

CERTIFICATE OF ANALYSIS

(Certificate No. KMA115004-01)

Release Date: 19/12/2025

Re-test Date: 18/12/2028

Ambroxol Hydrochloride

Identification

Chemical Name :

Trans-4-[(2-Amino-3,5-dibromobenzyl)amino]cyclohexanol hydrochloride (as per EP)

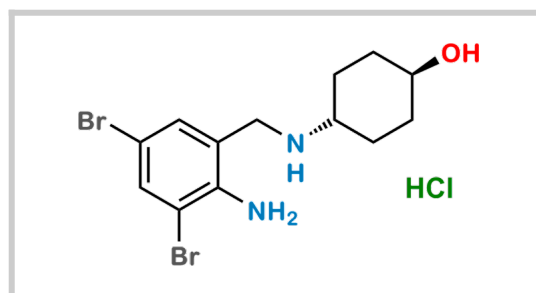
Alt. Name : Ambroxol Hydrochloride

CAT No. : KMA115004

CAS No. : 23828-92-4

Molecular Formula : C₁₃H₁₈Br₂N₂O : HCl

Molecular Weight : 378.1 : 36.5



Analytical Information

Batch No. : A115004-114-063

Description : White Solid

HPLC Purity : 99.87 %

Weight Loss By TGA : 0.11 %

% Potency : 99.76 %

Solubility : ACN : Water (1:1)

Mass : Confirm

IR : Confirm

¹H NMR : Confirm

¹³C NMR : Confirm

Additional Information

Long Term Storage : Store at 2-8 deg. C for long term storage

Shipping Condition : Product is stable to be Shipped at Room Temperature

% Potency = [100 - 0.11(Weight Loss By TGA)] x [99.87(HPLC Purity)]/100 = 99.76 %

Recommendation : Released

| | Department | Name | Signature | Date |
|------------------------|-----------------|---------------|-----------|------------|
| Prepared By | Analytical | Jignesh Patel | | 22/12/2025 |
| Reviewed & Approved By | Quality Control | Jatin Patel | | 22/12/2025 |

Attachments : COA, HPLC, MASS, ¹HNMR, ¹³CNMR, IR and TGA