METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

1586-TDS-ENG-2024

SODIO SALICILATO (EUR. PH.) PHARMA GRADE		
DESCRIPTION DCI: SALICYLATE SODIUM	DESCRIPTION DOE: SALICILATO SODIO	
CAS Nº: 54-21-7	EC Nº: 200-198-0	AEMPS CODE: 136SO
MOL. WEIGHT: 160.10	MOL. FORMULA: C7H5NaO3	ARTICLE CODE: 1586

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder or small, colourless crystals or shiny flakes
Solubility	Freely soluble in water, sparingly soluble in ethanol (96 %)
Identification A	Complies
Identification C	Complies
Appearance of solution	Clear and not more intensely colouyred than. ref. soll. BY6
Acidity	=< 2.0 mL of 0.01 M NaOH
Chlorides	=< 200 ppm
Sulfates	=< 600 ppm
Loss on drying	=< 0.5 %
Assay	99.0 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Keep the container tightly closed in a dry and well-ventilated place.

REMARKS

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

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.