



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 226114**

Product:	PRILOCAINE BASE
Lot:	226114
Expiry date:	31/12/2026
Reference:	Cumple PhEur10.8
Synonyms:	
Formula:	C <sub>13</sub> H <sub>20</sub> N <sub>2</sub> O
Molecular weight:	220,3 g/mol

Assay	Result	Specification	
Identification	Conform	Test PhEur	
Organoleptic properties	Conform	PhEur	
Appearance of solution	Conform	Test PhEur	
Related substances (HPLC)	Conform	Test PhEur	
Elemental impurities	Conform	Test PhEur	#
Moisture - K.F.	0,02 %	<= 0,5 %	
Sulphated ashes	0,00 %	<= 0,1 %	
Assay	100,0 %	99,0-101,0%	
Impurity B	16 ppm	<= 100 ppm	
Impurity G	< 0,05 %	<= 0,15 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	< 0,05 %	<= 0,2 %	
Residual solvent: methylene chloride	< 600 ppm	<= 600 ppm	#
Residual solvent: Toluene	< 890 ppm	<= 890 ppm	#
Residual solvent: Petroleum ether	< 1200 ppm	<= 1200 ppm	#
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#

Organoleptic characteristics: Crystalline, white or almost white powder. Slightly soluble in water, very soluble in acetone and 96% ethanol.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 14/12/2022

Judgement:  
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00020 GUFIC BIOCIENTES LIMITED

Manufacturer batch: API-PRB-221007

Product	Name	Capacity	Batch
1166848	PRILOCAINA BASE	250 g	226114-N-1

1166848	PRILOCAINA BASE	250 g	226114-N-2
1166849	PRILOCAINA BASE	1 kg	226114-P-1
1166850	PRILOCAINA BASE	5 g	226114-E-1
1166850	PRILOCAINA BASE	5 g	226114-E-2
1166851	PRILOCAINA BASE	25 g	226114-G-1
1166860	PRILOCAINA BASE	5 kg	226114-Q-1
1200271	PRILOCAINA BASE	100 g	226114-J-1

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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