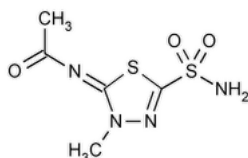


Status: Currently Official on 15-Feb-2025
 Official Date: Official as of 01-Aug-2022
 Document Type: USP Monographs
 DocId: GUID-54468977-9FD8-4AF8-AD4B-FC61DE955C49_5_en-US
 DOI: https://doi.org/10.31003/USPNF_M50530_05_01
 DOI Ref: zs9sf

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Methazolamide

Change to read:



$C_5H_8N_4O_3S_2$ Δ 236.26 Δ (USP 1-Aug-2022)

Acetamide, N-[5-(aminosulfonyl)-3-methyl-1,3,4-thiadiazol-2(3H)-ylidene]-;

N-(4-Methyl-2-sulfamoyl- Δ^2 -1,3,4-thiadiazolin-5-ylidene)-acetamide CAS RN[®]: 554-57-4; UNII: W733B0S9SD.

DEFINITION

Methazolamide contains NLT 98.0% and NMT 102.0% of methazolamide ($C_5H_8N_4O_3S_2$), calculated on the dried basis.

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS** (197), *Infrared Spectroscopy*: 197K
 - **B. SPECTROSCOPIC IDENTIFICATION TESTS** (197), *Ultraviolet-Visible Spectroscopy*: 197U
- Sample solution:** 10 µg/mL of Methazolamide in 0.1 N [sodium hydroxide](#) solution
- Acceptance criteria:** Meets the requirements

ASSAY

Change to read:

PROCEDURE

Buffer solution: 1.80 g/L of [anhydrous sodium acetate](#) in [water](#). Adjust, if necessary, with [glacial acetic acid](#) to a pH of 4.5. Δ Δ (USP 1-Aug-2022)

Mobile phase: [Acetonitrile](#) and *Buffer solution* (14:86)

System suitability stock solution: 0.3 mg/mL of Δ [USP Acetaminophen RS](#) Δ (USP 1-Aug-2022) and 0.5 mg/mL of [USP Methazolamide RS](#) in [acetonitrile](#)

System suitability solution: 30 µg/mL of Δ [USP Acetaminophen RS](#) Δ (USP 1-Aug-2022) and 50 µg/mL of [USP Methazolamide RS](#) in *Buffer solution* from the *System suitability stock solution*

Standard stock solution: 0.1 mg/mL of [USP Methazolamide RS](#) prepared as follows. Dissolve 20 mg of [USP Methazolamide RS](#) in 20 mL of [acetonitrile](#) contained in a 200-mL volumetric flask and dilute with *Buffer solution* to volume.

Standard solution: 50 µg/mL of [USP Methazolamide RS](#) in *Buffer solution* from the *Standard stock solution*

Sample stock solution: 0.5 mg/mL of Methazolamide prepared as follows. Dissolve 100 mg of Methazolamide in 20 mL of [acetonitrile](#) contained in a 200-mL volumetric flask and dilute with *Buffer solution* to volume.

Sample solution: 50 µg/mL of Methazolamide in *Buffer solution* from the *Sample stock solution*

Chromatographic system

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

Mode: LC

Detector: UV 265 nm

Column: 3.9-mm × 15.0-cm; Δ 10-µm Δ (USP 1-Aug-2022) packing L1

Flow rate: 1.5 mL/min

Injection volume: 10 µL

Δ **Run time:** NLT 5 times the retention time of methazolamide Δ (USP 1-Aug-2022)

System suitability

Samples: *System suitability solution* and *Standard solution*

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

Suitability requirements

Resolution: NLT 4.0 between acetaminophen and methazolamide, *System suitability solution*

Tailing factor: NMT 2.0 for methazolamide, *System suitability solution*

Relative standard deviation: NMT ▲0.73%,▲ (USP 1-Aug-2022) *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of methazolamide (C₅H₈N₄O₃S₂) in the portion of Methazolamide taken:

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

r_U = peak response of methazolamide from the *Sample solution*

r_S = peak response of methazolamide from the *Standard solution*

C_S = concentration of [USP Methazolamide RS](#) in the *Standard solution* (µg/mL)

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

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

IMPURITIES

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

Delete the following:

- ▲• [SELENIUM \(291\)](#).

Sample: 200 mg

Acceptance criteria: NMT 0.003%▲ (USP 1-Aug-2022)

SPECIFIC TESTS

- [LOSS ON DRYING \(731\)](#).

Analysis: Dry at 105° for 2 h.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed, light-resistant containers.

Change to read:

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

▲ [USP Acetaminophen RS](#)▲ (USP 1-Aug-2022)

[USP Methazolamide RS](#)

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

Topic/Question	Contact	Expert Committee
METHAZOLAMIDE	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. 47(2)

Current DocID: GUID-54468977-9FD8-4AF8-AD4B-FC61DE955C49_5_en-US

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