

Certificate of Analysis

Code Number / Product

44A029 MEXILETINE HYDROCHLORIDE

Batch No.:

24002

Analysis No.:

76907

Date of Manufacture:

19.April.2024

Weight:

268,2 kg

Test Spec. No.:

PSC-E-000025 26.0

| Test | Specification | Result |
|----------------------------------|--|-------------------|
| Appearance | White to off white crystalline powder | Conforms |
| Identification IR spectrum | Corresponding to reference spectrum | Conforms |
| Identification Test for chloride | White curdy precipitate form, which is soluble in an excess of 6N ammonium hydroxide | Conforms |
| Solubility | In methanol | Freely soluble |
| | In water | Freely soluble |
| | In dichloromethane | Sparingly soluble |
| Colour of solution | Not more intensely coloured than reference sol. B9 | Conforms |
| Clarity of solution | Clear as water or not more opalescent than reference susp. I | Conforms |
| pH | 4.0 - 5.5 | 4.9 |
| Chromatographic purity | Impurity A | <= 0.10% |
| | Impurity B | <= 0.10% |
| | Impurity C | <= 0.10% |
| | Any other Individual Impurity | <= 0.10% |
| | Total Impurities | <= 0.50% |
| Chromatographic purity | Impurity D | <= 0.10% |
| Residual Solvents | Methanol | <= 3000 ppm |
| | Acetone | <= 5000 ppm |
| | Toluene | <= 890 ppm |
| Loss on drying | <= 0.5 % | <0.1 % |
| Water | <= 0.5 % | 0.1 % |
| Sulphated ash | <= 0.10 % | 0.04 % |
| Assay | Titration with perchloric acid | 99.0% - 101.0% |
| | (calculated with reference to the dried substance) | 100.0 % |

Remarks:

Retesting Date: April.2029

Batch Comment:

Results: Manufacture of batch in compliance with GMPs
Batch specifications in conformance with market
authorisationBernat Turon
Quality Control

Approval

This is an electronic signature
Date of Issue : 25.April.2024 11:43:59