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Dexamethasone Acetate

$C_{24}H_{31}FO_6.H_2O$ 452.51

Pregna-1,4-diene-3,20-dione, 21-(acetyloxy)-9-fluoro-11,17-dihydroxy-16-methyl-, (11β,16α)-monohydrate.

9-Fluoro-11β,17,21-trihydroxy-16α-methylpregna-1,4-diene-3,20-dione 21-acetate monohydrate CAS RN®: 55812-90-3.

Anhydrous 434.51 CAS RN®: 1177-87-3.

» Dexamethasone Acetate contains one molecule of water of hydration or is anhydrous. It contains not less than 97.0 percent and not more than 102.0 percent of $C_{24}H_{31}FO_6$, calculated on the dried basis.

Packaging and storage—Preserve in well-closed containers. Store at 25°, excursions permitted between 15° and 30°.

Labeling—Label it to indicate whether it is hydrous or anhydrous.

USP Reference standards ⟨11⟩—

USP Dexamethasone Acetate RS

Identification—

Change to read:

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

Change to read:

B: ▲*Spectroscopic Identification Tests* ⟨197⟩*, Ultraviolet-Visible Spectroscopy: 197U*▲ *(CN 1-May-2020)*

Solution: 15 µg per mL.

Medium: methanol.

Absorptivities at 239 nm, calculated on the dried basis, do not differ by more than 3.0%.

Specific rotation ⟨781S⟩**:** between +82° and +88°.

Test solution: 10 mg per mL, in dioxane.

Loss on drying ⟨731⟩—Dry it in vacuum at 105° for 3 hours: the hydrous form loses between 3.5% and 4.5%, and the anhydrous form not more than 0.4%, of its weight.

Residue on ignition ⟨281⟩**:** not more than 0.1%.

Change to read:

Chromatographic purity—

▲*Formate*▲ *(ERR 1-May-2020) buffer*—Dissolve 1.32 g of ammonium formate in 1 L of water, adjust with formic acid to a pH of 3.6, and mix.

Mobile phase—Prepare a filtered and degassed mixture of *Formate buffer* and acetonitrile (3:2). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Test solution—Transfer about 200 mg of Dexamethasone Acetate, accurately weighed, to a 100-mL volumetric flask, dissolve in and dilute with acetonitrile to volume, and mix. Transfer about 40 mL of this solution to a 100-mL volumetric flask, dilute with *Formate buffer* to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 4.6-mm × 25-cm column that contains packing L11. The flow rate is about 1 mL per minute. Chromatograph the *Test solution,* and record the peak responses as directed for *Procedure:* the column efficiency is not less than 5400 theoretical plates.

Procedure—Inject a volume (about 10 µL) of the *Test solution* into the chromatograph, record the chromatogram, and measure the peak responses. Calculate the percentage of each impurity in the portion of Dexamethasone Acetate taken by the formula:

$$100(r_i/r_S)$$

in which r_i is the peak response for each impurity; and r_S is the sum of the responses of all the peaks: not more than 1.0% of any individual impurity is found; and not more than 2.0% of total impurities is found.

Assay—

Mobile phase—Prepare a filtered and degassed mixture of water and acetonitrile (550:450). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

pH 6.0 Buffer solution—Transfer 3 mL of 1 N sodium hydroxide, 138 mL of 0.5 N potassium chloride, and 50 mL of 0.5 M monobasic potassium phosphate to a 1-L volumetric flask, dilute with water to volume, and mix.

Diluent—Prepare a mixture of acetonitrile and *pH 6.0 Buffer solution* (1:1).

Standard preparation—Transfer about 25 mg of USP Dexamethasone Acetate RS, accurately weighed, to a 250-mL volumetric flask. Add 100 mL of *Diluent,* and sonicate until a clear solution is obtained. Dilute with *Diluent* to volume, and mix.

Assay preparation—Transfer about 25 mg of Dexamethasone Acetate, accurately weighed, to a 250-mL volumetric flask. Add 100 mL of *Diluent,* and sonicate until a clear solution is obtained. Dilute with *Diluent* to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 3.9-mm × 30-cm column containing 10-µm packing L1. The flow rate is about 2 mL per minute. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the capacity factor, *k′,* is not less than 2.0; the column efficiency is not less than 1500 theoretical plates; the tailing factor is not more than 2.0; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* (before and after injections of the *Assay preparation*) and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of $C_{24}H_{31}FO_6$ in the portion of Dexamethasone Acetate taken by the formula:

$$250C(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Dexamethasone Acetate RS in the *Standard preparation;* and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation,* respectively.

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

Topic/Question	Contact	Expert Committee
DEXAMETHASONE ACETATE	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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