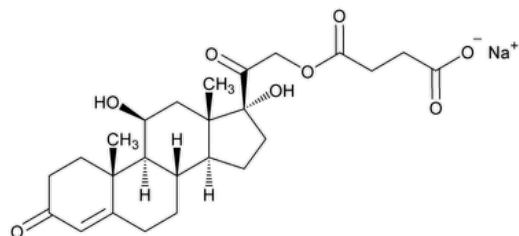


Status: Currently Official on 15-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: USP Monographs
 DocId: GUID-9436BC85-4A79-42F7-BC06-E6D31AD7B916_2_en-US
 DOI: https://doi.org/10.31003/USPNF_M38420_02_01
 DOI Ref: be6hb

© 2025 USPC
 Do not distribute

Hydrocortisone Sodium Succinate



$C_{25}H_{33}NaO_8$ 484.51

Pregn-4-ene-3,20-dione, 21-(3-carboxy-1-oxopropoxy)-11,17-dihydroxy-, monosodium salt, (11 β);

Cortisol 21-(sodium succinate) CAS RN®: 125-04-2; UNII: 50LQB69S1Z.

DEFINITION

Hydrocortisone Sodium Succinate contains NLT 97.0% and NMT 102.0% of total steroids, calculated as hydrocortisone sodium succinate ($C_{25}H_{33}NaO_8$), on the dried basis.

IDENTIFICATION

• A. INFRARED ABSORPTION

Sample: Transfer 100 mg of Hydrocortisone Sodium Succinate to a suitable container, and dissolve in 10 mL of water. In rapid succession, add 1 mL of 3 N [hydrochloric acid](#), shake briefly, immediately decant the aqueous layer, and wash the precipitate with two additional 10-mL portions of water, each time removing the water by decanting. Remove as much of the water as possible, spread the precipitate in a suitable container, and dry under vacuum at 60° for 3 h.

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

Change to read:

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

Sample solution: 20 µg/mL in [methanol](#)

Analytical wavelength: 242 nm

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

- C. Sodium compounds impart an intense yellow color to a nonluminous flame.

ASSAY

- [ASSAY FOR STEROIDS \(351\)](#).

Blue tetrazolium solution: 5 mg/mL of blue tetrazolium in [alcohol](#)

Tetramethylammonium hydroxide solution: [Tetramethylammonium hydroxide TS](#) in [alcohol](#) (1 in 10)

Standard solution: 12.5 µg/mL of [USP Hydrocortisone Hemisuccinate RS](#) in [alcohol](#)

Sample solution: 12.5 µg/mL of Hydrocortisone Sodium Succinate in [alcohol](#)

Blank solution: [Alcohol](#)

Analysis

Samples: *Standard solution, Sample solution, and Blank solution*

Transfer 20.0-mL aliquots of the *Samples* to separate glass-stoppered, 50-mL conical flasks. To each flask add 2.0 mL of *Blue tetrazolium solution*, mix, and add 4.0 mL of *Tetramethylammonium hydroxide solution*. Allow to stand in the dark for 90 min, and add 1.0 mL of [glacial acetic acid](#). Concomitantly determine the absorbances of the solutions from the *Sample solution* and the *Standard solution* at about 525 nm, with a suitable spectrophotometer, against the blank.

Calculate the percentage of total steroids, as hydrocortisone sodium succinate ($C_{25}H_{33}NaO_8$), in the portion of Hydrocortisone 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 Hydrocortisone Hemisuccinate RS](#) in the *Standard solution* (µg/mL)

C_U = concentration of Hydrocortisone Sodium Succinate in the *Sample solution* (µg/mL)

M_{r1} = molecular weight of hydrocortisone sodium succinate, 484.51

M_{r2} = molecular weight of hydrocortisone hemisuccinate, 462.53

Acceptance criteria: 97.0%–102.0% on the dried basis

SPECIFIC TESTS

• SODIUM CONTENT

Sample: 1 g

Analysis: Dissolve the *Sample*, with gentle heating, in 75 mL of [glacial acetic acid](#). Add 20 mL of [dioxane](#), then add crystal violet TS, and titrate with 0.1 N [perchloric acid](#) VS. Each mL of 0.1 N [perchloric acid](#) is equivalent to 2.299 mg of sodium (Na).

Acceptance criteria: 4.60%–4.84% on the dried basis

• OPTICAL ROTATION (781S), Procedures, Specific Rotation

Sample solution: 10 mg/mL in [alcohol](#)

Acceptance criteria: +140° to +150°

• LOSS ON DRYING (731)

Analysis: Dry at 105° for 3 h.

Acceptance criteria: NMT 2.0%

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.

• **USP REFERENCE STANDARDS (11).**

[USP Hydrocortisone Hemisuccinate RS](#)

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

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

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. 50(4)

Current DocID: GUID-9436BC85-4A79-42F7-BC06-E6D31AD7B916_2_en-US

DOI: https://doi.org/10.31003/USPNF_M38420_02_01

DOI ref: [be6hb](#)