

## Tetracaine HCL

<b>CODE ARTICLE:</b> 9206	<b>BATCH:</b> 0130618	<b>Active pharmaceutical ingredient</b>
<b>TEST DATE:</b> 18/09/2024	<b>TEST:</b> QC-00268107	
<b>EXPIRY DATE:</b> 30/11/2028	<b>FABRICATION DATE:</b> 01/12/2023	<b>MR:</b> 300,80
<b>CAS:</b> [136-47-0]	<b>FORMULA:</b> C <sub>15</sub> H <sub>24</sub> N <sub>2</sub> O <sub>2</sub> ·HCl	
<b>SYNONYMS / BOTANICAL NAME:</b> Butetamol; Clorhidrato de ametocaina; Clorhidrato de butilaminobenzoildimetilaminoetanol; Clorhidrato de dimetilaminetanol p-Aminobenzolbutano; Clorhidrato de pantocaina; Cloruro de tetracaina; Decicaina; Hidrocloruro de tetracaina; Pantocaina		
<b>STORAGE:</b> Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	PASS -			CRYSTALLINE POWDER	PH.EUR.*
COLOUR	PASS -			WHITE	PH.EUR.*
<b>SOLUBILITY</b>					
SOLUBLE	FREELY SOLUBLE IN WATER				PH.EUR.*
SOLUBLE	ETHANOL 96°				PH.EUR.*
INSOLUBLE	PRACTICALLY INSOLUBLE IN HEPTANE				PH.EUR.*
MELTING POINT	149 °C		134	150	PH.EUR.*
<b>IDENTIFICATION</b>					
IR IDENTIFICATION	PASS				PH.EUR.*
IDENTIFICATION B	PASS -				PH.EUR.
IDENTIFICATION C	PASS				PH.EUR.
IDENTIFICATION D	PASS				PH.EUR.*
DISSOLUTION ASPECT	PASS -			Limpid and colorless	PH.EUR.*
PH	5,9 -		4,5	6,5	PH.EUR.*
<b>RELATED SUBSTANCES (HPLC)</b>					
TOTAL IMPURITIES	0,1 %			<=0,5%	PH.EUR.*
UNSPECIFIED IMPURITIES	<LQ=0,05 %			<=0,10%	PH.EUR.*
IMPURITY A	<LQ=0,05 %			<=0,05%	PH.EUR.*
IMPURITY B	0,05 %			<=0,15%	PH.EUR.*
IMPURITY C	<LQ=0,05 %			<=0,15%	PH.EUR.*
LOSS ON DRYING	0,1 %		0,0	1	PH.EUR.*
SULPHATED ASHES	0,03 %		0,0	0,1	PH.EUR.*
ASSAY (DRY SUBSTANCE)	100,8 %		99	101	PH.EUR.*
ASSAY (HPLC) (DRY BASIS).	99,7 %		99	101	Manufacture's Standard
<b>RESIDUAL SOLVENTS</b>					
METHANOL	N.D. ppm			3000	Manufacture's Standard
ACETONE	N.D. ppm			5000	Manufacture's Standard
HEXANE	N.D. ppm			290	Manufacture's Standard
TOLUENE	N.D. ppm			890	Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SPECIFICATION	PH.EUR 11				Manufacture's Standard

The data expressed in this certificate of analysis is facilitated by our supplier and/or obtained in our control laboratory, in no case being exempted of the controls demanded by each sector. Tests marked with (\*) are verified in Guinama.

Manufacturer: 50591 V. N. A. I. PTV. LTD. (India) Manufacturer Batch: TH0201223 Manufacturer original CoA available under request

GUINAMA S.L. Calle Oslo, 3 46185 La Pobla de Vallbona (Valencia) Spain

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TEST	RESULTS	Units	MIN	MAX	METHOD
Elemental Impurities ICHQ3D	PASS				
Risk Assessment Evaluation for Nitrosamines	PASS				

*NON-sterile*



**The product has been handled in NON-sterile rooms, therefore this product IS NOT STERILE**

**Silvia Sancho-Tello Ripoll**  
Technical Director.

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