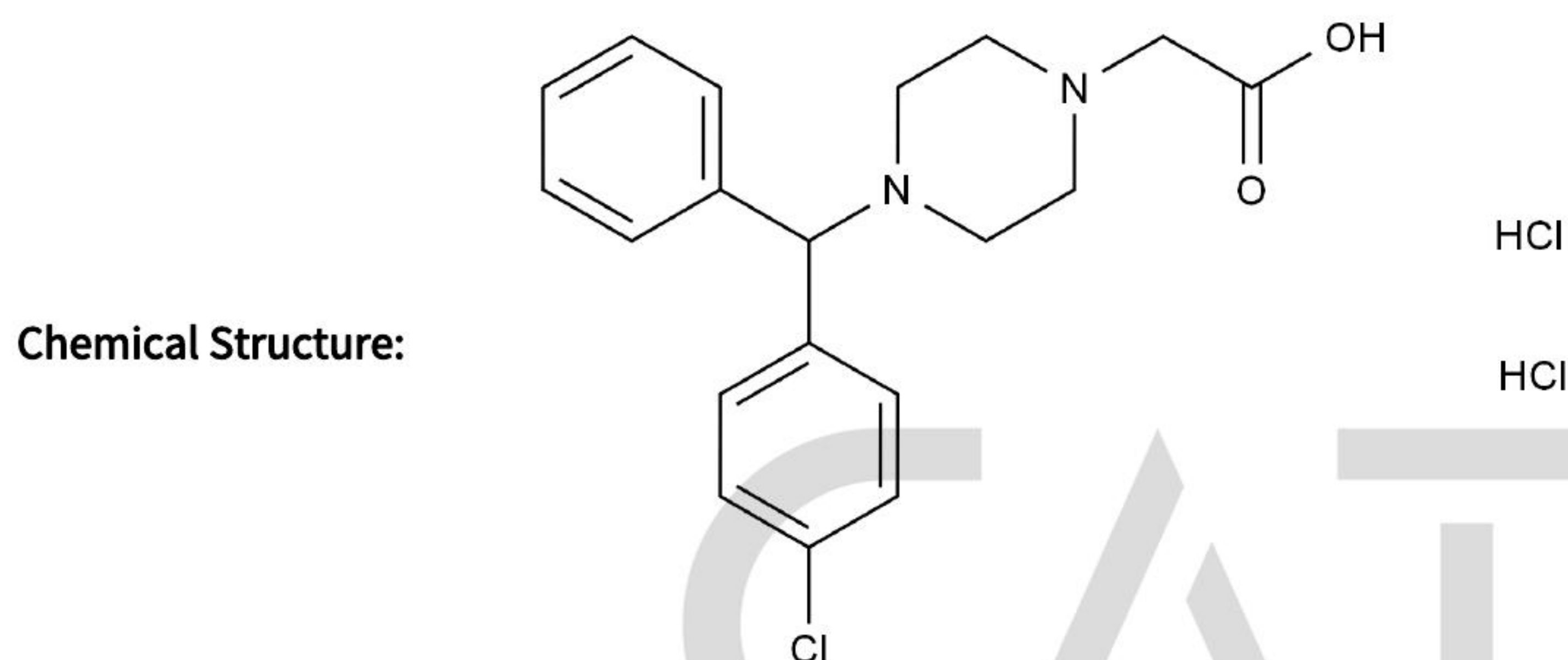


Certificate of Analysis

Reference Material & Standard

Product Name:	Cetirizine EP Impurity B	Catalogue Number:	C4X-10832
Synonyms:	N/A	Lot Number:	0825-RG-0118
CAS Number:	1000690-91-4	Expiry Date:	Mar 06, 2029
Molecular Formula:	C ₁₉ H ₂₁ ClN ₂ O ₂ 2*HCl	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	344.84 2*36.46		



Test Items	Method	Results
Appearance	Visual inspection	Off-White Solid
Identification	LCMS&UV&HNMR	Confirmed
Purity	HPLC	98.820%
Water Content	Karl Fischer	2.28%
Residual Solvents	NMR	0.06% acetone and 1.29% acetic acid
Assay		95.2%

Comment:

The calculation of the 100% 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:

Hin Lam

Approved by General Manager:

David

Date: Aug 26, 2025

Date: Aug 27, 2025

Date: Aug 27, 2025

