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Hydrocortisone and Acetic Acid Otic Solution

DEFINITION

Hydrocortisone and Acetic Acid Otic Solution is a solution of Hydrocortisone and Glacial Acetic Acid in a suitable nonaqueous solvent. It contains NLT 90.0% and NMT 120.0% of the labeled amount of hydrocortisone ($C_{21}H_{30}O_5$), and NLT 85.0% and NMT 130.0% of the labeled amount of acetic acid ($C_2H_4O_2$).

IDENTIFICATION

• **A.**

Analysis: Dilute 5 mL of Otic Solution with 10 mL of water, and adjust with 1 N sodium hydroxide to a pH of about 7. Add ferric chloride TS.

Acceptance criteria: A deep red color is produced, and it is destroyed by the addition of hydrochloric acid.

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, both relative to the internal standard, as obtained in the *Assay* for *Acetic Acid*.

• **C.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay* for *Hydrocortisone*.

ASSAY

• **Acetic Acid**

Internal standard solution: Dilute 2.0 mL of anisole with methanol to 100 mL.

Standard stock solution: 20 mg/mL of glacial acetic acid in methanol

Standard solution: 10 mg/mL of glacial acetic acid in methanol, prepared as follows. Transfer a sufficient volume of the *Standard stock solution* to a volumetric flask of suitable size, add 20% of the flask volume of the *Internal standard solution*, and dilute with methanol to volume.

Sample solution: Nominally 10 mg/mL of glacial acetic acid, prepared as follows. Transfer a sufficient volume of Otic Solution to a volumetric flask of suitable size, add 20% of the flask volume of the *Internal standard solution*, and dilute with methanol to volume.

Chromatographic system

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

Mode: GC

Detector: Flame ionization

Column: 2-mm × 1.8-m glass; packed with 20% liquid phase G35 on support S1A

Carrier gas: Nitrogen

Flow rate: 25 mL/min

Temperatures

Injection port: 180°

Detector: 220°

Column: See *Table 1*.

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
115	0	115	12
115	35	190	3

Injection volume: 4 µL

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for anisole and acetic acid are 1.0 and 1.5, respectively.]

Suitability requirements

Resolution: NLT 1.5 between anisole and acetic acid

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of acetic acid ($C_2H_4O_2$) in the portion of Otic Solution taken:

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

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

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

C_S = concentration of glacial acetic acid in the *Standard solution* (mg/mL)

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

Acceptance criteria: 85.0%–130.0%

- **HYDROCORTISONE**

Diluent: Dilute alcohol (1 in 2)

Mobile phase: Acetonitrile and water (30:70)

Standard solution: 0.5 mg/mL of USP Hydrocortisone RS in *Diluent*

Sample solution: Nominally equivalent to 0.5 mg/mL of hydrocortisone from Otic Solution in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4-mm × 30-cm; packing L1

Flow rate: 2 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

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 Otic Solution 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 Hydrocortisone RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–120.0%

SPECIFIC TESTS

- **pH ⟨791⟩**

Sample solution: Otic Solution and water (1:1)

Acceptance criteria: 2.0–4.0

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight, light-resistant containers.
- **USP Reference Standards** ⟨11⟩

  USP Hydrocortisone RS

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

Topic/Question	Contact	Expert Committee
HYDROCORTISONE AND ACETIC ACID OTIC SOLUTION	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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