

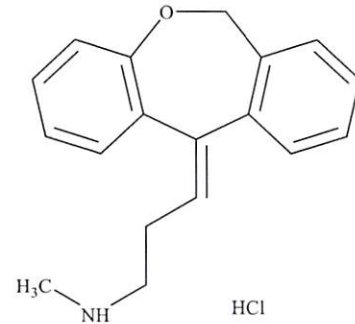
Certificate of Analysis

Certificate No.: 20250801005-2

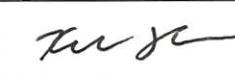

Date: August 1, 2025

Retest date: July 30, 2028

Compound Name: (Z)-Doxepin EP Impurity C HCl (Z)-Doxepin USP Related Compound C, Desmethyl (Z)-Doxepin HCl, (Z)-Nordoxepin HCl)	
Synonyms:	(Z)-3-(dibenzo[<i>b,e</i>]oxepin-11(6 <i>H</i>)-ylidene)- <i>N</i> -methylpropan-1-amine, hydrochloride (1:1)
TLC Catalogue Number:	D-1511
CAS Number:	124694-02-6
Alternate CAS Number:	58534-46-6 (free base)
Molecular Weight:	265.36 36.46
Molecular Formula:	C ₁₈ H ₁₉ NO. HCl
Source:	TLC Pharmaceutical Standards
Source Lot No.:	6747-093A9
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%	99.7%
Impurity (HPLC)	RT 9.55, 0.34%	
Water Content (KF)	N/A	0.3%
Residual Solvents (NMR)	0.6% methanol	
Assay (%)	Not less than 90.0%	98.8%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		09/19/2025
Approved by:	Quality Assurance		09/19/2025

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