BEYOND BIOPHARMA

TECHNICAL DATA SHEET

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Grade:	Pharmaceutical Excipient (ChP/USP/EP)

Product Name & Description

Product Name: Premium Pharmaceutical Gelatin for Tablet Coating & Formulation

Description: Premium pharmaceutical-grade gelatin processed under highly stringently monitored sanitary conditions from select raw bovine/porcine tissues. Specifically refined for advanced solid oral dosage applications including tablet film coating, sugar coating, and binding, this high-purity excipient delivers outstanding film-forming capacity, controlled dissolution kinetics, and batch-to-batch structural uniformity. It is fully certified to act as a highly bio-compatible drug delivery matrix with exceptional chemical compatibility towards various active pharmaceutical ingredients (APIs).

Key Specifications & Quality Parameters

Analysis Item	Specification Standard	Test Method Reference
Appearance	Faintly yellow to amber crystalline granules or powder	Visual / ChP / USP
Odor & Taste	Odorless, neutral tasteless profile	Sensory Analysis
Jelly Strength (Bloom)	**150 – 240 Bloom** (6.67% w/v solution, 10°C)	Standard Bloom Gelometer
Viscosity	3.5 – 6.0 mPa.s (6.67% w/v solution, 60°C)	Capillary Viscometer
pH (at 55°C)	4.5 – 7.0	Potentiometric
Clarity of Solution	≤ 5 NTU (Clear, transparent fluid matrix)	Turbidimetry
Transmittance	≥ 85% (at 450nm) / ≥ 93% (at 620nm)	UV-Vis Spectrophotometry
Loss on Drying (Moisture)	≤ 13.0%	105°C Oven Drying
Residue on Ignition (Ash)	≤ 1.5%	Gravimetric (550°C)
Sulphur Dioxide (SO_2)	≤ 30 ppm	Distillation / Titration
Heavy Metals (as Pb)	≤ 10 ppm	Atomic Absorption (AAS)
Arsenic (As)	≤ 0.8 ppm	ICP-MS
Total Aerobic Count (TAMC)	≤ 100 cfu/g	USP <61> / Microbial Count
Total Yeast/Mold (TYMC)	≤ 10 cfu/g	USP <61> / Microbial Count
Specified Microorganisms	E. coli, Salmonella, P. aeruginosa, S. aureus: Absent	USP <62>

Functional Advantages & Application Mechanics

- **High-Performance Film Coating:** Forms smooth, robust, and cohesive films around tablet cores. Effectively masks unpleasant drug taste/odor, protects against moisture-induced degradation, and minimizes light-sensitive core interactions.
- **Optimized Binding Capability:** Acts as a strong binder in wet granulation loops. Promotes superior tablet hardness, controls friability parameters, and yields mechanically sound cores ready for high-speed automated packaging.
- **Excellent Gloss & Aesthetic Appeal:** Provides an excellent base matrix for aqueous sugar coatings and film applications, giving tablets a high-gloss, premium polished surface finish that enhances consumer compliance.
- **Tunable Dissolution Kinetics:** Exhibits swift dissolution near physiological temperature (~37°C), supporting complete core disintegration and immediate bioavailability profile goals.

Regulatory Compliance & Excipient Safety

This product is manufactured under stringent current Good Manufacturing Practices (cGMP) tailored specifically for pharmaceutical excipients, fulfilling advanced pharmacopeial and biological criteria:

- **Pharmacopeia Alignment:** Fully complies with United States Pharmacopeia (USP), European Pharmacopoeia (EP), and Chinese Pharmacopoeia (ChP) guidelines.
- **Quality Management Systems:** Produced in a facility certified under ISO 9001, ISO 22000, EXCiPACT, or equivalent high-tier pharmaceutical quality networks.
- **Biological Safety:** Supported by strict Veterinary Health Certification. 100% sourced from healthy materials, thoroughly mitigating any risks associated with TSE/BSE contaminants.

Packaging, Storage & Shelf Life

Packaging Structure: Seep-proof Polyethylene (PE) inner barrier layer enclosed within multi-ply medical/food-grade Kraft paper bags or fiber drums. Standard net weight: 25 KG.

Logistical Loading Payload: Approx. 9 – 11 Metric Tons per 20ft FCL container without pallets.

Storage Requirements: Maintain in original, well-sealed containers. Store inside dry, cool pharmaceutical warehouses maintained below 25°C and relative humidity (RH) below 60%. Keep separate from chemical odors and volatile materials.

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