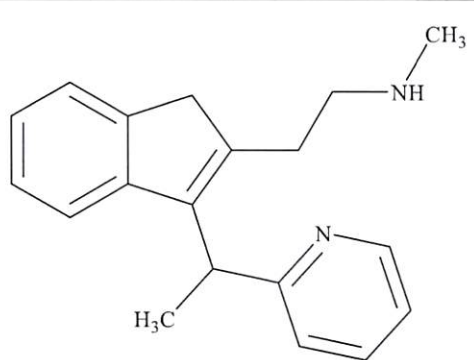


Certificate of Analysis



Certificate No.: **20250821005**

Date: August 21, 2025

Retest date: August 15, 2026

| | | |
|---|---|--|
| Compound Name: Dimetindene EP Impurity I | |  |
| Synonyms: | N-methyl-2-(3-(1-(pyridin-2-yl)ethyl)-1H-inden-2-yl)ethan-1-amine | |
| TLC Catalogue Number: | D-096025 | |
| CAS Number: | 151562-10-6 | |
| Alternate CAS Number: | 135784-57-5 (Maleate salt) | |
| Molecular Weight: | 278.40 | |
| Molecular Formula: | C ₁₉ H ₂₂ N ₂ | |
| Source: | TLC Pharmaceutical Standards | |
| Source Lot No.: | 7028-029A1 | |
| Storage Conditions: | Protect from light and air, store at -20 °C | |
| Solubility: | Methanol, DMSO | |

| Test Description | Specifications | Results |
|--------------------------------|--|-----------------|
| Visual Description | Green semi-solid | Conforms |
| Identification | | |
| IR | Conforms to structure | Conforms |
| MS | Conforms to structure | Conforms |
| ¹H NMR | Conforms to structure | Conforms |
| Purity (HPLC) | Not less than 90.0% | 93.8% |
| Impurity (HPLC) | RT 5.53, 1.39%; RT 6.61, 3.41%; RT 9.61, 0.97% | |
| Water Content (KF) | N/A | 1.5% |
| Residual Solvents (NMR) | 0.1% methanol | |
| Assay (%) | Not less than 85.0% | 92.3% |
| Recommendation: | Release. The compound is unstable and can easily deteriorate. It should be stored as the storage condition stated in COA, and to be used immediately upon received. It contains 3.4% isomeric impurity (RT 6.61) according to its HPLC and LC-MS. | |

| Name | Department | Signature | Date |
|---------------------------|-------------------|--|------------|
| Reviewed and approved by: | Quality Control |  | 08/21/2025 |
| Approved by: | Quality Assurance |  | 08/21/2025 |

Attachments: Peak Attribution Table, HPLC, IR, MS and NMR spectra.