

**PRILOCAINA BASE (EUR. PH.)**

PRODUCT CODE: 1494	CAS Nº: 721-50-6	ANALYSIS Nº: 056/23
MANUFACTURER BATCH: API/PRB/231002	CERTIFICATE ID: 37.605	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/01/2023	
METAPH BATCH: 0020323	EXPIRY DATE: 31/12/2027	

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	Complies
Related substances		
Impurity B	=< 100 ppm	98.8 ppm
Impurity G	=< 0.15 %	Not Detected
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.2 %	< 0.05 %
Water	=< 0.5 %	0.06 %
Sulfated ash	=< 0.1 %	0.01 %
Assay	99.0 - 101.0 %	100.6 %
Residual solvents [In-house]		(*) (**)
Methylene Chloride	=< 600 ppm	60 ppm
Toluene	=< 890 ppm	Not Detected
Petroleum ether	=< 1200 ppm	30 ppm
Acetone	=< 5000 ppm	Not Detected

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

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

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.

(*) Data adapted from the certificate of analysis of the manufacturer.

(**) According to the requirements of guides EMA/CHMP/ICH/82260/2006.

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

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

Analysis date: 04/04/2023

Signature: Ferran Gonzalez de Rivera Rier

Conclusion: Complies

Original certificate available upon request

Manufacturer: 40000497

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