

CERTIFICATE OF ANALYSIS

Product Name:	Tobramycin		
Batch No.	TOB2310001		
Manufacturing Date	October 23, 2023	Expiry Date TO	October 22, 2026
Packaging	5kg/Tin	Batch Size	78.10kg
Storage Conditions	Preserve in tight containers, store in dry place.		
Analytical results			
Items	Specifications		Results
Appearance	White to off-white powder.		Conform
Hygroscopicity	Hygroscopic		Conform
Identification	TLC: Tobramycin appears as a pink spot, and the R _F values of the spots from the sample solution and from mixed solution, respectively, correspond to those obtained from the standard solution.		Conform
	HPLC: The retention time of the major peak of the derivatized sample solution corresponds to that of the derivatized standard solution.		Conform
Assay (on the anhydrous basis)	≥900 µg/mg		982µg/mg
Residue on ignition	≤0.3%		0.080%
Chromatographic purity (TLC)	Any individual spot ≤1.0%.		Conform
PH	9.0~11.0		10.25
Water	≤7.5%		3.20%
Specific optical rotation	+138°~+148°		+141°
Clarity of solution	Clear, if the solution is turbid, it shall not exceed the turbidity of 0.5# turbidity standard solution.		Conform
Colour	If colour develops, the colour of test solution should not be more intense than yellow or yellow-green 2# standard colour solution		Conform
Bacterial endotoxins	<2.0EU/mg		Conform
Residual solvents	Ethanol ≤2000ppm		20ppm
	Acetaldehyde ≤450ppm		Not detected
Microbial limit	TAMC ≤1000cfu/g		<100cfu/g
	TYMC ≤100cfu/g		<1cfu/g
	E.Coli Should be absent/g		Absent
Conclusion	The product complies with USP and In-house Specifications.		

Inspector: Carlifor Wu

Verifier: Jack He