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Hydrocortisone Gel

DEFINITION

Hydrocortisone Gel is Hydrocortisone in a suitable hydroalcoholic gel base. It contains NLT 90.0% and NMT 110.0% of the labeled amount of hydrocortisone ($C_{21}H_{30}O_5$).

IDENTIFICATION

Delete the following:

▲ • **THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST** (201)

Sample solution: Transfer a quantity of Gel, equivalent to 5 mg of hydrocortisone, to a flask. Add 5 mL of alcohol, and heat on a steam bath for 5 min, with frequent shaking. Cool, and filter. Use the filtrate.

Acceptance criteria: Meets the requirements▲ (USP 1-May-2020)

Add the following:

▲ • **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.▲ (USP 1-May-2020)

Add the following:

▲ • **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.▲ (USP 1-May-2020)

ASSAY

Change to read:

• ▲ **PROCEDURE**

Solution A: 0.1% [glacial acetic acid](#) in [water](#)

Solution B: 0.1% [glacial acetic acid](#) in [acetonitrile](#)

Solution C: [Acetonitrile](#), [glacial acetic acid](#), and [water](#) (40:1:60)

Solution D: [Tetrahydrofuran](#) and [water](#) (50:50)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0.0	74	26
11.0	74	26
20.0	55	45
30.0	30	70
30.1	74	26
35.0	74	26

Diluent: *Solution C* and *Solution D* (80:20)

System suitability solution: 0.3 mg/mL of [USP Hydrocortisone RS](#) and 6 µg/mL of [USP Prednisolone RS](#) in *Diluent*. Sonicate to dissolve, if necessary.

Standard solution: 0.3 mg/mL of [USP Hydrocortisone RS](#) in *Diluent*. Sonicate to dissolve, if necessary.

Sample solution: Nominally 0.3 mg/mL of hydrocortisone prepared as follows. Transfer 3 mg of hydrocortisone from a portion of Gel to a 10-mL volumetric flask. Add 2 mL of *Solution D* and vortex for about 3 min or until the sample is thoroughly dispersed. Add about 6 mL of *Solution C* and sonicate for about 10 min with intermittent vortexing and shaking. Dilute with *Solution C* to volume. Centrifuge a portion of the solution to obtain a clear supernatant. [NOTE—The use of a centrifuge speed of 3500 rpm for 30 min may be suitable.] Use the supernatant.

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 246 nm. For *Identification B*, use a diode array detector in the range of 210–400 nm.

Column: 4.6-mm × 15-cm; 3-µm packing [L1](#)

Column temperature: 30°

Flow rate: 0.8 mL/min

Injection volume: 10 µL

System suitability

Samples: *System suitability solution* and *Standard solution* [NOTE—See [Table 2](#) for relative retention times.]

Suitability requirements

Resolution: NLT 1.5 between hydrocortisone and prednisolone, *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 hydrocortisone ($C_{21}H_{30}O_5$) in the portion of Gel 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)

▲ (USP 1-May-2020)

Acceptance criteria: 90.0%–110.0%

IMPURITIES

Add the following:

▲ • ORGANIC IMPURITIES

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

Sensitivity solution: 0.3 µg/mL of [USP Hydrocortisone RS](#) in *Diluent*. Sonicate to dissolve, if necessary.

Standard solution: 0.0015 mg/mL of [USP Hydrocortisone RS](#) in *Diluent*. Sonicate to dissolve, if necessary.

System suitability

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

[NOTE—See [Table 2](#) for relative retention times.]

Suitability requirements

Resolution: NLT 1.5 between hydrocortisone and prednisolone, *System suitability solution*

Relative standard deviation: NMT 5.0%, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of cortisone or hydrocortisone glyoxal analog in the portion of Gel taken:

