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 areas for the major peaks. Calculate the quantity, in mg, of C₉H₉Cl₂N₃O · HCl in the portion taken by the formula:

$$1.25C(r_0/r_s)$$

in which C is the concentration, in µg per mL, of USP Guanfacine Hydrochloride RS in the Standard preparation; and r₀ and rₛ are the guanfacine hydrochloride peaks obtained from the Assay preparation and the Standard preparation, respectively.

Dissolution (711)—
Medium: water; 500 mL.
Apparatus 2: 50 rpm.
Time: 45 minutes.
Procedure—Determine the amount of C₆H₆Cl₂N₂O dissolved, employing the procedure set forth in the Assay and making any necessary modifications.
Tolerances—Not less than 75% (Q) of the labeled amount of C₆H₆Cl₂N₂O is dissolved in 45 minutes.

Uniformity of dosage units (905): meet the requirements.

Assay—

pH 2.5 Diethylamine phosphate solution—Add 10.3 mL of diethylamine to about 70 mL of water. Adjust with phosphoric acid to a pH of 2.5, dilute with water to 100 mL, and mix.
Reagent solution—Dissolve an accurately weighed quantity of 2,6-dichlorophenylacetic acid in Mobile phase, and dilute quantitatively, and stepwise if necessary, to obtain a solution having a known concentration of about 18 µg per mL.

Mobile phase—Dissolve 600 mg of monobasic potassium phosphate and 3 mL of pH 2.5 Diethylamine phosphate solution in 480 mL of water, and mix. Adjust with 0.2 N sodium hydroxide to a pH of 4.0. While swirling, add 520 mL of acetonitrile. Filter and degas. Make adjustments if necessary (see System Suitability under Chromatography (621)).

Internal standard solution—Prepare a solution of butylparaben in Mobile phase containing 0.5 mg per mL.

Standard preparation—Dissolve an accurately weighed quantity of USP Guanfacine Hydrochloride RS in Mobile phase to obtain a solution having a known concentration of about 0.23 mg per mL. Transfer 5.0 mL of this solution to a 25-mL volumetric flask, and add 5.0 mL each of the Buffer solution and the Reagent solution and the Internal standard solution. Dilute with Mobile phase to volume, and mix.

Assay preparation—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 10 mg of guanfacine, to a 100-mL volumetric flask. Add 50 mL of Mobile phase, and heat on a steam bath for 5 minutes. Cool to room temperature, dilute with Mobile phase to volume, and mix. Transfer 10.0 mL of this solution to a 25-mL volumetric flask, add 5.0 mL of Internal standard solution, dilute with Mobile phase to volume, and mix.

Assay preparation—Transfer an accurately weighed quantity of about 50 mg of Guanfacine Hydrochloride to a 50-mL volumetric flask, dissolve in and dilute with a mixture of acetonitrile and water (3:1) to volume, and mix. Transfer 2.0 mL of this solution to a 50-mL volumetric flask, dilute with Mobile phase to volume, and mix.

Chromatographic system (see Chromatography (621))—The liquid chromatograph is equipped with a 220-nm detector and a 4.6-mm × 15-cm column that contains packing L1. The flow rate is about 1 mL per minute. Chromatograph the Standard preparation, and record the responses as directed for Procedure: the capacity factor, k', is between 2 and 5; the column efficiency is not less than 1500 theoretical plates; the tailing factor is not more than 2; and the relative standard deviation for replicate injections is not more than 2.0%.

Internal standard solution—Prepare a solution of butylparaben in Mobile phase containing 0.5 mg per mL.

Standard preparation—Dissolve an accurately weighed quantity of USP Guanfacine Hydrochloride RS in Mobile phase to obtain a solution having a known concentration of about 0.23 mg per mL. Transfer 5.0 mL of this solution to a 25-mL volumetric flask, and add 5.0 mL each of the Buffer solution and the Reagent solution and the Internal standard solution. Dilute with Mobile phase to volume, and mix.

Assay preparation—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 10 mg of guanfacine, to a 100-mL volumetric flask. Add 50 mL of Mobile phase, and heat on a steam bath for 5 minutes. Cool to room temperature, dilute with Mobile phase to volume, and mix. Transfer 10.0 mL of this solution to a 25-mL volumetric flask, add 5.0 mL of Internal standard solution, dilute with Mobile phase to volume, and mix.

Chromatographic system (see Chromatography (621))—The liquid chromatograph is equipped with a 220-nm detector and a 3.9-mm × 30-cm column that contains packing L1. The flow rate is about 1 mL per minute. Chromatograph the Standard preparation, and record the peak responses as directed for Procedure: the relative retention times are about 0.4 for guanfacine, 0.6 for 2,6-dichlorophenylacetic acid, and 1.0 for butylparaben; the resolution, R, between guanfacine and 2,6-dichlorophenylacetic acid is not less than 1.5, and the resolution, R, between 2,6-dichlorophenylacetic acid and butylparaben is not less than 1.5; and the relative standard deviation for replicate injections is not more than 2.0%.

Internal standard solution—Prepare a solution of butylparaben in Mobile phase containing 0.5 mg per mL.

Standard preparation—Dissolve an accurately weighed quantity of USP Guanfacine Hydrochloride RS in Mobile phase to obtain a solution having a known concentration of about 0.23 mg per mL. Transfer 5.0 mL of this solution to a 25-mL volumetric flask, and add 5.0 mL each of the Buffer solution and the Reagent solution and the Internal standard solution. Dilute with Mobile phase to volume, and mix.

Assay preparation—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 µg, of guanfacine (C₉H₉Cl₂N₃O · HCl) in the portion of Tablets taken by the formula:

$$\text{calculated concentration} = \frac{(246.09 + 282.55) \times 0.25 \left( \frac{C}{R_0} / \frac{R_s}{R_0} \right)}{C}$$

in which 246.09 and 282.55 are the molecular weights of guanfacine and guanfacine hydrochloride, respectively; C is the concentration, in µg per mL, of USP Guanfacine Hydrochloride RS in the Standard preparation; and R₀ and Rₛ are the peak response ratios of guanfacine to butylparaben obtained from the Assay preparation and the Standard preparation, respectively.

Guanfacine Tablets

Guanfacine Tablets contain an amount of Guanfacine Hydrochloride (C₉H₉Cl₂N₃O · HCl) equivalent to not less than 90.0 per cent and not more than 110.0 per cent of the labeled amount of guanfacine (C₉H₉Cl₂N₃O).
**Gutta Percha**

» Gutta Percha is the coagulated, dried, purified latex of the trees of the genera *Palaquium* and *Payena* and most commonly *Palaquium gutta* (Hooker) Baillon (Fam. Sapotaceae).

**Packaging and storage**—Preserve under water in well-closed containers, protected from light.

**Residue on ignition** (281): not more than 1.7%.