

Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-33F04AB6-55DF-4E7F-8B5A-761EFDE45162_2_en-US
DOI: https://doi.org/10.31003/USPNF_M52970_02_01
DOI Ref: ul78h

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Methylprednisolone Sodium Succinate

$C_{26}H_{33}NaO_8$ 496.53

Pregna-1,4-diene-3,20-dione, 21-(3-carboxy-1-oxopropoxy)-11,17-dihydroxy-6-methyl-, monosodium salt, (6 α ,11 β)-; 11 β ,17,21-Trihydroxy-6 α -methylpregna-1,4-diene-3,20-dione 21-(sodium succinate) CAS RN®: 2375-03-3.

DEFINITION

Methylprednisolone Sodium Succinate contains NLT 97.0% and NMT 103.0% of methylprednisolone sodium succinate ($C_{26}H_{33}NaO_8$), calculated on the dried basis.

IDENTIFICATION

• A. INFRARED ABSORPTION

Sample: 100 mg of Methylprednisolone Sodium Succinate

Analysis: Transfer the *Sample* to a separator, dissolve in 10 mL of water, add 1 mL of 3 N hydrochloric acid, and extract immediately with 50 mL of chloroform. Filter the chloroform extract through cotton, evaporate on a steam bath to dryness, and dry under vacuum at 60° for 3 h.

Acceptance criteria: The IR absorption spectrum of a mineral oil dispersion of the residue so obtained exhibits maxima only at the same wavelengths as those of a similar preparation of [USP Methylprednisolone Hemisuccinate RS](#).

Change to read:

• B. ▲[SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Ultraviolet-Visible Spectroscopy: 197U](#) ▲ (CN 1-MAY-2020)

Standard solution: 20 μ g/mL of [USP Methylprednisolone Hemisuccinate RS](#) in methanol

Sample solution: 20 μ g/mL of Methylprednisolone Sodium Succinate in methanol

Analytical wavelength: 243 nm

Acceptance criteria: Absorptivities, calculated on the dried basis, do not differ by more than 3.0%.

• C. The sample imparts an intense yellow color to a nonluminous flame.

ASSAY

• PROCEDURE

Solution A: 5 mg/mL of blue tetrazolium in alcohol

Solution B: Alcohol and tetramethylammonium hydroxide TS (9:1)

Standard solution: Proceed as directed for [Assay for Steroids \(351\), Standard Preparation](#), preparing 12.5 μ g/mL of [USP Methylprednisolone Hemisuccinate RS](#) in alcohol.

Sample solution: 12.5 μ g/mL of Methylprednisolone Sodium Succinate in alcohol

Blank: Alcohol

Instrumental conditions

Mode: Vis

Analytical wavelength: 525 nm

Analysis

Samples: Standard solution, Sample solution, and Blank

Pipet 20.0 mL of the *Blank*, *Standard solution*, and *Sample solution* into three different glass-stoppered, 50-mL conical flasks. Add 2.0 mL of *Solution A*, and mix. To each flask add 4.0 mL of *Solution B*. Mix, and allow to stand in the dark for 90 min. Add 1.0 mL of glacial acetic acid, and mix. Without delay, determine the absorbances of the *Standard solution* and the *Sample solution* against the *Blank*.

Calculate the percentage of methylprednisolone sodium succinate ($C_{26}H_{33}NaO_8$) in the portion of Methylprednisolone Sodium Succinate taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

C_U = concentration of Methylprednisolone Sodium Succinate in the *Sample solution* (μ g/mL)

M_{r1} = molecular weight of methylprednisolone sodium succinate, 496.53 M_{r2} = molecular weight of methylprednisolone hemisuccinate, 474.54**Acceptance criteria:** 97.0%–103.0% on the dried basis**OTHER COMPONENTS**• **SODIUM CONTENT****Sample solution:** Dissolve, with gentle heating, about 1 g of Methylprednisolone Sodium Succinate in 75 mL of glacial acetic acid. Add 20 mL of dioxane, then add 1 drop of crystal violet TS.**Titrimetric system****Mode:** Direct**Titrant:** 0.1 N perchloric acid VS**Endpoint detection:** Visual**Analysis:** Titrate with *Titrant* to a blue-green endpoint. Perform a blank determination, and make any necessary correction. Each mL of *Titrant* is equivalent to 2.299 mg of sodium (Na).**Acceptance criteria:** 4.49%–4.77% on the dried basis**SPECIFIC TESTS**• [OPTICAL ROTATION \(781S\), Specific Rotation](#)**Sample solution:** 10 mg/mL of Methylprednisolone Sodium Succinate in alcohol**Acceptance criteria:** +96° to +104°• [LOSS ON DRYING \(731\)](#)**Analysis:** Dry at 105° for 3 h.**Acceptance criteria:** NMT 3.0%**ADDITIONAL REQUIREMENTS**• **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.• [USP REFERENCE STANDARDS \(11\)](#)[USP Methylprednisolone Hemisuccinate RS](#)**Auxiliary Information** - Please [check for your question in the FAQs](#) before contacting USP.

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

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Pharmacopeial Forum: Volume No. 50(4)

Current DocID: [GUID-33F04AB6-55DF-4E7F-8B5A-761EFDE45162_2_en-US](#)**DOI:** https://doi.org/10.31003/USPNF_M52970_02_01**DOI ref:** [uI78h](#)