



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 215652

Product:	PRILOCAINE BASE
Lot:	215652
Expiry date:	01/04/2026
Reference:	Cumple PhEur10.5
Synonyms:	
Formula:	C ₁₃ H ₂₀ N ₂ 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.	0,16 %	<= 0,5 %	
Sulphated ashes	0,00 %	<= 0,1 %	
Assay	99,2 %	99,0-101,0%	
Impurity B	44 ppm	<= 100 ppm	
Impurity G	<= 0,05 %	<= 0,15 %	
Unspecified Impurities	<= 0,05 %	<= 0,10 %	
Total impurities	<= 0,2 %	<= 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: 22/10/2021

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00020 GUFIC BIOCIENTES LIMITED

Manufacturer batch: API-PRB-211014

Product	Name	Capacity	Batch
1166848	PRILOCAINE BASE	250 g	215652-N-1

1166848	PRILOCAINA BASE	250 g	215652-N-2
1166849	PRILOCAINA BASE	1 kg	215652-P-1
1166849	PRILOCAINA BASE	1 kg	215652-P-2
1166850	PRILOCAINA BASE	5 g	215652-E-1
1166850	PRILOCAINA BASE	5 g	215652-E-2
1166851	PRILOCAINA BASE	25 g	215652-G-1
1166851	PRILOCAINA BASE	25 g	215652-G-2
1200271	PRILOCAINA BASE	100 g	215652-J-1
1200271	PRILOCAINA BASE	100 g	215652-J-2

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

ACOFARMA DISTRIBUCIÓN, S.A.

C/ Llobregat, 20 - 08223 Terrassa (Barcelona)

Tel./ 93-736.00.88

www.acofarma.com

Date of edition: 03/08/2025