

## Certificate of analysis



Article	5419	Neomycinsulfat, API (Urspr.: Rind u. mikrob. Herk.)	
Synonym		Neomycini sulfas	
Synonym		Neomycin sulfate, API(origin:bovine and microbial)	
Batch	23000856		
Specification	Ph.Eur.10.1		
Production date	03.2022	Retest date	09.2025

Test	Specification	Result
Characters	According to specification	Complies
Appearance	According to specification	Complies
Solubility	According to specification	Complies
Identification	According to specification	Complies
HPLC	According to specification	Complies
Thin-layer chromatography	According to specification	Not carried out
B	According to specification	Complies
Tests	According to specification	Complies
pH-Value	5,0 ... 7,5	6,0
Specific optical rotation	53,5 ... 59,0	55,8
Related substances	According to specification	Complies
Impurity A	Max. 2,0 %	< 1,0 %
Impurity C	3,0 ... 15,0 %	11,1 %
Any other impurity	Max. 5,0 %	2,4 %
Sum of all further impurities	Max. 15,0 %	5,5 %
Sulphates	27,0 ... 31,0 %	27,4 %
Loss on drying	Max. 8,0 %	6,1 %
Sulphated ash	Max. 1,0 %	0,2 %
Determination of value (effectiveness)	Min. 680 I.E./mg	711 I.E./mg
Correction factor weighing (f, NRF)	1,000	1,161
Complies specification		Yes

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Release date	30.08.2023	Released by	Frau Dr. Haßel, QP, LQK
Manufacturer	Sichuan Long March		
Manufacturer batch	SC-NM-20220303		
Manufacturer street	No. 448, Changqing Road		
Manufacturer city	614000 Central City Leshan Sichuan Province		
Manufacturer country	Volksrepublik China **		

GMP-compliant production and testing of the active pharmaceutical ingredients

Results marked with # were taken from the manufacturer's certificate.

The batch 23000856 complies specification.

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