mg, of pseudoephedrine sulfate $[(C_{10}H_{15}NO)_2 \cdot H_2SO_4]$ in the portion of Tablets taken by the formula:

$$50C(r_U / r_S)$$

in which the terms are as defined therein, pseudoephedrine sulfate being substituted for pseudoephedrine hydrochloride.

Assay for acetaminophen *(if present)*—

Mobile phase—Prepare a filtered and degassed mixture of water, methanol, and glacial acetic acid (79:20:1). Make adjustments, if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Transfer about 50 mg of USP Acetaminophen RS, accurately weighed, to a 100-mL volumetric flask. Add 4 mL of methanol, and mix until solution is complete. Dilute with 0.1% phosphoric acid to volume, and mix.

Assay preparation—Weigh and powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 100 mg of acetaminophen, to a 50-mL volumetric flask. Add about 7.5 mL of methanol, and sonicate to disperse the powder. Add 0.5 mL of phosphoric acid, dilute with water to volume, mix, and filter. Transfer 25.0 mL of the filtered solution to a 100-mL volumetric flask, dilute with water to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 280-nm detector and a 4.6-mm × 15-cm column that contains packing L7. The flow rate is about 1 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the tailing factor for the acetaminophen peak is not greater than 2.0, and the relative standard deviation for replicate injections is not more than 2.0%.

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 acetaminophen peaks. Calculate the quantity, in mg, of acetaminophen ($C_8H_9NO_2$) in the portion of Tablets taken by the formula:

$$200C(r_U / r_S)$$

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

Assay for chlorpheniramine maleate *(if present)*—

Mobile phase and *Chromatographic system*—Proceed as directed in the *Assay for pseudoephedrine hydrochloride.*

Standard preparation—Dissolve an accurately weighed quantity of USP Chlorpheniramine Maleate RS in water to obtain a solution having a known concentration of about 0.8 mg per mL. Quantitatively dilute a portion of this solution with 0.1% phosphoric acid to obtain a solution having a known concentration of about 8 µg per mL.

Assay preparation—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 2 mg of chlorpheniramine maleate, to a 250-mL volumetric flask. Add 25 mL of methanol, and sonicate to disperse the powder. Add 1 mL of phosphoric acid, dilute with water to volume, mix, and filter.

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 chlorpheniramine peaks. Calculate the quantity, in mg, of chlorpheniramine maleate $(C_{16}H_{19}ClN_2 \cdot C_4H_4O_4)$ in the portion of Tablets taken by the formula:

$$250C(r_U / r_S)$$

in which C is the concentration, in mg per mL, of USP Chlorpheniramine Maleate RS in the *Standard preparation;* and r_U and r_S are the peak responses for chlorpheniramine obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Assay for dextromethorphan hydrobromide *(if present)*—

Mobile phase and *Chromatographic system*—Proceed as directed in the *Assay for pseudoephedrine hydrochloride.*

Standard preparation—Dissolve an accurately weighed quantity of USP Dextromethorphan Hydrobromide RS in water to obtain a solution having a known concentration of about 0.6 mg per mL. Quantitatively dilute a portion of this solution with 0.1% phosphoric acid to obtain a solution having a known concentration of about 0.06 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 6 mg of dextromethorphan hydrobromide, to a 100-mL volumetric flask. Add 10 mL of methanol, and sonicate to disperse the powder. Add 0.4 mL of phosphoric acid, dilute with water to volume, mix, and filter.

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 peak responses for the dextromethorphan peaks. Calculate the quantity, in mg, of dextromethorphan hydrobromide $(C_{18}H_{25}NO \cdot HBr \cdot H_2O)$ in the portion of Tablets taken by the formula:

$$(370.33 / 352.32)(100C)(r_U / r_S)$$

in which 370.33 and 352.32 are the molecular weights of dextromethorphan hydrobromide monohydrate and anhydrous dextromethorphan hydrobromide, respectively; C is the concentration, in mg per mL, of USP Dextromethorphan Hydrobromide RS in the *Standard preparation;* and r_U and r_S are the dextromethorphan peak responses obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Acetaminophen, Chlorpheniramine Maleate, and Dextromethorphan Hydrobromide Tablets

DEFINITION

Acetaminophen, Chlorpheniramine Maleate, and Dextromethorphan Hydrobromide Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of acetaminophen ($C_8H_9NO_2$), chlorpheniramine maleate ($C_{16}H_{19}ClN_2 \cdot C_4H_4O_4$), and dextromethorphan hydrobromide monohydrate ($C_{18}H_{25}NO \cdot HBr \cdot H_2O$).

IDENTIFICATION

- **A.** The retention time of the major peak for acetaminophen of the *Sample solution* corresponds to that of the *Standard solution,* as obtained in the *Assay* for *Acetaminophen.*
- **B.** The retention time of the major peak for chlorpheniramine of the *Sample solution* corresponds to that of the *Standard solution,* as obtained in the *Assay* for *Chlorpheniramine Maleate.*
- **C.** The retention time of the major peak for dextromethorphan of the *Sample solution* corresponds to that of the