

Lidocaine

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| CODE ARTICLE: 91759 | BATCH: 0128195 | 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: C14H22N2O | |
| SYNONYMS / BOTANICAL NAME: Lignocaína; Xilocaína | | |
| STORAGE: Store in tightly closed containers in a cool, dry place. | | |

| TEST | RESULTS | Units | MIN | MAX | METHOD |
|---|------------------------------------|-------|-----|--------------------------|------------------------|
| APPEARANCE | PASS | - | | POLVO CRISTAL | PH.EUR.* |
| COLOUR | PASS | - | | 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 | PASS | | | | PH.EUR.* |
| MELTING POINT | 67,3 °C | | 66 | 70 | PH.EUR. |
| IDENTIFICATION C | PASS | | | | PH.EUR. |
| RELATED SUBSTANCES (HPLC) | | | | | |
| TOTAL IMPURITIES | <DL=0,05% (CONFORM) - | | | <=0,5% (<5xÁrea SR D) | PH.EUR.* |
| UNSPECIFIED IMPURITIES | <DL=0,05% (CONFORM) - | | | <= 0.10% (<area RS d) | PH.EUR.* |
| IMPURITY A | N.D. - | | | <= 0.01% (<area RS D) | PH.EUR.* |
| SULPHATES | PASS % | | | <=0,1 | PH.EUR.* |
| CHLORIDES | PASS 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 | PASS | | | | |
| Elemental Impurities ICHQ3D | PASS | | | | |



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.