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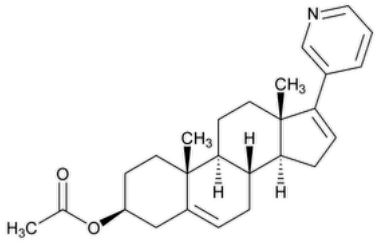
Abiraterone Acetate



$C_{26}H_{33}NO_2$ 391.55

Androsta-5,16-dien-3-ol, 17-(3-pyridinyl)-, acetate (ester), (3β);

17-(Pyridin-3-yl)androsta-5,16-dien-3β-yl acetate CAS RN®: 154229-18-2; UNII: EM5OCB9YJ6.

DEFINITION

Abiraterone Acetate contains NLT 98.0% and NMT 102.0% of abiraterone acetate ($C_{26}H_{33}NO_2$), calculated on the as-is basis.

IDENTIFICATION

Change to read:

• **A.** ▲Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: **197K**▲ (CN 1-May-2020)

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Solution A: 10 mM of ammonium acetate in water

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Acetonitrile (%)	Ethanol (%)
0	50	20	30
40	15	55	30
47	0	20	80
58	0	20	80
60	50	20	30
70	50	20	30

[Note—Protect solutions from light.]

System suitability solution: 0.625 mg/mL of USP Abiraterone System Suitability Mixture RS in acetonitrile. [Note—See *Table 2* for relative retention times of the main components of the mixture.]

Table 2

Name	Relative Retention Time
7-Ketoabiraterone acetate	0.42

Name	Relative Retention Time
α-Epoxyabiraterone acetate	0.62
β-Epoxyabiraterone acetate	0.66
Abiraterone	0.69
3-Deoxy-3-acetyl abiraterone-3-ene	0.85
Abiraterone acetate	1.0
Abiraterone ethyl ether	1.18
Abiraterone isopropyl ether	1.26
Anhydro abiraterone	1.29
3-Deoxy 3-chloroabiraterone	1.31
O-Chlorobutylabiraterone	1.33

Standard solution: 0.625 mg/mL of USP Abiraterone Acetate RS in acetonitrile

Sample solution: 0.625 mg/mL of Abiraterone Acetate in acetonitrile

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 254 nm

Column: 3-mm × 15-cm; 3-µm packing L1

Column temperature: 15°

Flow rate: 0.45 mL/min

Injection volume: 10 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 1.0 between anhydro abiraterone and 3-deoxy 3-chloroabiraterone peaks, *System suitability solution*

Relative standard deviation: NMT 0.73%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of abiraterone acetate ($C_{26}H_{33}NO_2$) in the portion of Abiraterone Acetate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Abiraterone Acetate RS in the *Standard solution* (mg/mL)

C_U = concentration of Abiraterone Acetate in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the as-is basis

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.1%

• **Organic Impurities**

[Note—Protect solutions from light.]

Solution A, Mobile phase, System suitability solution, Standard solution, Sample solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Sensitivity solution: 0.3 µg/mL of USP Abiraterone Acetate RS in acetonitrile, from *Standard solution*

System suitability

Samples: *System suitability solution*, *Standard solution*, and *Sensitivity solution*

Suitability requirements

Resolution: NLT 1.0 between anhydro abiraterone and 3-deoxy 3-chloroabiraterone peaks, *System suitability solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Relative standard deviation: NMT 0.73%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Abiraterone Acetate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak area of each impurity from the *Sample solution*

r_S = peak area of abiraterone acetate from the *Standard solution*

C_S = concentration of USP Abiraterone Acetate RS in the *Standard solution* (mg/mL)

C_U = concentration of Abiraterone Acetate in the *Sample solution* (mg/mL)

F = relative response factor for each individual impurity (see *Table 3*)

Acceptance criteria: See *Table 3*. Disregard any peak less than 0.05%.

Table 3

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
α-Epoxyabiraterone acetate	0.62	0.26	0.25
β-Epoxyabiraterone acetate	0.66	0.26	0.25
Abiraterone	0.69	1.0	0.20
Abiraterone acetate	1.0	—	—
Abiraterone ethyl ether	1.18	1.0	0.20
Abiraterone isopropyl ether	1.26	1.0	0.20
Unspecified impurity	—	1.0	0.10
Total impurities	—	—	0.80

SPECIFIC TESTS

• **Water Determination,** *Method Ic*⟨921⟩**:** NMT 0.25%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers. Store at controlled room temperature and protect from light.

• **USP Reference Standards** ⟨11⟩

USP Abiraterone Acetate RS

USP Abiraterone System Suitability Mixture RS

It contains Abiraterone Acetate and small amounts of the following:

Abiraterone
17-(Pyridin-3-yl)androsta-5,16-dien-3β-ol.
$C_{24}H_{31}NO$ 349.52

Abiraterone ethyl ether
3β-Ethoxy-17-(pyridin-3-yl)androsta-5,16-diene.
$C_{26}H_{35}NO$ 377.57

Abiraterone isopropyl ether
3β-Isopropoxy-17-(pyridin-3-yl)androsta-5,16-diene.
$C_{27}H_{37}NO$ 391.60

Anhydro abiraterone
17-(Pyridin-3-yl)androsta-3,5,16-triene.
$C_{24}H_{29}N$ 331.50

O-Chlorobutylabiraterone
3β-(4-Chlorobutoxy)-17-(pyridin-3-yl)androsta-5,16-diene.
$C_{28}H_{38}ClNO$ 440.07

3-Deoxy-3-acetyl abiraterone-3-ene
1-[17-(Pyridin-3-yl)androsta-3,5,16-trien-3-yl]ethanone.
$C_{26}H_{31}NO$ 373.53

3-Deoxy 3-chloroabiraterone
3β-Chloro-17-(pyridin-3-yl)androsta-5,16-diene.
$C_{24}H_{30}ClN$ 367.96

α-Epoxyabiraterone acetate
17-(Pyridin-3-yl)-16α,17α-epoxyandrost-5-en-3β-yl acetate.
$C_{26}H_{33}NO_3$ 407.55

β-Epoxyabiraterone acetate
17-(Pyridin-3-yl)-16β,17β-epoxyandrost-5-en-3β-yl acetate.
$C_{26}H_{33}NO_3$ 407.55

7-Ketoabiraterone acetate
7-Oxo-17-(pyridin-3-yl)androsta-5,16-dien-3β-yl acetate.
$C_{26}H_{31}NO_3$ 405.54

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
ABIRATERONE ACETATE	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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