Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2018
Document Type: USP Monographs
DocId: GUID-84C3F62A-BB15-4B9A-BE85-0F929B50B9FD_3_en-US
DOI: https://doi.org/10.31003/USPNF_M9080_03_01
DOI Ref: bon8f



# Betamethasone Sodium Phosphate Injection

» Betamethasone Sodium Phosphate Injection is a sterile solution of Betamethasone Sodium Phosphate 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 110.0 percent of the labeled amount of betamethasone ($C_{22}H_{29}FO_5$).

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

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

**Identification**—Dilute the Injection with methanol, if necessary, to obtain a solution containing about 2 mg of betamethasone sodium phosphate per mL. Separately apply 10 µL of this test solution and 10 µL of a solution of USP Betamethasone Sodium Phosphate RS in methanol containing 2 mg per mL to a thin-layer chromatographic plate (see *Chromatography* ⟨621⟩) coated with chromatographic silica gel mixture. Develop the chromatogram in an equilibrated chamber containing *n*-butyl alcohol previously shaken with 1 N hydrochloric acid, until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, air-dry, then spray with a mixture of sulfuric acid, methanol, and nitric acid (10:10:1). Heat the plate at 105° for 10 minutes: the $R_F$ value of the principal spot from the test solution corresponds to that obtained from the Standard solution.

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

**pH** ⟨791⟩: between 8.0 and 9.0.

**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 methanol and 0.05 M monobasic potassium phosphate (1:1). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

*Internal standard solution*—Transfer about 100 mg of butylparaben to a 100-mL volumetric flask, add methanol to volume, and mix.

*Standard preparation*—Using an accurately weighed quantity of USP Betamethasone Sodium Phosphate RS, prepare a solution in water containing 4 mg per mL. Transfer 3.0 mL of this solution to a 25-mL volumetric flask, add 5.0 mL of *Internal standard solution*, dilute with water to volume, and mix to obtain a solution having a known concentration of about 0.5 mg of USP Betamethasone Sodium Phosphate RS per mL.

*Assay preparation*—Transfer an accurately measured volume of Injection, equivalent to about 9 mg of betamethasone, to a 25-mL volumetric flask. Add 5.0 mL of the *Internal standard solution*, dilute with water 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 2 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the resolution, *R,* between the analyte and internal standard peaks is not less than 5; 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 2.4 for butylparaben and 1.0 for betamethasone sodium phosphate. Calculate the quantity, in mg, of $C_{22}H_{29}FO_5$ in each mL of the Injection taken by the formula:

$$(392.47/516.41)(25C/V)(R_U/R_S)$$

in which 392.47 and 516.41 are the molecular weights of betamethasone and betamethasone sodium phosphate, respectively; *C* is the concentration, in mg per mL, of USP Betamethasone Sodium Phosphate RS in the *Standard preparation; V* is the volume, in mL, of Injection taken; and $R_U$ and $R_S$ are the peak response ratios 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 |
|---|---|---|
| BETAMETHASONE SODIUM PHOSPHATE INJECTION | Documentary Standards Support | SM52020 Small Molecules 5 |

**Chromatographic Database Information:** Chromatographic Database

**Most Recently Appeared In:**
Pharmacopeial Forum: Volume No. Information currently unavailable

**Current DocID: GUID-84C3F62A-BB15-4B9A-BE85-0F929B50B9FD_3_en-US**
**Previous DocID: GUID-84C3F62A-BB15-4B9A-BE85-0F929B50B9FD_1_en-US**
**DOI: https://doi.org/10.31003/USPNF_M9080_03_01**
**DOI ref: bon8f**