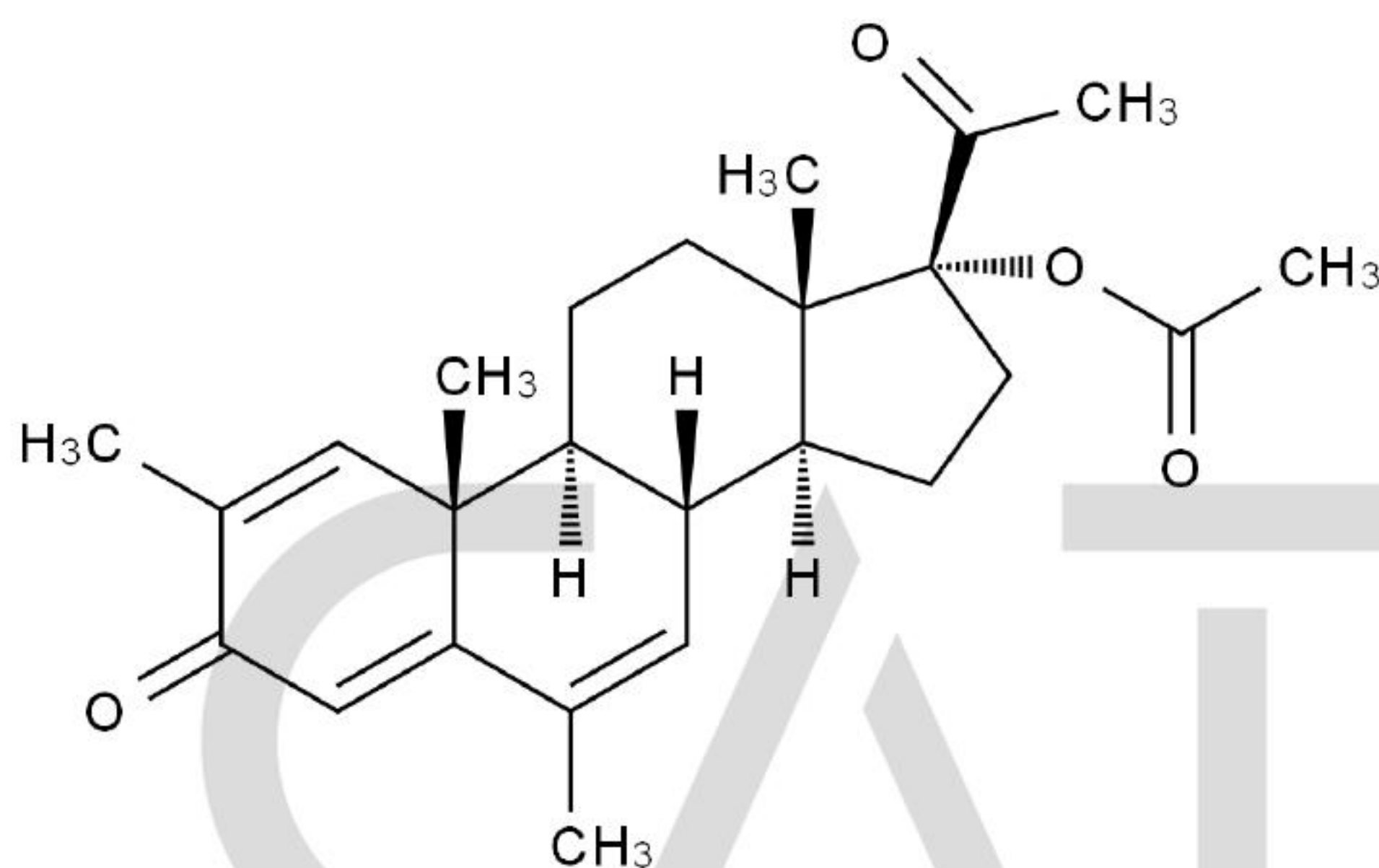


Certificate of Analysis

Reference Material & Standard

Product Name:	Megestrol Acetate EP Impurity I	Catalogue Number:	C4X-14149
Synonyms:	N/A	Lot Number:	0307-RF-0015
CAS Number:	N/A	Expiry Date:	Oct 12, 2026
Molecular Formula:	C ₂₅ H ₃₂ O ₄	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	396.52	Warning:	

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White to Off-White Solid
Identification	LCMS&IR&HNMR	Confirmed
Purity	HPLC	99.6411%
Water Content	Karl Fischer	0.30%
Residual Solvents	NMR	0.1% methanol and 0.1% dichloromethane
Assay		99.1%

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:

Hin Lam

Aproved by General Manager:

David

Date: Mar 11, 2024

Date: Mar 12, 2024

Date: Mar 12, 2024

