

**PROCAINA HCL (EUR. PH.)**

PRODUCT CODE: 1344	CAS Nº: 51-05-8	ANALYSIS Nº: 092/24
MANUFACTURER BATCH: PRC00124	CERTIFICATE ID: 41.726	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 27/01/2024	
METAPH BATCH: 0040424	RETEST DATE: 30/01/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder or colourless crystals	White crystalline powder
Solubility	Very soluble in water, soluble in ethanol (96 %)	Complies (*)
Identification A	Complies	Complies
Identification B	Complies	Complies
Identification E	Complies	Complies
Melting point	154 - 158 °C	156 °C
Appearance of solution	Clear and colourless	Clear and colourless
pH	5.0 - 6.5	5.4
Related substances	=< 0.05 %	< 0.05 %
Loss on drying	=< 0.5 %	0.04 %
Sulfated ash	=< 0.1 %	< 0.1 %
Assay	99.0 - 101.0 %	99.7 %

**COMPLIES WITH**

European Pharmacopeia 11.0

**REMARKS**

Procaine Hydrochloride 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**

Keep tightly closed, in a dry and cool place and protected from the light.

Analysis date: 07/05/2024  
Signature: Albert Sánchez López (QP)  
Conclusion: Complies  
Original certificate available upon request

Manufacturer: 40001481  
MICROSIN SRL  
STR. PERICLE PAPAAGI, NR 51-63  
BUCAREST  
032364 BUCAREST