

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

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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