Instrumental conditions
Mode: *UV*
Analytical wavelength: 249 nm
Analysis
Samples: *Standard solution* and *Sample solution*
Calculate the percentage of the labeled amount of acetaminophen ($C_8H_9NO_2$) dissolved.
Tolerances: NLT 75% (*Q*) of the labeled amount of acetaminophen ($C_8H_9NO_2$) is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

IMPURITIES

• **4-Aminophenol in Acetaminophen-Containing Drug Products ⟨227⟩:** Meet the requirements

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers, and store at controlled room temperature.
• **USP Reference Standards ⟨11⟩**
USP Acetaminophen RS

Acetaminophen Oral Solution

DEFINITION

Acetaminophen Oral Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of acetaminophen ($C_8H_9NO_2$).

IDENTIFICATION

• **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.
• **B. Thin-Layer Chromatographic Identification Test ⟨201⟩**
Sample solution: Nominally 1 mg/mL of acetaminophen in methanol from the Oral Solution
Chromatographic system
Developing solvent system: Methylene chloride and methanol (4:1)
Acceptance criteria: Meets the requirements

ASSAY

• **Procedure**
Mobile phase: Methanol and water (1:3)
Standard solution: 0.01 mg/mL of USP Acetaminophen RS in *Mobile phase*
Sample stock solution: Nominally 2 mg/mL in *Mobile phase*, prepared as follows. Transfer 500 mg of acetaminophen from a measured volume of Oral Solution to a 250-mL volumetric flask, and dilute with *Mobile phase* to volume.
Sample solution: Nominally 0.01 mg/mL of acetaminophen in *Mobile phase* from the *Sample stock solution*. Pass a portion of this solution through a filter of 0.5-µm or finer pore size, discarding the first 10 mL of the filtrate. Use the clear filtrate.
Chromatographic system
(See *Chromatography* ⟨621⟩, *System Suitability*.)
Mode: LC
Detector: UV 243 nm
Column: 3.9-mm × 30-cm; packing L1
Flow rate: 1.5 mL/min
Injection volume: 10 µL
System suitability
Sample: *Standard solution*
Suitability requirements
Column efficiency: NLT 1000 theoretical plates
Tailing factor: NMT 2
Relative standard deviation: NMT 2.0%
Analysis
Samples: *Standard solution* and *Sample solution*
Calculate the percentage of the labeled amount of acetaminophen ($C_8H_9NO_2$) in the portion of Oral Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*
r_S = peak response from the *Standard solution*
C_S = concentration of USP Acetaminophen RS in the *Standard solution* (mg/mL)
C_U = nominal concentration of acetaminophen in the *Sample solution* (mg/mL)
Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Deliverable Volume ⟨698⟩:** Meets the requirements for oral solutions packaged in multiple-unit containers
• **Uniformity of Dosage Units ⟨905⟩:** Meets the requirements for oral solutions packaged in single-unit containers

IMPURITIES

• **4-Aminophenol in Acetaminophen-Containing Drug Products ⟨227⟩:** Meets the requirements

SPECIFIC TESTS

• **pH ⟨791⟩:** 3.8–6.1
• **Alcohol Determination,** *Method II* ⟨611⟩ (if present)
Analysis: Determine by the gas–liquid chromatographic procedure, using acetone as the internal standard.
Acceptance criteria: 90.0%–115.0% of the labeled amount of alcohol (C_2H_5OH)

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers, and store at controlled room temperature.
• **USP Reference Standards ⟨11⟩**
USP Acetaminophen RS

Acetaminophen for Effervescent Oral Solution

DEFINITION

Acetaminophen for Effervescent Oral Solution contains, in each 100 g, NLT 5.63 g and NMT 6.88 g of acetaminophen ($C_8H_9NO_2$).

IDENTIFICATION

• **A.** A 10-g portion dissolves, with effervescence, in water when dissolved as directed for the *Sample solution* in the *Assay*.
• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.
• **C. Thin-Layer Chromatographic Identification Test ⟨201⟩**
Sample solution: *Triturate 0.4 g of the powder with 25 mL of methanol, and filter.*