

Tetracaine HCL

CODE ARTICLE: 96921	BATCH: 0119733	Active pharmaceutical ingredient
TEST DATE: 04/04/2023	TEST: QC-00252021	
EXPIRY DATE: 30/08/2027	FABRICATION DATE: 30/09/2022	MR: 300,80
CAS: [136-47-0]	FORMULA: C15H24N2O2·HCl	
SYNONYMS / BOTANICAL NAME: TETRACAÍNA HCL; [Pancocaína]		
STORAGE: Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	CRISTAL POWDER				PH.EUR.*
COLOUR	WHITE				PH.EUR.*
SOLUBILITY					
SOLUBLE	FREELY SOLUBLE IN WATER				PH.EUR.*
SOLUBLE	ETHANOL 96°				PH.EUR.*
INSOLUBLE	PRACTICALLY INSOLUBLE IN HEPTANE				PH.EUR.*
MELTING POINT	148 °C		134	150	PH.EUR.*
IDENTIFICATION					
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	5,2 -		4,5	6,5	PH.EUR.*
RELATED SUBSTANCES (HPLC)					
TOTAL IMPURITIES	<LQ=0,05% -			<=0,5%	PH.EUR.*
UNSPECIFIED IMPURITIES	<LQ=0,05% -			<=0,10%	PH.EUR.*
IMPURITY A	<LQ=0,05% -			<=0,05%	PH.EUR.*
IMPURITY B	<LQ=0,05% -			<=0,15%	PH.EUR.*
IMPURITY C	<LQ=0,05% -			<=0,15%	PH.EUR.*
LOSS ON DRYING	0,04 %		0,0	1	PH.EUR.*
SULPHATED ASHES	0,02 %		0,0	0,1	PH.EUR.*
ASSAY (DRY SUBSTANCE)	100,7 %		99	101	PH.EUR.*
ASSAY (HPLC) (DRY BASIS).	99,6 %		99	101	Manufacture's Standard
RESIDUAL SOLVENTS					
METHANOL	<LOD(150) ppm			3000	Manufacture's Standard
ACETONE	< LOQ (750) ppm			5000	Manufacture's Standard
HEXANE	< LOD (14,5) ppm			290	Manufacture's Standard
TOLUENE	< LOD (44,5) ppm			890	Manufacture's Standard
GENOTOXIC IMPURITIES CONTENT (GC)					
N-BUTYL BROMIDE	<LIMITE DE DETECCION (3,0) MG/KG			<=15	Manufacture's Standard
N,N-DIMETHYL AMINO ETHYL CHLORIDE HCL	<LIMITE DE DETECCION (3,0) 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: TH0140922 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	PASS				
Risk Assessment Evaluation for Nitrosamines	PASS				

This product has been handled in a non-sterile room, for batches suitable for sterile use, consult availability.



This product has been manipulated in a NON-sterile clean room, for batches suitable for sterile use, consult availability.

Silvia Sancho-Tello Ripoll
Technical Director.

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