

Certificate of Analysis

Product name: Sulfur
Batch number / Weight: 23D21-B02-228569 / 100 G
Analysed according to: Ph.Eur.11.1
Number of analysis / Inspection Code 23D21-B02 / INS-23-4119
Reference Code / No.: V00582 / 2023125172

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, (pale) yellow powder The size of most of the particles is not greater than 20 µm and that of almost all the particles is not greater than 40 µm	Conform Conform		
Identification A	Conform	Conform		
Identification B	White	Conform		
Melting point	About 120	120,3	°C	
Appearance of solution	Colourless	Conform		
Odour- / precipitation	Conform	Conform		
Acidity or alkalinity	Conform	Conform		
Chlorides	<= 100	<100	ppm	
Sulfates	<= 100	<100	ppm	
Sulfides	Conform	Conform		
Sulfated ash	<= 0,2	0,19	%	
Assay	99,0 - 101,0	99,5	%m/m	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Total aerobic microbial count (TA)	<= 10 ³	<10	CFU/g	
Total yeasts and moulds (TYMC)	<=10 ²	<10	CFU/g	

fagron.pl

Fagron Sp. z o.o.
 ul. Armii Krajowej 3
 32-540 Trzebinia, Poland
 e-mail: biuro@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 Fagron PL, EI Spol, CBMiA

Release:
Dominika Soltysik
Qualified Person

19-06-2023

Expiration: 11-03-2028

Conclusion: APPROVED

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

fagron.pl

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