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Butorphanol Tartrate Injection

» Butorphanol Tartrate Injection is a sterile solution of Butorphanol Tartrate in Water for Injection. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{21}H_{29}NO_2 \cdot C_4H_6O_6$. It may contain a suitable preservative and a buffer.

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

USP Reference standards ⟨11⟩—

USP Butorphanol Tartrate RS

Identification—Apply 10-µL portions of the Injection and a Standard solution of USP Butorphanol Tartrate RS having the same concentration about 2 cm apart to a line parallel to and about 2 cm from the bottom of a thin-layer chromatographic plate (see *Chromatography* ⟨621⟩) coated with a 0.25-mm layer of chromatographic silica gel mixture. Place the plate in a developing chamber containing a mixture of chloroform, ethyl acetate, and methanol (40:10:9), and develop the chromatogram until the solvent front has moved about 10 cm above the line of application. Remove the plate, mark the solvent front, and allow the solvent to evaporate. Examine the plate 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. Benzethonium chloride, if present, is observed as a streaked zone near the point of application. Visualize the butorphanol spots by lightly spraying the plate with a 1 in 250 solution of bromocresol purple in dehydrated alcohol: butorphanol appears as a blue spot against a light yellow background.

pH ⟨791⟩**:** between 3.0 and 5.5.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 88.0 USP Endotoxin Units per mg of butorphanol tartrate.

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

Assay—

Mobile phase—Prepare a mixture of 0.05 M ammonium acetate and acetonitrile (3:1) adjusted by the addition of glacial acetic acid to a pH of 4.1. The mixture is appropriately filtered and degassed.

Internal standard solution—Dissolve about 50 mg of propylparaben in 5.0 mL of methanol contained in a 250-mL volumetric flask. Add water to volume, and mix.

Standard preparation—Transfer about 50 mg of USP Butorphanol Tartrate RS, accurately weighed, to a 25-mL volumetric flask containing 1.0 mL of 1 N sulfuric acid. Swirl the flask to dissolve the powder completely, add water to volume, and mix. Pipet 5 mL of the resulting solution into a 50-mL volumetric flask containing 10.0 mL of *Internal standard solution*. Add water to volume, mix, and filter through a microporous filter, discarding the first 5 mL of the filtrate and collecting the remainder in a suitable container.

Assay preparation—Transfer an accurately measured volume of Injection, equivalent to about 10 mg of butorphanol tartrate, to a 50-mL volumetric flask. Add 10.0 mL of *Internal standard solution*, mix, add water to volume, and mix. Filter through a microporous filter, discarding the first 5 mL of the filtrate and collecting the remainder in a suitable container.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 280-nm detector and a 4-mm × 30-cm column that contains packing L11. The flow rate is about 2 mL per minute. Chromatograph five replicate injections of the *Standard preparation*, and record the peak responses as directed for *Procedure:* the relative standard deviation is not more than 1.5%, and the capacity factor for butorphanol tartrate is not less than 2.0.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, adjusting the flow rate and other operating parameters, if necessary, until satisfactory chromatography and peak responses are obtained. Record the chromatograms, and measure the responses for the major peaks. The relative retention times are about 1.7 for propylparaben and 1.0 for butorphanol tartrate. Calculate the quantity, in mg, of $C_{21}H_{29}NO_2 \cdot C_4H_6O_6$ in each mL of the Injection taken by the formula:

$$50(C/V)(R_U/R_S)$$

in which C is the concentration, in mg per mL, of USP Butorphanol Tartrate 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 of the butorphanol tartrate peak and the internal standard peak 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
BUTORPHANOL TARTRATE INJECTION	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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