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Prednisone Injectable Suspension

» Prednisone Injectable Suspension is a sterile suspension of Prednisone in a suitable aqueous medium. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{21}H_{26}O_5$.

Packaging and storage—Preserve in multiple-dose containers, preferably of Type I glass.

Labeling—Label it to indicate that it is for veterinary use only. Label it to indicate that it is for intramuscular administration only.

USP Reference Standards ⟨11⟩—
USP Prednisone RS

Identification—The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that of the *Standard preparation*, both relative to the internal standard, as obtained in the *Assay*.

pH ⟨791⟩**:** between 3.0 and 7.0.

Sterility Tests ⟨71⟩ —It meets the requirements when tested as directed for *Direct Inoculation of the Culture Medium* under *Test for Sterility of the Product to be Examined*.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 2.27 Endotoxin Units per mg of prednisone.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products* ⟨1⟩.

Assay—

Mobile phase—Prepare a filtered and degassed mixture of methanol and 0.05 M monobasic potassium phosphate (350:300). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Internal standard solution—Dissolve a quantity of betamethasone in methanol to obtain a solution containing about 0.4 mg per mL.

Standard preparation—Dissolve an accurately weighed quantity of USP Prednisone RS in methanol, and dilute quantitatively, and stepwise if necessary, with methanol to obtain a solution having a known concentration of about 0.25 mg per mL. Transfer 10.0 mL of this solution to a 50-mL volumetric flask. Add 10.0 mL of *Internal standard solution*, dilute with methanol to volume, and mix.

Assay preparation—Transfer an accurately measured volume of well-mixed Suspension, equivalent to about 80 mg of prednisone, to a 100-mL volumetric flask. Dilute with methanol to volume, and mix. Transfer 3.0 mL of this solution to a 50-mL volumetric flask. Add 10.0 mL of *Internal standard solution*, dilute with methanol to volume, and mix.

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 L1. 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 1.9 for betamethasone and 1.0 for prednisone, the resolution, *R,* between the prednisone peak and the betamethasone peak is not less than 3.5, 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 analyte peaks. Calculate the quantity, in mg, of prednisone in each mL of the Suspension taken by the formula:

$$5000(C/3V)(R_U/R_S)$$

in which C is the concentration, in mg per mL, of USP Prednisone RS in the *Standard preparation*, V is the volume, in mL, of the Suspension taken to prepare the *Assay preparation,* and R_U and R_S are the ratios of the prednisone peak to the internal standard peak obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Topic/Question	Contact	Expert Committee
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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