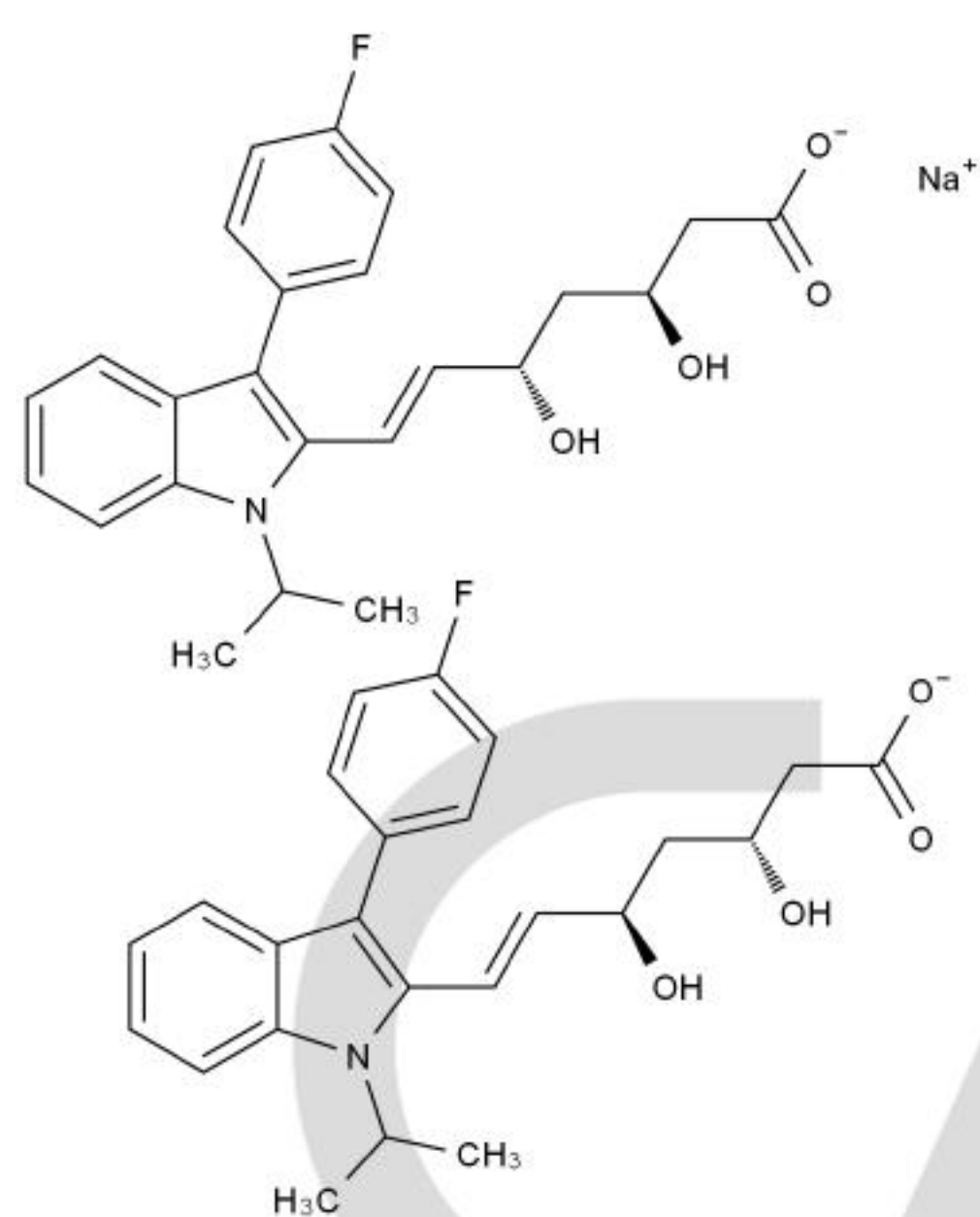


Certificate of Analysis

Reference Material & Standard

Product Name:	Fluvastatin EP Impurity A Sodium Salt(and enantiomer)	Catalogue Number:	C4X-16511
Synonyms:	N/A	Lot Number:	0628-RE-0040
CAS Number:	93957-58-5	Expiry Date:	Jun 02, 2028
Molecular Formula:	2*C ₂₄ H ₂₅ FN ₂ O ₄ 2*Na	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	2*410.46 2*22.99		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Pale Yellow Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	99.262%
Water Content	Karl Fischer	2.98%
Residual Solvents	NMR	1.02% ethanol and 0.65% n-hexane
Assay		94.6%

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: Jul 09, 2025

Date: Jul 09, 2025

Date: Jul 09, 2025

