

Certificate of Analysis

Product name: **Phenazonum cryst.**
Batch number / Weight: **22K28-B11-235173 / 250 G**
Analysed according to: **Ph.Eur.11.2**
Number of analysis / Inspection Code **22K28-B11 / INS-22-10223**
Reference Code / No.: **V00581 / 2105020**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White and / or colourless crystals	Conform		
Appearance	colourless crystals			
Identification A	109 - 113	111,32	°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	<100	ppm	
Sulphates	<= 100	<100	ppm	
Loss on drying	<= 1,0	0,06	%	
Sulphated ash	<= 0,1	0,02	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Phenazone	99,0 - 101,0	100,02	%m/m	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

fagron.pl

Fagron Services Northern Europe Sp. z o.o.
 ul. Armii Krajowej 3
 32-540 Trzebinia, Poland
 e-mail: fsne@fagron.pl

fagron.pl

Fagron sp. z o.o.
 ul. Pasternik 26, 31-354 Kraków, Poland
 tel.: +48 12 3343 512
 e-mail: biuro@fagron.pl

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 Own lab

Release:

Ewelina Gadzinowska

Qualified Person

11-12-2023

Expiration: 31-05-2026

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

fagron.pl

Fagron Services Northern Europe Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:fsne@fagron.pl