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Prednisolone Acetate

$C_{23}H_{30}O_6$ 402.48

Pregna-1,4-diene-3,20-dione, 21-(acetyloxy)-11,17-dihydroxy-, (11β)-.

11β,17,21-Trihydroxypregna-1,4-diene-3,20-dione 21-acetate CAS RN®: 52-21-1; UNII: 8B2807733D.

» Prednisolone Acetate contains not less than 97.0 percent and not more than 102.0 percent of $C_{23}H_{30}O_6$, calculated on the dried basis.

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

USP Reference standards ⟨11⟩—

USP Prednisolone Acetate RS

Identification—

Change to read:

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

Change to read:

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

Solution: 10 µg per mL.

Medium: methanol.

Absorptivities at 242 nm, calculated on the dried basis, do not differ by more than 2.5%.

Specific rotation ⟨781S⟩**:** between +112° and +119°.

Test solution: 10 mg per mL, in dioxane.

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

Chromatographic purity—

Mobile phase—Prepare a filtered and degassed mixture of isooctane, butyl chloride and methanol (49:49:2). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Test solution—Transfer about 10 mg of Prednisolone Acetate, accurately weighed, to a suitable container, dissolve in 10 mL of chloroform, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 6.0-mm × 4.0-cm column that contains packing L3. The flow rate is about 3 mL per minute. Chromatograph the *Test solution,* and record the peak responses as directed for *Procedure:* the column efficiency is not less than 800 theoretical plates; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Inject a volume (about 10 µL) of the *Test solution* into the chromatograph, record the chromatogram, and measure all the peak responses. Calculate the percentage of each impurity in the portion of Prednisolone 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 for 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 solution containing a mixture of *n*-butyl chloride, water-saturated *n*-butyl chloride, tetrahydrofuran, methanol, and glacial acetic acid (95:95:14:7:6). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Internal standard solution—Prepare a solution of beta methasone in tetrahydrofuran containing 10 mg per mL. Dilute this solution with water-saturated chloroform, and mix to obtain a solution having a final concentration of about 1 mg of betamethasone per mL.

Standard preparation—Transfer about 10 mg of USP Prednisolone Acetate RS, accurately weighed, to a 100-mL volumetric flask; add 20.0 mL of *Internal standard solution;* and dissolve, using sonication if necessary. Dilute with water-saturated chloroform to volume, and mix. Dilute 5.0

mL of the solution so obtained with water-saturated chloroform to 20.0 mL to obtain a solution having a known concentration of about 25 µg of USP Prednisolone Acetate RS per mL.

Assay preparation—Transfer about 10 mg of Prednisolone Acetate, accurately weighed, to a 100-mL volumetric flask; add 20.0 mL of *Internal standard solution;* and dissolve, using sonication if necessary. Dilute with water-saturated chloroform to volume, and mix. Dilute 5.0 mL of the solution so obtained with water-saturated chloroform to 20.0 mL.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 4-mm × 30-cm column that contains packing L3. The flow rate is about 1 mL per minute. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the relative retention times are about 1.6 for betamethasone and 1.0 for prednisolone acetate; the resolution, *R,* between prednisolone acetate and betamethasone 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 $C_{23}H_{30}O_6$ in the portion of Prednisolone Acetate taken by the formula:

$$0.4C(R_U/R_S)$$

in which C is the concentration, in µg per mL, of USP Prednisolone Acetate RS in the *Standard preparation;* and R_U and R_S are the peak response ratios 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
PREDNISOLONE 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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