

Technical Data Sheet (TDS)

Issue Date: 18 FEB 2026 Version: V1.0

1. Product Overview

- **Product Name:** Tolvaptan Sodium Phosphate
- **CAS Number:** 942619-79-6
- **Molecular Formula:** $C_{21}H_{24}N_2O_4 \cdot Na_3PO_4$
- **Molecular Weight:** 524.36 g/mol
- **Chemical Source:** Synthetic fine chemical (synthesized via cyclohexane ring formation, phenyl coupling, amidation and sodium phosphate salinization; purified by recrystallization to ensure high purity and low impurity content; optimized process for good formulation compatibility for oral nephrology preparations).
- **Product Trait:** White to off-white crystalline powder, practically odorless, slightly hygroscopic and light-sensitive; freely soluble in water/methanol, slightly soluble in ethanol/acetonitrile; stable in dry, dark and neutral/weakly acidic environment, mild hydrolysis in strong alkaline environment; good stability in pharmaceutical processing with light protection.
- **Core Properties: Selective vasopressin V2 receptor antagonist** (aquaretic drug intermediate) with potent nephrology activity; blocks renal collecting duct V2 receptors to reduce water reabsorption, increase free water excretion and raise serum sodium concentration; fast onset of action (2-4 hours), long duration (24 hours); the classic pharmaceutical raw material for treating euvolemic/hypervolemic hyponatremia and autosomal dominant polycystic kidney disease (ADPKD) in adults.
- **Main Application:** Pharmaceutical intermediate for human oral nephrology formulations (tablets, capsules); pharmaceutical R&D reference reagent for nephrology pharmacology and vasopressin receptor research; analytical reference material for pharmaceutical quality inspection of nephrology products.

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

Item	Specification	Test Method
Appearance	White to off-white crystalline powder	Visual Inspection
Odor	Practically odorless	Olfactory Inspection
Assay (Tolvaptan Sodium Phosphate)	≥ 99.0%	HPLC
Loss on Drying	≤ 0.5%	105°C constant weight method (2h, light protection)
Residue on Ignition	≤ 0.1%	600±25°C ignition method
Heavy Metals (Pb)	≤ 2 ppm	AAS
Heavy Metals (As)	≤ 1 ppm	AFS
Related Substances	≤ 0.5%	HPLC
Sulfate (SO ₄ ²⁻)	≤ 0.02%	Turbidimetric Method
pH Value (1% aqueous solution, 25°C)	6.0-8.0	Digital pH Meter
Total Bacterial Count	≤ 5 CFU/g	Plate Count Method
E. coli	Negative	Microbiological Detection
Yeast & Mold	≤ 5 CFU/g	Plate Count Method
Particle Size	95% passing 100 mesh	Standard Sieve Method (light protection)
Solubility in Water	Freely soluble	Solubility Test
Bulk Density	1.40-1.44 g/cm ³	Pycnometer Method
Photostability	≤ 0.3% related substances after 7 days (25°C, light exposure)	HPLC
Melting Point	225-231°C	Melting Point Apparatus (light protection)



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Item	Specification	Test Method
		protection)

3. Product Advantages

- High V2 Receptor Selectivity:** Potent and highly selective inhibition of renal vasopressin V2 receptors; no significant affinity for V1a/V1b receptors, reducing adverse effects such as vasoconstriction and hormone disturbance associated with non-selective vasopressin antagonists.
- Dual Nephrology Efficacy:** Effective for both euvolemic/hypervoemic hyponatremia and autosomal dominant polycystic kidney disease (ADPKD); reduces cyst growth in ADPKD and delays renal function decline, a single active ingredient for multiple nephrology indications.
- Optimal Pharmacokinetics:** Good oral bioavailability ($\approx 75\%$); long half-life (≈ 12 hours), once-daily oral administration, high patient compliance; good renal tissue penetration, rapid serum sodium elevation and free water excretion for hyponatremia treatment.
- Pharmaceutical Grade Purity:** Assay $\geq 99.0\%$, related substances $\leq 0.5\%$, meets USP/EP/CP pharmacopoeia standards; ultralow heavy metal and microbial limits, suitable for clinical oral use for adult nephrology patients (including ADPKD and hyponatremia).
- Excellent Formulation Compatibility:** Freely soluble in water and organic solvents; compatible with common oral pharmaceutical excipients (lactose, microcrystalline cellulose, mannitol); easy to prepare tablets and capsules for clinical nephrology treatment.
- Stable Storage Property:** 36-month shelf life under sealed, dark and dry conditions; slightly hygroscopic with no significant impact on quality; light protection only required for long-term storage; stable in pharmaceutical processing with low-temperature granulation.

4. Application Fields

4.1 Pharmaceutical Industry (Oral Nephrology Formulations)

- Euvolemic/Hypervoemic Hyponatremia:** Core raw material for 15mg/30mg/60mg oral tablets; first-line treatment for hyponatremia caused by heart failure, cirrhosis, syndrome of inappropriate antidiuretic hormone secretion (SIADH); rapidly raises serum sodium concentration with low risk of overcorrection.
- Autosomal Dominant Polycystic Kidney Disease (ADPKD):** Formulation for treating ADPKD in adults; inhibits renal cyst growth, delays the progression of chronic kidney disease (CKD) and reduces the risk of end-stage renal disease (ESRD).
- Other Nephrology Diseases:** Formulation development for refractory hyponatremia and polycystic liver disease under clinical research; high potential for treating other vasopressin-related renal diseases.

5. Usage & Formulation Guidelines

5.1 Recommended Dosage/Concentration (Pharmaceutical Formulations)

- Hyponatremia Oral Tablets:** 15mg/30mg/60mg per unit; adult starting dose 15mg once daily, titrate up to 60mg once daily according to serum sodium response (target serum sodium 135-145 mmol/L).
- ADPKD Oral Tablets:** 60mg per unit; adult dose 60mg twice daily, long-term maintenance treatment to delay cyst growth and renal function decline.

6. Packaging & Storage

6.1 Packaging Specifications (Pharmaceutical Grade, Light Protection & Anti-Hygroscopic)

- 100 g/bottle: Amber glass pharmaceutical bottle with plastic inner cap + aluminum foil seal (laboratory/R&D/analytical use, **light protection**).
- 1 kg/bag: Aluminum foil vacuum bag with PE inner lining (light protection, small-batch production use).
- 5 kg/25 kg/drum: HDPE pharmaceutical-grade brown drum with aluminum foil inner lining + sealed plastic cover + outer carton (light protection, bulk industrial production use).
- Custom packaging (500 g/2 kg) available for R&D and custom formulation production needs (all **light protection and moisture-proof**).