Lote: 0160317

medichem

# ANALYSIS CERTIFICATE

FDA Labeler Code No. 053296

PRODUCT: MEXILETINE HCl USP

Certificate of Analysis No. : 16A0487/08 Lot No. : A-160491 Quantity. : 10 KG

| ANALYTICAL DATA | SPECIFICATIONS | RESULTS | NOTES |
|---|---|---|---|
| Description | White or almost white crystalline powder. | Conforms | |
| Identification | Test A.- IR, Test B-. HPLC and Test C.- Chloride identification. | Conforms | |
| pH | 3.5 - 5.5 | 5.4 | |
| Loss on Drying | NMT 0.5% | 0.17 % | |
| Residue on ignition | NMT 0.1% | Less than 0.05 % | |
| Heavy Metals | NMT 10 ppm | Conforms | |
| Chromatographic purity. Impurity MXT-200 | NMT 0.10% | 0 % | 0.00% |
| Chromatographic purity. Impurity MXT-300. | NMT 0.10% | 0 % | 0.00% |
| Chromatographic purity. Any other individual impurity | NMT 0.10% | 0.03 % | |
| Chromatographic purity. Total impurities | NMT 1.5% | 0.05 % | |
| Assay | 98.0 - 102.0% (on dry basis) | 100.9 % | |
| 2,6-Dimethylphenol | NMT 0.1% | Conforms | |

Manufacturing Date November 25, 2016

Re-Test date November 25, 2019

22.03.17

Analyst

22.03.17

Head of Quality Control

Printed date: March 21, 2017

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