

Product Name & Description

Product Name: High Bloom Pharmaceutical Gelatin (Optimized for Hard Capsule Shell Production)

Description: Premium pharmaceutical-grade gelatin featuring a highly calibrated high-bloom profile (240–260 Bloom), manufactured from rigorously audited, healthy bovine or porcine tissue vectors. Specifically developed to satisfy the precise structural demands of two-piece hard gelatin capsule manufacturing, this high-purity excipient ensures exceptional film-forming thermal kinetics, fast gel setting speeds, and optimized structural elasticity. It helps capsule shell manufacturers achieve minimal wall-thickness tolerances and excellent pin-stripping mechanical yields on modern high-speed automated machinery.

Key Specifications & Quality Parameters

Analysis Item	Specification Standard	Test Method Reference
Appearance	Light yellow to faint amber crystalline particles or granules	Visual / USP Standard
Odor & Taste	Completely odorless and neutral taste profile	Sensory Analysis
Jelly Strength (Bloom)	240 – 260 Bloom (High mechanical network grade)	6.67% sol, 10°C, Bloom Gelometer
Kinematic Viscosity (6.67%, 60°C)	3.8 – 5.0 mPa·s	Capillary Viscometer / ChP
Clarity (Transmittance)	≥ 85.0% (at 450 nm) / ≥ 93.0% (at 620 nm)	UV-Vis Spectrophotometer
pH (6.67% Solution at 55°C)	4.5 – 6.5	Potentiometric / USP
Loss on Drying (Moisture)	≤ 13.0%	105°C Oven Drying
Residue on Ignition (Ash)	≤ 2.0%	Gravimetric (550°C)
Peroxides (as H ₂ O ₂)	≤ 10 ppm	Pharmacopoeia Protocol
Sulfur Dioxide (SO ₂)	≤ 30 ppm	Distillation / Titration
Heavy Metals (as Pb)	≤ 10 ppm	AAS / ICP-MS
Arsenic (As)	≤ 0.8 ppm	ICP-MS
Chromium (Cr)	≤ 2.0 ppm (Strictly regulated for shell safety)	ICP-MS
Total Aerobic Microbial Count	≤ 100 cfu/g (Strict pharmaceutical limits)	USP <61> / EP
Molds & Yeasts	≤ 20 cfu/g (or Absent / g)	USP <61>
Escherichia Coli & Salmonella	Absent / 10g	USP <62> / Negative

Functional Advantages & Application Mechanics

- **Precise Wall Thickness Control:** The high gelling network strength (240–260 Bloom) combined with stable kinematic viscosity allows for uniform gelatin film distribution on stainless steel dipping pins, keeping capsule cap and body dimensions within precise micron tolerances.
- **Optimal Film-Forming Elasticity:** Provides excellent tensile strength to the capsule walls. This significantly reduces shell brittle-fracture defects during high-speed pin stripping, trimming, and automated filling cycles with dry powders or pellets.
- **Swift Thermal Reversibility:** Melts smoothly and predictably at human body temperature (~37°C), ensuring capsule shell disintegration takes less than 15 minutes, supporting excellent active pharmaceutical ingredient (API) bioavailability profiles.
- **Low Reactive Impurity Profile:** Meticulous purification keeps reactive trace aldehydes to a minimum. This significantly retards gelatin pellicle formation and cross-linking reactions over long shelf life storage, ensuring stable dissolution properties.

Core Applications

- **Two-Piece Hard Capsule Manufacture:** Designed as the primary base structural material for the automated industrial manufacturing of size 00, 0, 1, 2, 3, and 4 pharmaceutical capsule shells.
- **Nutraceutical Dry-Powder Encapsulation:** Ideal protective oxygen-barrier matrix for encapsulation of highly moisture-sensitive or oxidizable vitamins, minerals, pro-biotics, and sports nutrition supplements.

Regulatory Compliance & Excipient Quality Control

Produced under world-class processing chains ensuring strict dynamic compliance with global pharmaceutical frameworks:

- **Pharmacopoeia Harmony:** In absolute compliance with the current monographs of the United States Pharmacopeia (USP), European Pharmacopoeia (EP), and Chinese Pharmacopoeia (ChP) for gelatin excipients.
- **Safety Frameworks:** Processed inside state-of-the-art facilities in strict accordance with cGMP, ISO 9001, and FSSC 22000 standard configurations. Sourced 100% from healthy veterinary-inspected materials backed by Veterinary Health Certification. Fully certified BSE/TSE-free, Halal, and Kosher verified.

Packaging, Storage & Logistics Architecture

Packaging: Heavy-duty industrial multi-ply Kraft paper bags integrated with an airtight Polyethylene (PE) heat-sealed moisture barrier inner bag. Standard net weight: 25 KG per bag.

Storage Guidelines: Maintain in unopened original bags inside a clean, dry, and well-ventilated pharmaceutical-grade warehouse. Keep temperature continuously **below 25°C** and ambient relative humidity (RH) **between 45% and 65%** to protect against ambient moisture migration or structural hardening.

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Disclaimer: The analytical metrics reported inside this Technical Data Sheet reflect current factory excipient quality parameters. Regulatory dossiers and DMF documentation support are available upon official business inquiry.