

## Certificate of Analysis

### Product Information

Item	Details
Product Name	Pulvis Cholestyramini (Cholestyramine Powder)
Product Number	PC-20260228
Batch Number	PC-SH2026022801
Brand	SIGALD
CAS Number	11041-12-6
MDL Number	MFCD00130807
Formula	$(C_{27} H_{46} NO)_n \cdot Cl_n$ (n≈500)
Formula Weight	≈40000-50000 g/mol (average)
Quality Release Date	28 FEB 2026

### Test Results

Test	Specification (Pharmacopoeial Standard)	Result	Unit	Test Method
Appearance (Color)	White to off-white	White	-	Visual Inspection
Appearance (Form)	Free-flowing powder	Free-flowing powder	-	Visual Inspection
Assay (Cholestyramine)	≥ 98.0%	98.9%	%	Potentiometric Titration
Loss on Drying	≤ 5.0%	2.1%	%	105°C, 4 hours
Residue on Ignition	≤ 1.0%	0.3%	%	600±25°C Ignition Method
Heavy Metals (Pb)	≤ 10 ppm	2.5 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 2 ppm	0.6 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Chloride Content	13.0-16.0%	14.7%	%	Volumetric Titration
pH Value (5% aqueous suspension, 25°C)	4.0-6.0	5.2	-	Digital pH Meter
Particle Size (90% passing)	≤ 150 μm	120 μm	μm	Standard Sieve Method
Swelling Capacity	≥ 4.0 mL/g	5.8 mL/g	mL/g	Pharmacopoeia Method
Total Bacterial Count	≤ 100 CFU/g	18 CFU/g	CFU/g	Plate Count Method
E. coli	Negative	Negative	-	Microbiological Detection
Yeast & Mold	≤ 50 CFU/g	12 CFU/g	CFU/g	Plate Count Method
Staphylococcus aureus	Negative	Negative	-	Microbiological Detection
Supplier Information	Confirmed	Confirmed	-	-

### Certification

This batch of product has been tested in accordance with the pharmacopoeial and industrial standards for Pulvis Cholestyramini and meets all specified requirements. It is qualified for use.  
Issue Date:28 FEB 2026