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Droperidol Injection

» Droperidol Injection is a sterile solution of Droperidol in Water for Injection, prepared with the aid of Lactic Acid. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{22}H_{22}FN_3O_2$, as the lactate.

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

USP Reference standards ⟨11⟩—

USP Droperidol RS

Identification—

A: Dissolve about 25 mg of USP Droperidol RS in 10 mL of water containing 0.3 mL of 50% acetic acid in a separator to obtain a solution containing about 2.5 mg per mL. Transfer a volume of Injection, equivalent to about 25 mg of droperidol, to a second separator. Separately add 2 mL of ammonia TS to each separator, and mix. Extract each solution with two 10-mL portions of chloroform, collecting the chloroform extracts from the solutions in separate 50-mL beakers. Apply separately 20 µL of the test solution and the Standard solution to a thin-layer chromatographic plate (see *Chromatography ⟨621⟩*) coated with a 0.25-mm layer of chromatographic silica gel. Allow the spots to dry, and develop the chromatogram in a chamber with an unequilibrated solvent system consisting of a mixture of ethyl acetate, chloroform, methanol, and acetate buffer (0.2 M sodium acetate adjusted with 50% acetic acid to a pH of 4.7) (54:23:18:5) 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 on the plate by lightly spraying with dinitrophenylhydrazine TS, then examine under short-wavelength UV light: the R_F value of the principal spot obtained from the test solution corresponds to that obtained from the Standard solution.

B: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation* as obtained in the *Assay*.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 35.7 USP Endotoxin Units per mg of droperidol.

pH ⟨791⟩: between 3.0 and 3.8.

Chromatographic purity—

Mobile phase, System suitability preparation, Standard stock preparation, Standard preparation, and *Chromatographic system*—Proceed as directed in the *Assay.*

Test preparation—Use the *Assay preparation.*

Procedure—Inject a volume (about 100 µL) of the *Test preparation* into the chromatograph, record the chromatogram of twice the retention time of droperidol, and measure the peak responses. Calculate the percentage of each impurity in the portion of Droperidol taken by the formula:

$$100(r_i/r_s)$$

in which r_i is the peak response for each impurity, and r_s is the sum of the responses of all the peaks: the sum of all impurities is not more than 2.0%.

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

Assay—

Borate buffer—Dissolve 31 g of boric acid in about 800 mL of water. Slowly add sodium hydroxide solution (1 in 5) in small quantities until all of the boric acid is dissolved and the pH is constant at 7.0. Quantitatively transfer the solution to a glass-stoppered, 1000-mL volumetric flask, dilute with water to volume, and mix.

Mobile phase—Prepare a filtered and degassed mixture of methanol, water, and *Borate buffer* (700:280:20). Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

Standard stock preparation—Dissolve an accurately weighed quantity of USP Droperidol RS in methanol to obtain a solution having a known concentration of about 1 mg per mL.

Standard preparation—Transfer 5.0 mL of *Standard stock preparation* to a 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

System suitability preparation—Prepare a solution of 4'-fluoroacetophenone in methanol containing about 1 mg per mL. Transfer 5.0 mL of this solution and 5.0 mL of *Standard stock preparation* to a 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

Assay preparation—Transfer an accurately measured volume of Injection, equivalent to about 5 mg of droperidol, to a 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 280-nm detector and a 4.6-mm × 25-cm column that contains 10-µm packing L1. The flow rate is about 1.0 mL per minute. Chromatograph the *System suitability preparation* and the *Standard preparation*, and record the peak responses as directed for *Procedure:* the resolution, *R,* between 4'-fluoroacetophenone and droperidol is not less than 5.0; the tailing factor for the analyte peak is not more than 2.0; and the relative standard deviation for replicate injections of the *Standard preparation* is not more than 1.5%.

Procedure—Separately inject equal volumes (about 10 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 droperidol ($C_{22}H_{22}FN_3O_2$) in each mL of the Injection taken by the formula:

$$100(C/V)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Droperidol RS in the *Standard preparation;* V is the volume, in mL, of Injection 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
DROPERIDOL INJECTION	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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