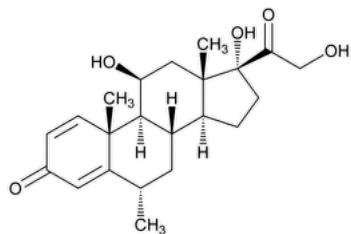


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Methylprednisolone

Change to read:



$C_{22}H_{30}O_5$ ▲374.48▲ (USP 1-Dec-2023)
Pregna-1,4-diene-3,20-dione, 11,17,21-trihydroxy-6-methyl-, (6α,11β)-;
11β,17,21-Trihydroxy-6α-methylpregna-1,4-diene-3,20-dione CAS RN®: 83-43-2; UNII: X4W7ZR7023.

DEFINITION
Methylprednisolone contains NLT 97.0% and NMT 103.0% of methylprednisolone ($C_{22}H_{30}O_5$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K▲ or 197A▲ (USP 1-Dec-2023)

Delete the following:

- ▲• **B. SPECTROSCOPIC IDENTIFICATION TESTS (197), Ultraviolet-Visible Spectroscopy:**▲ (USP 1-Dec-2023)

Add the following:

- ▲• **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)

Delete the following:

- ▲• **C.**▲ (USP 1-Dec-2023)

ASSAY

Change to read:

• **PROCEDURE**

▲**Solution A:** [Acetonitrile](#), [tetrahydrofuran](#), [phosphoric acid](#), and [water](#) (10: 1.5: 0.1: 90)

Solution B: [Acetonitrile](#), [tetrahydrofuran](#), and [phosphoric acid](#) (100: 1.5: 0.1)

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	83	17
14	83	17
30	52	48
30.1	83	17
35	83	17

Diluent: [Acetonitrile](#), [phosphoric acid](#), and [water](#) (50: 0.1: 50)

System suitability solution: 0.6 mg/mL of [USP Methylprednisolone System Suitability Mixture RS](#) in *Diluent*

Standard solution: 0.6 mg/mL of [USP Methylprednisolone RS](#) in *Diluent*

Sample solution: 0.6 mg/mL of Methylprednisolone in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 247 nm

Column: 4.6-mm × 15-cm; 3-μm packing [L1](#)

Column temperature: 45°

Flow rate: 1.5 mL/min

Injection volume: 10 μL

System suitability

Sample: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for methylprednisolone related compound A and methylprednisolone are 0.93 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.7 between methylprednisolone related compound A and methylprednisolone, *System suitability solution*

Relative standard deviation: NMT 1.10%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of methylprednisolone ($C_{22}H_{30}O_5$) in the portion of Methylprednisolone taken:

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

r_U = peak response of methylprednisolone from the *Sample solution*

r_S = peak response of methylprednisolone from the *Standard solution*

C_S = concentration of [USP Methylprednisolone RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Methylprednisolone in the *Sample solution* (mg/mL)▲ (USP 1-Dec-2023)

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

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.2%

Change to read:

- **ORGANIC IMPURITIES**

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

Sensitivity solution: 0.0003 mg/mL of [USP Methylprednisolone RS](#) in *Diluent*

Standard solution: 0.006 mg/mL of [USP Methylprednisolone RS](#) in *Diluent*

System suitability

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

[NOTE—See [Table 2](#) for the relative retention times. The relative retention times in [Table 2](#) are provided for information that could aid in peak assignment.]

Table 2

Name	Relative Retention Time
Methylprednisolone related compound B	0.85
Methylprednisolone related compound H	0.88
Methylprednisolone related compound A	0.93
Methylprednisolone	1.0
Methylprednisolone related compound F	1.10
Methylprednisolone related compound G	1.56
Impurity I	1.60
Methylprednisolone related compound C	1.72