ash, opaque	NMT 5.0% w/w	
Loss on drying	10.0 to 15.0 % 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.