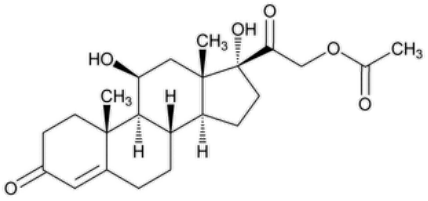
Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-858493A5-CD49-4816-A83C-377C10CE6CDB_2_en-US
DOI: https://doi.org/10.31003/USPNF_M38190_02_01
DOI Ref: s0rbh

Hydrocortisone Acetate



$C_{23}H_{32}O_6$ 404.50

Pregn-4-ene-3,20-dione, 21-(acetyloxy)-11,17-dihydroxy-, (11β)-;

Cortisol 21-acetate CAS RN®: 50-03-3; UNII: 3X7931PO74.

DEFINITION

Hydrocortisone Acetate contains NLT 97.0% and NMT 102.0% of $C_{23}H_{32}O_6$, calculated on the dried basis.

IDENTIFICATION

Change to read:

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

Change to read:

• **B.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Ultraviolet-Visible Spectroscopy*: 197U**▲ (CN 1-May-2020)

Analytical wavelength: 242 nm

Sample solution: 10 µg/mL in methanol

Acceptance criteria: Absorptivities, calculated on the dried basis, do not differ by more than 2.5%.

ASSAY

• **Procedure**

Mobile phase: Butyl chloride, water-saturated butyl chloride, tetrahydrofuran, methanol, and glacial acetic acid (475:475:70:35:30)

Standard solution: 0.10 mg/mL of USP Hydrocortisone Acetate RS in *Mobile phase*

Sample solution: 0.10 mg/mL of Hydrocortisone Acetate in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; 10-µm packing L3

Flow rate: 1 mL/min

Injection size: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of hydrocortisone acetate ($C_{23}H_{32}O_6$) in the portion of Hydrocortisone Acetate taken:

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

r_U = peak response of hydrocortisone acetate from the *Sample solution*

r_S = peak response of hydrocortisone acetate from the *Standard solution*

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

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

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

IMPURITIES

• **Residue on Ignition ⟨281⟩**

Sample: 100 mg

Acceptance criteria: NMT 0.5%

• **Organic Impurities**

Solution A: Acetonitrile and water (20:80)

Solution B: Acetonitrile and water (70:30)

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	90	10
5	90	10
25	10	90
30	10	90
35	90	10
40	90	10

Diluent: Acetonitrile, glacial acetic acid, and water (700:1:300)

Standard solution: 5 µg/mL of USP Hydrocortisone Acetate RS in *Diluent*

Sample solution: 1 mg/mL of Hydrocortisone Acetate in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 15-cm; 3-µm packing L1

Flow rate: 1 mL/min

Injection size: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 5.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Hydrocortisone Acetate taken:

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

r_U = peak response of each impurity from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria

Individual impurities: NMT 1.0%

Total impurities: NMT 2.0%

SPECIFIC TESTS

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

Sample solution: 10 mg/mL in dioxane

Acceptance criteria: Between +158° and +167° at 20°

- **Loss on Drying** ⟨731⟩**:** Dry a sample in vacuum at 60° for 3 h: it loses NMT 1.0% of its weight.

ADDITIONAL REQUIREMENTS

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

USP Hydrocortisone Acetate RS

Pregn-4-ene-3,20-dione, 21-(acetyloxy)-11,17-dihydroxy-, (11β)-.

$C_{23}H_{32}O_6$ 404.50

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

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 44(3)

Current DocID: GUID-858493A5-CD49-4816-A83C-377C10CE6CDB_2_en-US

DOI: https://doi.org/10.31003/USPNF_M38190_02_01

DOI ref: s0rbh