

CERTIFICATE OF ANALYSIS

Product : **TOBRAMYCIN SULPHATE**
 Product number : T0153
 Batch number : 012291
 Date of production : xx-08-2015
 Date of analysis : 02-02-2016
 Date of expiry : 31-08-2018
 Packaging and storage : store in a well-closed container at 2 – 8°C

	SPECIFICATION	RESULT	UNITS	REMARKS
Appearance	white crystalline powder	complies		
Solubility	soluble in water	complies		
Identification:				
- A (TLC)	conform	complies		
- B (HPLC)	conform	complies		
- C (sulphate)	conform	complies		
pH	6.0 – 8.0	7.4		4% in H ₂ O
Water	≤ 2.0	0.8	%	Karl Fischer
Sulphated ash	≤ 1.0	0.1	%	
Heavy metals	≤ 30	complies	ppm	
Related substances	≤ 1.0	complies	%	TLC
Bacterial endotoxins	≤ 2.0	≤ 0.06	IU/mg	
Residual solvents	conform	complies		
Assay tobramycin	634 – 739	693	µg/mg	

This certificate of analysis is conform the results of the manufacturer.

Conclusion: approved

Released by: drs. M. van Wissen, pharmacist
 Department of Quality Control Duchefa B.V.

Date: 01-08-2016



The buyer is responsible to test each batch to ensure the product is suitable for their specific purpose.