

Product Name & Description

Product Name: Ultra-High Viscosity Bovine Gelatin (Specialized Softgel Ribbon Grade)

Description: Premium pharmaceutical-grade Type B gelatin engineered specifically with an ultra-high viscosity profile (4.5–6.0 mPa·s) paired with high mechanical bloom (180–220 Bloom). Extracted 100% from BSE-free bovine hides/bones, this specialized bio-polymer is designed to address the challenges of high-speed rotary die encapsulation machines. It provides exceptional ribbon seal strength, optimal elasticity under thermal stress, and resistance to aggressive, highly hygroscopic, or chemically active liquid core formulations.

Key Specifications & Quality Parameters

Analysis Item	Specification Standard	Test Method Reference
Appearance	Light yellow to amber granules	Visual / USP Standard
Odor & Taste	Completely odorless and neutral flavor	Sensory Panel
Kinematic Viscosity (6.67%, 60°C)	4.5 – 6.0 mPa·s (Ultra-High Range)	Capillary Viscometer / USP
Jelly Strength (Bloom)	180 – 220 Bloom (High mechanical grade)	6.67% sol, 10°C, Bloom Gelometer
Clarity (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
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	ICP-MS
Total Aerobic Microbial Count	≤ 100 cfu/g (Strict pharma thresholds)	USP <61> / EP
Molds & Yeasts	Absent / g (or ≤ 20 cfu/g)	USP <61>
Escherichia Coli & Salmonella	Absent / 10g	USP <62> / Negative

Functional Features & Manufacturing Advancements

- **Enhanced Ribbon Sealing Performance:** The ultra-high viscosity ensures excellent gel mass cohesion during extrusion, allowing precise control over gelatin ribbon thickness and achieving outstanding seam seal fusion at lower sealing wedge temperatures.
- **Resistance to Aggressive Core Fill Matrix:** Prevents softgel deformation, dimpling, or leaking caused by chemically reactive fillers, highly hygroscopic formulations (such as PEG mixtures), or multi-phase active ingredients.
- **Reduced Glycation/Cross-Linking Susceptibility:** Low reactive trace properties mitigate the aging effect and cross-linking over shelf storage, providing optimal long-term capsule shell dissolution profiles.
- **Optimized Drying Kinetic Profiles:** High polymer network stability accelerates water migration during the tumble and tunnel drying cycles, shortening the production time loop.

Core Softgel Applications

- **High-Speed Soft Gelatin Encapsulation:** Ideal for modern high-output rotary die encapsulation lines producing complex oil-based, paste-based, or emulsion-based pharmaceutical and nutraceutical softgels.
- **Hygroscopic & Complex Core Formulations:** Excellent shell matrix for packaging demanding active materials like multivitamin paste, herbal extracts, and PEG-based oral solutions.
- **Enteric & Modified Release Softgels:** Serves as a strong premium polymer baseline for softgel matrices requiring secondary enteric coating or delayed release profiles.

Global Regulatory Compliance & Certifications

- **Pharmacopoeia Alignment:** Fully compliant with current specifications of the United States Pharmacopoeia (USP), European Pharmacopoeia (EP), and Chinese Pharmacopoeia (ChP).
- **BSE/TSE-Free Guarantee:** 100% BSE-free certified bovine source. Derived exclusively from healthy veterinary-inspected herds under fully integrated supply-chain traceability.
- **Quality Registrations:** Extracted in D-grade clean facilities operating under validated Pharma-GMP, ISO 9001, and FSSC 22000 architectures. Certified Halal and Kosher.

Packaging, Logistics & Storage Architecture

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

Storage Guidelines: Store inside unopened original bags within a clean, cool (< 25°C), and dry warehouse space. Maintain relative humidity (RH) ****between 45% and 65%**** to prevent moisture migration or structural hardening. Protect against high-intensity light vectors and intense ambient heat.

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Disclaimer: The chemical and physical metrics reported above comply strictly with international pharmacopoeia standards. Regulatory dossiers and EDQM validation support documentation are available upon official business request.