

Certificate of Analysis

Product name: **Neomycini sulfas**
Batch number / Weight: **22E12-B10-224860 / 30 G**
Analysed according to: **Ph. Eur. 10.8**
Number of analysis / Inspection Code **22E12-B10 / INS-22-5173**
Reference Code / No.: **V00613 / 202112003**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or yellowish-white powder, hygroscopic	Conform		
Identification A	acc. to Ph. Eur.	Conform		
Identification B	acc. to Ph. Eur.	Conform		
Specific optical rotation	+53,5 - +59,0	+56,3		
pH	5,0 - 7,5	6,48		
Related substances	acc. to Ph. Eur.	Conform		
Impurity A	<=2,0	<1,0	%	
Impurity C	<=15,0	14,4	%	
Any other impurity	<=5,0	<1,0	%	
Total other impurities	<=15,0	<1,0	%	
Sulfate	27,0 - 31,0	30,81	%	
Loss on drying	<= 8,0	5,16	%	
Sulfated ash	<=1,0	0,06	%	
Assay	min. 680 (dried substance)	685	IU/mg	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL, Hasco, Eurofins

Release:

Ewelina Gadzinowska

Qualified Person

12-10-2022

Expiration: 02-12-2025

Conclusion: APPROVED

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