

Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-Jun-2022
Document Type: USP Monographs
DocId: GUID-7C004B50-371F-4A60-8A1E-09A528B9803C_4_en-US
DOI: https://doi.org/10.31003/USPNF_M52810_04_01
DOI Ref: q8mrw

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Methylprednisolone Tablets

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

DEFINITION

Methylprednisolone Tablets contain NLT 92.5% and NMT 107.5% of the labeled amount of methylprednisolone ($C_{22}H_{30}O_5$).

IDENTIFICATION

• A. [SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy](#): 197K

Sample: Digest an amount nominally equivalent to about 40 mg of methylprednisolone from powdered Tablets with 25 mL of solvent [hexane](#) for 15 min. Filter, and discard the filtrate. Digest the residue with 25 mL of [chloroform](#) for 15 min. Filter, evaporate the filtrate to dryness, and dry at 105° for 2 h.

Acceptance criteria: Meets the requirements

• B.

Sample: Use the *Sample* from *Identification A*.

Analysis: Dissolve about 5 mg of *Sample* in 2 mL of [sulfuric acid](#).

Acceptance criteria: A red color is produced

ASSAY

• PROCEDURE

Mobile phase: Butyl chloride, water-saturated butyl chloride, [tetrahydrofuran](#), [methanol](#), and [glacial acetic acid](#) (95:95:14:7:6)

Solution A: 3% [Glacial acetic acid](#) in [chloroform](#)

Internal standard solution: 0.2 mg/mL of prednisone in *Solution A*

Standard solution: 0.2 mg/mL of [USP Methylprednisolone RS](#) in the *Internal standard solution*

Sample solution: Nominally 0.19 mg/mL of methylprednisolone prepared as follows. Transfer an amount nominally equivalent to about 10 mg of methylprednisolone, from 20 finely powdered Tablets in a mortar and pestle, to a suitable container. Add 2.5 mL of [water](#) and swirl to form a fine slurry. Add 50.0 mL of *Internal standard solution* and shake for 15 min. If necessary, pass a portion of the solution through a suitable filter or centrifuge a portion of the solution and analyze the clear supernatant.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.0-mm × 25.0-cm; packing [L3](#)

Flow rate: 1 mL/min

Injection volume: 10 μ L

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for prednisone and methylprednisolone are about 0.7 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 4.0 between prednisone and methylprednisolone

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

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

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak response ratio of methylprednisolone to prednisone from the *Sample solution*

R_S = peak response ratio of methylprednisolone to prednisone from the *Standard solution*

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

C_u = nominal concentration of methylprednisolone in the *Sample solution* (mg/mL)**Acceptance criteria:** 92.5%–107.5%**PERFORMANCE TESTS****Change to read:**

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

▲Test 1▲ (RB 1-Jun-2022)**Medium:** [Water](#); 900 mL**Apparatus 2:** 50 rpm**Time:** 30 min

Standard solutions: 20 µg/mL of [USP Methylprednisolone RS](#) prepared as follows. Dissolve a suitable quantity of [USP Methylprednisolone RS](#) in 0.1% of the flask volume of [alcohol](#) and dilute with [water](#) to volume. Prepare quantitative dilutions of this solution for the development of a standard curve.

Sample solution: Pass a portion of the solution under test through a suitable filter. Dilute with *Medium*, if necessary

Instrumental conditions**Mode:** UV**Analytical wavelength:** 246 nm**Cell:** 1 cm**Blank:** [Water](#)**Analysis****Samples:** *Standard solutions, Sample solution, and Blank*

Using a standard curve, representing the absorbance versus concentration of the *Standard solutions*, determine the labeled amount of methylprednisolone ($C_{22}H_{30}O_5$) dissolved.

Tolerances: NLT 70% (Q) of the labeled amount of methylprednisolone ($C_{22}H_{30}O_5$) is dissolved.

