

Certificate of Analysis

Product name: **Acidum salicylicum (90)**
Batch number / Weight: **20A30-B02-196359 / 1 KG**
Analysed according to: **Ph.Eur. + Monogr.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, white to almost white powder	Conform		
Particle size	>=97% < 90 µm	100	%	
Particle size	X50 (D50)	9,5	µm	
Identification A	158 - 161	160	°C	
Identification B	Conform	Conform		
Appearance of solution	Clear / colourless	Conform		
Related substances	Conform	Conform		
Impurity A	<=0,1	0,04	%	
Impurity B	<=0,05	0,04	%	
Impurity C	<=0,02	0,00	%	
Any other impurity	<=0,05	0,00	%	
Total impurities	<=0,2	0,08	%	
Chlorides	<= 100	Conform	ppm	
Sulphates	<= 200	Conform	ppm	
Heavy metals	<= 20	Conform	ppm	
Loss on drying	<=0,5	0,02	%	
Sulphated ash	<= 0,1	Conform	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Salicylic acid	99,0 - 100,5	99,22	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer

Analysis performed by the authorized lab.

Release:
 Dominika Sołtysik
 Qualified Person

27-04-2020

Expiration: 09-06-2024

Conclusion: APPROVED

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