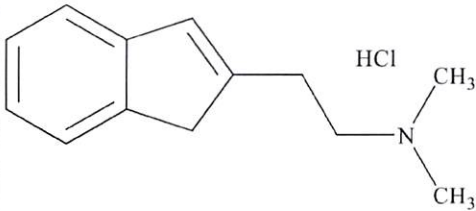


Certificate of Analysis



Certificate No.: **20231026016**

Date: October 26, 2023

Retest date: October 23, 2026

Compound Name: Dimetindene EP Impurity B HCl		
Synonyms:	2-(1 <i>H</i> -inden-2-yl)- <i>N,N</i> -dimethylethan-1-amine, hydrochloride (1:1)	
TLC Catalogue Number:	D-096008	
CAS Number:	92039-35-5	
Molecular Weight:	187.29 36.46	
Molecular Formula:	C ₁₃ H ₁₇ N. HCl	
Source:	TLC Pharmaceutical Standards	
Source Lot No.:	3925-001A4	
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%	98.7%
Impurity (HPLC)	RT 15.29, 0.29%; RT 15.96, 1.01%	
Water Content (KF)	N/A	0.2%
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 1 27 2023
Approved by:	Quality Assurance		10 1 27 2023

Attachments: HPLC, IR, MS and NMR spectra.