

Tetracaine HCL

CODE ARTICLE: 9206	BATCH: 0126083	Active pharmaceutical ingredient
TEST DATE: 11/03/2024	TEST: QC-00262297	
EXPIRY DATE: 30/03/2028	FABRICATION DATE: 01/04/2023	MR: 300,80
CAS: [136-47-0]	FORMULA: C ₁₅ H ₂₄ N ₂ O ₂ ·HCl	
SYNONYMS / BOTANICAL NAME: Butetamol; Clorhidrato de ametocaina; Clorhidrato de butilaminobenzoildimetilaminoetanol; Clorhidrato de dimetilaminetanol p-Aminobenzolbutano; Clorhidrato de pantocaina; Cloruro de tetracaina; Decicaina; Hidrocloruro de tetracaina; Pantocaina		
STORAGE: Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	CONFORM	-		POWDER	PH.EUR.*
COLOUR	CONFORM	-		BLANCO	PH.EUR.*
<u>SOLUBILITY</u>					
SOLUBLE	FREELY SOLUBLE IN WATER				PH.EUR.*
SOLUBLE	ETHANOL 96°				PH.EUR.*
INSOLUBLE	PRACTICALLY INSOLUBLE IN HEPTANE				PH.EUR.*
MELTING POINT	139 °C		134	150	PH.EUR.*
<u>IDENTIFICATION</u>					
IR IDENTIFICATION	CONFORM				PH.EUR.*
IDENTIFICATION B	CONFORM	-			PH.EUR.
IDENTIFICATION C	CONFORM				PH.EUR.
IDENTIFICATION D	CONFORM				PH.EUR.*
DISSOLUTION ASPECT	CONFORM	-		Limpid and colorless	PH.EUR.*
PH	5,6	-	4,5	6,5	PH.EUR.*
<u>RELATED SUBSTANCES (HPLC)</u>					
TOTAL IMPURITIES	<RT=0,05 %			<=0,5%	PH.EUR.*
UNSPECIFIED IMPURITIES	<RT=0,05 %			<=0,10%	PH.EUR.*
IMPURITY A	N.D. %			<=0,05%	PH.EUR.*
IMPURITY B	N.D. %			<=0,15%	PH.EUR.*
IMPURITY C	N.D. %			<=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)	100,3 %		99	101	PH.EUR.*
ASSAY (HPLC) (DRY BASIS).	100 %		99	101	Manufacture's Standard
<u>RESIDUAL SOLVENTS</u>					
METHANOL	N.D. ppm			3000	Manufacture's Standard
ACETONE	< LIMITE DETECCION (250) ppm			5000	Manufacture's Standard
HEXANE	N.D. ppm			290	Manufacture's Standard
TOLUENE	N.D. ppm			890	Manufacture's Standard
<u>GENOTOXIC IMPURITIES CONTENT (GC)</u>					
N-BUTYL BROMIDE	N.D. MG/KG			<=15	Manufacture's Standard
N,N-DIMETHYL AMINO ETHYL CHLORIDE HCL	N.D. MG/KG			<=15	Manufacture's Standard
SAMPLING	COLLECT				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: TH0080423 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
CORRECT BATCH	YES				Manufacture's Standard
SPECIFICATION	PH.EUR 11				Manufacture's Standard
Elemental Impurities ICHQ3D	CONFORM				
Risk Assessment Evaluation for Nitrosamines	CONFORM				

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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