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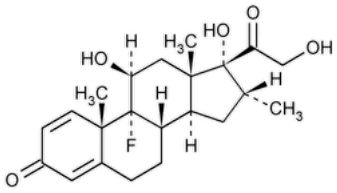
Dexamethasone



$C_{22}H_{29}FO_5$ 392.46

Pregna-1,4-diene-3,20-dione, 9-fluoro-11,17,21-trihydroxy-16-methyl-, (11β,16α)-;

9-Fluoro-11β,17,21-trihydroxy-16α-methylpregna-1,4-diene-3,20-dione CAS RN®: 50-02-2; UNII: 7S5I7G3JQL.

DEFINITION

Dexamethasone contains NLT 97.0% and NMT 102.0% of dexamethasone ($C_{22}H_{29}FO_5$), calculated on the dried basis.

IDENTIFICATION

Change to read:

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

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

ASSAY

• **Procedure**

Solution A: 3.4 g/L of monobasic potassium phosphate in water. Adjust with phosphoric acid to a pH of 3.0.

Solution B: Acetonitrile

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0.0	76	24
10	76	24
15	45	55
16	10	90
16.1	76	24
20.0	76	24

Diluent: Acetonitrile and water (56:44)

System suitability solution: 0.3 mg/mL of USP Dexamethasone RS and 20 µg/mL of USP Betamethasone RS in *Diluent*. Sonicate to dissolve as needed.

Standard solution: 0.3 mg/mL of USP Dexamethasone RS in *Diluent*. Sonicate to dissolve as needed.

Sample solution: 0.3 mg/mL of Dexamethasone in *Diluent*. Sonicate to dissolve as needed.

Chromatographic system

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

Mode: LC

Detector: UV 240 nm

Column: 2.1-mm × 10-cm; 1.7-µm packing L1

Column temperature: 35°

Flow rate: 0.4 mL/min

Injection volume: 2 µL

System suitability

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

[NOTE—See *Table 2* for the relative retention times.]

Suitability requirements

Resolution: NLT 1.5 between betamethasone and dexamethasone, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 0.73%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of dexamethasone ($C_{22}H_{29}FO_5$) in the portion of Dexamethasone 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 Dexamethasone RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 97.0%–102.0% on the dried basis

IMPURITIES

- **RESIDUE ON IGNITION ⟨281⟩**

Sample: 250 mg

Analysis: Use a platinum crucible.

Acceptance criteria: NMT 0.2%

- **ORGANIC IMPURITIES**

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

Standard solution: 4.0 µg/mL of USP Dexamethasone RS, 6.0 µg/mL each of USP Betamethasone RS and USP Desoximetasone RS, and 12.0 µg/mL of USP Dexamethasone Acetate RS in *Diluent*

Sample solution: 4.0 mg/mL of Dexamethasone in *Diluent*. Sonicate to dissolve as needed.

System suitability

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

[NOTE—See *Table 2* for the relative retention times.]

Suitability requirements

Resolution: NLT 1.5 between betamethasone and dexamethasone, *System suitability solution*

Relative standard deviation: NMT 5.0% for betamethasone, dexamethasone, desoximetasone, and dexamethasone acetate, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of betamethasone, desoximetasone, and dexamethasone acetate in the portion of Dexamethasone taken:

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

r_U = peak response of betamethasone, desoximetasone, or dexamethasone acetate from the *Sample solution*

r_S = peak response of the corresponding USP Reference Standard from the *Standard solution*

C_S = concentration of the corresponding USP Reference Standard in the *Standard solution* (mg/mL)

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

Calculate the percentage of 16α-methylprednisone, dexamethasone 7,9-diene, and any individual unspecified impurity in the portion of Dexamethasone taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak response of 16α-methylprednisone, dexamethasone 7,9-diene, or any individual unspecified impurity from the *Sample solution*

r_S = peak response of dexamethasone from the *Standard solution*

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

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

F = relative response factor (see *Table 2*)

Acceptance criteria: See *Table 2*. The reporting threshold is 0.05%.

Table 2

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
16α-Methylprednisone[a]	0.86	1.0	0.15
Betamethasone	0.94	—	0.15
Dexamethasone	1.00	—	—
Dexamethasone 7,9-diene[b]	1.40	1.7	0.10
Desoximetasone	1.58	—	0.15
Dexamethasone acetate	1.74	—	0.30
Any individual unspecified impurity	—	1.0	0.10
Total impurities	—	—	0.5

[a] 17,21-Dihydroxy-16α-methylpregna-1,4-diene-3,11,20-trione.

[b] 17,21-Dihydroxy-16α-methylpregna-1,4,7,9(11)-tetraene-3,20-dione.

SPECIFIC TESTS

• **Optical Rotation** ⟨781S⟩, *Procedures, Specific Rotation*

Sample solution: 10 mg/mL of Dexamethasone in dioxane

Acceptance criteria: +72° to +80°

• **Loss on Drying** ⟨731⟩

Analysis: Dry at 105° for 3 h.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

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

• **USP Reference Standards** ⟨11⟩

USP Betamethasone RS
USP Desoximetasone RS
USP Dexamethasone RS
USP Dexamethasone Acetate RS

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

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

Chromatographic Database Information: Chromatographic Database

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