

Tetracaine HCL

CODE ARTICLE: 85599	BATCH: 0129534	Active pharmaceutical ingredient
TEST DATE: 23/07/2024	TEST: QC-00266719	
EXPIRY DATE: 30/03/2027	FABRICATION DATE: 01/04/2022	MR: 300,80
CAS: [136-47-0]	FORMULA: C15H24N2O2·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	PASS -			CRYSTALLINE POWDER	PH.EUR.*
COLOUR	PASS -			WHITE	PH.EUR.*
SOLUBILITY					
SOLUBLE	FREELY SOLUBLE IN WATER				PH.EUR.*
SOLUBLE	ALCOHOL				PH.EUR.*
INSOLUBLE	PRACTICALLY INSOLUBLE IN HEPTANE				PH.EUR.*
MELTING POINT	149 °C		134	150	PH.EUR.*
IDENTIFICATION					
IR IDENTIFICATION	PASS				PH.EUR.*
IDENTIFICATION B	PASS -			131°C (aprox.)	PH.EUR.
IDENTIFICATION C	PASS				PH.EUR.
IDENTIFICATION D	PASS				PH.EUR.*
DISSOLUTION ASPECT	PASS -			Clear and colourless	PH.EUR.*
PH	5,7 -		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	0,04 %		0,0	0,1	PH.EUR.*
ASSAY (DRY SUBSTANCE)	100,2 %		99	101	PH.EUR.*
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
ASSAY (HPLC) (DRY BASIS).	100,4 %		99	101	Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SAMPLING	COLLECT				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: TH0080422 Manufacturer original CoA available under request

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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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