NEWAY SINOPHC TECH. LIMITED
ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.
Email:marketing01@newayphc.com； Phone:+86-021-50350029 https://www.newayphc.com

Technical Data Sheet (TDS)

Issue Date: 28 FEB 2026Version: V1.0

1. Product Overview

- **Product Name**: Pulvis Cholestyramini (Cholestyramine Powder)
- **CAS Number**: 11041-12-6
- **Molecular Formula**: $(C_{27}H_{46}NO)_n \cdot Cl_n$ (n≈500)
- **Average Molecular Weight**: ≈40000-50000 g/mol
- **Chemical Source**: Synthetic high-molecular-weight anion exchange resin (styrene-divinylbenzene copolymer quaternary ammonium chloride); prepared by suspension polymerization and quaternization; purified by washing and drying to meet pharmaceutical grade requirements for lipid-lowering drug formulations.
- **Product Trait**: White to off-white free-flowing powder, practically odorless, slightly hygroscopic; insoluble in water/organic solvents, swells in aqueous solutions to form a gelatinous suspension; stable in neutral/weakly acidic environment, non-combustible, no explosive properties; acts as an anion exchanger to bind bile acids in the gastrointestinal tract.
- **Core Properties**: **Non-absorbable anion exchange resin** with potent lipid-lowering activity; binds intestinal bile acids to form an insoluble complex excreted in feces, stimulating hepatic cholesterol conversion to bile acids and reducing serum low-density lipoprotein cholesterol (LDL-C); acts only in the gastrointestinal tract (no systemic absorption), high safety; the classic pharmaceutical raw material for treating primary hypercholesterolemia and bile acid malabsorption.
- **Main Application**: Pharmaceutical raw material for human oral lipid-lowering formulations (powder, granules, chewable tablets); treatment of primary hypercholesterolemia and familial hypercholesterolemia; management of pruritus caused by cholestasis and bile acid malabsorption-related diarrhea; pharmaceutical R&D reference reagent for cardiovascular pharmacology and bile acid metabolism research.

2. Technical Specifications (Pharmaceutical Grade, Complies with USP/EP/CP)

Item	Specification	Test Method
Appearance	White to off-white free-flowing powder	Visual Inspection
Odor	Practically odorless	Olfactory Inspection
Assay (Cholestyramine)	≥ 98.0%	Potentiometric Titration
Loss on Drying	≤ 5.0%	105℃ constant weight method (4h)
Residue on Ignition	≤ 1.0%	600±25℃ ignition method
Heavy Metals (Pb)	≤ 10 ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 2 ppm	Atomic Fluorescence Spectrometry (AFS)
Chloride Content	13.0-16.0%	Volumetric Titration
pH Value (5% aqueous suspension,25℃)	4.0-6.0	Digital pH Meter
Particle Size	90% passing 150 μm	Standard Sieve Method
Swelling Capacity	≥ 4.0 mL/g	Pharmacopoeia Method
Total Bacterial Count	≤ 100 CFU/g	Plate Count Method
E. coli	Negative	Microbiological Detection
Yeast & Mold	≤ 50 CFU/g	Plate Count Method
Staphylococcus aureus	Negative	Microbiological Detection
Bulk Density	0.35-0.45 g/cm³	Pycnometer Method
Moisture Absorption	≤ 3.0% (25℃, 75% RH, 48h)	Gravimetric Method

Item	Specification	Test Method
Flowability	≤ 10s/100g (Hausner ratio ≤ 1.25)	Flow Rate Test

3. Product Advantages

1. **Non-Absorbable & High Safety**: High-molecular-weight polymeric resin, insoluble in water and gastrointestinal fluids, no systemic absorption; acts only in the gastrointestinal tract, no liver/kidney metabolism, no drug-drug interactions via cytochrome P450; suitable for long-term lipid-lowering treatment and use in special populations (elderly, pregnant women).
2. **Potent Lipid-Lowering Efficacy**: Selectively binds intestinal bile acids (primary/secondary) with high affinity; effectively reduces serum LDL-C by 15-30% alone, and up to 50% in combination with statins; the first-line adjuvant therapy for familial hypercholesterolemia and statin-intolerant patients.
3. **Dual Clinical Efficacy**: Not only for hypercholesterolemia, but also for bile acid malabsorption-related diarrhea and cholestatic pruritus; binds excess bile acids to relieve pruritus and reduce intestinal water secretion, a single raw material for multiple bile acid-related disorders.
4. **Excellent Formulation Compatibility**: Free-flowing powder with good flowability and compressibility; compatible with common oral pharmaceutical excipients (lactose, mannitol, microcrystalline cellulose, maltodextrin); easy to prepare powder, granules, chewable tablets and oral suspensions for clinical use.

4. Application Fields

4.1 Pharmaceutical Industry (Oral Lipid-Lowering & Bile Acid-Related Formulations)

- **Primary Hypercholesterolemia**: Core raw material for 4g/5g oral powder/granules; first-line treatment for mild-to-moderate hypercholesterolemia; reduces serum LDL-C and total cholesterol, lowers the risk of cardiovascular events (myocardial infarction, stroke).
- **Familial Hypercholesterolemia**: Adjuvant raw material for combination therapy with statins; further reduces LDL-C in patients with insufficient response to statins alone; suitable for heterozygous familial hypercholesterolemia in adults and children (over 10 years old).

5. Usage & Formulation Guidelines

5.1 Recommended Dosage/Concentration (Pharmaceutical Formulations)

- **Oral Powder/Granules**: 4g/5g per unit; adult starting dose 4g once daily (before meals), titrate up to 4g twice daily according to LDL-C response; maximum daily dose 16g.
- **Chewable Tablets**: 2g/4g per unit; adult dose 4g twice daily (chewed before meals); suitable for patients with poor compliance to powder/granules.

6. Packaging & Storage

6.1 Packaging Specifications (Pharmaceutical Grade, Moisture-Proof)

- 100 g/bottle: HDPE pharmaceutical-grade bottle with desiccant and screw cap (laboratory/R&D/analytical use, **moisture-proof**).
- 1 kg/bag: Aluminum foil vacuum bag with PE inner lining (moisture-proof, small-batch production use).
- 5 kg/25 kg/drum: HDPE pharmaceutical-grade drum with inner plastic lining, desiccant and sealed cover (moisture-proof, bulk industrial production use).

7. Safety & Protection

- The product is a non-absorbable anion exchange resin lipid-lowering pharmaceutical raw material with mild skin/eye/respiratory irritation effects (dust only); **all operations must be conducted by trained professional personnel** with full specified PPE (N95 dust mask, safety goggles, nitrile rubber gloves, impermeable lab coat).
- Avoid direct contact with eyes/skin/respiratory tract; avoid inhaling dust and prolonged skin contact; operate in a well-ventilated dust-free fume hood with **moisture-proof measures**; clean the work area regularly to avoid dust accumulation.
- Avoid high humidity and direct contact with strong oxidizing agents/strong acids/organic solvents in the work area; keep the operation tools clean and dry; do not mix with fat-soluble vitamins and other lipid-lowering drugs randomly.