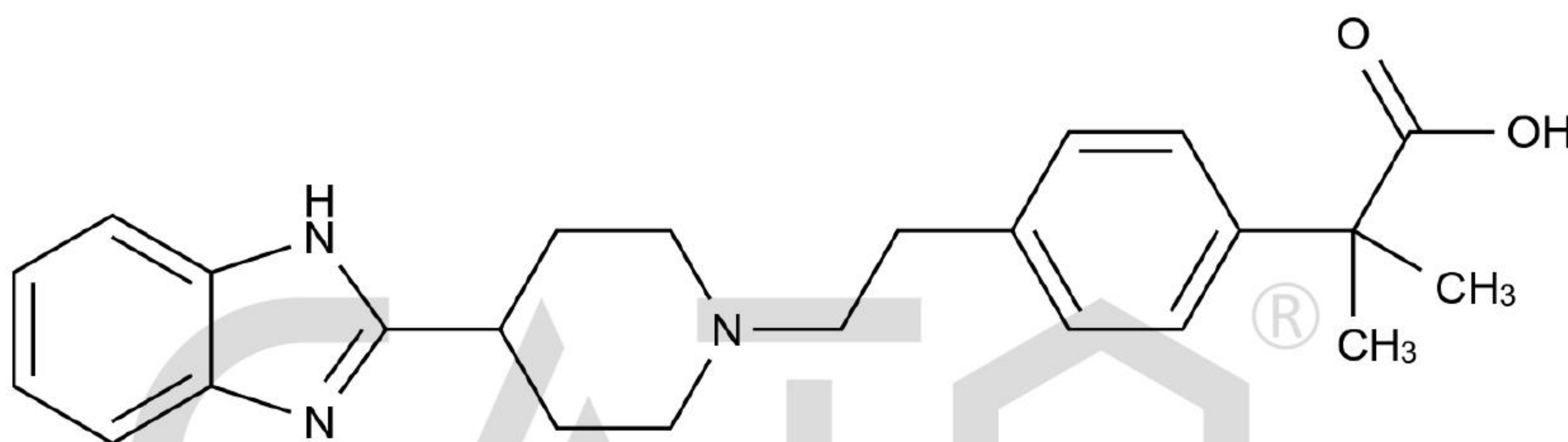


Certificate of Analysis

Reference Material & Standard

Product Name:	Bilastine Impurity 12	Catalogue Number:	C4X-225312
Synonyms:	N/A	Lot Number:	0901-RG-0101
CAS Number:	2099128-83-1	Expiry Date:	Sep 03, 2029
Molecular Formula:	C ₂₄ H ₂₉ N ₃ O ₂	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	391.51		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&UV&HNMR	Confirmed
Purity	HPLC	99.563%
Water Content	Karl Fischer	9.22%
Residual Solvents	NMR	Not detected in NMR
Assay		90.4%

Comment:

The calculation of the mass balance method follows the formula (calculated on the non-dried basis):

Assay (%) = (100% - Water Content - Residual Solvents) * Purity HPLC (%) / 100%

Water Content and Residual Solvents are considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Lily

Reviewed by:

Hinlam

Approved by General Manager:

David

Date: Sep 04, 2025

Date: Sep 08, 2025

Date: Sep 08, 2025



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