Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-Dec-2014
Document Type: USP Monographs
DocId: GUID-3517B4C8-0093-4C97-A534-887F1AD8B2D4_1_en-US
DOI: https://doi.org/10.31003/USPNF_M180_01_01
DOI Ref: 3c9t6

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

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

Topic/Question	Contact	Expert Committee
ACETAMINOPHEN ORAL SOLUTION	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 44(4)

Current DocID: GUID-3517B4C8-0093-4C97-A534-887F1AD8B2D4_1_en-US

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