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Isoproterenol Hydrochloride Injection

» Isoproterenol Hydrochloride Injection is a sterile solution of Isoproterenol Hydrochloride in Water for Injection. It contains not less than 90.0 percent and not more than 115.0 percent of the labeled amount of isoproterenol hydrochloride ($C_{11}H_{17}NO_3 \cdot HCl$).

Packaging and storage—Preserve in single-dose containers, preferably of Type I glass, protected from light. Store at controlled room temperature.

Labeling—Label it to indicate that the Injection is not to be used if its color is pinkish or darker than slightly yellow or if it contains a precipitate.

USP Reference standards ⟨11⟩—
USP Isoproterenol Hydrochloride RS

Change to read:

Color and clarity—

▲*Standard solution*—Transfer 2.0 mL of 0.100 N iodine VS to a 500-mL volumetric flask, dilute with water to volume, and mix.
Procedure—Visually examine a portion of the Injection (*Test solution*) in a suitable clear glass test tube against a white background: it is not pinkish and it contains no precipitate. If any yellow color is observed in the *Test solution*, concomitantly determine the absorbances of the *Test solution* and the *Standard solution* in 1-cm cells with a suitable spectrophotometer set at 460 nm: the absorbance of the *Test solution* does not exceed that of the *Standard solution*.▲ (ERR 1-Dec-2021)

Identification—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 1250.0 USP Endotoxin Units per mg of isoproterenol hydrochloride.

pH ⟨791⟩**:** between 2.5 and 4.5.

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—Dissolve 1.76 g of sodium 1-heptanesulfonate in 800 mL of water. Add 200 mL of methanol, and adjust with 1 M phosphoric acid to a pH of 3.0 ± 0.1. Pass the solution through a membrane filter having a 1-µm or finer porosity.
Standard preparation—Dissolve an accurately weighed quantity of USP Isoproterenol Hydrochloride RS in freshly prepared sodium bisulfite solution (1 in 1000) to obtain a solution having a known concentration of about 20 µg per mL.
Resolution solution—Prepare a solution of epinephrine bitartrate in freshly prepared *Mobile phase* containing 1.0% of sodium bisulfite, having a concentration of about 200 µg per mL. Mix 2.0 mL of this solution and 18.0 mL of the *Standard preparation.*
Assay preparation—Quantitatively dilute an accurately measured volume of Injection with freshly prepared sodium bisulfite solution (1 in 1000) to obtain a solution having a concentration of about 20 µg per mL.
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 L1. The flow rate is about 2 mL per minute. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the relative standard deviation for replicate injections is not more than 1.5%. Chromatograph the *Resolution solution:* the relative retention times are about 0.55 for epinephrine and 1.0 for isoproterenol; the resolution, *R,* for epinephrine and isoproterenol is not less than 3.5; and the tailing factors for the epinephrine and isoproterenol peaks are not more than 2.5.
Procedure—Separately inject equal volumes (about 100 µL) of the *Standard preparation* and the *Assay preparation,* record the chromatograms, and measure the peak responses. Calculate the quantity, in mg, of isoproterenol hydrochloride ($C_{11}H_{17}NO_3 \cdot HCl$) in each mL of the Injection taken by the formula:

$$C(L/D)(r_U/r_S)$$

in which C is the concentration, in µg per mL, of USP Isoproterenol Hydrochloride RS in the *Standard preparation; L* is the labeled quantity, in µg per mL, of isoproterenol hydrochloride in the Injection; D is the concentration, in µg per mL, of isoproterenol hydrochloride in the *Assay preparation,* on the basis of the labeled quantity in each mL and the extent of dilution; and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Topic/Question	Contact	Expert Committee
ISOPROTERENOL HYDROCHLORIDE INJECTION	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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