▲Test 2: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.**Medium:** [Water](#); 500 mL**Apparatus 2:** 50 rpm**Time:** 20 min

Standard stock solution: 0.2 mg/mL of [USP Methylprednisolone RS](#) prepared as follows. Transfer a suitable amount of [USP Methylprednisolone RS](#) to an appropriate volumetric flask. Add 2% of the flask volume of [ethyl alcohol](#) and sonicate to dissolve. Dilute with [water](#) to volume.

Standard solution A: 0.002 mg/mL of [USP Methylprednisolone RS](#) from *Standard stock solution* in water

Standard solution B: 0.004 mg/mL of [USP Methylprednisolone RS](#) from *Standard stock solution* in water

Standard solution C: 0.008 mg/mL of [USP Methylprednisolone RS](#) from *Standard stock solution* in water

Standard solution D: 0.010 mg/mL of [USP Methylprednisolone RS](#) from *Standard stock solution* in water

Standard solution E: 0.012 mg/mL of [USP Methylprednisolone RS](#) from *Standard stock solution* in water

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size.

Instrumental conditions**Mode:** UV**Analytical wavelength:** 246 nm**Cell:** 1 cm**Blank:** [Water](#)**System suitability****Samples:** *Standard solution A, Standard solution B, Standard solution C, Standard solution D, and Standard solution E***Suitability requirements**

Correlation coefficient: NLT 0.99, as determined from the linear calibration constructed in the *Analysis*

Analysis**Samples:** *Standard solution A, Standard solution B, Standard solution C, Standard solution D, Standard solution E, Sample solution, and Blank*

Determine the responses for *Standard solution A, Standard solution B, Standard solution C, Standard solution D, and Standard solution E*.

Construct a linear calibration curve by plotting response values of *Standard solution A, Standard solution B, Standard solution C, Standard solution D, and Standard solution E* versus their corresponding concentrations in mg/mL. Determine the concentration (C) in mg/mL of methylprednisolone ($C_{22}H_{30}O_5$) in the portion of Tablets taken from the calibration curve.

Calculate the percentage of the labeled amount of methylprednisolone ($C_{22}H_{30}O_5$) dissolved:

$$\text{Result} = C \times V \times (1/L) \times 100$$

C = concentration of methylprednisolone in the *Sample solution* (mg/mL), as determined from the calibration curve

V = volume of *Medium*, 500 mL

L = label claim (mg/Tablet)

Tolerances: NLT 80% (Q) of the labeled amount of methylprednisolone ($C_{22}H_{30}O_5$) is dissolved.▲ (RB 1-Jun-2022)

- **UNIFORMITY OF DOSAGE UNITS (905):** Meet the requirements

Procedure for content uniformity

Mobile phase, Solution A, Internal Standard solution, Standard solution, Chromatographic system, and System suitability: Proceed as directed in the Assay.

Sample solution: Place 1 Tablet in a suitable container. For tablet-labeled strengths of 10 mg or less, add 0.5 mL of [water](#). For tablet-labeled strengths greater than 10 mg, add 1.0 mL of [water](#). Allow the Tablet to stand for about 2 min, then swirl the container to disperse the Tablet. Add 5.0 mL of *Internal standard solution* for each milligram of labeled Tablet strength, shake for 15 min, and pass a portion of solution through a suitable filter or centrifuge a portion of the solution and analyze the clear supernatant.

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of methylprednisolone ($C_{22}H_{30}O_5$) in the Tablet taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak response ratio of methylprednisolone to prednisone from the *Sample solution*

R_S = peak response ratio of methylprednisolone to prednisone from the *Standard solution*

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

C_U = nominal concentration of methylprednisolone in the *Sample solution* (mg/mL)

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.

Add the following:

- ▲ **LABELING:** When more than one *Dissolution Test* is given, the labeling states the test used only if *Test 1* is not used.▲ (RB 1-Jun-2022)

- **USP REFERENCE STANDARDS (11):**

[USP Methylprednisolone RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
METHYLPREDNISOLONE TABLETS	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: [Chromatographic Database](#)

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Pharmacopeial Forum: Volume No. 45(1)

Current DocID: GUID-7C004B50-371F-4A60-8A1E-09A528B9803C_4_en-US

DOI: https://doi.org/10.31003/USPNF_M52810_04_01

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