

Lidocaine hydrochloride

| | | |
|---|--|---|
| CODE ARTICLE: 11693 | BATCH: 0132729 | Active pharmaceutical ingredient |
| TEST DATE: 28/05/2024 | TEST: QC-00264761 | |
| EXPIRY DATE: 31/12/2028 | FABRICATION DATE: 01/01/2024 | MR: 288,80 |
| CAS: [6108-05-0] | FORMULA: C ₁₄ H ₂₂ N ₂ O·HCl·H ₂ O | |
| 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 | FREELY SOLUBLE IN ETHANOL | | | | PH.EUR.* |
| SOLUBLE | VERY SOLUBLE IN WATER | | | | PH.EUR.* |
| IDENTIFICATION | | | | | |
| IR IDENTIFICATION | PASS | | | | PH.EUR.* |
| IDENTIFICATION D | PASS | | | | PH.EUR.* |
| DISSOLUTION ASPECT | PASS | - | | Sol. límpida e incolora | PH.EUR.* |
| PH | 5,2 | - | 4 | 5,5 | PH.EUR.* |
| RELATED SUBSTANCES | | | | | |
| TOTAL IMPURITIES | N.D. | - | | <= 0.5% (<= 5xArea Lidocaine RS d) | PH.EUR.* |
| UNSPECIFIED IMPURITIES | N.D. | - | | <= 0.10% (<= Lidocaine area RS D) | PH.EUR.* |
| IMPURITY A | N.D. | - | | <= 0.01% (<= Lidocaine area RS D) | PH.EUR.* |
| WATER | 6,3 | % | 5,5 | 7 | PH.EUR.* |
| SULPHATED ASHES | 0,1 | % | 0,0 | 0,1 | PH.EUR.* |
| ASSAY (ANHIDROUS BASIS) | 99,9 | % | 99 | 101 | PH.EUR.* |
| SOLVENT RESIDUE | | | | | |
| ACETONE | 398 | ppm | 0,0 | 5.000 | Manufacture's Standard |
| TOLUENE | N.D. | 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 | PASS | | | | |
| Elemental Impurities ICHQ3D | PASS | | | | |

NON-sterile

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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|------|---------|-------|-----|-----|--------|
|------|---------|-------|-----|-----|--------|



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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