

Certificate of Analysis

Product name: Phenazonum cryst.
Batch number / Weight: 20A08-B08-197542 / 250 G
Analysed according to: Ph. Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance	White and / or colourless crystals	Conform		
Identification A	109 - 113	111,5	°C	
Identification B	Conform	Conform		
Appearance of solution	Clear and colourless	Conform		
Acidity or alkalinity	Conform	Conform		
Related substances	Conform	Conform		
Impurity A	<=0,05	0,00	%	
Unspecified impurities	<=0,05	0,00	%	
Total impurities	<=0,1	0,00	%	
Chlorides	<= 100	Conform	ppm	
Sulphates	<= 100	Conform	ppm	
Loss on drying	<= 1,0	0,06	%	
Sulphated ash	<= 0,1	Conform	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Phenazone	99,0 - 101,0	100,35	%m/m	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
 Dominika Sołtysik
 Qualified Person

08-06-2020

Expiration: 30-06-2023

Conclusion: APPROVED

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