

## **Certificate of Analysis**

## Product name:

Batch number / Weight: 2 Analysed according to:

## Acidum salicylicum 20G20-B04-203755 / 250 G Ph.Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, white powder	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	0,052	%	
Impurity B	<=0,05	0,036	%	
Impurity C	<=0,02	0,00	%	
Any other impurity	<=0,05	<0,03	%	
Total impurities	<=0,2	0,088	%	
Chlorides	<=100	Conform	ppm	
Sulphates	<=200	Conform	ppm	
Loss on drying	<=0,5	0,02	%	
Sulfated ash	<=0,1	0,01	%	
Assay Salicylic acid	99,0 - 100,5 (dried substance)	100,23	%m/m	
Particle size	>=97% < 180 µm	99	%	
Particle size	>=90% < 150  µm	98	%	
Particle size	X50 (D50)	27,601	μm	
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

Analysis performed by the authorized lab.

Release: Dominika Sołtysik Qualified Person

24-11-2020

Expiration: 21-10-2024

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Conclusion: APPROVED

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

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