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Penicillin G Benzathine Injectable Suspension

» Penicillin G Benzathine Injectable Suspension is a sterile suspension of Penicillin G Benzathine in Water for Injection with one or more suitable buffers, dispersants, preservatives, and suspending agents. It contains not less than 90.0 percent and not more than 115.0 percent of the labeled amount of penicillin.

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

USP Reference standards ⟨11⟩—

USP Penicillin G Benzathine RS
USP Penicillin G Potassium RS

Change to read:

Identification—▲Mix a portion of it with methanol to obtain a solution containing about 3000 Penicillin G Units per mL. Apply 20 µL of this test solution and 20 µL of a Standard solution of USP Penicillin G Benzathine RS in methanol containing 2.5 mg per mL to a suitable thin-layer chromatographic plate (see *Chromatography ⟨621⟩*) coated with a 0.25-mm layer of chromatographic silica gel, and allow the spots to dry. Using an unlined developing chamber, develop the chromatogram in a solvent system consisting of a mixture of methanol, acetonitrile, and ammonium hydroxide (70:30:3) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, and allow to air-dry. Spray the plate uniformly with a spray reagent prepared as follows. Dissolve 20 g of tartaric acid and 1.7 g of bismuth subnitrate in 80 mL of water. Add 2.5 mL of this solution, 2.5 mL of potassium iodide solution (4 in 10), and 10 g of tartaric acid to 50 mL of water, and mix. Examine the chromatograms: the principal spot obtained from the test solution corresponds in R_F value to that obtained from the Standard solution.▲ (ERR 1-Dec-2022)

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 0.01 Endotoxin Unit per 100 Penicillin G Units.

Sterility Tests ⟨71⟩ —It meets the requirements when tested as directed for *Direct Inoculation of the Culture Medium* under *Test for Sterility of the Product to be Examined*, except to use Fluid Thioglycollate Medium and Soybean–Casein Digest Medium containing polysorbate 80 solution (1 in 200) and an amount of sterile penicillinase sufficient to inactivate the penicillin G in each vessel, and to shake the vessels once daily.

pH ⟨791⟩: between 5.0 and 7.5.

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

Assay—

Standard preparation—Using USP Penicillin G Potassium RS, prepare as directed for *Standard preparation* under *Iodometric Assay—Antibiotics ⟨425⟩*.

Assay preparation—Using a suitable hypodermic needle and syringe, withdraw an accurately measured volume of Injectable Suspension, equivalent to about 300,000 Penicillin G Units, and dilute quantitatively with 1.0 N sodium hydroxide to obtain an *Assay preparation* containing about 2000 Penicillin G Units per mL. Pipet 2.0 mL of this solution into a glass-stoppered, 125-mL conical flask.

Blank preparation—Using a suitable hypodermic needle and syringe, withdraw an accurately measured volume of Injectable Suspension, equivalent to about 300,000 Penicillin G Units, and quantitatively dilute with *Buffer B.1* to obtain a suspension containing about 2000 Penicillin G Units per mL. Pipet 2 mL of this solution into a glass-stoppered, 125-mL conical flask.

Procedure—Proceed as directed for *Procedure* under *Iodometric Assay—Antibiotics ⟨425⟩*, except in performing the *Inactivation and Titration* to omit the addition of 1.0 N sodium hydroxide to the *Assay preparation*, and in performing the *Blank Determination* to use the *Blank preparation* in place of the *Assay preparation.* Calculate the quantity, in Penicillin G Units, in each mL of the Injectable Suspension taken by the formula:

$$(L/2D)(F)(B - I)$$

in which L is the labeled quantity, in Penicillin G Units per mL, in the Injectable Suspension taken, and D is the concentration, in Penicillin G Units per mL, in the *Assay preparation* on the basis of the labeled quantity in the Injectable Suspension and the extent of dilution, and the other terms are as defined therein.

Topic/Question	Contact	Expert Committee
PENICILLIN G BENZATHINE INJECTABLE SUSPENSION	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

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