

Certificate of Analysis

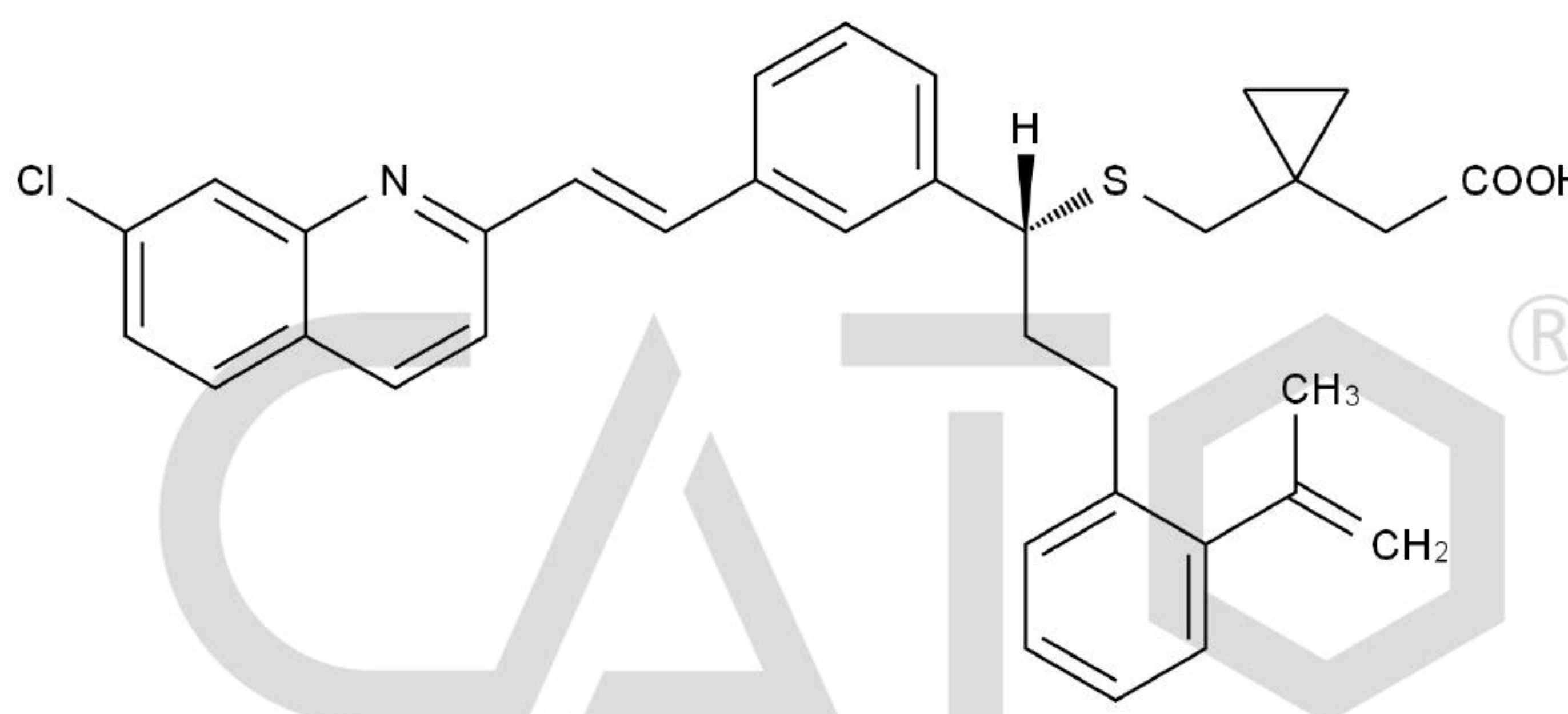
Reference Material & Standard

Product Name:	Montelukast EP Impurity B	Catalogue Number:	C4X-103113
Synonyms:	Methylstyrene impurity	Lot Number:	0127-RH-0043
CAS Number:	918972-54-0	Expiry Date:	Jan 26, 2030
Molecular Formula:	C ₃₅ H ₃₄ ClNO ₂ S	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	568.17	Shipping Condition:	Shipping at Room Temperature

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Yellow Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	97.985%
Loss On Drying	TGA	1.6396%
Assay		96.4%

Comment:

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

Assay (%) = (100% - Loss On Drying) * Purity HPLC (%) / 100%

Loss On Drying is considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

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Reviewed by:

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Date: Jan 27, 2026

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