

### Certificate of Analysis

**Product name:** Acidum salicylicum  
**Batch number:** 19B12-B04-194383  
**Base unit:** 250g  
**Expiration date:** 26.03.2023  
**Quality:** Ph.Eur.  
**Manufacturing date:** 17.09.2019  
**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		Fagron Poland
Particle size	$\geq 97\% < 180 \mu\text{m}$ $\geq 90\% < 150 \mu\text{m}$	99 99	%	Eurofins
Particle size	X50 (D50)	45,26	$\mu\text{m}$	Eurofins
Identification A	158 - 161°C	159	°C	Fagron Poland
Identification B	acc. to Ph. Eur.	conform		Fagron Poland
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	<100	ppm	Quercus Labo
Sulfates	max. 200 ppm	<200	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:  
Dominika Sołtysik  
Qualified Person



Fagron sp. z o.o.  
**Dominika Sołtysik**  
osoba wykwalifikowana  
qualified person

Date of releasing: 26.09.2019

Conclusion: Approved