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# Isoxsuprine Hydrochloride Tablets

» Isoxsuprine Hydrochloride Tablets contain not less than 93.0 percent and not more than 107.0 percent of the labeled amount of $C_{18}H_{23}NO_3 \cdot HCl$.

**Packaging and storage**—Preserve in tight containers.

**USP Reference standards** ⟨11⟩—
USP Isoxsuprine Hydrochloride RS

**Identification**—Transfer a portion of finely powdered Tablets, equivalent to about 10 mg of isoxsuprine hydrochloride, to a 60-mL beaker, add about 20 mL of water, mix, and filter. Transfer the clear filtrate to a 60-mL separator, add 10 mL of pH 9.0 alkaline borate buffer (see *Buffer Solutions* in the section *Reagents, Indicators, and Solutions*), and shake vigorously to mix. Extract with 2 mL of chloroform, filter the extract through a pledget of cotton, and mix the filtrate with 500 mg of potassium bromide. Evaporate the chloroform, carefully removing the last trace of solvent in a small vacuum flask: the IR absorption spectrum of a potassium bromide dispersion of the isoxsuprine so obtained exhibits maxima only at the same wavelengths as that of a similar preparation of USP Isoxsuprine Hydrochloride RS that has been treated in the same manner.

**Dissolution** ⟨711⟩—
*Medium:* water; 900 mL.
*Apparatus 1:* 100 rpm.
*Time:* 45 minutes.
*Procedure*—Determine the amount of $C_{18}H_{23}NO_3 \cdot HCl$ dissolved from UV absorbances at the wavelength of maximum absorbance at about 269 nm of filtered portions of the solution under test, suitably diluted with *Dissolution Medium*, if necessary, in comparison with a Standard solution having a known concentration of USP Isoxsuprine Hydrochloride RS in the same medium.
*Tolerances*—Not less than 75% *(Q)* of the labeled amount of $C_{18}H_{23}NO_3 \cdot HCl$ is dissolved in 45 minutes.

**Uniformity of dosage units** ⟨905⟩: meet the requirements.

**Assay**—
*Buffer solution*—Transfer about 1.32 g of anhydrous dibasic ammonium phosphate to a 1-liter volumetric flask, add about 950 mL of water, and mix. Adjust with phosphoric acid to a pH of 7.5, dilute with water to volume, and mix.
*Mobile phase*—Prepare a filtered and degassed mixture of methanol and *Buffer solution* (2:1). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).
*Standard preparation*—Dissolve an accurately weighed quantity of USP Isoxsuprine Hydrochloride RS in *Mobile phase*, and dilute quantitatively, and stepwise if necessary, with *Mobile phase* to obtain a solution having a known concentration of about 0.4 mg per mL.
*Assay preparation*—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 20 mg of isoxsuprine hydrochloride, to a 50-mL volumetric flask, and add about 25 mL of *Mobile phase*. Shake by mechanical means for 30 minutes, sonicate for ten minutes to dissolve, dilute with *Mobile phase* to volume, mix, and filter.
*Chromatographic system* (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 274-nm detector and a 3.9-mm × 30-cm column that contains packing L1. The flow rate is about 1.5 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the column efficiency is not less than 1800 theoretical plates, 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. Calculate the quantity, in mg, of $C_{18}H_{23}NO_3 \cdot HCl$ in the portion of Tablets taken by the formula:

$$50C(r_U/r_S)$$

in which $C$ is the concentration, in mg per mL, of USP Isoxsuprine Hydrochloride RS in the *Standard preparation;* and $r_U$ and $r_S$ are the 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 |
|---|---|---|
| ISOXSUPRINE HYDROCHLORIDE TABLETS | Documentary Standards Support | SM22020 Small Molecules 2 |
| REFERENCE STANDARD SUPPORT | RS Technical Services<br>RSTECH@usp.org | SM22020 Small Molecules 2 |

**Chromatographic Database Information:** Chromatographic Database

**Most Recently Appeared In:**
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