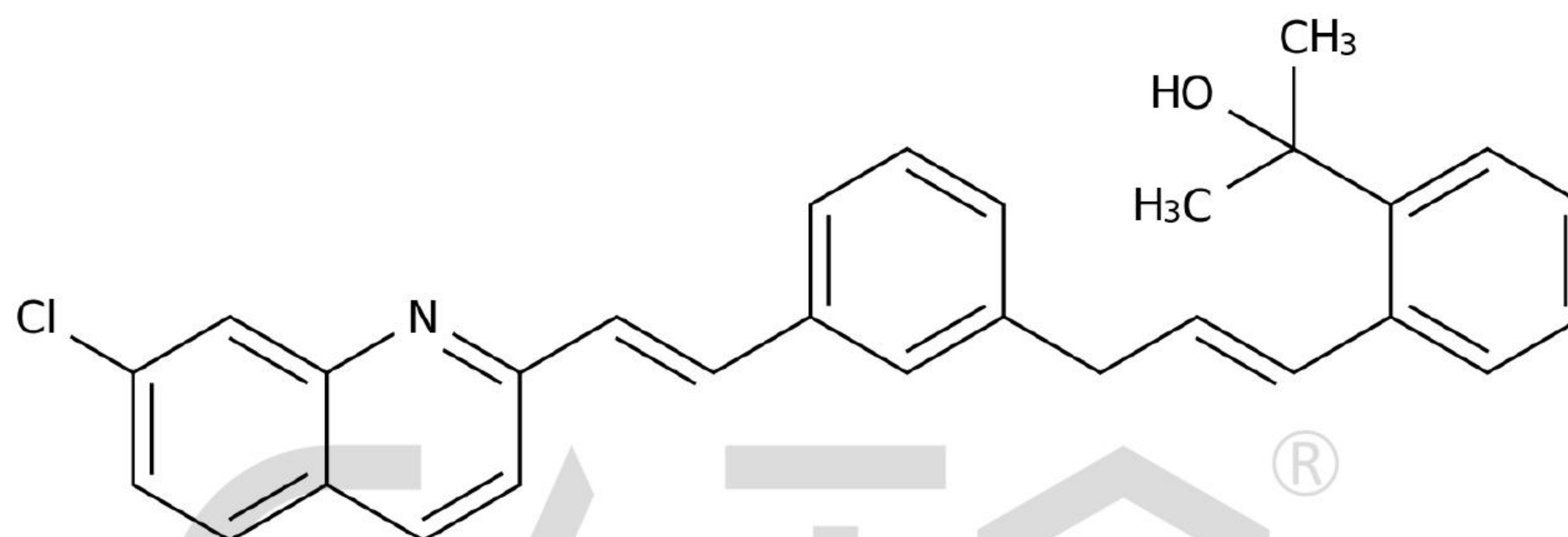


Certificate of Analysis

Reference Material

Product Name:	Montelukast Impurity 37	Catalogue Number:	C4X-103137
Chemical Name:	N/A	Lot Number:	0919-RD-0016
CAS Number:	N/A	Expiry Date:	Sep 06, 2025
Molecular Formula:	C ₂₉ H ₂₆ ClNO	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	439.98		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Pale Yellow Solid
Identification	LCMS&IR&HNMR	Confirmed
Purity	HPLC	98.7932%
Water Content	Karl Fischer	0.1%
Residual Solvents	NMR	1.0% methanol
Assay		97.7%

Comment:

- The compound contains 1.2% Montelukast Impurity 6 (RT 21.636) according to its HPLC and proton NMR.
- The calculation of the 100% method follows the formula (calculated on the non-dried basis):

$$\text{Assay (\%)} = (100\% - \text{Water Content} - \text{Residual Solvents}) * \text{Purity HPLC (\%)} / 100\%$$
 Water Content and Residual Solvents are considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Hinlam

Reviewed by:

Xenia

Aporoved by General manager:

David

Date: Sep 07, 2022

Date: Sep 23, 2022

Date: Sep 23, 2022

