

Certificate of Analysis

Product name: Neomycini sulfas
Batch number: 19I23-B03-196881
Base unit: 30g
Expiration date: 03.05.2023
Quality: Ph.Eur.
Manufacturing date: 12.02.2020
Inspection report no.: INS-19-04564
IIN: 100810-114-91

Description	Claim	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		
pH	5,0 - 7,5	6,20		
Specific optical rotation	+53,5 - +59,0	+56,3		
Related substances	Impurity A: max. 2,0% Impurity C: 3,0% - 15,0% Any other impurity: max. 5,0% Total other impurities: max. 15,0%	0,16 13,0 1,5 1,5	%	data producer
Sulfate	27,0 - 31,0%	27,64	%	
Loss on drying	max. 8,0%	5,25	%	
Sulfated ash	max. 1,0%	0,21	%	
Assay	min. 680 IU/mg	684	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

Analysis performed by the laboratory Fagron Poland

Release:
 Dorota Sutkowska
 Qualified Person



Fagron sp. z o.o.
 Dorota Sutkowska
 osoba wykwalifikowana
 qualified person

Date of releasing: 10.03.2020
Conclusion: Approved