Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-Aug-2023
Document Type: USP Monographs
DocId: GUID-CA8F090E-705F-4685-AF68-00641196FAA6_3_en-US
DOI: https://doi.org/10.31003/USPNF_M38180_03_01
DOI Ref: e7jka

Hydrocortisone Tablets

DEFINITION

Hydrocortisone Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of hydrocortisone ($C_{21}H_{30}O_5$).

IDENTIFICATION

• **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197M**

Sample: Powder a number of Tablets, equivalent to 50 mg of hydrocortisone, and digest with 15 mL of solvent hexane for 15 min. Decant the solvent hexane as completely as possible, and extract the residue first with 10 mL of solvent hexane, then with 10 mL of peroxide-free ether in the same manner as before, and discard the extracts. Digest the final residue with 25 mL of dehydrated alcohol for 15 min with frequent agitation. Filter, and evaporate the alcohol extract on a steam bath to dryness. Use the residue.

Acceptance criteria: Meet the requirements

ASSAY

• **Procedure**

Mobile phase: Butyl chloride, water-saturated butyl chloride, tetrahydrofuran, methanol, and glacial acetic acid (95:95:14:7:6)

Internal standard solution: 0.06 mg/mL of USP Prednisone RS in water-saturated chloroform

Standard solution: 0.1 mg/mL of USP Hydrocortisone RS in *Internal standard solution*

Sample solution: Nominally 0.1 mg/mL of hydrocortisone from NLT 10 finely powdered Tablets, prepared as follows. Transfer a portion of the powder, equivalent to 5 mg of hydrocortisone, to a suitable container, and add 50.0 mL of the *Internal standard solution*. Shake vigorously for 30 min, and centrifuge a portion. Use the clear supernatant.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; packing L3

Flow rate: 0.9 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 3.0 between hydrocortisone and prednisone

Relative standard deviation: NMT 2.0% for four replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of hydrocortisone ($C_{21}H_{30}O_5$) in the portion of Tablets taken:

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

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

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

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

C_U = nominal concentration of hydrocortisone in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: Water; 900 mL

Apparatus 2: 50 rpm

Time: 30 min

Standard solution: USP Hydrocortisone RS at a known concentration in *Medium*

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

Instrumental conditions

(See *Ultraviolet-Visible Spectroscopy ⟨857⟩*.)

Mode: UV

Analytical wavelength: Maximum absorbance at about 248 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Determine the amount of hydrocortisone ($C_{21}H_{30}O_5$) dissolved.

Tolerances: NLT 70% (*Q*) of the labeled amount of hydrocortisone ($C_{21}H_{30}O_5$) is dissolved.

Change to read:

• **Uniformity of Dosage Units ⟨905⟩:** ▲Meet the requirements▲ (CN 1-Aug-2023)

Procedure for content uniformity

Mobile phase, Internal standard solution, Standard solution, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*.

Sample solution: Nominally 0.1 mg/mL of hydrocortisone, prepared as follows. Transfer 1 Tablet to a suitable container, and add 0.3 mL of water directly onto the Tablet. Allow the Tablet to stand for about 5 min. Shake the container to break up the Tablet, and sonicate briefly to ensure complete disintegration. Add a few small glass beads and 50.0 mL of the *Internal standard solution* to the container. Shake the container for about 30 min. Dilute an accurately measured volume of the clear supernatant with a known, accurately measured volume of the *Internal standard solution* to obtain the desired concentration. Shake the contents of the container to mix.

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of hydrocortisone ($C_{21}H_{30}O_5$) in the Tablet taken:

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

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

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

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

C_U = nominal concentration of hydrocortisone in the *Sample solution* (mg/mL)

▲▲ (CN 1-Aug-2023)

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

• **USP Reference Standards ⟨11⟩**

USP Hydrocortisone RS

USP Prednisone RS

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

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 44(6)
Current DocID: GUID-CA8F090E-705F-4685-AF68-00641196FAA6_3_en-US
DOI: https://doi.org/10.31003/USPNF_M38180_03_01
DOI ref: e7jka