

CERTIFICATE OF ANALYSIS

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| PRODUCT NAME: | BUPIVACAINE HCL | CAS NO.: | 14252-80-3 |
| ITEMS | SPECIFICATION | RESULTS | |
| DESCRIPTION | WHITE OR OFF-WHITE CRYSTALLINE POWDER | CONFORMS | |
| SOLUBILITY | FREELY SOLUBLE IN WATER AND IN ALCOHOL; SLIGHTLY SOLUBLE IN CHLOROFORM AND IN ACETONE | CONFORMS | |
| IDENTIFICATION | A. BY IR, TO MATCH WITH WORKING STANDARD B. BY UV, TO MATCH WITH WORKING STANDARD C. THE TEST FOR CHLORIDE | CONFORMS | |
| PH | 4.5 ~ 6.0 | 4.87 | |
| WATER (K.F) | 4.0% ~ 6.0% | 5.45% | |
| RESIDUE ON IGNITION | NOT MORE THAN 0.1% | 0.05% | |
| HEAVY METALS | NOT MORE THAN 10PPM | <10PPM | |
| CHROMATOGRAPHIC PURIT | MEET THE REQUIREMENTS | CONFORMS | |
| RESIDUAL SOLVENTS | THE SUM OF THE CONTENT OF ALCOHOL AND THE CONTENT OF ISOPROPYL ALCOHOL: NOT MORE THAN 2% | NOT DETECTED | |
| ASSAY | 98.5 ~ 101.5% (C ₁₈ H ₂₈ N ₂ O·HCL) | 99.74% | |
| CONCLUSION | THE RESULTS CONFORM TO THE STANDARD OF USP30. | | |

STORAGE: PRESERVE IN WELL-CLOSED, LIGHT-RESISTANT AND TIGHT CONTAINERS.

STORE IN COOL & DRY PLACE.