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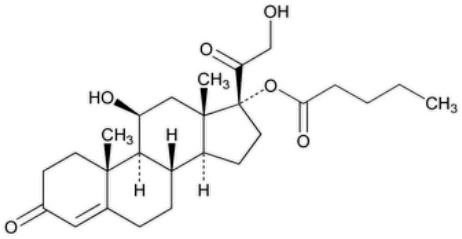
Hydrocortisone Valerate



$C_{26}H_{38}O_6$ 446.58

Pregn-4-ene-3,20-dione, 11,21-dihydroxy-17-[(1-oxopentyl)oxy]-, (11β)-;

Cortisol 17-valerate;

11β,17,21-Trihydroxypregn-4-ene-3,20-dione 17-valerate CAS RN®: 57524-89-7; UNII: 68717P8FUZ.

DEFINITION

Hydrocortisone Valerate contains NLT 97.0% and NMT 102.0% of hydrocortisone valerate ($C_{26}H_{38}O_6$), calculated on the dried basis.

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests** ⟨197⟩, *Infrared Spectroscopy*: **197K**▲ (CN 1-May-2020)

ASSAY

• **Procedure**

Mobile phase: Acetonitrile and water (45:55)

Internal standard solution: 2.0 mg/mL of ethyl benzoate in methanol

Standard stock solution: 0.5 mg/mL of USP Hydrocortisone Valerate RS in methanol. Prepare immediately before use.

Standard solution: 0.1 mg/mL of USP Hydrocortisone Valerate RS in methanol, prepared as follows. Pipet 2 mL of the *Standard stock solution* and 2 mL of the *Internal standard solution* into a 10-mL volumetric flask, and dilute with methanol to volume.

Sample stock solution: 1 mg/mL of Hydrocortisone Valerate in methanol

Sample solution: 0.1 mg/mL of Hydrocortisone Valerate in methanol, prepared as follows. Pipet 1 mL of the *Sample stock solution* and 2 mL of the *Internal standard solution* into a 10-mL volumetric flask, and dilute with methanol to volume.

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability*.)

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—The relative retention times for ethyl benzoate and hydrocortisone valerate are about 0.8 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 3.0 between ethyl benzoate and hydrocortisone valerate

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of hydrocortisone valerate ($C_{26}H_{38}O_6$) in the portion of Hydrocortisone Valerate taken:

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

R_U = peak response ratio of hydrocortisone valerate to the internal standard from the *Sample solution*

R_S = peak response ratio of hydrocortisone valerate to the internal standard from the *Standard solution*

C_S = concentration of USP Hydrocortisone Valerate RS in the *Standard solution* (mg/mL)

C_U = concentration of Hydrocortisone Valerate in the *Sample solution* (mg/mL)

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

SPECIFIC TESTS

- **Loss on Drying ⟨731⟩**

  Sample: Dry at 105° for 3 h.

  Acceptance criteria: NMT 1.0%

- **Optical Rotation, *Specific Rotation*⟨781S⟩**

  Sample: 10 mg/mL in dioxane

  Acceptance criteria: +37° to +43°

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers.
- **USP Reference Standards ⟨11⟩**

  USP Hydrocortisone Valerate RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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