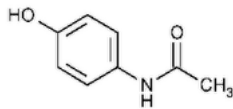


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Acetaminophen



$C_8H_9NO_2$ 151.16
Acetamide, *N*-(4-hydroxyphenyl)-;
4'-Hydroxyacetanilide CAS RN®: 103-90-2; UNII: 362091TL9D.

DEFINITION
Acetaminophen contains NLT 98.0% and NMT 102.0% of acetaminophen ($C_8H_9NO_2$), calculated on the dried basis.

- IDENTIFICATION**
- **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), *Infrared Spectroscopy*: 197K
 - **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY



Quality Assist

Methods Simplified

Be one of 100 participants to test USP-QualityAssist, a tool designed to simplify workflows for raw material release testing, using the Acetaminophen API as an example case. Seats are limited. Thank you!

Time (min)	Solution A (%)	Solution B (%)
0	99	1
3	99	1
7	19	81
7.1	99	1
10	99	1

Standard [▲]stock[▲] (IRA 1-Jan-2023) **solution:** 0.1 mg/mL of [USP Acetaminophen RS](#) in [methanol](#)

[▲]Standard solution: 0.02 mg/mL of [USP Acetaminophen RS](#) from the *Standard stock solution* in *Solution A* [▲] (IRA 1-Jan-2023)

Sample [▲]stock[▲] (IRA 1-Jan-2023) **solution:** 0.1 mg/mL of Acetaminophen in [methanol](#)

[▲]Sample solution: 0.02 mg/mL of Acetaminophen from the *Sample stock solution* in *Solution A* [▲] (IRA 1-Jan-2023)

Chromatographic system
(See [Chromatography \(621\)](#), *System Suitability*.)

Mode: LC

Detector: UV 230 nm

Column: 4.6-mm × 10-cm; 3.5-μm packing [L7](#)

Column temperature: 35°

Flow rate: [▲]1 [▲] (IRA 1-Jan-2023) mL/min

Injection volume: 25 µL (IRA 1-Jan-2023)

System suitability

Sample: Standard solution

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 0.73% (IRA 1-Jan-2023)

Analysis

Samples: Standard solution and Sample solution

Calculate the percentage of acetaminophen ($C_8H_9NO_2$) in the portion of Acetaminophen taken:

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

r_U = peak response of acetaminophen (IRA 1-Jan-2023) from the Sample solution

r_S = peak response of acetaminophen (IRA 1-Jan-2023) from the Standard solution

C_S = concentration of [USP Acetaminophen RS](#) in the Standard solution (mg/mL)

C_U = concentration of Acetaminophen in the Sample solution (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

Change to read:

- **LIMIT OF FREE 4-AMINOPHENOL**

Solution A, Solution B, and Mobile phase (IRA 1-Jan-2023): Prepare as directed in the Assay.



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Injection volume: 5 µL (IRA 1-Jan-2023)

System suitability

Sample: Standard solution

[NOTE—The relative retention times for 4-aminophenol and acetaminophen are 0.6 and 1.0, respectively.]

Suitability requirements

Relative standard deviation: NMT 5.0%

Analysis

Samples: Standard solution and Sample solution

Calculate the percentage of 4-aminophenol in the portion of Acetaminophen taken:

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

r_U = peak response of 4-aminophenol from the Sample solution

r_S = peak response of 4-aminophenol (IRA 1-Jan-2023) from the Standard solution

C_S = concentration of [USP 4-Aminophenol RS](#) in the Standard solution (µg/mL)

C_U = concentration of Acetaminophen in the Sample solution (µg/mL)

Acceptance criteria: NMT 0.005%

Change to read:

- **ORGANIC IMPURITIES**

Solution A: [Methanol](#), [glacial acetic acid](#), and [water](#) (50:1:950)

Solution B: [Methanol](#), [glacial acetic acid](#), and [water](#) (500:1:500)