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Prednisolone Acetate Injectable Suspension

DEFINITION

Prednisolone Acetate Injectable Suspension is a sterile suspension of Prednisolone Acetate in a suitable aqueous medium. It contains NLT 90.0% and NMT 110.0% of the labeled amount of prednisolone acetate ($C_{23}H_{30}O_6$).

IDENTIFICATION

• **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197K

Sample: Allow a volume of Injectable Suspension equivalent to 50 mg of prednisolone acetate to settle. Decant and discard the supernatant. Dissolve the residue in 6 mL of alcohol. Evaporate the resulting solution, with the aid of a current of air, to half its volume, when crystallization occurs. Chill, if necessary, to aid crystallization. Filter the crystals, and allow to dry with the aid of a current of air. Use the crystals.

Acceptance criteria: Meets the requirements

Add the following:

▲• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲ (USP 1-Aug-2020)

ASSAY

Change to read:

• **Procedure**

Mobile phase: Acetonitrile and water (40:60)

Diluent: Methanol and acetonitrile (50:50)

Standard solution: 0.1 mg/mL of USP Prednisolone Acetate RS in *Diluent*

Sample solution: Nominally 0.1 mg/mL of prednisolone acetate, from a volume of Injectable Suspension, in *Diluent*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; ▲5-µm▲ (USP 1-Aug-2020) packing L1

Flow rate: 1 mL/min

Injection volume: 10 µL

▲**Run time:** NLT 2 times the retention time of prednisolone acetate▲ (USP 1-Aug-2020)

System suitability

Sample: *Standard solution*

Suitability requirements

Capacity factor, *k'*: NLT 3.0

Relative standard deviation: NMT 3.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of prednisolone acetate ($C_{23}H_{30}O_6$) in each milliliter of Injectable Suspension taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of prednisolone acetate from the *Sample solution*

r_S = peak response of prednisolone acetate from the *Standard solution*

C_S = concentration of USP Prednisolone Acetate RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of prednisolone acetate in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

Add the following:

▲• **Bacterial Endotoxins Test ⟨85⟩:** Meets the requirements▲ (USP 1-Aug-2020)

• **pH ⟨791⟩:** 5.0–7.5

Add the following:

▲• **Sterility Tests ⟨71⟩:** Meets the requirements▲ (USP 1-Aug-2020)

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

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in single-dose or in multiple-dose containers, preferably of Type I glass.

• **USP Reference Standards** ⟨11⟩

USP Prednisolone Acetate RS

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

Topic/Question	Contact	Expert Committee
PREDNISOLONE ACETATE INJECTABLE SUSPENSION	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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