

Certificate of Analysis

Product name: Acidum salicylicum
Batch number: 19B12-B04-192118
Base unit: 250g
Expiration date: 26.03.2023
Quality: Ph.Eur.
Manufacturing date: 14.10.2019
Inspection report no.: INS-19-01271
IIN: 100055-304-91

Description	Claim	Result	Unit	Laboratory
Appearance	white or almost white, crystalline powder or white or colourless, acicular crystals	conform		
Particle size	$\geq 97\% < 180 \mu\text{m}$ $\geq 90\% < 150 \mu\text{m}$	99 99	%	Eurofins
Particle size	X50 (D50)	45,26	μm	Eurofins
Identification A	158 - 161°C	159	°C	
Identification B	acc. to Ph. Eur.	conform		
Appearance of solution	acc. to Ph. Eur.	conform		Quercus Labo
Related substances	Impurity A - max. 0,1 % Impurity B - max. 0,05 % Impurity C - max. 0,02 % Unspecified Impurities - max. 0,05 % Total impurity - max. 0,2 %	0,06 <0,03 0,0 0,0 0,06	%	Quercus Labo
Chlorides	max. 100 ppm	conform	ppm	Quercus Labo
Sulfates	max. 200 ppm	conform	ppm	Quercus Labo
Loss on drying	max. 0,5 %	0,0	%	Quercus Labo
Sulfated ash	max. 0,1 %	0,01	%	Quercus Labo
Assay	99,0 – 100,5%	100,3	%	Quercus Labo
Elemental impurities	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

Analysis performed by the laboratory: Quercus Labo, Eurofins and Fagron Poland.

Release:
 Dorota Sutkowska
 Qualified Person



Fagron sp. z o.o.
Dorota Sutkowska
osoba wykwalifikowana
qualified person

Date of releasing: 24.10.2019

Conclusion: Approved