

Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-DDDBCE7A-13D8-4F47-A5E8-DC98191DB3C6_4_en-US
DOI: https://doi.org/10.31003/USPNF_M68870_04_01
DOI Ref: b2mvw

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Prednisolone Tebutate Injectable Suspension

» Prednisolone Tebutate Injectable Suspension is a sterile suspension of Prednisolone Tebutate 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 $C_{27}H_{38}O_6$.

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

USP REFERENCE STANDARDS (11).—
[USP Prednisolone Tebutate RS](#)

Change to read:

Identification, ▲**SPECTROSCOPIC IDENTIFICATION TESTS (197)**, *Ultraviolet-Visible Spectroscopy: 197U*▲ (CN 1-May-2020) —

Solution: Dilute a portion of the Injectable Suspension with methanol to obtain a solution having a concentration of about 20 µg per mL.

BACTERIAL ENDOTOXINS TEST (85).—It contains not more than 8.8 USP Endotoxin Units per mg of prednisolone tebutate.

pH (791): between 6.0 and 8.0.

Other requirements—It meets the requirements under [Injections and Implanted Drug Products \(1\)](#).

Assay—

Mobile solvent—Prepare a mixture of isooctane, tetrahydrofuran, and alcohol (89:10:8).

Standard preparation—Dissolve an accurately weighed quantity of [USP Prednisolone Tebutate RS](#) in a mixture of tetrahydrofuran and isooctane (1:1) to obtain a solution having a known concentration of about 1 mg per mL.

Assay preparation—Transfer to a separator an accurately measured volume, freshly mixed, of Injectable Suspension, equivalent to about 100 mg of prednisolone tebutate, and dilute with about 10 mL of water. Extract with three 25-mL portions of methylene chloride, filtering each portion through methylene chloride-washed cotton into a 100-mL volumetric flask. Add methylene chloride to volume, and mix. Pipet 10 mL of this solution into a 50-mL centrifuge tube, evaporate the methylene chloride on a steam bath just to dryness, cool, and dissolve the residue in 10.0 mL of tetrahydrofuran and isooctane (1:1). Filter through a 1-µm membrane filter.

Procedure—Introduce equal volumes, about 10 µL, of the *Assay preparation* and the *Standard preparation* into a high-pressure liquid chromatograph (see [Chromatography \(621\)](#)), operated at room temperature, by means of a suitable microsyringe or sampling valve, adjusting the sample size and other operating parameters such that the peak obtained with the *Standard preparation* is about 0.6 full-scale. Typically, the apparatus is fitted with a 3.9-mm × 30-cm column containing packing L3 and is equipped with an UV detector capable of monitoring absorption at 254 nm and a suitable recorder. In a suitable chromatogram, the coefficient of variation for five replicate injections of a single specimen is not more than 3.0%. Measure the height of the peaks, at identical retention times, obtained with the *Assay preparation* and the *Standard preparation*. Calculate the quantity, in mg, of $C_{27}H_{38}O_6$, in the volume of Injectable Suspension taken by the formula:

$$100C(r_U/r_S)$$

in which C is the concentration, in mg per mL, of [USP Prednisolone Tebutate RS](#) in the *Standard preparation*, and r_U and r_S are the peak heights 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 TEBUTATE 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](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

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