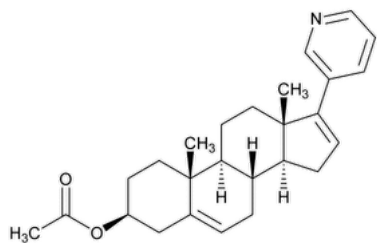


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Abiraterone Acetate



$C_{26}H_{33}NO_2$ 391.55
Androsta-5,16-dien-3-ol, 17-(3-pyridinyl)-, acetate (ester), (3 β);
17-(Pyridin-3-yl)androsta-5,16-dien-3-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 $\times$ 15-cm; 3- μ m packing L1

Column temperature: 15°

Flow rate: 0.45 mL/min

Injection volume: 10 μ L

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 μ g/mL of [USP Abiraterone Acetate RS](#) in acetonitrile, from *Standard solution*

System suitability

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