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Oxybutynin Chloride Oral Solution

» Oxybutynin Chloride Oral Solution contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{22}H_{31}NO_3 \cdot HCl$.

Packaging and storage—Preserve in tight, light-resistant containers.

USP Reference standards ⟨11⟩—

USP Oxybutynin Chloride RS

Identification—Place a volume of Oral Solution, equivalent to about 50 mg of oxybutynin chloride, in a separator, and extract with 10 mL of chloroform. The extract so obtained responds to the *Thin-Layer Chromatographic Identification Test* ⟨201⟩, methanol being used as the developing solvent, and iodine vapor being used to visualize the spots.

Assay—

pH 4 Phosphate buffer—Place 38 mL of 0.2 M dibasic sodium phosphate in a 100-mL volumetric flask. Dilute with 0.1 M citric acid to volume, and mix. Adjust the pH, if necessary, with either the dibasic sodium phosphate solution or the citric acid solution.

pH 5.6 Phosphate buffer—Place 58 mL of 0.2 M dibasic sodium phosphate in a 100-mL volumetric flask. Dilute with 0.1 M citric acid to volume, and mix. Adjust the pH, if necessary, with either the dibasic sodium phosphate solution or the citric acid solution.

Bromocresol green solution—Transfer 125 mg of bromocresol green to a 25-mL volumetric flask, dissolve in 3.5 mL of 0.05 N sodium hydroxide, dilute with water to volume, and mix.

Standard preparation—Dissolve an accurately weighed quantity of USP Oxybutynin Chloride RS in 0.05 N sulfuric acid to obtain a solution having a known concentration of about 100 µg per mL.

Assay preparation—Transfer an accurately measured volume of Oral Solution, equivalent to about 10 mg of oxybutynin chloride, to a 100-mL volumetric flask, dilute with water to volume, and mix.

Procedure—Separately transfer 10.0 mL of the *Standard preparation* and the *Assay preparation* to separate 125-mL separators. Add 20 mL of *pH 4 Phosphate buffer* to each separator, and extract each solution with a 25-mL portion of chloroform. [Note—Allow at least 10 minutes for the layers to separate.] Collect the chloroform extracts in respective 125-mL separators, each containing a mixture of 2 mL of *pH 5.6 Phosphate buffer* and 1 mL of *Bromocresol green solution*. Shake the separators, and filter the chloroform extracts through rayon pledgets, collecting the extracts in respective 100-mL volumetric flasks. Repeat the double extractions with 25-mL portions of chloroform. Wash the rayon pledgets with chloroform, collecting the washings in the respective 100-mL volumetric flasks. Dilute both solutions with chloroform to volume, and mix. Concomitantly determine the absorbances of both solutions at the wavelength of maximum absorbance at about 415 nm, with a suitable spectrophotometer, against a blank prepared using 10 mL of 0.05 N sulfuric acid treated in the same manner as the *Standard preparation* and the *Assay preparation*. Calculate the quantity, in mg, of $C_{22}H_{31}NO_3 \cdot HCl$ in each mL of Oral Solution taken by the formula:

$$(0.1C/V)(A_U/A_S)$$

in which C is the concentration, in µg per mL, of USP Oxybutynin Chloride RS in the *Standard preparation; V* is the volume, in mL, of Oral Solution taken; and A_U and A_S are the absorbances of the solutions 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
OXYBUTYNIN CHLORIDE ORAL SOLUTION	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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