

ACIDO SALICILICO POLVO 99,5 % (EUR. PH.)			
PRODUCT CODE: 0083		CAS Nº: 69-72-7	ANALYSIS Nº: 314/24
MANUFACTURER BATCH:	RAS 2314700	CERTIFICATE ID:	44.408
SUPPLIER BATCH:	233764	MANUFACTURING DATE:	27/05/2023
METAPH BATCH:	0011224	EXPIRY DATE:	26/05/2028

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder or white or colourless, acicular crystals	White crystalline powder (*)
Solubility	Slightly soluble in water, freely soluble in ethanol (96 %), sparingly soluble in methylene chloride	Complies
Melting point	158 - 161 °C	160.5 °C (*)
Identification A	Complies	Complies (*)
Identification B	Complies	Complies (*)
Appearance of solution	Clear and colourless	Complies
Related substances		
Impurity A	=< 0.1 %	0.02 %
Impurity B	=< 0.05 %	0.02 %
Impurity C	=< 0.02 %	< 0.01 %
Unspecified impurities	=< 0.05 %	< 0.01 %
Total impurities	=< 0.2 %	0.05 %
Chlorides	=< 100 ppm	< 100 ppm
Sulfates	=< 200 ppm	< 200 ppm
Loss on drying	=< 0.5 %	0.02 % (*)
Sulfated ash	=< 0.1 %	0.04 % (*)
Assay	99.0 - 100.5 %	100.0 % (*)

COMPLIES WITH

European Pharmacopeia 11.0

REMARKS

Product fully analyzed within the EU, in compliance with the current regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Salicylic Acid is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

(*) Data controlled by Metapharmaceutical Industrial SL.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

Release date: 13/01/2025
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies



Manufacturer: 40000359
 NOVACYL SAS
 29 Avenue Joannes Masset
 Le Carré Joannes - CS 10619
 69009 Lyon

Original certificate available upon request

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STORAGE

In a tightly closed container protected from light.

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