Oxybutynin Chloride Tablets

» Oxybutynin Chloride Tablets contain 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.

Add the following:

•**Labeling—**When more than one *Dissolution* test is given, the labeling states the *Dissolution* test used only if *Test 1* is not used.• (RB 1-Dec-2009)

USP Reference standards ⟨11⟩**—***USP Oxybutynin Chloride RS*.

Identification—Add a portion of powdered Tablets, equivalent to about 50 mg of oxybutynin chloride, to 10 mL of chloroform. Mix for 2 minutes, and centrifuge. The supernatant layer of the solution 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.

Change to read:

Dissolution ⟨711⟩

•TEST 1—•(RB 1-Dec-2009)

Medium: water; 900 mL.

Apparatus 2: 50 rpm.

Time: 30 minutes.

Procedure—Determine the amount of $C_{22}H_{31}NO_3 \cdot HCl$ dissolved using the method set forth in the *Assay*, making any necessary modifications to the concentration of the *Standard preparation* to correspond to that of the solution under test.

Tolerances—Not less than 80% *(Q)* of the labeled amount of $C_{22}H_{31}NO_3 \cdot HCl$ is dissolved in 30 minutes.

•TEST 2—If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

Medium: 0.01 N hydrochloric acid; 900 mL.

Apparatus 2: 50 rpm.

Time: 30 minutes.

Standard solution—Dilute an accurately weighed quantity of USP Oxybutynin Chloride RS with *Medium* to obtain a final concentration of 5 µg per mL. This solution is stable for 5 days at ambient conditions.

Test solution—Pass a portion of the solution under test through a suitable 0.45-µm filter, discarding the first few mL.

Mobile phase—Prepare a filtered and degassed mixture of water, acetonitrile, and phosphoric acid (760 : 240 : 1). Make adjustments if necessary (see *Chromatography* ⟨621⟩*, System Suitability*).

Chromatographic system (see *Chromatography* ⟨621⟩*, System Suitability*)—The liquid chromatograph is equipped with a 203-nm detector and a 4.6-mm × 7.5-cm column that contains 3.5-µm packing L7. The column is maintained at 40°. The flow rate is about 1.5 mL per minute. Chromatograph the *Standard solution*, and record the peak responses as directed for *Procedure*: the tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more than 3.0%.

Procedure—Separately inject equal volumes (about 100 µL) of the *Standard solution* and *Test solution* into the chromatograph, record the chromatograms, and measure the peak responses. Calculate the percentage of oxybutynin chloride dissolved by the formula:

$$\frac{r_U \times C_S \times 900 \times 100}{r_S \times L}$$

in which r_U and r_S are the peak responses obtained from the *Test solution* and *Standard solution*, respectively; C_S is the concentration, in mg per mL, of oxybutynin chloride in the *Standard solution*; 900 is the volume, in mL, of *Medium*; 100 is the conversion factor to percentage; and L is the Tablet label claim, in mg.

Tolerances—Not less than 80% *(Q)* of the labeled amount of $C_{22}H_{31}NO_3 \cdot HCl$ is dissolved in 30 minutes.• (RB 1-Dec-2009)

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

Assay—

Solvent A—Add about 0.9 mL of triethylamine to a filtered and deaerated mixture of water and methanol (3200 : 800). Adjust with phosphoric acid to a pH of 3.5 ± 0.05.

Mobile phase—Prepare a degassed and filtered mixture of *Solvent A* and acetonitrile (80 : 20).

Standard preparation—Prepare a solution of USP Oxybutynin Chloride RS in *Mobile phase* having an accurately known concentration of about 0.05 mg per mL.

Assay preparation—Weigh and finely powder not less than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 50 mg of oxybutynin chloride, to a 1000-mL volumetric flask, add about 400 mL of *Mobile phase*, sonicate for about 10 minutes, shake by mechanical means for about 45 minutes, dilute with *Mobile phase* to volume, and mix.

Chromatographic system—The liquid chromatograph is equipped with a 203-nm detector, and a 4-mm × 30-cm column that contains packing L10. The flow rate is about 2 mL per minute. Chromatograph the *Standard preparation*, and record the chromatogram as directed for *Procedure:* the tailing factor is not more than 2.0, and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separatel y 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 $C_{22}H_{31}NO_3 \cdot HCl$ in the portion of Tablets taken by the formula:

$$1000 \times C \times (r_U / r_S)$$

in which C is the concentration, in mg per mL, of USP Oxybutynin Chloride RS in the *Standard preparation*, and r_U and r_S are the oxybutynin peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.