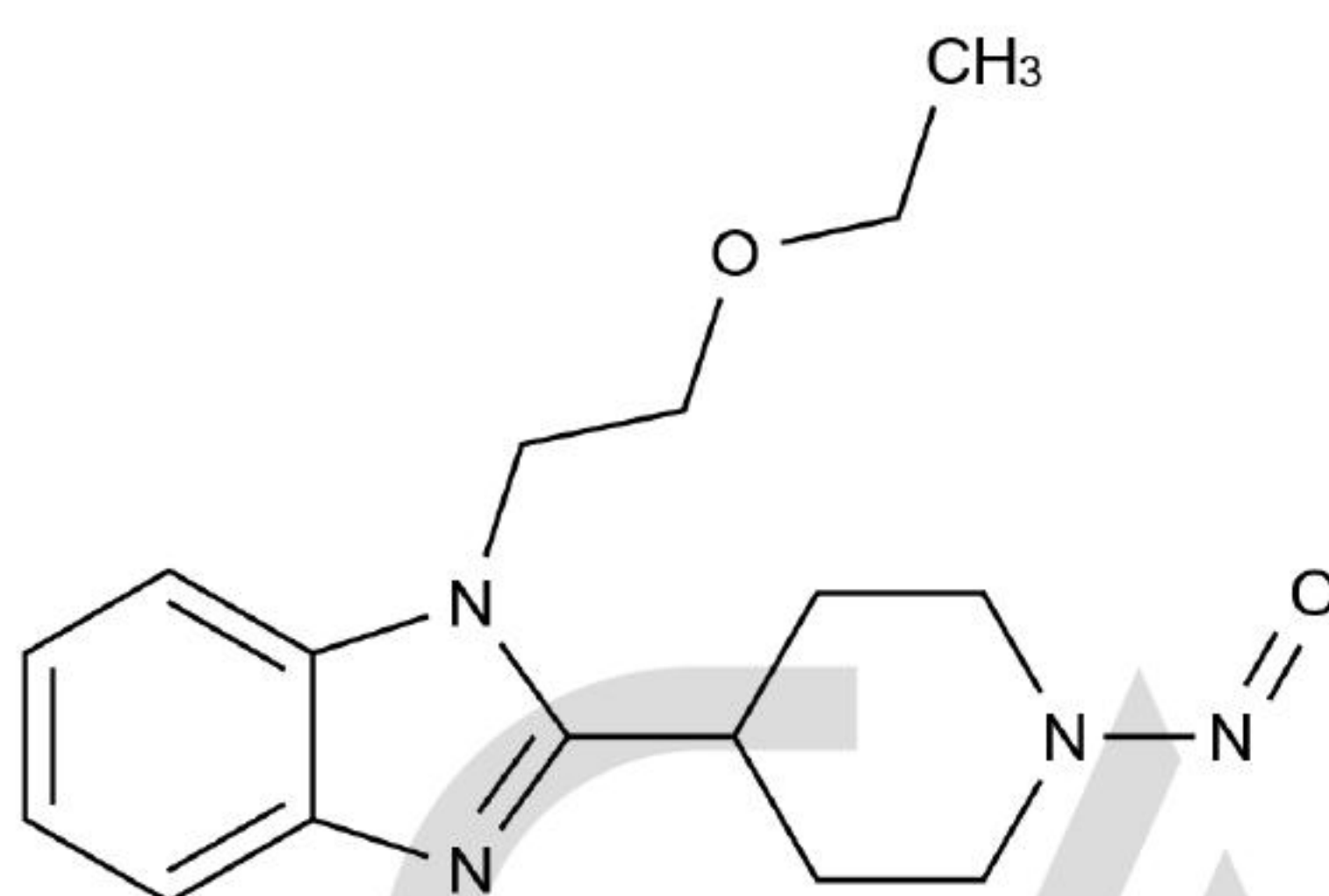


Certificate of Analysis

Reference Material & Standard

Product Name:	Bilastine Impurity 42	Catalogue Number:	C4X-225342
Synonyms:	1-(2-Ethoxyethyl)-2-(1-nitrosopiperidin-4-yl)-1H-benzo[d]imidazole	Lot Number:	0410-RH-0019
CAS Number:	3112735-82-4	Expiry Date:	May 08, 2030
Molecular Formula:	C ₁₆ H ₂₂ N ₄ O ₂	Storage:	2°C ~ 8°C Sealed
Molecular Weight:	302.37	Shipping Condition:	Shipping at Room Temperature
Solubility:	Soluble in Acetonitrile and DMSO		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Light Yellow Sticky Solid
Identification	LCMS&IR&CNMR&HNMR	Confirmed
Purity	HPLC	99.686%
Residue on Ignition	TGA	0.4539%
Loss on Drying	TGA	1.5689%
Assay	qNMR	97.1%
Assay	Mass Balance	97.7%

Comment:

- The retest date of this product is May 08, 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: May 28, 2026

Date: May 28, 2026

Date: May 28, 2026



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