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Prednisolone Tablets

» Prednisolone Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{21}H_{28}O_5$.

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩—

USP Prednisolone RS

Identification—Pulverize a number of Tablets, equivalent to about 50 mg of prednisolone, and digest with 25 mL of chloroform for 15 minutes. Filter the mixture, and evaporate the filtrate on a steam bath to dryness. Wash the residue with two 10-mL portions of hot solvent hexane, decanting the supernatant each time and discarding it. Digest the residue with 25 mL of dehydrated alcohol, warming slightly, for 15 minutes. Filter the warm solution, and evaporate the filtrate to a volume of 2 to 3 mL. Add solvent hexane until the mixture just becomes turbid, chill it to effect crystallization, collect the crystals, and dry them at 60° for 1 hour: the crystals of prednisolone so obtained respond to *Identification* test *A* under *Prednisolone*.

Dissolution ⟨711⟩—

Medium: water; 900 mL.

Apparatus 2: 50 rpm.

Time: 30 minutes.

Procedure—Determine the amount in solution on filtered portions of the *Dissolution Medium*, suitably diluted at the wavelength of maximum absorbance at about 246 nm, with a suitable spectrophotometer in comparison with a Standard solution having a known concentration of USP Prednisolone RS. An amount of alcohol not to exceed 5% of the total volume of the Standard solution may be used to bring the prednisolone standard into solution prior to dilution with water.

Tolerances—Not less than 70% *(Q)* of the labeled amount of $C_{21}H_{28}O_5$ is dissolved in 30 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Procedure for content uniformity—

Mobile phase, Internal standard solution, Standard preparation, and *Chromatographic system*—Prepare as directed in the *Assay* under *Prednisolone*.

Test preparation—Place 1 tablet in a suitable container. Place 0.5 mL of water directly on the tablet, and allow to stand until disintegrated (about 30 minutes). Gently agitate the container to ensure that the tablet is completely disintegrated. Add 2.0 mL of *Internal standard solution* for each mg of labeled tablet strength, and sonicate for about 10 minutes. Dilute with a quantity of water-saturated chloroform approximately four times the volume of added *Internal standard solution*. Add a few glass beads, close the container, and shake vigorously for about 30 minutes. Centrifuge, or allow to stand until a clear solution is obtained. Analyze the clear solution as directed under *Procedure*.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Prednisolone*. Calculate the quantity, in mg, of $C_{21}H_{28}O_5$ in the Tablet taken by the formula:

$$(FW_S)(R_U/R_S)$$

in which F is the ratio of the volume of the *Internal standard solution*, in mL, in the *Test preparation* to the volume, in mL, of the *Internal standard solution* in the *Standard preparation*, W_S is the weight, in mg, of USP Prednisolone RS taken for the *Standard preparation,* and the other terms are as defined therein.

Assay—

Mobile phase, Internal standard solution, Standard preparation, and *Chromatographic system*—Prepare as directed in the *Assay* under *Prednisolone*.

Assay preparation—Weigh and finely powder not less than 10 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 10 mg of prednisolone, to a 100-mL volumetric flask. Add 20.0 mL of *Internal standard solution*, and sonicate for 10 minutes. Dilute with water-saturated chloroform to volume, and shake for 30 minutes. Centrifuge this mixture, and use the clear supernatant.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Prednisolone*. Calculate the quantity, in mg, of $C_{21}H_{28}O_5$ in the portion of Tablets taken by the formula:

$0.1C(R_U/R_S)$

in which the terms are as defined therein.

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

Topic/Question	Contact	Expert Committee
PREDNISOLONE TABLETS	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

Most Recently Appeared In:
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