

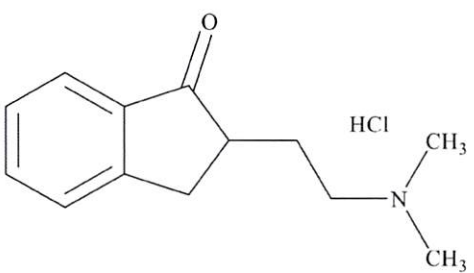
Certificate of Analysis

Certificate No.: **20231026018**



Date: October 26, 2023

Retest date: October 23, 2026

Compound Name: Dimetindene EP Impurity E HCl	
Synonyms:	2-(2-(dimethylamino)ethyl)-2,3-dihydro-1H-inden-1-one, hydrochloride (1:1)
TLC Catalogue Number:	D-096011
CAS Number:	5143-99-7
Molecular Weight:	203.29 36.46
Molecular Formula:	C ₁₃ H ₁₇ NO. HCl
Source:	TLC Pharmaceutical Standards
Source Lot No.:	3925-021A3
Storage Conditions:	Store at 2-8 °C
Solubility:	Methanol, DMSO



Test Description	Specifications	Results
Visual Description	White to off-white solid	Conforms
Identification		
IR	Conforms to structure	Conforms
MS	Conforms to structure	Conforms
¹ H NMR	Conforms to structure	Conforms
Purity (HPLC)	Not less than 95.0%	98.8%
Impurity (HPLC)	RT 19.59, 0.42%; RT 20.03, 0.50%; RT 20.73, 0.13%	
Water Content (KF)	N/A	0.3%
Residual Solvents (NMR)	No residual solvent	
Assay (%)	Not less than 90.0%	98.5%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		10 / 27 / 2023
Approved by:	Quality Assurance		10 / 27 / 2023

Attachments: HPLC, IR, MS and NMR spectra.