

Product Name & Description

Product Name: Pharmaceutical Grade Bovine Bone Gelatin (BSE-Free, Optimized for Hard Capsules)

Description: Premium pharmaceutical-grade Type B gelatin, manufactured via the lime-treatment of 100% BSE-free bovine bones sourced from strictly controlled, veterinary-inspected healthy herds. Engineered specifically for high-speed automated hard capsule shell manufacturing, this ingredient provides premium mechanical elasticity, rapid dissolution profiles, and zero cross-linking susceptibility. It guarantees optimal thermal stability during shell dipping, drying, and pinning processes, satisfying all global compliance protocols for prescription medicine, OTC drugs, and high-end nutraceutical encapsulation.

Key Specifications & Pharmacopoeia Parameters

Analysis Item	Specification Standard	Test Method Reference
Appearance	Light yellow to amber granular or fine particles	Visual / USP Standard
Odor & Taste	Odorless, completely neutral taste profile	Sensory Panel
Jelly Strength (Bloom)	240 – 260 Bloom (High mechanical strength grade)	6.67% sol., 10°C, Bloom Gelometer
Kinematic Viscosity (6.67%, 60°C)	4.0 – 5.5 mPa·s (Optimized for wall uniformity)	Capillary Viscometer / ChP
Clarity of Solution (Transmittance)	≥ 85.0% (at 450 nm) / ≥ 90.0% (at 620 nm)	UV-Vis Spectrophotometer
pH (6.67% Solution at 55°C)	5.0 – 6.8	Potentiometric / USP
Loss on Drying (Moisture)	≤ 13.0%	105°C for 16 Hours
Residue on Ignition (Ash)	≤ 2.0%	Gravimetric (550°C)
Peroxides (as H ₂ O ₂)	≤ 10 ppm	Pharmacopoeia Method
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 (Strict limit for capsule safety)	ICP-MS
Total Aerobic Microbial Count	≤ 100 cfu/g (Strict pharma limits)	USP <61> / EP
Molds & Yeasts	Absent / g (or ≤ 20 cfu/g)	USP <61>
Escherichia Coli & Salmonella	Absent / 10g	USP <62> / Negative

Functional Features & Manufacturing Optimization

- **Perfect Film-Forming Elasticity:** High bloom value (240–260 Bloom) provides exceptional tensile strength and optimal wall thickness distribution, preventing shell brittleness, cracking, or deformation during automated high-speed capsule filling.
- **Precise Viscosity-Temperature Kinetics:** The narrow viscosity range (4.0–5.5 mPa·s) yields uniform dipping films on stainless steel pins, ensuring precise dimensional tolerances for the capsule cap and body lock mechanisms.
- **Minimized Cross-Linking Susceptibility:** Low reactive aldehyde profiles significantly reduce gelatin cross-linking over extended storage, preventing encapsulation aging and ensuring long-term stable API release dissolution curves.
- **Outstanding Thermal Reversibility:** Melts rapidly and predictably at body temperature (~37°C), satisfying pharmacopoeia disintegration time limits (≤ 15 minutes) for fast-acting drug delivery.

Core Applications

- **Two-Piece Hard Gelatin Capsules:** The primary structural polymer for automated encapsulation lines manufacturing size 000, 00, 0, 1, 2, 3, and 4 pharmaceutical capsule shells.
- **Controlled-Release Cross-Linking Matrix:** Functions as a baseline binder for specific immediate-release granules and multi-layered tablet formulations.
- **Nutraceutical Dry Powder Filling:** Ideal protective matrix for oxygen-sensitive vitamins, minerals, herbal extracts, and sports nutrition formulations.

Global Regulatory Compliance & Safety Certifications

Manufactured under elite pharmaceutical quality control loops with full dynamic traceability:

- **Pharmacopoeia Harmony:** In full compliance with current editions of the United States Pharmacopeia (USP), European Pharmacopoeia (EP), and Chinese Pharmacopoeia (ChP).
- **BSE/TSE-Free Guarantee:** Certified 100% free from Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathies (TSE). Raw bones are exclusively derived from clinically healthy animals passed by official quarantine audits.
- **Quality System Accreditations:** Processed within state-of-the-art D-grade clean rooms under strict Pharma-GMP, ISO 9001, and FSSC 22000 management architectures. Halal and Kosher verified.

Packaging, Storage & Shelf-Life Architecture

Packaging: Heavy-duty, multi-layer kraft paper bags or woven bags integrated with an airtight Polyethylene (PE) heat-sealed inner liner. Standard net weight: 25 KG per bag.

Storage Requirements: Keep in unopened original bags inside a cool, dry, and well-ventilated pharmaceutical warehouse. Maintain ambient temperatures ****below 25°C**** and relative humidity (RH) ****between 45% and 65%**** to prevent moisture migration or structural hardening.

Shelf-Life: 36 months from manufacturing date when safely stored under the specified environmental parameters.

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*Disclaimer: The chemical and physical data parameters reported above comply strictly with international pharmacopoeia standards.
Regulatory dossiers and EDQM certification documentation are available upon official business request.*