Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-FBD82831-D40D-4188-A521-D94AF9AAF50B_6_en-US
DOI: https://doi.org/10.31003/USPNF_M20290_06_01
DOI Ref: 04wc9

Cortisone Acetate Tablets

DEFINITION

Cortisone Acetate Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of cortisone acetate ($C_{23}H_{30}O_6$).

IDENTIFICATION

Change to read:

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

Sample: Powder a number of Tablets equivalent to 25 mg of cortisone acetate. Add 25 mL of solvent hexane, and extract for 15 min with occasional agitation. Decant and discard the supernatant, then extract the residue with 5 mL of chloroform, with frequent agitation, for 5 min. Filter, add 10 mL of methanol to the filtrate, mix, evaporate the solvent on a steam bath with the aid of a current of air, then dry the residue at 105° for 30 min. Use the residue.

Acceptance criteria: Meet the requirements

Add the following:

▲• **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: Nominally 1000 µg/mL of cortisone acetate from Tablets in *Diluent*, prepared as follows. Transfer an appropriately weighed portion of finely powdered Tablets (NLT 20) to a suitable volumetric flask. Add 80% of the final flask volume of *Diluent* and sonicate for 10 min. Dilute with *Diluent* to volume and mix well. Pass through a suitable filter of 0.2-µm pore size.

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 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of cortisone acetate ($C_{23}H_{30}O_6$) in the portion of Tablets 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 = nominal concentration of cortisone acetate in the *Sample solution* (µg/mL)▲2S *(USP41)*

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

• **DISSOLUTION** ⟨711⟩

Medium: 0.5% sodium lauryl sulfate solution; 1000 mL

Apparatus 2: 50 rpm

Time: 45 min

Standard solution: ▲0.00555 mg/mL▲2S *(USP41)* of USP Cortisone Acetate RS in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter. Dilute with *Medium*, if necessary.

Instrumental conditions

Mode: UV

Analytical wavelength: Maximum absorbance at about 242 nm

Cell: 1 cm

Analysis

Samples: *Standard solution* and *Sample solution*

▲Calculate the percentage of the labeled amount of cortisone acetate ($C_{23}H_{30}O_6$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times V \times D \times (1/L) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

V = volume of *Medium*, 1000 mL

D = dilution factor for the *Sample solution*, if applicable

L = label claim (mg/Tablet)▲2S *(USP41)*

Tolerances: NLT 75% (Q) of the labeled amount of cortisone acetate ($C_{23}H_{30}O_6$) is dissolved.

Change to read:

• **UNIFORMITY OF DOSAGE UNITS** ⟨905⟩**:** ▲Meet the requirements▲2S *(USP41)*

IMPURITIES

Add the following:

▲• **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: 5 µg/mL of USP Cortisone 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%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of any individual unspecified degradation product in the portion of Tablets taken:

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

r_U = peak response of any individual unspecified degradation product 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 = nominal 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[a]	0.8	—
Cortisone acetate	1.0	—
Any individual unspecified degradation product	—	0.5
Total degradation products	—	1.5

[a] Process impurity included in the table for identification only. Process impurities are controlled in the drug substance, and are not to be reported or included in the total impurities for the drug product.

▲2S *(USP41)*

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in well-closed containers.

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.

Topic/Question	Contact	Expert Committee
CORTISONE ACETATE TABLETS	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 43(2)

Current DocID: GUID-FBD82831-D40D-4188-A521-D94AF9AAF50B_6_en-US
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