

Certificate of Analysis

Product name: **Bacitracinum micronisatum**

Batch number / Weight: **21H03-B04-219701 / 10 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder, hygroscopic	Conform		
Particle size	99% <50 µm	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Appearance of solution	Clear	Conform		
Absorbance at 420 nm	<=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 Bacitracin	>=60	62,108	IU/mg	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:

Ewelina Gadzinowska

Qualified Person

25-03-2022

Expiration: 30-09-2024

Conclusion: APPROVED

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