



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 215216

Product:	TETRACAINE HYDROCHLORIDE
Lot:	215216
Expiry date:	01/07/2026
Reference:	Cumple PhEur10.5
Synonyms:	Ametocaína clorhidrato. Pantocaína clorhidrato.
Formula:	C15H25CIN2O2
Molecular weight:	300,83 g/mol

Assay	Result	Specification	
Identification	Conform (A,B,D)	Test PhEur (A,D)	
Organoleptic properties	Conform	PhEur	
Melting point (Mettler)	149 °C		
Appearance of the aqueous solution 2%	Conform		
pH of the 1% water solution	6,01	4,50-6,50	
Heavy metals	<=10ppm	<= 10 ppm	
Related substances (HPLC)	Conform	Test PhEur	
Loss on drying (1 g, 105°C)	0,08 %	<= 1,0%	
Sulphated ashes	0,07 %	<= 0,1 %	
Assay	99,9 %	99,0-101,0%	
Impurity A	<=0,05 %	<= 0,05 %	
Impurity B	<=0,05 %	<= 0,1 %	
Impurity C	<=0,05 %	<= 0,1 %	
Unspecified Impurities	<=0,05 %	<= 0,10 %	
Total impurities	<=0,5 %	<= 0,5 %	
Residual solvent: Methanol	<=3000 ppm	<= 3000 ppm	#
Residual solvent: acetone	<=5000 ppm	<= 5000 ppm	#
Residual solvent: Hexane	<=290 ppm	<= 290 ppm	#
Residual solvent: Toluene	<=890 ppm	<= 890 ppm	#

Organoleptic characteristics: White or almost white, slightly hygroscopic, crystalline powder. Freely soluble in water, soluble in ethanol (96%) and practically insoluble in heptane.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 30/09/2021

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00392 VENKATA NARAYANA ACTIVE INGREDIENTS PRIVATE LIMITED

Manufacturer batch: TH0090821

Product	Name	Capacity	Batch
1184535	TETRACAINA CLORHIDRATO (INACTIVO)	10 g	215216-F-1
1184536	TETRACAINA CLORHIDRATO	25 g	215216-G-2
1184536	TETRACAINA CLORHIDRATO	25 g	215216-G-3
1184538	TETRACAINA CLORHIDRATO	100 g	215216-J-2
1184538	TETRACAINA CLORHIDRATO	100 g	215216-J-3
1184539	TETRACAINA CLORHIDRATO	250 g	215216-N-1
1184539	TETRACAINA CLORHIDRATO	250 g	215216-N-2
1184541	TETRACAINA CLORHIDRATO	1 kg	215216-P-1
1184541	TETRACAINA CLORHIDRATO	1 kg	215216-P-2
1370145	TETRACAINA CLORHIDRATO (FLB)	25 g	215216-G-1
1370146	TETRACAINA CLORHIDRATO (FLB)	100 g	215216-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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