



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 241370

Product:	PRILOCAINE BASE
Lot:	241370
Expiry date:	30/03/2029
Reference:	Cumple PhEur11.5
Synonyms:	
Formule:	C ₁₃ H ₂₀ N ₂ O
Poids moléculaire:	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.	0,04 %	<= 0,5 %	
Sulphated ashes	0,03 %	<= 0,1 %	
Assay	101,0 %	99,0-101,0%	
Impurity B	31 ppm	<= 100 ppm	
Impurity G	< 0,05 %	<= 0,15 %	
Unspecified Impurities	0,08 %	<= 0,10 %	
Total impurities	0,08 %	<= 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: 12/07/2024

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00020 GUFIC BIOCIENCES LIMITED

Manufacturer batch: AE240117A

Produit	Nom	Capacité	Lot
1166848	PRILOCAINA BASE	250 g	241370-N-1

1166848	PRILOCAINA BASE	250 g	241370-N-2
1166848	PRILOCAINA BASE	250 g	241370-N-3
1166849	PRILOCAINA BASE	1 kg	241370-P-1
1166849	PRILOCAINA BASE	1 kg	241370-P-2
1166849	PRILOCAINA BASE	1 kg	241370-P-3
1166850	PRILOCAINA BASE	5 g	241370-E-1
1166850	PRILOCAINA BASE	5 g	241370-E-2
1166850	PRILOCAINA BASE	5 g	241370-E-3
1166851	PRILOCAINA BASE	25 g	241370-G-1
1166851	PRILOCAINA BASE	25 g	241370-G-2
1166851	PRILOCAINA BASE	25 g	241370-G-3
1166860	PRILOCAINA BASE	5 kg	241370-Q-1
1166860	PRILOCAINA BASE	5 kg	241370-Q-2
1200271	PRILOCAINA BASE	100 g	241370-J-1
1200271	PRILOCAINA BASE	100 g	241370-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

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Date d'édition: 03/04/2026

