

## Certificate of Analysis

**Product name:** **Acidum salicylicum**

**Batch number / Weight:** **24B06-B15 / KG**

**Analysed according to:** **Ph.Eur. 01/2017:0138**

**Number of analysis / Inspection Code /**

**Reference Code / No.:** **V00585 / RAS2314700**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(almost) white, crystalline powder or white or colourless, acicular crystals	750/S/0324 Conform		
Identification	Conform	Conform		
Identification A	158 - 161	160,7	°C	
Identification B	Conform	Conform		
Solubility	Slightly soluble in water	Conform		
	Freely soluble in ethanol (96%)	Conform		
	Sparingly soluble in methylene chloride	Conform		
Appearance of solution	Clear / colourless	Conform		
Related substances	Conform	Conform		
Impurity A	<=0,1	<0,03	%	
Impurity B	<=0,05	0,027	%	
Impurity C	<=0,02	0,000	%	
Any other impurity	<=0,05	<0,03	%	
Total impurities	<=0,2	0,03	%	
Chlorides	<=100	<100	ppm	
Sulphates	<=200	<200	ppm	
Loss on drying	<=0,5	0,01	%	
Sulfated ash	<=0,1	0,00	%	
Assay Salicylic acid	99,0 - 100,5 (dried substance)	99,54	%m/m	
Total yeasts and moulds (TYMC)	<=10 <sup>2</sup>	<10 <sup>2</sup>	CFU/g	
Total aerobic microbial count (TA)	<=10 <sup>3</sup>	<10 <sup>2</sup>	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 lab

Release:

Magdalena Łatak

Quality Control Supervisor/Speciali

18-04-2024

Expiration: 26-05-2028

Conclusion: APPROVED

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