

**ACIDO SALICILICO POLVO 99,5 % (EUR. PH.)**

PRODUCT CODE: 0083		CAS Nº: 69-72-7	ANALYSIS Nº: 065/24
MANUFACTURER BATCH:	RAS2314700	CERTIFICATE ID:	41.458
SUPPLIER BATCH:	233764	MANUFACTURING DATE:	27/05/2023
METAPH BATCH:	0190324	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 °C
Identification A	Complies	Complies
Identification B	Complies	Complies
Appearance of solution	Clear and colourless	Clear and colourless
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 %	0.23 %
Sulfated ash	=< 0.1 %	< 0.1 %
Assay	99.0 - 100.5 %	99.9 %

COMPLIES WITH

European Pharmacopeia 11.0

REMARKS

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 adapted from the supplier's certificate of analysis.

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.

STORAGE

In a tightly closed container protected from light.

Analysis date: 16/04/2024
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

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