

Certificate of Analysis

Product name: **Natrii salicylas**
Batch number / Weight: **22J18-B04-222268 / 250 G**
Analysed according to: **Ph. Eur. 10.8**
Number of analysis / Inspection Code **22J18-B04 / INS-22-9016**
Reference Code / No.: **V01380 / 102072210**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(almost) White, crystalline powder or flakes małe, bezbarwne kryształy lub błyszczące płatki	conform		
Identification A, C	Conform	Conform		
Appearance of solution	Clear <=BY6	Conform		
Acidity	Conform	Conform		
Chlorides	<=200	<200	ppm	
Sulphates	<=600	<600	ppm	
Loss on drying	<=0,5	0,03	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay Sodium salicylate	99,0 -101,0 (dried)	100,08	%	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		
Residual solvents				
Methanol	<= 3000	<3000	ppm	
Benzene	<= 2	<2	ppm	

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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:
Ewelina Gadzinowska
Qualified Person

28-11-2022

Expiration: 31-07-2025

Conclusion: APPROVED

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