

Product Data Sheet

Product

Natural Pullulan Capsules

Specification No.: GSP-06

Specification valid from 2020-12-10

General parameters

| | | | |
|------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------|
| Description | Empty, two-piece, cylindrical hard natural 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 supplements | Country of origin | China |
| Composition | Pullulan (FCC & E-1204) 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 |
| Vegetarian and Vegan | The capsules fulfil the requirements for “vegetarian” and “vegan” as defined by the consumer protection ministers of the federal states of Germany agreed on April 2016 and endorsed by the EVU (European Vegetarian Union). | | |

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 | 186 ±9 | 140 ±8 | 108 ±7 | 78 ±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 | 0.115 ±0.02 | 0.105 ±0.02 | 0.100 ±0.02 | 0.095 ±0.02 |

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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 0.5 mg/kg | |
| Mercury (Hg) | NMT 0.1 mg/kg | |
| Heavy metals | NMT 10 mg/kg | |
| Sulphated ash, transparent | 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 | ≤ 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. |