

**TECHNICAL DATA SHEET**

0180-TDS-ENG-2026

<b>BENZOCAINA (ANESTESINA) (EUR. PH.)</b>		
DESCRIPTION DCI: BENZOCAINE		DESCRIPTION DOE: BENZOCAINA
CAS N°: 94-09-7	EC N°: 202-303-5	AEMPS CODE: 85A
MOL. WEIGHT: 165,19	MOL. FORMULA: C9H11NO2	ARTICLE CODE: 0180

<u>ATTRIBUTES</u>	<u>SHOULD BE</u>
Appearance	White or almost white, crystalline powder or colourless crystals
Solubility	Very slightly soluble in water, freely soluble in ethanol (96 %)
Identification A	Complies
Related substances	
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.2 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	99.0 - 101.0 %

**COMPLIES WITH**

European Pharmacopoeia 12.1

**STORAGE**

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

**REMARKS**

It shows polymorphism.

Benzocaine 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.