Status: Currently Official on 14-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-F04E8A2A-BCF7-4B6C-A406-A6D264EE5E6D_2_en-US
DOI: https://doi.org/10.31003/USPNF_M23310_02_01
DOI Ref: qij5e

Dexamethasone Elixir

» Dexamethasone Elixir contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{22}H_{29}FO_5$.

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩—

USP Dexamethasone RS

Identification—Evaporate 9 mL of the *Assay preparation*, prepared as directed in the *Assay*, on a steam bath just to dryness, and dissolve the residue in 2 mL of a mixture of methylene chloride and methanol (1:1). Apply separately 5 µL of this solution and 5 µL of a solution of USP Dexamethasone RS in the mixture of methylene chloride and methanol (1:1), containing 0.5 mg per mL, to a thin-layer chromatographic plate coated with a 0.25-mm layer of chromatographic silica gel mixture (see *Chromatography ⟨621⟩*). Allow the spots to dry, and develop the chromatogram in a solvent system consisting of a mixture of chloroform, acetone, and glacial acetic acid (80:40:1) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, and allow the solvent to evaporate. Locate the spots by viewing under short-wavelength UV light: the R_F value of the principal spot obtained from the solution under test corresponds to that obtained from the Standard solution.

Alcohol Determination, *Method II* ⟨611⟩: between 3.8% and 5.7% of C_2H_5OH, *n*-propyl alcohol being used as the internal standard.

Assay—

Mobile phase—Prepare a filtered and degassed mixture of water and acetonitrile (2:1). Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

Standard preparation—Dissolve an accurately weighed quantity of USP Dexamethasone RS in dilute methanol (1 in 2), and dilute quantitatively, and stepwise if necessary, with dilute methanol (1 in 2) to obtain a solution having a known concentration of about 0.1 mg per mL.

Assay preparation—Transfer an accurately measured volume of Elixir, freshly mixed and free from air bubbles, equivalent to about 1 mg of dexamethasone, to a 10-mL volumetric flask, dilute with water to volume, mix, and filter through a suitable membrane filter.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 254-nm detector and a 4.6-mm × 30-cm column that contains packing L1. The flow rate is about 1.5 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed under *Procedure:* the relative standard deviation for replicate injections is not more than 3.0%.

Procedure—Separately inject equal volumes (between 5 µL and 25 µL) of the *Standard 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 $C_{22}H_{29}FO_5$ in each mL of the Elixir taken by the formula:

$$10(C/V)(r_U/r_S)$$

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 Elixir 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 ELIXIR	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 43(6)

Current DocID: GUID-F04E8A2A-BCF7-4B6C-A406-A6D264EE5E6D_2_en-US
Previous DocID: GUID-F04E8A2A-BCF7-4B6C-A406-A6D264EE5E6D_1_en-US
DOI: https://doi.org/10.31003/USPNF_M23310_02_01
DOI ref: qij5e