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Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension

» Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension is a sterile preparation of Betamethasone Sodium Phosphate in solution and Betamethasone Acetate in suspension in Water for Injection. It contains an amount of betamethasone sodium phosphate ($C_{22}H_{28}FNa_2O_8P$) equivalent to not less than 90.0 percent and not more than 115.0 percent of the labeled amount of betamethasone ($C_{22}H_{29}FO_5$), and not less than 90.0 percent and not more than 115.0 percent of the labeled amount of betamethasone acetate ($C_{24}H_{31}FO_6$).

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

USP Reference standards ⟨11⟩—
USP Betamethasone Acetate RS
USP Betamethasone Sodium Phosphate RS

Identification—

A: *Thin-layer chromatographic identification test* ⟨201⟩—

Test solution—Dilute 2 mL with 2 mL of methanol.

Standard solution—Prepare a solution of USP Betamethasone Sodium Phosphate RS in a mixture of methanol and water (1:1) having a concentration of 2 mg per mL.

Developing solvent system, Spray reagent, and *Procedure*—Proceed as directed for *Identification* test *B* under *Betamethasone sodium phosphate*.

B: *Test solution*—Use the *Test solution* prepared for *Identification* test *A*.

Standard solution—Prepare a solution of USP Betamethasone Acetate RS in a mixture of methanol and water (1:1) having a concentration of 1.5 mg per mL.

Developing solvent system and *Procedure*— Proceed as directed for *Identification* test *B* under *Betamethasone.*

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 29.2 USP Endotoxin Units per mg of betamethasone.

pH ⟨791⟩**:** between 6.8 and 7.2.

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

Assay—

Mobile phase—Prepare a filtered and degassed mixture of methanol and 0.075 M monobasic potassium phosphate (7:5). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Internal standard solution—Transfer about 50 mg of methyltestosterone to a 50-mL volumetric flask, add methanol to volume, and mix.

Standard preparation—Transfer about 63 mg of USP Betamethasone Sodium Phosphate RS, accurately weighed, to a 25-mL volumetric flask, add *Mobile phase* to volume, and mix (*Solution 1*). Transfer about 45 mg of USP Betamethasone Acetate RS, accurately weighed, to a 25-mL volumetric flask, add methanol to volume, and mix (*Solution 2*). Pipet 5 mL each of *Solution 1* and *Solution 2* into a 100-mL volumetric flask. Add 10.0 mL of *Internal standard solution*, dilute with *Mobile phase* to volume, and mix to obtain a *Standard preparation* having known concentrations of about 126 µg of USP Betamethasone Sodium Phosphate RS per mL and 90 µg of USP Betamethasone Acetate RS per mL.

Assay preparation—Using a "To contain" pipet transfer an accurately measured volume of the well-mixed Injectable Suspension, equivalent to about 9 mg of betamethasone acetate, to a 100-mL volumetric flask. Rinse the pipet with about 10 mL of *Mobile phase*, collecting the rinse in the volumetric flask. Add 10.0 mL of *Internal standard solution*, 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 3.9-mm × 30-cm column that contains packing L1. The flow rate is about 1.2 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the resolution, *R,* between the betamethasone phosphate and betamethasone acetate peaks is not less than 5.0, and the resolution, *R,* between the betamethasone acetate and internal standard peaks is not less than 3.0, and 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 responses for the major peaks. The relative retention times are about 0.5 for betamethasone phosphate, 1.7 for methyltestosterone, and 1.0 for betamethasone acetate. Calculate the quantity, in mg, of betamethasone acetate

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($C_{24}H_{31}FO_6$) in each mL of the Injectable Suspension taken by the formula:

$$0.1C/V(R_U/R_S)$$

in which C is the concentration, in µg per mL, of USP Betamethasone 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 response ratios obtained for betamethasone acetate and methyltestosterone from the *Assay preparation* and the *Standard preparation*, respectively. Calculate the quantity, in mg, of betamethasone ($C_{22}H_{29}FO_5$) equivalent to the quantity of betamethasone sodium phosphate ($C_{22}H_{28}FNa_2O_8P$), in each mL of the Injectable Suspension taken by the formula:

$$(392.46/516.41)(0.1C/V)(R_U/R_S)$$

in which 392.46 and 516.41 are the molecular weights of betamethasone and betamethasone sodium phosphate, respectively; C is the concentration, in µg per mL, of USP Betamethasone Sodium Phosphate RS in the *Standard preparation*; V is the volume, in mL, of Injectable Suspension taken; and R_U and R_S are the peak response ratios obtained for betamethasone phosphate and methyltestosterone 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
BETAMETHASONE SODIUM PHOSPHATE AND BETAMETHASONE ACETATE INJECTABLE SUSPENSION	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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