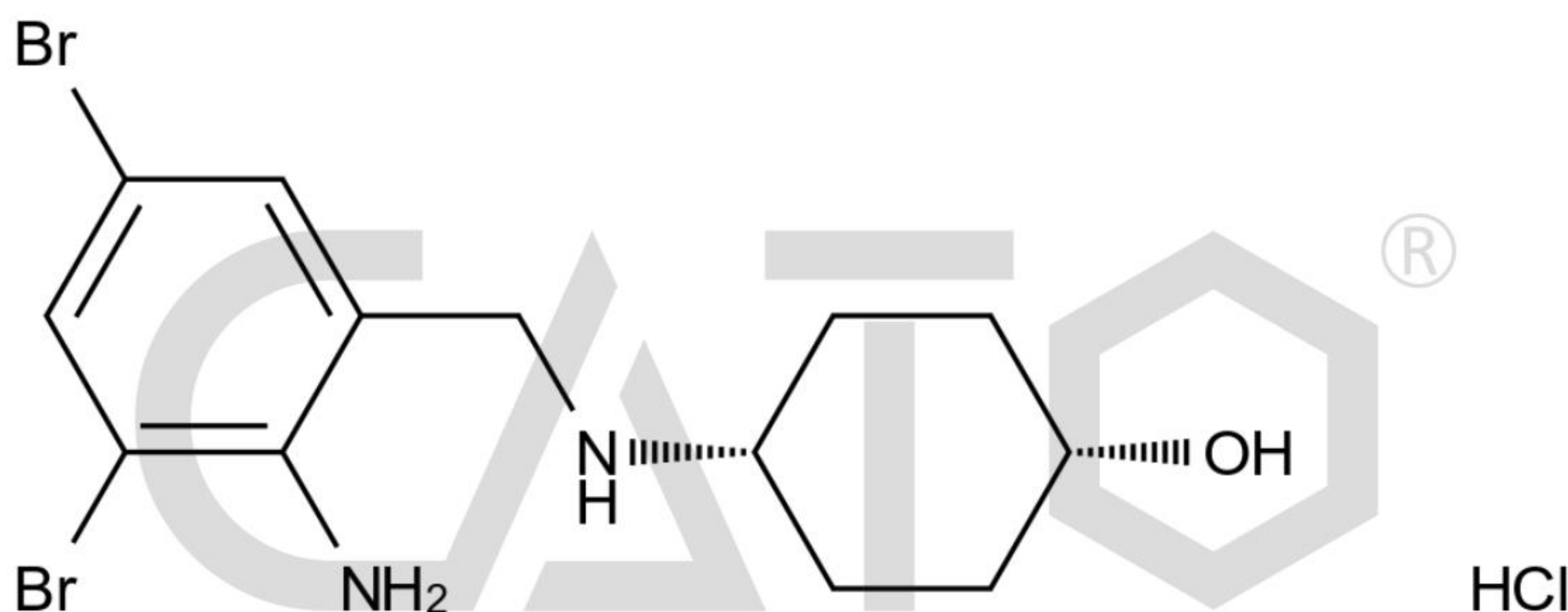


Certificate of Analysis

Reference Material & Standard

Product Name:	Ambroxol EP Impurity D HCl	Catalogue Number:	C4X-10854
Synonyms:	cis-4-[(2-Amino-3,5-dibromobenzyl) amino]cyclohexanol hydrochloride (1:1)	Lot Number:	0327-RH-0057
CAS Number:	1384955-66-1	Expiry Date:	Apr 16, 2030
Molecular Formula:	C ₁₃ H ₁₈ Br ₂ N ₂ O HCl	Storage:	2°C ~ 8°C Sealed
Molecular Weight:	378.10 36.46	Shipping Condition:	Shipping at Room Temperature
Solubility:	Soluble in Acetonitrile and DMSO	Warning:	

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Off-White Solid
Identification	LCMS&IR&CNMR&HNMR	Confirmed
Purity	HPLC	99.819%
Residue on Ignition	TGA	0.2430%
Loss on Drying	TGA	4.1680%
Content of Cl ⁻	IC	8.69%
Assay	qNMR	95.9%
Assay	Mass Balance	95.4%

Comment:

- The retest date of this product is Apr 16, 2029.
- The calculation of the mass balance method follows the formula (calculated on the non-dried basis):

$$\text{Assay (\%)} = (100\% - \text{Residue on Ignition} - \text{Loss on Drying}) * \text{Purity HPLC (\%)} / 100\%$$
Residue on Ignition and Loss on Drying are considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Koi

Reviewed by:

Alice

Approved by General Manager:

David

Date: Apr 17, 2026

Date: Apr 17, 2026

Date: Apr 17, 2026

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