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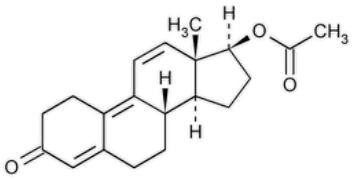
Trenbolone Acetate

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click www.uspnf.com/rb-trenbolone-acetate-20230630.

Change to read:



$C_{20}H_{24}O_3$ ▲312.41▲ (CN 1-Aug-2023)
Estra-4,9,11-trien-3-one, 17-(acetyloxy)-, (17β)-;
▲(17β)-3-Oxoestra-4,9,11-trien-17-yl acetate▲ (CN 1-Aug-2023) CAS RN®: 10161-34-9; UNII: RUD5Y4SV0S..

DEFINITION
Trenbolone Acetate contains NLT 97.0% and NMT 103.0% of $C_{20}H_{24}O_3$, calculated on the dried basis.

IDENTIFICATION
• **A.** **Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**
• **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**
Diluent: Acetonitrile, methanol, water, and acetic acid (36.5:30:33.5:0.1)
Solution A: Acetonitrile, methanol, and water (36.5:30:33.5)
Solution B: Acetonitrile and methanol (9:1)
Mobile phase: See the gradient table below.

Time (min)	Solution A (%)	Solution B (%)
0	100	0
6	100	0
16	0	100
26	0	100
26.1	100	0
30	100	0

Standard solution: 1 mg/mL of USP Trenbolone Acetate RS in *Diluent*. Sonicate, if necessary, to dissolve.
Sample solution: 1 mg/mL of Trenbolone Acetate in *Diluent*. Sonicate, if necessary, to dissolve.
Chromatographic system
(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 229 nm

Column: 4.6-mm × 10-cm; 3-µm packing L1

Flow rate: 1.0 mL/min

Injection size: 5 µL

System suitability

Samples: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of $C_{20}H_{24}O_3$ in the portion of Trenbolone Acetate taken:

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

r_U = peak response of Trenbolone Acetate from the *Sample solution*

r_S = peak response of trenbolone acetate from the *Standard solution*

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

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

Acceptance criteria: 97.0%–103.0%, on the dried basis

IMPURITIES

Inorganic Impurities

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

Change to read:

Organic Impurities

• **Procedure**

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

System suitability solution: 1 mg/mL of USP Trenbolone Acetate System Suitability Mixture RS in *Diluent*. Sonicate, if necessary, to dissolve.

System suitability

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

[Note—The relative retention times for ▲11,12-dihydrotrenbolone acetate▲ (CN 1-Aug-2023) and trenbolone acetate are 1.2 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 3.0 between trenbolone acetate and ▲11,12-dihydrotrenbolone acetate▲ (CN 1-Aug-2023), *System suitability solution*

Column efficiency: NLT 8000 theoretical plates for the trenbolone acetate peak, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Sample: *Sample solution*

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

$$\text{Result} = (100 \times r_U)/[(r_S + S) \times F]$$

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

r_S = peak response of Trenbolone Acetate from *Sample solution*

S = sum of the peak responses of each impurity, each divided by their respective response factor

F = relative response factor (see *Impurity Table 1*)

Acceptance criteria

Individual impurities: See *Impurity Table 1*.

Total specified and unspecified impurities: NMT 2.0%

Reporting level for impurities: NMT 0.10%

Impurity Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
▲Trenbolone[a]▲ (CN 1-Aug-2023)	0.4	1.04	1.0
▲α-Trenbolone acetate[b]▲ (CN 1-Aug-2023)	0.8	1.10	0.5
Trenbolone acetate	1.0	—	—
▲11,12-Dihydrotrenbolone acetate[c]▲ (CN 1-Aug-2023)	1.2	1.0	▲1.0▲ (RB 1-Aug-2023)
Any unspecified impurity	—	1.00[d]	0.5

[a] 17β-Hydroxyestra-4,9,11-trien-3-one.

[b] (17α)-3-Oxoestra-4,9,11-trien-17-yl acetate.

[c] (17β)-3-Oxoestra-4,9-dien-17-yl acetate

[d] Unless determined otherwise.

SPECIFIC TESTS

• **Absorbance**

Sample solution: 100 mg/mL in dehydrated alcohol

Spectrometric conditions

(See *Ultraviolet-Visible Spectroscopy* ⟨857⟩.)

Analytical wavelength: 440 nm

Cell: 2 cm

Blank: Dehydrated alcohol

Analysis

Samples: *Sample solution* and *Blank*

Acceptance criteria: NMT 0.3

• **Optical Rotation,** *Specific Rotation* ⟨781S⟩**:** +39° to +43°

Sample solution: 5 mg/mL in methanol

• **Loss on Drying** ⟨731⟩**:** Dry a sample in a vacuum at 60° for 2 h: it loses NMT 0.5% of its weight.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers, and store in a refrigerator.

• **Labeling:** Label it to indicate that it is for veterinary use only.

Change to read:

• **USP Reference Standards** ⟨11⟩

USP Trenbolone Acetate RS

USP Trenbolone Acetate System Suitability Mixture RS

Mixture containing trenbolone and ▲11,12-dihydrotrenbolone acetate▲ (CN 1-Aug-2023) in a matrix of trenbolone acetate.

Topic/Question	Contact	Expert Committee
TRENBOLONE 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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