

Certificate of Analysis

Product name: **Acidum salicylicum (90)**
Batch number / Weight: **22J20-B01-227181 / 1 KG**
Analysed according to: **Ph.Eur.11.0**
Number of analysis / Inspection Code **22J20-B01 / INS-22-9015**
Reference Code / No.: **V00585 / RAS2009500**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, white powder white or colourless, acicular crystals	Conform		
Identification A	158 - 161	160,6	°C	
Identification B	Conform	Conform		
Appearance of solution	Clear / colourless	Conform		
Related substances	Conform	Conform		
Impurity A	<=0,1	0,03	%	
Impurity B	<=0,05	0,03	%	
Impurity C	<=0,02	<0,02	%	
Any other impurity	<=0,05	<0,03	%	
Total impurities	<=0,2	0,06	%	
Chlorides	<=100	<100	ppm	
Sulphates	<=200	<200	ppm	
Loss on drying	<=0,5	0,03	%	
Sulphated ash	<=0,1	0,03	%	
Assay	99,0 - 100,5 (dried substance)	99,6	%m/m	
Particle size	X50 (D50)	8,2 µm		
Particle size	>=97% < 90 µm	100	%	
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

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 lab

Release:
Ewelina Gadzinowska
Qualified Person

17-01-2023

Expiration: 04-04-2025

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