

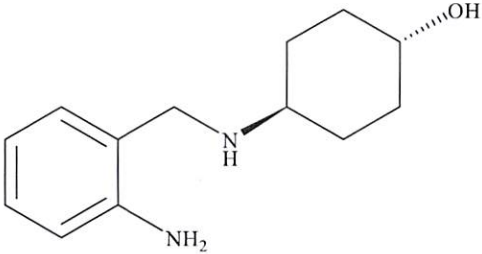
Certificate of Analysis

Certificate No.: 20230526011



Date: May 26, 2023

Retest date: May 25, 2026

Compound Name: Ambroxol Impurity 8	
Synonyms:	(1r,4r)-4-((2-aminobenzyl)amino)cyclohexan-1-ol
TLC Catalogue Number:	A-6022
CAS Number:	46727-91-7
Molecular Weight:	220.32
Molecular Formula:	C ₁₃ H ₂₀ N ₂ O
Source:	TLC Pharmaceutical Standards
Source Lot No.:	3866-043A3
Storage Conditions:	Store at 2-8 °C
Solubility:	Methanol, Ethanol, DMSO, DMF



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%	98.9%
Impurity (HPLC)	RT 15.86, 0.36%; RT 23.48, 0.36%	
Water Content (KF)	N/A	0.2%
Residual Solvents (NMR)	0.2% dichloromethane	
Assay (%)	Not less than 90.0%	98.5%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		05 129 1/2023
Approved by:	Quality Assurance		05 129 1/2023

Attachments: HPLC, IR, MS and NMR spectra.