

Certificate of Analysis

Product name: Acidum salicylicum (90)

Batch number / Weight: 20E07-F01-217216 / 250 G

Analysed according to: Ph.Eur. + Monogr.

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, white powder	Conform		
	white or colourless, acicular crystals			
Identification A	158 - 161	160	°C	
Identification B	Conform	Conform		
Appearance of solution	Clear / colourless	Conform		
Related substances	Conform	Conform		
Impurity A	<=0,1	0,0	%	
Impurity B	<=0,05	<0,03	%	
Impurity C	<=0,02	0	%	
Any other impurity	<=0,05	0	%	
Total impurities	<=0,2	0	%	
Chlorides	<=100	Conform	ppm	
Sulphates	<=200	Conform	ppm	
Loss on drying	<=0,5	0,0	%	
Sulphated ash	<=0,1	0,0	%	
Assay	99,0 - 100,5 (dried substance)	99,8	%m/m	
Particle size	>=97% < 90 µm	97	%	
Particle size	X50 (D50)	20	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: Ewelina Gadzinowska Qualified Person

25-01-2022

Expiration: 30-11-2024

Conclusion: APPROVED

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