

Status: Currently Official on 17-Feb-2025
 Official Date: Official as of 01-Nov-2021
 Document Type: USP Monographs
 DocId: GUID-8690AABC-4A2A-468C-9B04-D62048F76DF7_10_en-US
 DOI: https://doi.org/10.31003/USPNF_M19080_10_01
 DOI Ref: jb8de

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Acetaminophen Oral Suspension

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click

<https://www.uspnf.com/rb-acetaminophen-oral-susp-20211029>.

DEFINITION

Acetaminophen Oral Suspension is a suspension of Acetaminophen in a suitable aqueous vehicle. It contains NLT 90.0% and NMT 110.0% of the labeled amount of acetaminophen ($C_8H_9NO_2$).

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K

Sample: Transfer a volume of Oral Suspension, equivalent to 240 mg of acetaminophen, to a separator. Add 50 mL of [ethyl acetate](#), and shake. Filter the ethyl acetate extract through a funnel containing glass wool and 10 g of [anhydrous sodium sulfate](#). Collect the filtrate in a beaker, and evaporate on a steam bath to dryness. Dry the residue under vacuum over silica gel.

Acceptance criteria: The crystals so obtained meet the requirements.

- **B.** The retention time of the acetaminophen peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

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 0.5 mg/mL of acetaminophen prepared as follows. Transfer 100 mg of acetaminophen from a volume of Oral Suspension, previously well shaken, to a 200-mL volumetric flask. Add 100 mL of *Mobile phase*, and shake by mechanical means for 10 min. Dilute with *Mobile phase* to volume.

Sample solution: Nominally 0.01 mg/mL of acetaminophen from the *Sample stock solution* in *Mobile phase*. Pass a portion of this solution through a filter of 0.5- μ m pore size or finer, 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 $\times$ 30-cm; packing [L1](#)

Flow rate: 1.5 mL/min

Injection volume: 10 μ L

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 percentage of the labeled amount of acetaminophen ($C_8H_9NO_2$) in the portion of Oral Suspension 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%

Delete the following:

▲ (RB 1-Nov-2021)

PERFORMANCE TESTS

- [UNIFORMITY OF DOSAGE UNITS \(905\)](#).

For single-unit containers: Meets the requirements

- [DELIVERABLE VOLUME \(698\)](#).

For multiple-unit containers: Meets the requirements

IMPURITIES

- [4-AMINOPHENOL IN ACETAMINOPHEN-CONTAINING DRUG PRODUCTS \(227\)](#): Meets the requirements

Delete the following:

▲ (RB 1-Nov-2021)

SPECIFIC TESTS

- [pH \(791\)](#): 4.0–6.9

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers, and store at controlled room temperature.

- [USP REFERENCE STANDARDS \(11\)](#).

[USP Acetaminophen RS](#)

[USP 4-Aminophenol RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
ACETAMINOPHEN ORAL SUSPENSION	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 42(6)

Current DocID: GUID-8690AABC-4A2A-468C-9B04-D62048F76DF7_10_en-US

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