

Certificate of Analysis

Product name: **Metamizolum natricum*1H2O**
Batch number / Weight: **21D13-B04-215091 / 250 G**
Analysed according to: **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white crystalline powder	Conform		
Identification A	Conform	Conform		
Identification D	Conform	Conform		
Appearance of solution	Clear / colour <=BY6	Conform		
Acidity or alkalinity	Conform	Conform		
Related substances	Conform	Conform		
Impurity C	<=0,5	0,03	%	
Impurity E	<=0,15	0,057	%	
Unspecified impurities	<=0,05	<0,03	%	
Total impurities	<=0,5	0,09	%	
Sulphates	<=0,1	<0,1	%	
Loss on drying	4,9 - 5,3	5,04	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	99,0 - 101,0	100,45	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
 Dominika Sołtysik
 Qualified Person

27-09-2021

Expiration: 31-12-2024

Conclusion: APPROVED

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