

Certificate of Analysis

Product name: **Bacitracinum micronisatum**

Batch number / Weight: **21H03-B04-233521 / 5 G**

Analysed according to: **Ph.Eur.11.2**

Number of analysis / Inspection Code **21H03-B04-213911 / INS-22-1660**

Reference Code / No.: **V01766 / C2280151**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder, hygroscopic powder	Conform		
Particle size	99% <50 µm	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Appearance of solution	Clear	Conform		
Absorbance	<=0,45	0,161		
pH	6,0 - 7,0	6,26		
Composition	Conform	Conform		
Bacitracin A	>=45,0	54,00	%	
Sum of bacitracins A, B1, B2 and	>=77,0	80,10	%	
Related substances	Conform	Conform		
Sum of impurities L and N	<=8,0	6,04	%	
Impurity E	<=4,0	0,78	%	
Impurity A	<=3,5	1,79	%	
Impurity B	<=3,0	1,45	%	
Impurity M	<=3,0	1,26	%	
Impurity C	<=2,5	1,67	%	
Sum of impurities O,P and Q	<=2,5	0,71	%	
Sum impurities F and G	<=2,0	<0,25	%	
Impurity H	<=1,0	<0,25	%	
Any other impurity	<=2,0	1,33	%	
Total impurities	<=23,0	19,90	%	
Loss on drying	<=5,0	3,23	%	
Sulphated ash	<=1,0	0,08	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	>=60	62,108	IU/mg	

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TSE/BSE-statement:

No contamination with TSE/BSE-risk materials

Conform

Data producer

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 lab

Release:

Ewelina Gadzinowska

Qualified Person

25-09-2023

Expiration: 30-09-2024

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

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