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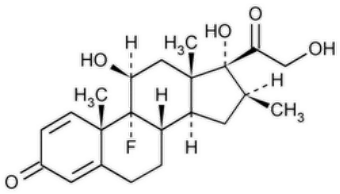
Betamethasone



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

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

9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione CAS RN®: 378-44-9; UNII: 9842X06Q6M.

» Betamethasone contains not less than 97.0 percent and not more than 103.0 percent of $C_{22}H_{29}FO_5$, calculated on the dried basis.

Packaging and storage—Preserve in tight containers. Store between 2° and 30°.

USP Reference standards ⟨11⟩—

USP Betamethasone RS

Identification—

Change to read:

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

B: *Thin-Layer Chromatographic Identification Test* ⟨201⟩—

Test solution—Prepare a solution of Betamethasone in dehydrated alcohol containing 0.5 mg per mL.

Developing solvent system: a mixture of chloroform and diethylamine (2:1).

Procedure—Proceed as directed in the chapter, except to locate the spots by lightly spraying with dilute sulfuric acid (1 in 2) and heating on a hot plate or under a lamp until spots appear.

Specific rotation ⟨781S⟩**:** between +118° and +126°, calculated on the dried basis.

Test solution: 5 mg per mL, in methanol.

Loss on drying ⟨731⟩—Dry it at 105° for 3 hours: it loses not more than 1.0% of its weight.

Residue on ignition ⟨281⟩**:** not more than 0.2%, a platinum crucible being used.

Ordinary impurities ⟨466⟩—

Test solution: methanol.

Standard solution: methanol.

Application volume: 10 µL.

Eluant: a mixture of toluene, acetone, methyl ethyl ketone, and formic acid (55:20:20:5), in a nonequilibrated chamber.

Visualization: 5.

Assay—

Mobile phase—Prepare a filtered and degassed mixture of water and acetonitrile (63:37). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Internal standard solution—Prepare a solution of propylparaben in alcohol having a known concentration of about 0.25 mg per mL.

Standard preparation—Dissolve an accurately weighed quantity of USP Betamethasone RS in alcohol to obtain a solution having a known concentration of about 0.2 mg per mL. Transfer 10.0 mL of this solution to a suitable vial, and add 10.0 mL of *Internal standard solution,* to obtain a *Standard preparation* having known concentrations of about 0.1 mg of betamethasone and about 0.125 mg of propylparaben per mL.

Assay preparation—Using about 80 mg of Betameth asone, accurately weighed, prepare as directed for *Standard preparation.*

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 240-nm detector and a 4.6-mm × 25-cm column that contains packing L1. The flow rate is about 1.0 mL per minute. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the relative retention times are about 1.0 for betamethasone and 1.4 for propylparaben; the resolution, *R,* between betamethasone and propylparaben is not less than 3.0; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard 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 $C_{22}H_{29}FO_5$ in the portion of

Betamethasone taken by the formula:

$$800C(R_U/R_S)$$

in which C is the concentration, in mg per mL, of USP Betamethasone RS in the *Standard preparation;* and R_U and R_S are the peak height ratios of the betamethasone peak and the internal standard peak 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
BETAMETHASONE	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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