

Certificate of Analysis

Product name: Sulfadiazinum argenticum micr.
Batch number / Weight: 25B07-B43-017543 / 10 g
Analyzed according to: USP
Number of Analysis / Certificate no.: 25B07-B43 / QO0025437
Reference code / No.: V01800 / 20240081MIC

	Requirement	Result	Unit	Standard remark
Appearance	White to creamy-white, crystalline powder, odorless to having a slight odor	Conform		
Identification	A, B, C	Conform		
Particle size	99%<25um / 95%<10um	Conform		
Loss on drying	<=0,5	0,11	%	
Nitrates	<=0,1	Conform	%	
Related substances	Conform	Conform		
Sulfanilic acid	<=0,3	0,00	%	
2-aminopyrimidine	<=0,3	0,00	%	
Acetylsulfadiazine	<=0,2	<0,05	%	
Specified unidentified imp.	<=0,15	<0,05	%	
Unspecified impurity, for each imp.	<=0,10	0,061	%	
Total impurities	<=0,5	0,06	%	
Silver	29,3 - 30,5	30,32	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Assay	98,0 - 102,0	99,32	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
TSE/BSE-statement:	EMA/410/01 guidance compliant – no contamination	Conform		DP

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

Release:

11-12-2025
 Dominika Sołtysik
 Qualified Person

Expiration: 9-7-2029

Conclusion: APPROVED

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