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Trihexyphenidyl Hydrochloride Oral Solution

» Trihexyphenidyl Hydrochloride Oral Solution contains not less than 90.0 percent and not more than 110.0 percent of trihexyphenidyl hydrochloride ($C_{20}H_{31}NO \cdot HCl$).

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩—
USP Trihexyphenidyl Hydrochloride RS

Identification—

A: To 50 mL of Oral Solution add 50 mL of water and 50 mL of 1 N sodium hydroxide, and stir. Cool the mixture at 4° to 5° for 30 minutes: a white precipitate or cloudiness is observed. Add 100 mL of water to the cooled mixture, stir, and filter by means of vacuum through a 47-mm membrane filter of 1-µm pore size. Wash the crystals with about 100 mL of water, and allow to air-dry: the IR absorption spectrum of a potassium bromide dispersion of the crystals so obtained exhibits maxima only at the same wavelengths as that of the crystalline base obtained from about 20 mg of USP Trihexyphenidyl Hydrochloride RS, similarly prepared and measured.

B: The retention time exhibited by trihexyphenidyl hydrochloride in the chromatogram of the *Assay preparation* corresponds to that of the *Standard preparation* as obtained in the *Assay*.

pH ⟨791⟩: between 2.0 and 3.0.

Alcohol Determination ⟨611⟩: between 90.0% and 110.0% of the labeled amount of C_2H_5OH.

Assay—

Mobile phase—Prepare a mixture of acetonitrile, water, and triethylamine (920:80:0.2), adjust with phosphoric acid to a pH of 4.0, mix, filter, and degas. Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

Standard preparation—Dissolve an accurately weighed quantity of USP Trihexyphenidyl Hydrochloride RS in methanol, and dilute quantitatively, and stepwise if necessary, with methanol to obtain a solution having a known concentration of about 0.08 mg per mL.

Assay preparation—Transfer an accurately measured volume of Oral Solution, equivalent to about 2 mg of trihexyphenidyl hydrochloride, to a 25-mL volumetric flask, dilute with methanol to volume, and mix.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 210-nm detector and a 4.6-mm × 8-cm column that contains 3-µm 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 column efficiency determined from the analyte peak is not less than 1300 theoretical plates, the tailing factor for the analyte peak is not more than 3.0, and the relative standard deviation for replicate injections is not more than 1.0%.

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 trihexyphenidyl hydrochloride ($C_{20}H_{31}NO \cdot HCl$) in each mL of the Oral Solution taken by the formula:

$$(25C/V)(r_U/r_S)$$

in which V is the volume, in mL, of Oral Solution taken to prepare the *Assay preparation*, C is the concentration, in mg per mL, of USP Trihexyphenidyl Hydrochloride RS in the *Standard preparation*, r_U and r_S are the trihexyphenidyl 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
TRIHEXYPHENIDYL HYDROCHLORIDE ORAL SOLUTION	Documentary Standards Support	SM42020 Small Molecules 4

Topic/Question	Contact	Expert Committee
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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