

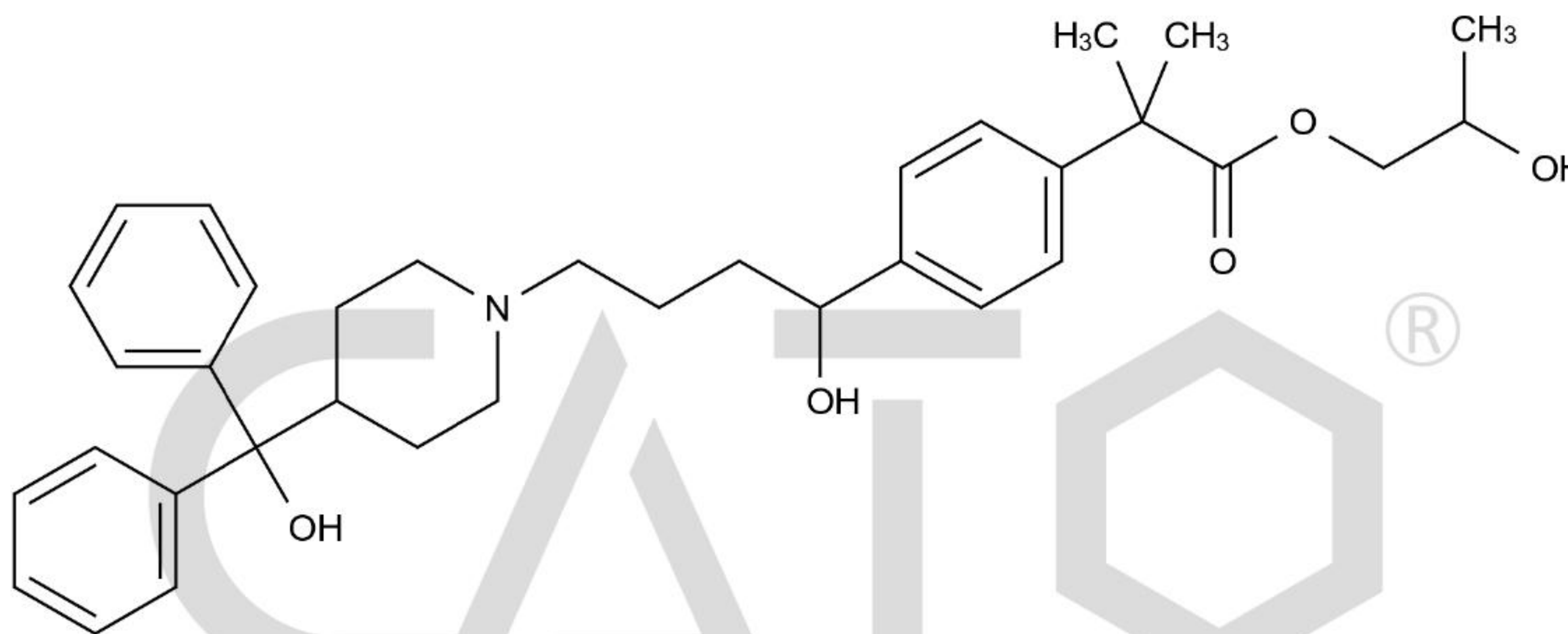
Certificate of Analysis

Reference Material & Standard

Product Name:	Fexofenadine Impurity 34	Catalogue Number:	C4X-179434
Synonyms:	N/A	Lot Number:	1220-RF-0036
CAS Number:	N/A	Expiry Date:	Feb 28, 2027
Molecular Formula:	C35H45NO5	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	559.74	Warning:	



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	99.015%
Water Content	Karl Fischer	0.08%
Residual Solvents	NMR	4.44% ethyl acetate
Assay		94.5%

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:

Lisa

Approved by General Manager:

David

Date: Dec 20, 2024

Date: Dec 23, 2024

Date: Dec 23, 2024

