

Certificate of Analysis

Productname: Acidum salicylicum (90)
Number of analysis/Inspection Code: 1 / KEUR-185161B
Batchnumber: 20E07-F01-372503
Reference code / No.: 4097 / RAS1930900
Analysed according to: PHEUR10.2+

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) White crystalline powder or,	Conform		
Appearance	white, or colorless needle-shaped crystals	Conform		
Particle size	>=97% < 90 µm	97	%	Sieve Analysis
Particle size	X50 (D50)	20	µm	Laser
Identification A	158 - 161	160	°C	Melting point
Identification B	Conform	Conform		IR-spectrum
Appearance of solution	Clear / colourless	Conform		1 g / 10 ml alcohol
Related substances	Conform	Conform		HPLC
Impurity A	<=0,1	0,0	%	
Impurity B	<=0,05	<0,03	%	
Impurity C	<=0,02	n.d.	%	
Any other impurity	<=0,05	n.d.	%	
Total impurities	<=0,2	0,0	%	
Chlorides	<= 100	Conform	ppm	
Sulphates	<= 200	Conform	ppm	
Loss on drying	<=0,5	0,0	%	Desiccator
Sulphated ash	<= 0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Salicylic acid	99,0 - 100,5	99,8	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
CEP	CEP available	Conform		Data producer

Analysis performed by the authorized laboratory Quercus BE.

Release:
 Paul Hofman
 Pharmacist - Qualified Person

08/20/20

Expiration: 11-2024

Conclusion: APPROVED

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