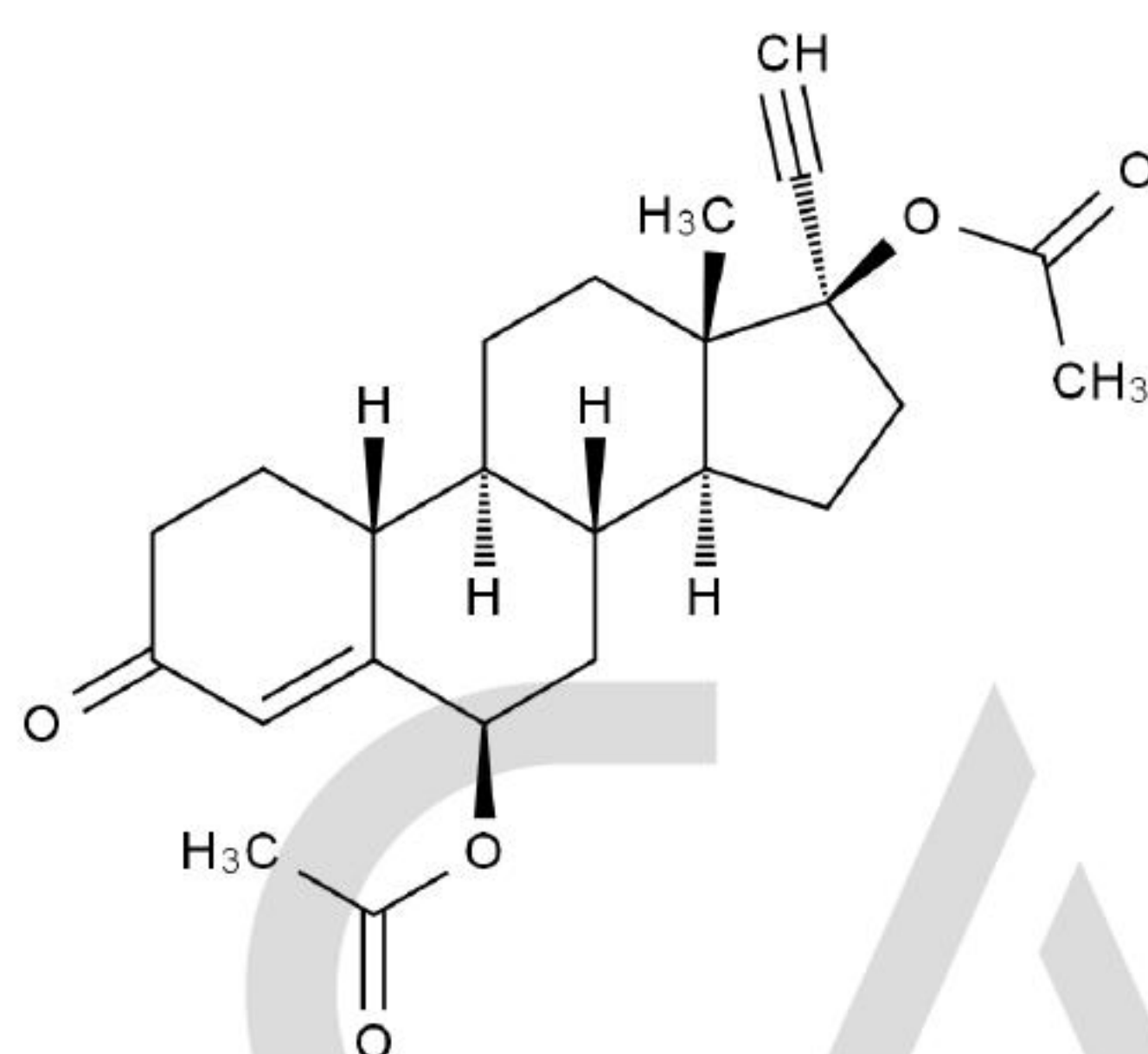


Certificate of Analysis

Reference Material & Standard

Product Name:	Norethindrone Acetate EP Impurity D	Catalogue Number:	C4X-171311
Synonyms:	N/A	Lot Number:	0226-RF-0010
CAS Number:	N/A	Expiry Date:	Feb 04, 2027
Molecular Formula:	C ₂₄ H ₃₀ O ₅	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	398.49		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White to Off-White Solid
Identification	LCMS&IR&HNMR	Confirmed
Purity	HPLC	99.7664%
Water Content	Karl Fischer	0.00%
Residual Solvents	NMR	0.4% ethyl acetate
Assay		99.4%

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

Aporoved by General Manager:

David

Date: Feb 27, 2024

Date: Feb 27, 2024

Date: Feb 27, 2024

