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Dexamethasone Acetate Injectable Suspension

» Dexamethasone Acetate Injectable Suspension is a sterile suspension of Dexamethasone Acetate in Water for Injection. It contains an amount of dexamethasone acetate monohydrate ($C_{24}H_{31}FO_6 \cdot H_2O$) equivalent to not less than 90.0 percent and not more than 110.0 percent of the labeled amount of dexamethasone ($C_{22}H_{29}FO_5$).

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

USP Reference standards ⟨11⟩—
USP Dexamethasone Acetate RS

Change to read:

▲**Identification, Spectroscopic Identification Tests** ⟨197⟩, *Infrared Spectroscopy*: **197M**▲ (CN 1-May-2020) —Obtain the test specimen as follows. Transfer the contents of a well-shaken container of Injectable Suspension to a fine-porosity, sintered-glass vacuum filter, filter, and wash with several 10-mL portions of water. Remove the powder from the filter and allow to air-dry. [Note—Do not use heat to dry the specimen. Total or partial dehydration may occur. Use a similar undried preparation of USP Dexamethasone Acetate RS.]

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 21.7 USP Endotoxin Units per mg of dexamethasone acetate.

pH ⟨791⟩: between 5.0 and 7.5.

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

Assay—

Mobile phase, pH 6.0 Buffer solution, Diluent, and *Chromatographic system*—Proceed as directed in the *Assay* under *Dexamethasone Acetate*.

Standard preparation—Dissolve an accurately weighed quantity of USP Dexamethasone Acetate RS in *Diluent* to obtain a solution having a known concentration of about 0.09 mg per mL.

Assay preparation—Transfer an accurately measured volume of well-shaken Injectable Suspension, equivalent to about 40 mg of dexamethasone, to a 100-mL volumetric flask. Add 75 mL of *Diluent*, and sonicate until a clear solution is obtained. Dilute with *Diluent* to volume, and mix. Transfer 10.0 mL of this solution to a 50-mL volumetric flask, dilute with *Diluent* to volume, and mix.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* (before and after injections of the *Assay 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 dexamethasone ($C_{22}H_{29}FO_5$) in each mL of the Injectable Suspension taken by the formula:

$$(392.47/434.51)(500C/V)(r_U/r_S)$$

in which 392.47 and 434.51 are the molecular weights of dexamethasone and anhydrous dexamethasone acetate, respectively; C is the concentration, in mg per mL, of USP Dexamethasone Acetate RS in the *Standard preparation*; V is the volume, in mL, of Injectable Suspension taken; and r_U and r_S are the peak responses 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
DEXAMETHASONE ACETATE INJECTABLE SUSPENSION	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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