

Certificate of Analysis

Product name: Bacitracinum micronisatum
Batch number / Weight: 25D28-B11-011436 / 1 g
Producer / Producer Batch Number: Xellia (Taizhou) Pharmaceuticals Co., Ltd / C2280259
Analyzed according to: Ph. Eur. 11.8
Number of Analysis / Certificate no.: 25D28-B11 / QO0017018

	Requirement	Result	Unit	Standard remark
Appearance	White or almost white, hygroscopic powder	Conform		
Particle size	99% <50 µm	Conform		
Identification	B, C	Conform		
Appearance of solution	Clear	Conform		
pH	6,0-7,0	6,32		
Composition	Conform	Conform		
Bacitracin A	>=45,0	56,23	%	
Sum of bacitracins A, B1, B2 and B3	>=77,0	81,99	%	
Related substances	Conform	Conform		
Sum of impurities L and N	<=8,0	5,94	%	
Impurity E	<=4,0	0,72	%	
Impurity A	<=3,5	1,61	%	
Impurity B	<=3,0	1,34	%	
Impurity M	<=3,0	1,06	%	
Impurity C	<=2,5	1,37	%	
Sum of impurities O,P and Q	<=2,5	0,90	%	
Sum of impurities F and G	<=2,0	<0,25	%	
Impurity H	<=1,0	<0,25	%	
Any other impurity	<=2,0	1,15	%	
Total impurities	<=23,0	18,01	%	
Loss on drying	<=5,0	1,3	%	
Sulfated ash	<=1,0	0,02	%	
Assay	>=60	63	IU/mg	
Absorbance	<=0,45 at 420nm	<0,45		
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
TSE/BSE-statement:	EMA/410/01 guidance compliant – no contamination	Conform		DP
TAMC	<=10 ³	<10 ¹	cfu/g	
TYMC	<=10 ²	0	cfu/g	

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.

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Analysis performed by the authorized lab FSNE lab

Release:

13-8-2025

Agnieszka Pszczółka

Qualified Person

Expiration: 30-11-2028

Conclusion: APPROVED

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