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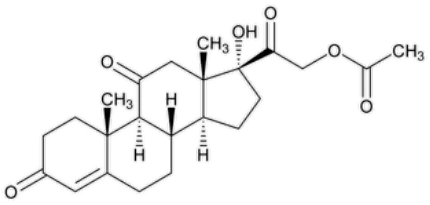
Cortisone Acetate



$C_{23}H_{30}O_6$ 402.48

Pregn-4-ene-3,11,20-trione, 21-(acetyloxy)-17-hydroxy-;

17,21-Dihydroxypregn-4-ene-3,11,20-trione 21-acetate CAS RN®: 50-04-4; UNII: 883WKN7W8X.

DEFINITION

Cortisone Acetate contains NLT 97.0% and NMT 102.0% of cortisone acetate ($C_{23}H_{30}O_6$), calculated on the dried basis.

IDENTIFICATION

Change to read:

• **A.** ▲▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**▲ (CN 1-May-2020) **:** [Note—Methods described in ⟨197K⟩ or ⟨197A⟩ may be used.]▲2S *(USP41)*

Sample: Dissolve in methanol, evaporate the methanol on a steam bath, and dry at 105° for 30 min.

Acceptance criteria: Meets the requirements

Change to read:

• **B.** ▲The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲2S *(USP41)*

ASSAY

Change to read:

• **Procedure**

▲**Solution A:** Water

Solution B: Acetonitrile

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0.0	70	30
20	70	30
27	30	70
27.1	70	30
30	70	30

Diluent: Acetonitrile, glacial acetic acid, and water (70:1:30)

System suitability solution: 1000 µg/mL of USP Cortisone Acetate RS and 150 µg/mL of USP Hydrocortisone Acetate RS in *Diluent*

Standard solution: 1000 µg/mL of USP Cortisone Acetate RS in *Diluent*

Sample solution: 1000 µg/mL of Cortisone Acetate in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 242 nm

Column: 4.0-mm × 10-cm; 3-µm packing L1

Flow rate: 1.5 mL/min

Injection volume: 15 µL

System suitability

[NOTE—See *Table 2* for the relative retention times.]

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 4.2 between cortisone acetate and hydrocortisone acetate, *System suitability solution*

Tailing factor: NMT 1.5, *Standard solution*

Relative standard deviation: NMT 0.73%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of cortisone acetate ($C_{23}H_{30}O_6$) in the portion of Cortisone Acetate taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

C_U = concentration of Cortisone Acetate in the *Sample solution* (µg/mL) ▲2S *(USP41)*

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

IMPURITIES

Change to read:

• **RESIDUE ON IGNITION ⟨281⟩:** ▲NMT 0.50%▲2S *(USP41)*

Change to read:

• **ORGANIC IMPURITIES**

▲**Solution A, Solution B, Mobile phase, Diluent, System suitability solution, Sample solution,** and **Chromatographic system:** Proceed as directed in the *Assay*.

Standard solution: 1 µg/mL of USP Cortisone Acetate RS and 5 µg/mL of USP Hydrocortisone Acetate RS in *Diluent*

System suitability

[NOTE—See *Table 2* for the relative retention times.]

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 4.2 between cortisone acetate and hydrocortisone acetate, *System suitability solution*

Relative standard deviation: NMT 5.0%, hydrocortisone acetate and cortisone acetate, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of hydrocortisone acetate in the portion of Cortisone 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* (µg/mL)

C_U = concentration of Cortisone Acetate in the *Sample solution* (µg/mL)

Calculate the percentage of any individual unspecified impurity in the portion of Cortisone Acetate taken:

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

r_U = peak response of any individual unspecified impurity from the *Sample solution*

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

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

C_U = concentration of Cortisone Acetate in the *Sample solution* (µg/mL)

Acceptance criteria: See *Table 2*.

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Hydrocortisone acetate	0.8	0.5
Cortisone acetate	1.0	—
Any individual unspecified impurity	—	0.10
Total impurities	—	1.5▲2S *(USP41)*

SPECIFIC TESTS

• **Optical Rotation** ⟨781S⟩, *Procedures, Specific Rotation*

Sample solution: 10 mg/mL in dioxane

Acceptance criteria: +208° to +217°

• **Loss on Drying** ⟨731⟩

Analysis: Dry at 105° for 30 min.

Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers. Store at 25°, excursions permitted between 15° and 30°.

Change to read:

• **USP Reference Standards** ⟨11⟩

USP Cortisone Acetate RS

▲ USP Hydrocortisone Acetate RS▲2S *(USP41)*

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

We apologize for the inconvenience. The exact auxiliary information for this Documentary Standard is currently unavailable. Please contact Documentary Standards Support (stdsmonographs@usp.org) for assistance during this time.

Chromatographic Database Information: Chromatographic Database

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