

Certificate of Analysis

Product name: **Sulfadimidinum natricum**

Batch number / Weight: **22A25-B05-219269 / 250 G**

Analysed according to: **Monograph**

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	0,7	%	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	100,3	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

05-06-2022

Expiration: 30-04-2024

Conclusion: APPROVED

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