

Lidocaine HCL

CODE ARTICLE: 92274	BATCH: 0120598	Active pharmaceutical ingredient
TEST DATE: 04/07/2023	TEST: QC-00254932	
EXPIRY DATE: 30/07/2027	FABRICATION DATE: 01/08/2022	MR: 288,80
CAS: [6108-05-0]	FORMULA: C14H22N2O·HCl·H2O	
SYNONYMS / BOTANICAL NAME: Lidocaine hydrochloride Clorhidrato de lignocaina; Clorhidrato de xilocaína; Hidrocloruro de lidocaína		
STORAGE: Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	CONFORM	-		POLVO CRISTAL	PH.EUR.*
COLOUR	CONFORM			BLANCO	PH.EUR.*
SOLUBILITY					
SOLUBLE	FREELY SOLUBLE IN ETHANOL				PH.EUR.*
SOLUBLE	VERY SOLUBLE IN WATER				PH.EUR.*
IDENTIFICATION					
IR IDENTIFICATION	CONFORM				PH.EUR.*
IDENTIFICATION D	CONFORM				PH.EUR.*
DISSOLUTION ASPECT	CONFORM	-		Sol. límpida e incolora	PH.EUR.*
PH	4,9	-	4	5,5	PH.EUR.*
RELATED SUBSTANCES					
TOTAL IMPURITIES	<DL (0,05%) (PASS)	-		<= 0.5% (<= 5xArea Lidocaine RS d)	PH.EUR.*
UNSPECIFIED IMPURITIES	<DL (0,05%) (PASS)	-		<= 0.10% (<= Lidocaine area RS D)	PH.EUR.*
IMPURITY A	N.D.	-		<= 0.01% (<= Lidocaine area RS D)	PH.EUR.*
WATER	6,4 %		5,5	7	PH.EUR.*
SULPHATED ASHES	0,1 %		0,0	0,1	PH.EUR.*
ASSAY (ANHYDROUS BASIS)	99,6 %		99	101	PH.EUR.*
SOLVENT RESIDUE					
ACETONE	741 ppm		0,0	5.000	Manufacture's Standard
TOLUENE	<LOD ppm			890	Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SPECIFICATION	PH.EUR 11, BP 2022				Manufacture's Standard
Risk Assessment Evaluation for Nitrosamines	CONFORM				
Elemental Impurities ICHQ3D	CONFORM				
<i>This product has been handled in a non-sterile room, for batches suitable for sterile use, consult availability.</i>					

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.

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Silvia Sancho-Tello Ripoll
Technical Director.

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

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