



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 225999

Product:	TETRACAINE HYDROCHLORIDE
Lot:	225999
Expiry date:	31/08/2027
Reference:	Cumple PhEur10.8
Synonyms:	Ametocaína clorhidrato. Pantocaína clorhidrato.
Formula:	C ₁₅ H ₂₅ CIN ₂ O ₂
Molecular weight:	300,83 g/mol

Assay	Result	Specification	
Identification	Conform(A,D)		
Organoleptic properties	Conform	PhEur	
Melting point	148 °C	134 - 150°C	
Appearance of solution	Conform	Test PhEur	
pH	6,1	4,5 - 6,5	
Related substances (HPLC)	Conform	Test PhEur	
Loss on drying	0,05 %	<= 1,0 %	
Sulphated ashes	0,05 %	<= 0,1 %	
Assay	99,7 %	99,0-101,0%	
Impurity A	0,01 %	<= 0,05 %	
Impurity B	< 0,05 %	<= 0,15 %	
Impurity C	< 0,05 %	<= 0,15 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	< 0,05 %	<= 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	#
Elemental impurities	Conform	Test PhEur	#

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: 19/12/2022

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00392 VENKATA NARAYANA ACTIVE INGREDIENTS PRIVATE LIMITED

Manufacturer batch: TH0130922

Product	Name	Capacity	Batch
1184535	TETRACAINA CLORHIDRATO (INACTIVO)	10 g	225999-F-1
1184536	TETRACAINA CLORHIDRATO	25 g	225999-G-2
1184536	TETRACAINA CLORHIDRATO	25 g	225999-G-3
1184536	TETRACAINA CLORHIDRATO	25 g	225999-G-4
1184536	TETRACAINA CLORHIDRATO	25 g	225999-G-5
1184538	TETRACAINA CLORHIDRATO	100 g	225999-J-2
1184538	TETRACAINA CLORHIDRATO	100 g	225999-J-3
1184538	TETRACAINA CLORHIDRATO	100 g	225999-J-5
1184539	TETRACAINA CLORHIDRATO	250 g	225999-N-1
1184539	TETRACAINA CLORHIDRATO	250 g	225999-N-2
1184541	TETRACAINA CLORHIDRATO	1 kg	225999-P-1
1184541	TETRACAINA CLORHIDRATO	1 kg	225999-P-2
1184541	TETRACAINA CLORHIDRATO	1 kg	225999-P-3
1370145	TETRACAINA CLORHIDRATO (FLB)	25 g	225999-G-1
1370145	TETRACAINA CLORHIDRATO (FLB)	25 g	225999-G-6
1370146	TETRACAINA CLORHIDRATO (FLB)	100 g	225999-J-1
1370146	TETRACAINA CLORHIDRATO (FLB)	100 g	225999-J-4
1370152	TETRACAINA CLORHIDRATO (FLB) (INACTIVO)	10 g	225999-F-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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