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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.
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: Dissolve 10 g of Acetaminophen for Effervescent Oral Solution in 200 mL of water in a 1000-mL volumetric flask, using gentle heat if necessary, until effervescence subsides, and then dilute with water to volume.
Sample solution: Nominally 0.16 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.
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 2.0
Relative standard deviation: NMT 2.0%
Analysis
Samples: *Standard solution* and *Sample solution*
Calculate the quantity, in g, of acetaminophen ($C_8H_9NO_2$) in 100 g of Acetaminophen for Effervescent Oral Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F_1) \times L \times F_2$$

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)

F_1 = conversion factor, 1000 mg/g

L = label claim (mg/unit)

F_2 = conversion factor, 100, based on the label claim of g of acetaminophen per 100 g of sample

Acceptance criteria: 5.63–6.88 g

PERFORMANCE TESTS

- **Minimum Fill ⟨755⟩:** Meets the requirements for solids packaged in multiple-unit containers
- **Uniformity of Dosage Units ⟨905⟩:** Meets the requirements for solids packaged in single-unit containers

IMPURITIES

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

ADDITIONAL REQUIREMENTS

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

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
ACETAMINOPHEN FOR EFFERVESCENT ORAL SOLUTION	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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