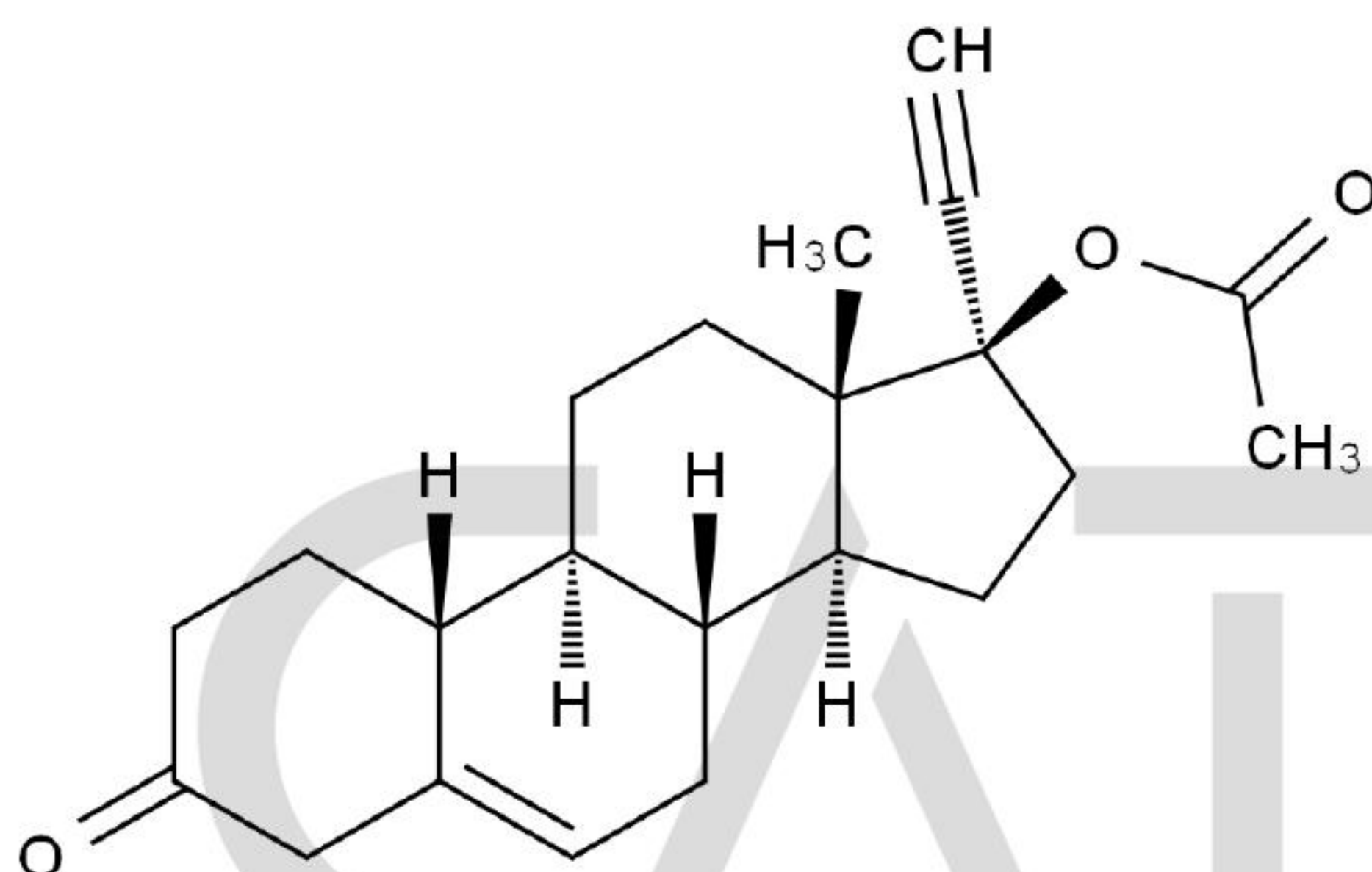


Certificate of Analysis

Reference Material & Standard

Product Name:	Norethisterone Acetate EP Impurity C	Catalogue Number:	C4X-171312
Synonyms:	N/A	Lot Number:	0115-RF-0011
CAS Number:	1175129-26-6	Expiry Date:	Jan 24, 2025
Molecular Formula:	C ₂₂ H ₂₈ O ₃	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	340.46	Shipping Condition:	Shipping at Room Temperature

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White to Off-White Solid
Identification	LCMS&IR&HNMR	Confirmed
Purity	HPLC	98.1153%
Water Content	Karl Fischer	0.60%
Residual Solvents	NMR	0.3% methanol
Assay		97.2%

Comment:

- The compound contains 1.0% Norethindrone Acetate (RT 6.71) according to its HPLC.
- The calculation of the mass balance 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:

Hin Lam

Reviewed by:

Lisa

Approved by General Manager:

David

Date: Jan 16, 2024

Date: Jan 16, 2024

Date: Jan 16, 2024



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