



BENZOCAINA (ANESTESINA) (EUR. PH.)

PRODUCT CODE: 0180	CAS Nº: 94-09-7	ANALYSIS Nº: 113/24
MANUFACTURER BATCH: BCAH0181023	CERTIFICATE ID: 41.980	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/10/2023	
METAPH BATCH: 0260424	EXPIRY DATE: 30/09/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder or colourless crystals	Whitec crystalline powder
Solubility	Very slightly soluble in water, freely soluble in ethanol (96 %)	Complies (*)
Identification A	Complies	Complies
Related substances		
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.2 %	< 0.05 %
Loss on drying	=< 0.5 %	0.04 %
Sulfated ash	=< 0.1 %	< 0.1 %
Assay	99.0 - 101.0 %	100.2 %

COMPLIES WITH

European Pharmacopoeia 11.0

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.

(*) Data adapted from the manufacturer'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

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

Analysis date: 24/05/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40001488