

Certificate of Analysis

Product name: Bacitracinum micronisatum
Batch number / Weight: 25A17-B12-008237 / 1 g
Producer / Producer Batch Number: Xellia (Taizhou) Pharmaceuticals Co., Ltd / C2280246
Analyzed according to: Ph. Eur. 11
Number of Analysis / Certificate no.: 25A17-B12 / QO0013210

	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, hygroscopic powder	Conform		
Identification	C	Conform		
Particle size	99% <50 µm	Conform		
Appearance of solution	Clear	Conform		
Absorbance	at 420 nm ≤0,45	Conform		
pH	6,0 - 7,0	6,54		
Sulfated ash	≤1,0	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	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.

Analysis performed by the authorized lab FSNE lab, Quercus

Release:

11-4-2025
 Agnieszka Pszczółka
 Qualified Person

Expiration: 30-6-2028

Conclusion: APPROVED

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