

Lidocaine

CODE ARTICLE: 97580	BATCH: 0122173	Active pharmaceutical ingredient
TEST DATE: 25/09/2023	TEST: QC-00256993	
EXPIRY DATE: 30/11/2027	FABRICATION DATE: 01/12/2022	MR: 234,30
CAS: [137-58-6]	FORMULA: C ₁₄ H ₂₂ N ₂ O	
SYNONYMS / BOTANICAL NAME: Lignocaína; Xilocaína		
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	VERY SOLUBLE IN ETHANOL 96				PH.EUR.*
SOLUBLE	VERY SOLUBLE IN METHYLENE CHLORIDE				PH.EUR.*
INSOLUBLE	PRACTICALLY INSOLUBLE IN WATER				PH.EUR.*
IDENTIFICATION					
IR IDENTIFICATION	CONFORM				PH.EUR.*
MELTING POINT	67,3 °C		66	70	PH.EUR.
IDENTIFICATION C	CONFORM				PH.EUR.
RELATED SUBSTANCES (HPLC)					
TOTAL IMPURITIES	<DL=0,05% (CONFORME) -			<=0,5% (<5xÁrea SR D)	PH.EUR.*
UNSPECIFIED IMPURITIES	<DL=0,05% (CONFORME) -			<= 0.10% (<area RS d)	PH.EUR.*
IMPURITY A	N.D. -			<= 0.01% (<area RS D)	PH.EUR.*
SULPHATES	CONFORM	%		<=0,1	PH.EUR.*
CHLORIDES	CONFORM	ppm		<=35	PH.EUR.*
WATER	<0,1 %			<=1,0	PH.EUR.*
SULPHATED ASHES	0,1 %		0,0	0,1	PH.EUR.*
ASSAY (ANHYDROUS BASIS)	100,4 %		99	101	PH.EUR.*
RESIDUAL SOLVENTS					
TOLUENE	0 ppm		0,0	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				



Silvia Sancho-Tello Ripoll
Technical Director.

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.

