about 100 mL of *Mobile phase,* and shake by mechanical means for 10 minutes. Dilute with *Mobile phase* to volume, and mix. Transfer 5.0 mL of this solution to a 250-mL volumetric flask, dilute with *Mobile phase* to volume, and mix. Pass a portion of this solution through a filter having a 0.5- µm or finer porosity, discarding the first 10 mL of the filtrate. Use the clear filtrate as the *Assay preparation.*

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Acetaminophen Capsules*. Calculate the quantity, in mg, of acetaminophen ($C_8H_9NO_2$) in each mL of the Oral Suspension taken by the formula:

$$10{,}000(C/V)(r_U / r_S)$$

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

Acetaminophen Tablets

» Acetaminophen Tablets contain not less than 90.0 percent and not more than 110.0 per cent of the labeled amount of acetaminophen ($C_8H_9NO_2$).

Packaging and storage—Preserve in tight containers, and store at controlled room temperature.

Labeling—Label Tablets that must be chewed to indicate that they are to be chewed before swallowing.

USP Reference standards ⟨11⟩**—**
USP Acetaminophen RS

Identification—

A: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay.*

B: Triturate an amount of powdered Tablets, equivalent to about 50 mg of acetaminophen, with 50 mL of methanol, and filter: the clear filtrate (test solution) responds to the *Thin-layer Chromatographic Identification Test* ⟨201⟩, a solvent system consisting of a mixture of methylene chloride and methanol (4:1) being used.

Dissolution ⟨711⟩**—**

Medium: pH 5.8 phosphate buffer (see *Buffer Solutions* in the section *Reagents, Indicators, and Solutions*); 900 mL.

Apparatus 2: 50 rpm.

Time: 30 minutes.

Procedure—Determine the amount of $C_8H_9NO_2$ dissolved by employing UV absorption at the wavelength of maximum absorbance at about 243 nm on filtered portions of the solution under test, suitably diluted with *Dissolution Medium*, if necessary, in comparison with a Standard solution having a known concentration of USP Acetaminophen RS in the same *Medium.*

Tolerances—Not less than 80% *(Q)* of the labeled amount of $C_8H_9NO_2$ is dissolved in 30 minutes.

FOR TABLETS LABELED AS CHEWABLE—

Medium: pH 5.8 phosphate buffer (see *Buffer Solutions* in the section *Reagents, Indicators, and Solutions*); 900 mL.

Apparatus 2: 75 rpm.

Time: 45 minutes.

Procedure—Proceed as directed for *Procedure* for *Acetaminophen Tablets*.

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_8H_9NO_2$ is dissolved in 45 minutes.

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

Assay—

Mobile phase, Standard preparation, and *Chromatographic system*—Proceed as directed in the *Assay* under *Acetaminophen Capsules*.

Assay preparation—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 100 mg of acetaminophen, to a 200-mL volumetric flask, add about 100 mL of *Mobile phase,* shake by mechanical means for 10 minutes, sonicate for about 5 minutes, dilute with *Mobile phase* to volume, and mix. T ransfer 5.0 mL of this solution to a 250-mL volumetric flask, dilute with *Mobile phase* to volume, and mix. Pass a portion of this solution through a filter having a 0.5- µm or finer porosity, discarding the first 10 mL of the filtrate. Use the clear filtrate as the *Assay preparation.*

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Acetaminophen Capsules*. Calculate the quantity, in mg, of acetaminophen ($C_8H_9NO_2$) in the portion of T ablets taken by the formula:

$$10{,}000C(r_U / r_S)$$

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.

Acetaminophen Extended-Release Tablets

» Acetaminophen Extended-Release T ablets contain not less than 90.0 per cent and not more than 110.0 per cent of the labeled amount of acetaminophen ($C_8H_9NO_2$).

Packaging and storage—Preserve in tight containers.

Labeling—Where the Tablets are gelatin-coated, the label so states. When more than one *Dissolution* test is given, the labeling states the *Dissolution* test used only if *Test 1* is not used.

USP Reference standards ⟨11⟩**—**
USP Acetaminophen RS

Identification—

A: *Infrared Absorption* ⟨197K⟩—Use a portion of powdered Tablets.

B: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay*.

Dissolution ⟨711⟩**—**

TEST 1—

Medium: simulated gastric fluid TS (without enzyme); 900 mL.

Apparatus 2: 50 rpm.

Times: 15 minutes, 1 hour, and 3 hours.

Procedure—Determine the amount of $C_8H_9NO_2$ dissolved from UV absorbances at 280 nm, using a filtered portion of the solution under test in comparison with a Standard solution having a known concentration of USP Acetaminophen RS in the same *Medium.*

Tolerances—The percentages of the labeled amount of $C_8H_9NO_2$ dissolved at the times specified conform to *Acceptance Table 2*.