

Certificate of Analysis

Product name: **Sulfadimidinum natricum**

Batch number / Weight: **21K05-B03-222908 / 250 G**

Analysed according to: **Monograph**

Number of analysis / Inspection Code **21K05-B03 / INS-22-2786**

Reference Code / No.: **V01775 / 2101048.0319**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Creamy-)white powder	Conform		
Identification A	Conform	Conform		IR-spectrum
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Alcalinity	10,0 - 11,0	10,1		
Appearance of solution	Clear <=Y4	Conform		33,3% _{m/V}
Related substances	<=0,5	Conform		TLC
Loss on drying	<=2,0	1,53	%	105 °C
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Sulfadimidine sodium	98,0 - 101,0	100,9	% _{m/m}	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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 EL Spol

Release:
Ewelina Gadzinowska
Qualified Person

22-12-2022

Expiration: 31-01-2025

Conclusion: APPROVED

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