

Certificate of Analysis

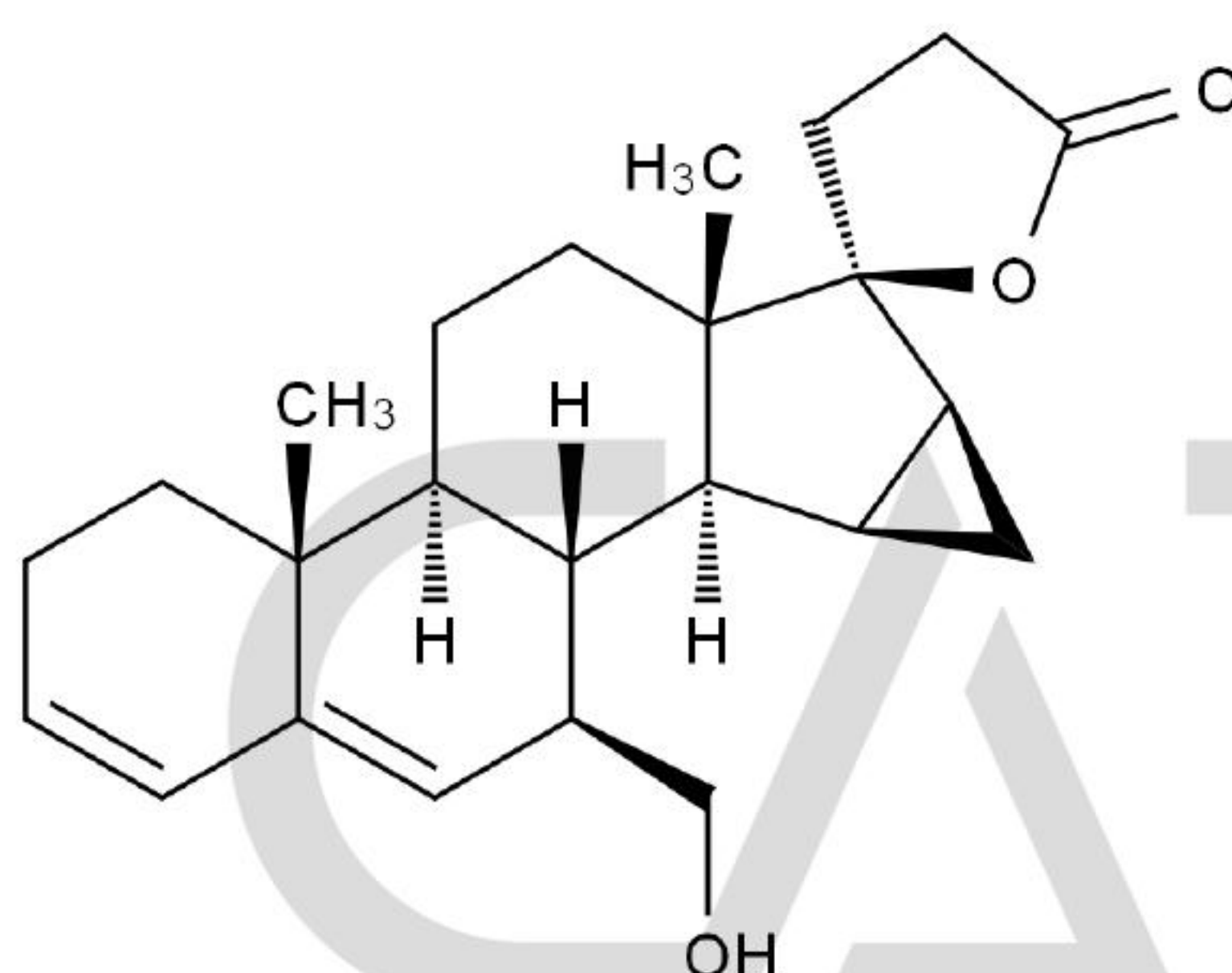
Reference Material & Standard

Product Name:	Drospirenone EP Impurity I	Catalogue Number:	C4X-16248
Synonyms:	N/A	Lot Number:	0520-RC-0038
CAS Number:	2896199-04-3	Expiry Date:	May 10, 2024
Molecular Formula:	C ₂₄ H ₃₂ O ₃	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	368.51	Shipping Condition:	Shipping at Room Temperature

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White to Off-White Solid
Identification	LCMS&IR&HNMR	Confirmed
Purity	HPLC	99.5835%
Water Content	Karl Fischer	0.1%
Residual Solvents	NMR	0.2% dichloromethane and 0.2% diethyl ether
Assay		99.1%

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:

Debia

Reviewed by:

Debia

Approved by General Manager:

David

Date: May 20, 2021

Date: May 24, 2021

Date: May 24, 2021



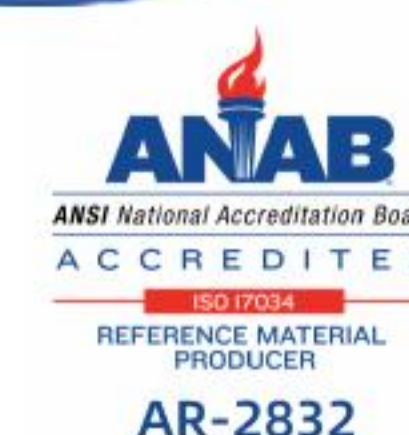
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