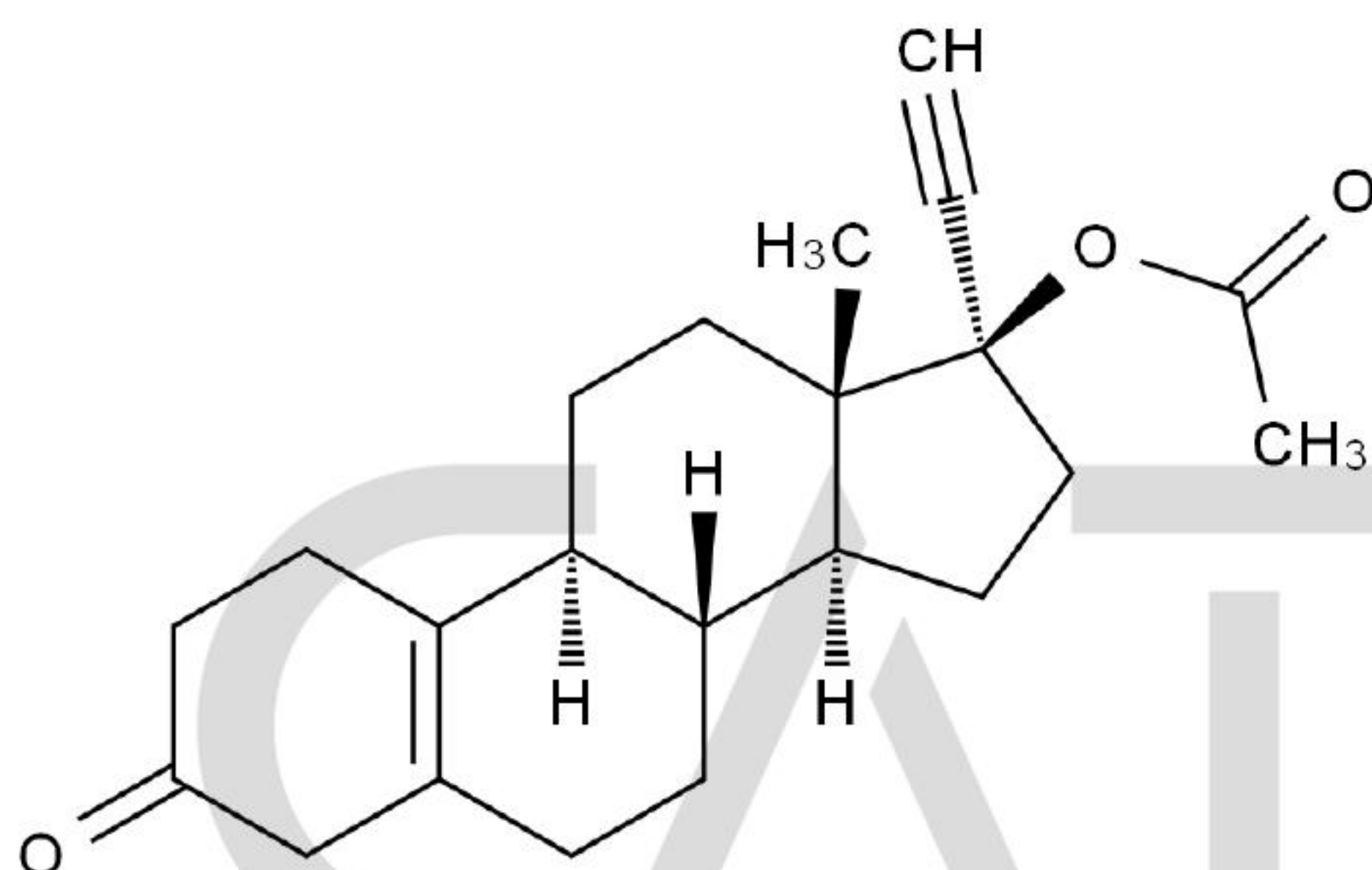


Certificate of Analysis

Reference Material & Standard

Product Name:	Norethisterone Acetate EP Impurity B	Catalogue Number:	C4X-17138
Synonyms:	N/A	Lot Number:	0115-RF-0012
CAS Number:	19637-28-6	Expiry Date:	Jan 19, 2026
Molecular Formula:	C ₂₂ H ₂₈ O ₃	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	340.46		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White to Off-White Solid
Identification	LCMS&IR&HNMR	Confirmed
Purity	HPLC	99.32%
Water Content	Karl Fischer	1.00%
Residual Solvents	NMR	0.3% ethyl acetate and 0.1% dichloromethane
Specific Rotation		[α] _D 23.0(c=0.53,CH ₃ OH): +105.2°
Assay		97.9%

Comment:

The calculation of the mass balance 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:

Hin Lam

Reviewed by:

Lisa

Approved by General Manager:

David

Date: Jan 16, 2024

Date: Jan 16, 2024

Date: Jan 16, 2024



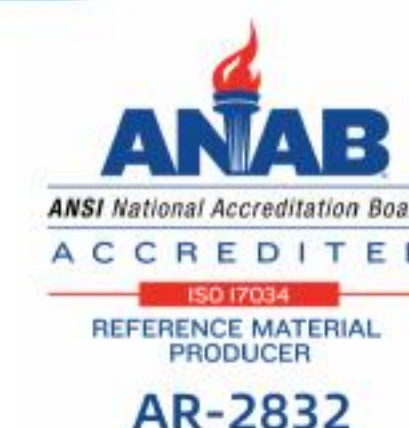
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