Certificate of Analysis

Product name: **Acidum salicylicum**

Batch number / Weight: **22E12-B05-226705 / 250 G**

Analysed according to: **Ph.Eur.11.0**

Number of analysis / Inspection Code **22E12-B05 / INS-22-3985**

Reference Code / No.: **V00585 / RAS2117000**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(almost) white, crystalline powder or white or colourless, acicular crystals	Conform		
Identification A	158 - 161	161	°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	0,033	%	
Impurity C	<=0,02	0,00	%	
Any other impurity	<=0,05	<0,03	%	
Total impurities	<=0,2	0,07	%	
Chlorides	<=100	<100	ppm	
Sulphates	<=200	<200	ppm	
Loss on drying	<=0,5	0,00	%	
Sulfated ash	<=0,1	0,04	%	
Assay Salicylic acid	99,0 - 100,5 (dried substance)	99,76	%m/m	
Particle size	X50 (D50)	31,242	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
Total yeasts and moulds (TYMC)	<=10^2	<10	CFU/g	
Total aerobic microbial count (TA	<=10^3	<10	CFU/g	

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL, Novasome, CBM

Release:
Dominika Sołtysik
Qualified Person

15-01-2023

Expiration: 19-06-2026

Conclusion: APPROVED

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