

Certificate of Analysis

Product name: **Acidum salicylicum (90)**
Batch number / Weight: **20A30-B02-200841 / 250 G**
Analysed according to: **Ph.Eur. + Monogr.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, white to almost white powder	Conform		
Particle size	$\geq 97\% < 90 \mu\text{m}$	100	%	
Particle size	X50 (D50)	9,5	μm	
Identification A	158 - 161	160	$^{\circ}\text{C}$	
Identification B	Conform	Conform		
Appearance of solution	Clear / colourless	Conform		
Related substances	Conform	Conform		
Impurity A	$\leq 0,1$	0,04	%	
Impurity B	$\leq 0,05$	0,04	%	
Impurity C	$\leq 0,02$	0,00	%	
Any other impurity	$\leq 0,05$	0,00	%	
Total impurities	$\leq 0,2$	0,08	%	
Chlorides	≤ 100	Conform	ppm	
Sulphates	≤ 200	Conform	ppm	
Loss on drying	$\leq 0,5$	0,02	%	
Sulphated ash	$\leq 0,1$	Conform	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	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

Analysis performed by the authorized lab.

Release:
Dominika Sołtysik
Qualified Person

10-06-2020

Expiration: 09-06-2024

Conclusion: APPROVED

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