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Abiraterone Acetate Tablets

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click www.uspnf.com/rb-abiraterone-acetate-tabs-20220527.

DEFINITION

Abiraterone Acetate Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of abiraterone acetate (C₂₆H₃₃NO₂).

IDENTIFICATION

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

Name	Relative Retention Time
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: Nominally equivalent to 0.625 mg/mL of abiraterone acetate in [acetonitrile](#), prepared from NLT 20 powdered Tablets as follows. Transfer the powder to a suitable volumetric flask. Add 50% of the flask volume of [acetonitrile](#), shake by mechanical means for 30 min, and dilute with [acetonitrile](#) to volume. Pass a portion of the solution through a suitable filter of 0.45-µm pore size, and use the clear solution for analysis.

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 254 nm or diode array. [NOTE—Use a diode array detector to perform *Identification B*.]

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 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of abiraterone acetate ($C_{26}H_{33}NO_2$) in the portion of Tablets 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 = nominal concentration of abiraterone acetate in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

- [DISSOLUTION \(711\)](#).

Test 1

[NOTE—Protect solutions from light.]

Buffer: 56.5 mM of [monobasic sodium phosphate](#) in [water](#). Adjust with [5 N sodium hydroxide](#) or [phosphoric acid](#) to a pH of 4.5.

Medium: 0.25% of [sodium lauryl sulfate](#) in *Buffer*; 900 mL

Apparatus 2: 50 rpm

Time: 45 min

Standard solution: 0.3 mg/mL of [USP Abiraterone Acetate RS](#) in *Medium* prepared as follows. Transfer [USP Abiraterone Acetate RS](#) into a suitable volumetric flask. Add 4% of the flask volume of [acetonitrile](#) to dissolve, and dilute with *Medium* to volume.

Sample solution: Pass a portion of the solution under test through a suitable filter of 10-µm pore size. Use the filtrate.

Mobile phase: [Acetonitrile](#), [formic acid](#), and [water](#) (55: 0.05: 45)

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)