

Certificate of Analysis

Product name: **Sulfadiazinum argenticum micr.**

Batch number / Weight: **23C20-B05-232318 / 10 G**

Analysed according to: **USP**

Number of analysis / Inspection Code **23C20-B05 / INS-23-7743**

Reference Code / No.: **V01800 / 20220091MIC**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White to creamy-white, crystalline powder odorless to having a slight odor	Conform		
Particle size	99%<25µm / 95%<10µm	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Loss on drying	<=0,5	0,05	%	
Nitrates	<=0,1	0,004	%	
Related substances	Conform	Conform	%	
Sulfanilic acid	<=0,3	0,00	%	
2-aminopyrimidine	<=0,3	0,00	%	
Acetylsulfadiazine	<=0,2	<0,05	%	
Specified unidentified impurity	<=0,15	0,061	%	
Individual unspecified impurity	<=0,10	<0,05	%	
Total impurities	<=0,5	0,06	%	
Silver	29,3 - 30,5	30,06	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay Silver sulfadiazine	98,0 - 102,0	99,56	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		

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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

07-12-2023

Expiration: 18-07-2027

Conclusion: APPROVED

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