

PRILOCAINA BASE (EUR. PH.)

PRODUCT CODE: 1494	CAS Nº: 721-50-6	ANALYSIS Nº: 010/24
MANUFACTURER BATCH: API/PRB/231018	CERTIFICATE ID: 40.800	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/05/2023	
METAPH BATCH: 0090124	EXPIRY DATE: 30/04/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder
Solubility	Slightly soluble in water, very soluble in acetone and in ethanol (96 %)	Complies (*)
Identification	Complies	Complies
Appearance of solution	Clear and colourless	Clear and colourless
Related substances		
Impurity B	=< 100 ppm	61 ppm
Impurity G	=< 0.15 %	Not Detected
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.2 %	< 0.05 %
Water	=< 0.5 %	0.16 %
Sulfated ash	=< 0.1 %	0.06 %
Assay	99.0 - 101.0 %	100.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Prilocaine is subjected to the requirements of the ICH Q3D "Elemental Impurities" 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, 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

Keep the containers tightly closed. Store in a cool, dry and well-ventilated place.

Analysis date: 13/02/2024
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000497
 GUFIC BIOSCIENCES LIMITED
 2nd Floor, Dorr-Oliver House,
 Chakala
 400 099 Andheri (East)

