

Certificate of Analysis

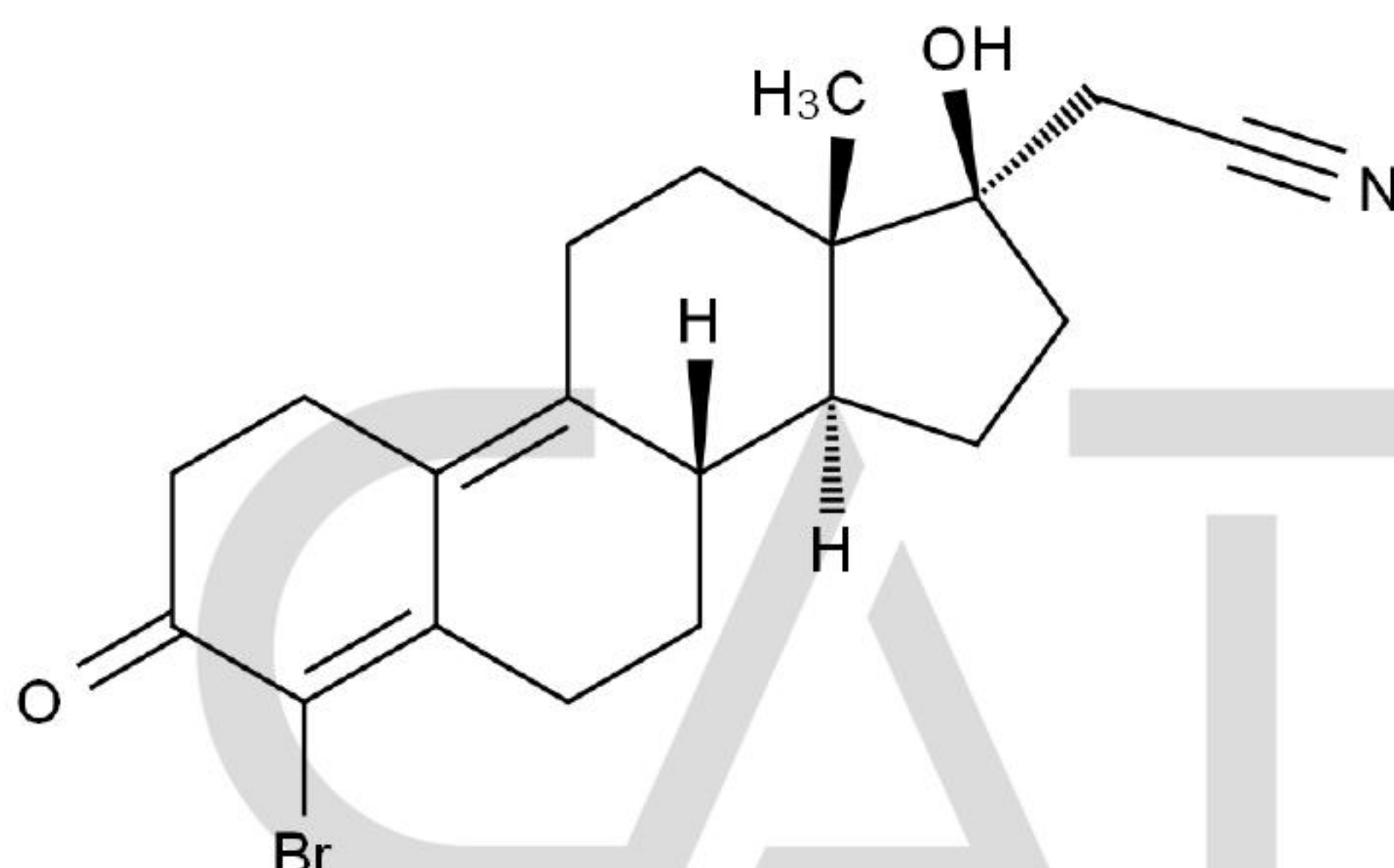
Reference Material & Standard

Product Name:	Dienogest EP Impurity M	Catalogue Number:	C4X-229514
Synonyms:	N/A	Lot Number:	0422-RD-0014
CAS Number:	98149-13-4	Expiry Date:	Sep 22, 2024
Molecular Formula:	C ₂₀ H ₂₄ BrNO ₂	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	390.31		

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Pale Yellow Solid
Identification	LCMS&IR&HNMR	Confirmed
Purity	HPLC	96.5217%
Water Content	Karl Fischer	2.9%
Residual Solvents	NMR	1.6% methanol
Specific Rotation		[α] _D ^{25.0} (c=0.44,pyridine): -167.4°
Assay		92.2%

Comment:

- The compound contains 2.1% Dienogest according to its HPLC and LC-MS.
- 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:

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