

05/06/2025

Hallochem Group

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Chongqing Waycome Pharmaceutical Co.,Ltd.

CERTIFICATE OF ANALYSIS

Product name	Tobramycin Sulfate	Batch No.	TBS20250401
Manuf. Date	2025-04-14	Expiry Date	2029-04-13
Batch Quantity	150Kg	Test Standard	USP 43

TEST	SPECIFICATIONS	RESULTS
Characters	Appearance: White or almost white powder. Hygroscopicity: Hygroscopic	conform
Identification	TLC : The colour and location of the principal spot obtained from test solution correspond to that obtained from standard solution. HPLC : The retention time of major peak of the sample solution corresponds to that of the standard solution obtained as directed in the assay. Sulfate test: Present the identification reaction of sulfate	Complies Complies Complies
pH	6.0~8.0	7.27
Water	≤7.0%	0.70%
Heavy metals	≤30ppm	<30ppm
Residue on ignition	≤1.0%	0.080%
Chromatographic purity	Any individual impurity≤1.0%	<1.0%
Residual solvent	Ethanol : ≤5000ppm Acetaldehyde : ≤450ppm	Not detected Not detected
Bacterial endotoxins	≤ 2.0EU/mg	<2.0EU/mg
Assay	634~739μg/mg	685μg/mg

Conclusion: The product complies with the requirements of USP 43 standard

Quality Manager:

Rechecker:

Analyst:

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