

CERTIFICATE OF ANALYSIS

Product : **TOBRAMYCIN SULPHATE**
 Product number : T0153
 Batch number : 013709
 Manufacturing date : xx-05-2017
 Date of analysis : 13-11-2017
 Date of expiry : 31-05-2020

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	0.4	%	Karl Fischer
Sulphated ash	≤ 1.0	< 0.1	%	
Heavy metals	≤ 30	complies	ppm	
Related substances	conform	complies		TLC
Residual solvents	conform	complies		
Assay tobramycin	634 – 739	647	µg/mg	HPLC

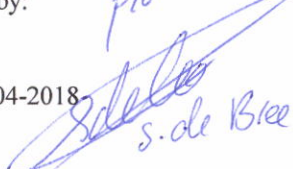
This certificate of analysis is conform the results of the manufacturer.

Conclusion: approved

Released by:

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

Date: 20-04-2018

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 S. de Bree

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