

Metolazone Compounded Oral Suspension

DEFINITION
Metolazone Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of metolazone ($C_{16}H_{16}ClN_3O_3S$).
Prepare Metolazone Compounded Oral Suspension 1 mg/mL as follows (see [Pharmaceutical Compounding—Nonsterile Preparations \(.795\)](#)).

Metolazone	100 mg
Vehicle: a 1:1 mixture of Vehicle for Oral Solution, (regular or sugar-free), NF, and Vehicle for Oral Suspension, NF, a sufficient quantity to make	100 mL

Place the required number of tablets in a suitable mortar and comminute to a fine powder, or use *Metolazone* powder. Add 20 mL of *Vehicle*, and mix to a uniform paste. Add the *Vehicle* in small portions, and transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add *Vehicle* in portions to rinse the mortar, then add sufficient *Vehicle* to bring to final volume, and mix well.

ASSAY

• **PROCEDURE**

Mobile phase: Methanol and water (70:30) containing 1.5 g/L of ammonium acetate and 1 mL/L of diisopropylamine. Filter, and degas.

Standard solution: 1.0 µg/mL of [USP Metolazone RS](#)

Sample solution: Agitate the container of Oral Suspension for 30 min on a rotating mixer, remove a 5-mL sample, and store in a clear glass vial at -70° until analyzed. At the time of analysis, remove the sample from the freezer, allow it to reach room temperature, and mix on a vortex mixer for 30 s. Pipet 1.0 mL of the sample to a 1000-mL volumetric flask, and dilute with *Mobile phase* to volume.

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 20-cm; 5-µm packing L3

Flow rate: 1.0 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[NOTE—The retention time for metolazone is about 6.0 min.]

Suitability requirements

Relative standard deviation: NMT 2.2% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of metolazone ($C_{16}H_{16}ClN_3O_3S$) in the portion of Oral Suspension taken:

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 Metolazone RS](#) in the *Standard solution* (µg/mL)

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- **pH** (791): 3.6–4.6

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Package in tight, light-resistant containers. Store at controlled room temperature, or in a refrigerator.
- **BEYOND-USE DATE:** NMT 60 days after the date on which it was compounded when stored at controlled room temperature, or in a refrigerator
- **LABELING:** Label it to state that it is to be well shaken, and to state the *Beyond-Use Date*.
- **USP REFERENCE STANDARDS** (11).
[USP Metolazone RS](#)

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

Topic/Question	Contact	Expert Committee
METOLAZONE COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 40(6)

Current DocID: GUID-9F353F3C-6839-471C-8727-5C5D7F29FBC0_1_en-US

DOI: https://doi.org/10.31003/USPNF_M1395_01_01

DOI ref: [yt5jz](#)

OFFICIAL