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Dexamethasone Injection

» Dexamethasone Injection is a sterile solution of Dexamethasone in Water for Injection. It contains 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 light-resistant single-dose or multiple-dose containers, preferably of Type I glass.

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

USP Reference Standards ⟨11⟩—
USP Dexamethasone RS

Identification—

A: *Thin-Layer Chromatographic Identification Test ⟨201⟩*—

Test solution—Transfer a quantity of Injection, equivalent to about 5 mg of dexamethasone, to a 50-mL separator, add 10 mL of water, and extract with two 20-mL portions of chloroform. Filter the lower layers through chloroform-saturated cotton into a 50-mL conical flask, and evaporate to dryness. Dissolve the residue in 10 mL of chloroform.

Developing solvent system: a mixture of methylene chloride and methanol (180:16).

Procedure—Visualize the spots using a 1 in 5 solution of *p*-toluenesulfonic acid in a mixture of alcohol and propylene glycol (9:1), followed by heat.

B: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay*.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 21.0 USP Endotoxin Units per mg of dexamethasone.

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

pH ⟨791⟩: between 4.0 and 5.5.

Particulate Matter in Injections ⟨788⟩: meets the requirements for small-volume injections.

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

Assay—

Mobile phase—Prepare a filtered and degassed mixture of water and acetonitrile (70:30). Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

System suitability solution—Prepare a solution in *Mobile phase* containing in each mL about 0.3 mg of USP Dexamethasone RS, 1.35 mg of benzyl alcohol, 0.27 mg of methylparaben, and 0.03 mg of propylparaben.

Standard preparation—Quantitatively dissolve an accurately weighed amount of USP Dexamethasone RS in methanol to obtain a stock solution having a known concentration of about 7.5 mg per mL. Transfer 4.0 mL to a 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix to obtain a solution having a known concentration of about 0.3 mg of USP Dexamethasone RS per mL.

Assay preparation—Transfer an accurately measured volume of Injection, equivalent to about 30 mg of dexamethasone, to a 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 254-nm detector and a 4.6-mm × 25-cm column that contains 5-µm packing L7. The flow rate is about 2 mL per minute. Chromatograph the *System suitability solution*, and record the peak responses as directed for *Procedure:* the relative retention times are about 0.4 for benzyl alcohol, 0.5 for methylparaben, 1.0 for dexamethasone, and 1.4 for propylparaben; and the resolution, *R,* between the neighboring peaks for benzyl alcohol and methylparaben, methylparaben and dexamethasone, and dexamethasone and propylparaben is not less than 3. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the peak responses for dexamethasone. Calculate the quantity, in mg, of dexamethasone ($C_{22}H_{29}FO_5$) in each mL of the Injection taken by the formula:

$$100(C/V)(r_U/r_S)$$

in which *C* is the concentration, in mg per mL, of USP Dexamethasone RS in the *Standard preparation; V* is the volume, in mL, of Injection 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 INJECTION	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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