



NEWAY SINOPHC TECH. LIMITED

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Certificate of Analysis

Product Information

Item	Details
Product Name	Tolvaptan Sodium Phosphate
Product Number	TSP-20260218
Batch Number	TSP-SH2026021801
Brand	SIGALD
CAS Number	942619-79-6
MDL Number	N/A
Formula	$C_{21}H_{24}N_2O_4 \cdot Na_3PO_4$
Formula Weight	524.36 g/mol
Quality Release Date	18 FEB 2026

Test Results

Test	Specification (Industry Standard)	Result	Unit	Test Method
Appearance (Color)	White to off-white	White	-	Visual Inspection
Appearance (Form)	Crystalline powder	Crystalline powder	-	Visual Inspection
Assay (Tolvaptan Sodium Phosphate)	$\geq 99.0\%$	99.6%	%	High Performance Liquid Chromatography (HPLC)
Loss on Drying	$\leq 0.5\%$	0.05%	%	105°C, 2 hours
Residue on Ignition	$\leq 0.1\%$	0.003%	%	600±25°C Ignition Method
Heavy Metals (Pb)	≤ 2 ppm	0.01 ppm	ppm	Atomic Absorption Spectrometry (AAS)
Heavy Metals (As)	≤ 1 ppm	0.006 ppm	ppm	Atomic Fluorescence Spectrometry (AFS)
Related Substances	$\leq 0.5\%$	0.07%	%	High Performance Liquid Chromatography (HPLC)
Sulfate (SO_4^{2-})	$\leq 0.02\%$	0.001%	%	Turbidimetric Method
pH Value (1% aqueous solution, 25°C)	6.0-8.0	7.3	-	Digital pH Meter
Total Bacterial Count	≤ 5 CFU/g	0 CFU/g	CFU/g	Plate Count Method
E. coli	Negative	Negative	-	Microbiological Detection
Yeast & Mold	≤ 5 CFU/g	0 CFU/g	CFU/g	Plate Count Method
Solubility in Water	Freely soluble	Complies	-	Pharmacopoeia Method
Supplier Information	Confirmed	Confirmed	-	-

Certification

This batch of product has been tested in accordance with the industrial standards for Tolvaptan Sodium Phosphate and meets all specified requirements. It is qualified for use.

Issue Date: 18 FEB 2026