$C_{27}H_{37}NO$ 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

Abiraterone Acetate Tablets

DEFINITION
Abiraterone Acetate Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of abiraterone acetate ($C_{26}H_{33}NO_2$).

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

Table 2 *(Continued)*

Name	Relative Retention Time
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: 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 diode array detector to perform *Identification* test *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
- **DISSOLUTION** ⟨711⟩

[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.