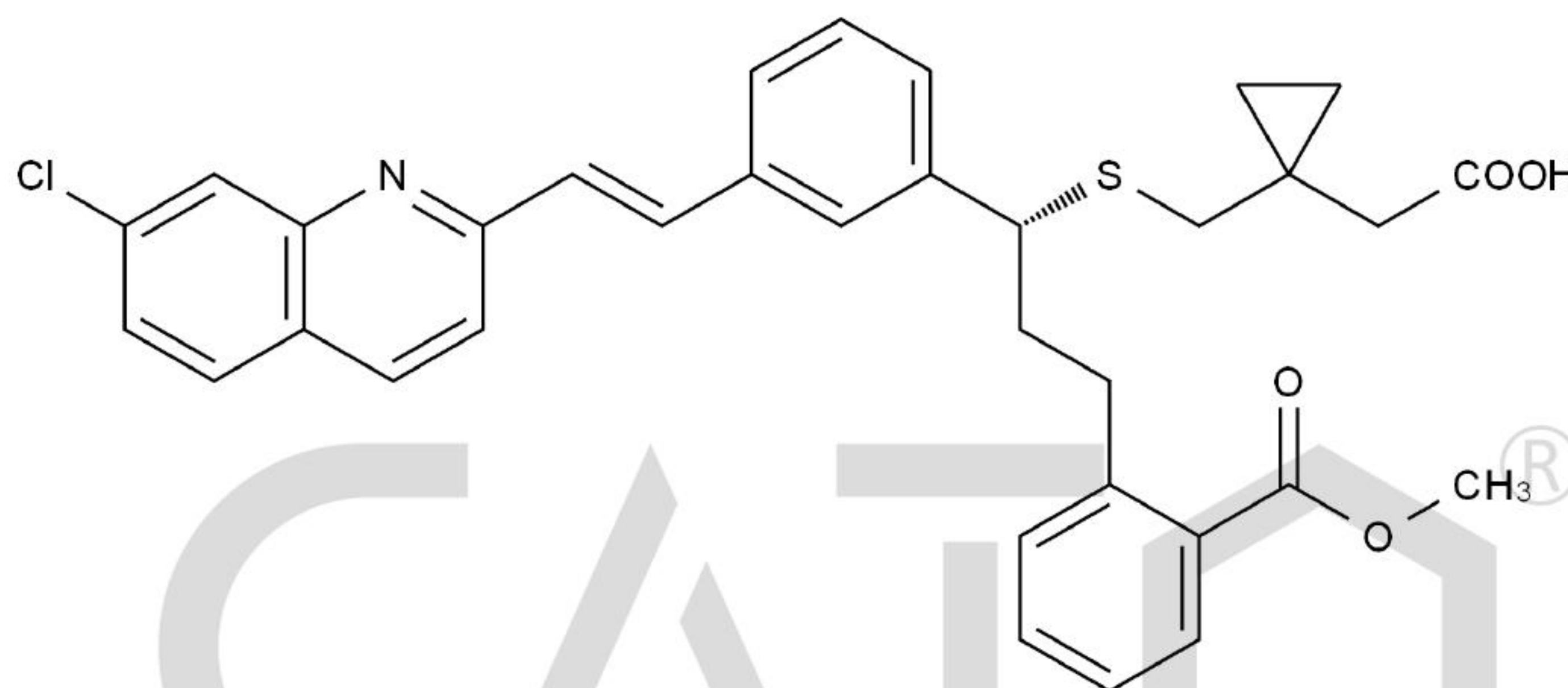


Certificate of Analysis

Reference Material & Standard

Product Name:	Montelukast EP Impurity H	Catalogue Number:	C4X-103117
Synonyms:	N/A	Lot Number:	1210-RF-0025
CAS Number:	851755-56-1	Expiry Date:	Dec 15, 2027
Molecular Formula:	C ₃₄ H ₃₂ ClNO ₄ S	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	586.14		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Yellow Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	98.262%
Residual Solvents	NMR	Ethyl acetate
Loss On Drying	TGA	0.1195%
Assay		98.1%

Comment:

The calculation of the 100% method follows the formula (calculated on the non-dried basis):

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

Residual Solvents and Loss On Drying are considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Koi

Reviewed by:

Lisa

Approved by General Manager:

David

Date: Dec 16, 2024

Date: Dec 16, 2024

Date: Dec 16, 2024

