



SWAPNROOP DRUGS & PHARMACEUTICALS

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CERTIFICATE OF ANALYSIS

Product Name	Tobramycin Sulfate USP (Sterile)	CAS No:	79645-27-5
Batch No.	2605001	Manufactured by	Swapnroop Drugs & Pharmaceuticals
Date of Mfg.	MAY-2026	Date of Analysis	20/05/2026
Batch Quantity	-	Retest Date	APR-2031

Sr No	Test	Acceptance Criteria	Results
1	Description	White to off-white, hygroscopic powder.	Off white, hygroscopic powder.
2	Solubility	Freely soluble in water	Freely soluble in water
3	Identification – By TLC	Tobramycin appears as a pink spot, and the Rf values of the spots of the sample solution and of solution A, respectively, correspond to those of the standard solution.	Tobramycin appears as a pink spot, and the Rf values of the spots of the sample solution and of solution A, respectively, correspond to those of the standard solution.
4	Identification – By HPLC	The retention time of the major peak of the Derivatized sample solution corresponds to that of the Derivatized standard solution obtained as directed in the assay.	The retention time of the major peak of the Derivatized sample solution corresponds to that of the Derivatized standard solution obtained as directed in the assay.
5	Identification – By chemical sulfate test	With barium chloride TS, solutions of sulfates yield a white precipitate that is insoluble in hydrochloric acid and in nitric acid	With barium chloride TS, solutions of sulfates yield a white precipitate that is insoluble in hydrochloric acid and in nitric acid
6	Bacterial Endotoxins Test	Less than 2.00 USP Endotoxin Units/mg of tobramycin.	Not more than 2.00 USP Endotoxin Units/mg of tobramycin.
7	Sterility test	Should be sterile	Passes the Sterility
8	pH	6.0 and 8.0	6.489
9	Water Determination (by K.F)	Not more than 7.0%	2.9318%
10	Residue on ignition	Not more than 1.0%	0.14%
11	Assay (By HPLC)	Not less than 634 µg/mg and not more than 739 µg/mg of Tobramycin (C ₁₈ H ₃₇ N ₅ O ₉).	666.42 µg/mg
12	Organic Impurities (Additional tests)	Bluish-purple spots are immediately visible. Other than the principal tobramycin spot, no spot observed in the sample solution is more intense than the principal spot from the Standard solution (1.0%).	Bluish-purple spots are immediately visible. Other than the principal tobramycin spot, no spot observed in the sample solution is more intense than the principal spot from the Standard solution (1.0%).
13	Particulate matter: (i) By Visual	≥ 10 µm, NMT 6000/gram	≥ 10 µm: 81
14	Particulate matter: (ii) By light obscuration particle count test	≥ 25 µm, NMT 6000/gram	≥ 25 µm: 02

Sr No	Test	Acceptance Criteria	Results
15	Appearance of Solution (10% solution in water)	Abs of solution at 430 nm: 0.009 Transmittance at 650 nm: 99.8%	Abs of solution at 430 nm: NMT 0.15 Transmittance at 650 nm: Min 95%
16	Tapped Density	For Information Purpose	0.72 g/ml

Storage: Store in air tight container below room Temperature

Conclusion: Product Complies as per above Specifications

Prepared By  Sonali Nirmal Date: 23/05/2026	Checked by  Dadarao Kakde Date: 23/05/2026	Approved By  Nayna Nehete Date: 23/05/2026 
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