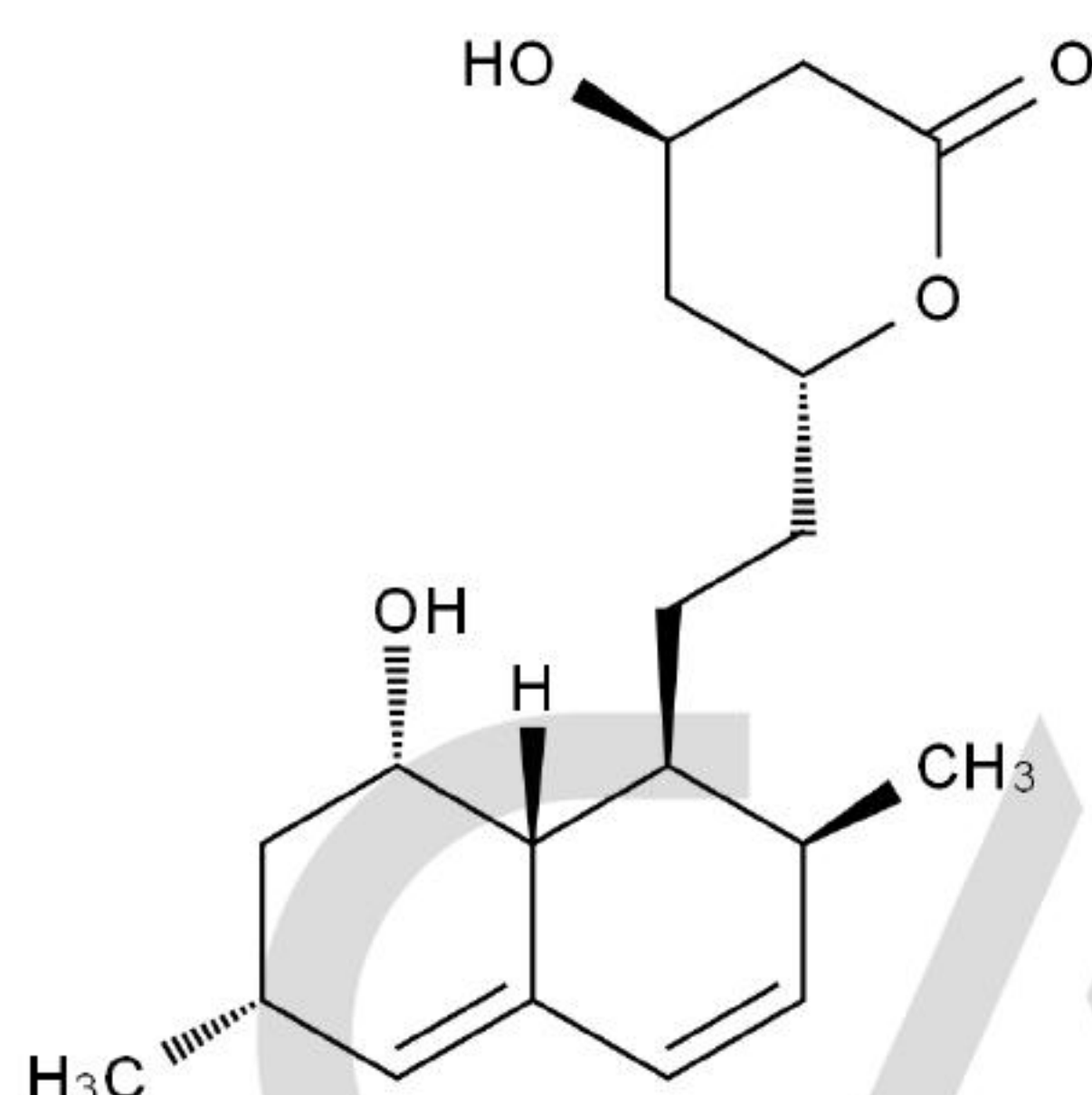


Certificate of Analysis

Reference Material & Standard

Product Name:	Simvastatin EP Impurity H	Catalogue Number:	C4X-119910
Synonyms:	N/A	Lot Number:	0324-RG-0150
CAS Number:	79952-42-4	Expiry Date:	May 17, 2026
Molecular Formula:	C ₁₉ H ₂₈ O ₄	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	320.42		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Off-White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	98.219%
Water Content	Karl Fischer	0.40%
Residual Solvents	NMR	Not detected in NMR
Assay		97.8%

Comment:

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:

Lily

Reviewed by:

Hin Lam

Approved by General Manager:

David

Date: Mar 25, 2025

Date: Mar 25, 2025

Date: Mar 25, 2025

