

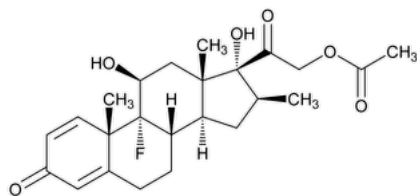
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Betamethasone Acetate

Add the following:

▲



▲ (USP 1-Dec-2023)

$C_{24}H_{31}FO_6$ 434.50

Pregna-1,4-diene-3,20-dione, 9-fluoro-11,17-dihydroxy-16-methyl-21-(acetyloxy)-, (11β,16β)-;

9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 21-acetate CAS RN®: 987-24-6; UNII: T105A053L7.

DEFINITION

Betamethasone Acetate contains NLT 97.0% and NMT 103.0% of betamethasone acetate ($C_{24}H_{31}FO_6$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- A. [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197M▲ or 197A▲ (USP 1-Dec-2023)

Change to read:

- B. ▲The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.▲ (USP 1-Dec-2023)

ASSAY

Change to read:

PROCEDURE

▲Solution A: [Water](#)

Solution B: [Acetonitrile](#)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0.0	61	39
10.0	61	39
12.0	50	50
17.0	50	50
17.1	61	39
22.0	61	39

Diluent: *Solution A* and *Solution B* (44:56)

System suitability solution: 200 µg/mL of [USP Betamethasone Acetate RS](#) and 40 µg/mL each of [USP Betamethasone Acetate Related Compound C RS](#), [USP Betamethasone Acetate Related Compound D RS](#), and [USP Dexamethasone Acetate RS](#) in *Diluent*. Sonicate to dissolve, if necessary.

Standard solution: 200 µg/mL of [USP Betamethasone Acetate RS](#) in *Diluent*. Sonicate to dissolve, if necessary.

Sample solution: 200 µg/mL of Betamethasone Acetate in *Diluent*. Sonicate to dissolve, if necessary.

Chromatographic system

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

Mode: LC

Detector: UV 240 nm

Column: 4.6-mm × 15-cm; 3.5-µm packing [L1](#)

Autosampler temperature: 4°

Flow rate: 0.8 mL/min

Injection volume: 15 µL

System suitability

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

[NOTE—See [Table 2](#) for relative retention times.]

Suitability requirements

Resolution: NLT 3.0 between betamethasone acetate and dexamethasone acetate; NLT 1.2 between betamethasone acetate related compound C and betamethasone acetate related compound D, *System suitability solution*

Tailing factor: NMT 1.5, *Standard solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of betamethasone acetate ($C_{24}H_{31}FO_6$) in the portion of Betamethasone Acetate taken:

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

r_U = peak response of betamethasone acetate from the *Sample solution*

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

C_S = concentration of [USP Betamethasone Acetate RS](#) in the *Standard solution* (µg/mL)

C_U = concentration of Betamethasone Acetate in the *Sample solution* (µg/mL)

▲ (USP 1-Dec-2023)

Acceptance criteria: 97.0%–103.0% on the anhydrous basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.2%, a platinum crucible being used

Delete the following:

- ▲ • [ORDINARY IMPURITIES \(466\)](#), ▲ (USP 1-Dec-2023)

Add the following:

- ▲ • ORGANIC IMPURITIES

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

Standard solution: 0.2 µg/mL each of [USP Betamethasone Acetate RS](#), [USP Betamethasone RS](#), and [USP Betamethasone Acetate Related Compound D RS](#), and 0.3 µg/mL each of [USP Betamethasone Acetate Related Compound C RS](#) and [USP Dexamethasone Acetate RS](#) in *Diluent*. Sonicate to dissolve, if necessary.

Sensitivity solution: 0.1 µg/mL of [USP Betamethasone Acetate RS](#) in *Diluent*. Sonicate to dissolve, if necessary.

System suitability

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

[NOTE—See [Table 2](#) for relative retention times.]

Suitability requirements

Resolution: NLT 3.0 between betamethasone acetate and dexamethasone acetate; NLT 1.2 between betamethasone acetate related compound C and betamethasone acetate related compound D, *System suitability solution*

Relative standard deviation: NMT 5.0% for all standard peaks, *Standard solution*

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

Analysis

Samples: *Sample solution* and *Standard solution*

Calculate the percentage of betamethasone, betamethasone related compound C, betamethasone related compound D, and dexamethasone acetate in the portion of Betamethasone Acetate taken:

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