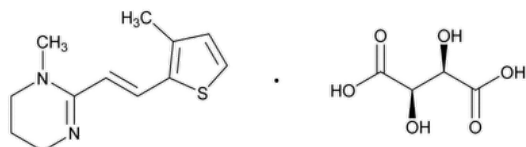


Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-A12E18B1-B78F-41DC-9DF7-4245BD880E72_4_en-US
DOI: https://doi.org/10.31003/USPNF_M54780_04_01
DOI Ref: 8o26r

© 2025 USPC
Do not distribute

Morantel Tartrate



$C_{12}H_{16}N_2S \cdot C_4H_6O_6$ 370.42

Pyrimidine, 1,4,5,6-tetrahydro-1-methyl-2-[2-(3-methyl-2-thienyl)ethenyl]-, (E)-, [R-(R*,R*)]-2,3-dihydroxybutanedioate (1:1).

(E)-1,4,5,6-Tetrahydro-1-methyl-2-[2-(3-methyl-2-thienyl)vinyl]pyrimidine tartrate (1:1) CAS RN®: 26155-31-7; UNII: 5WF7E9QC3F.

Morantel CAS RN®: 20574-50-9; UNII: 7NJ031HAX5.

» Morantel Tartrate contains not less than 96.4 percent and not more than 101.5 percent of $C_{12}H_{16}N_2S \cdot C_4H_6O_6$, calculated on the dried basis.

Packaging and storage—Preserve in well-closed, light-resistant containers. Store at 25°, excursions permitted between 15° and 30°.

Labeling—Label it to indicate it is for veterinary use only.

USP REFERENCE STANDARDS (11)—

[USP Morantel Tartrate RS](#)

Clarity and color of solution—Dissolve and dilute 0.25 g to 25.0 mL in carbon dioxide-free water. The solution is clear and yellow to greenish yellow in color.

Identification—

Change to read:

A: ▲ [Spectroscopic Identification Tests \(197\)](#), [Infrared Spectroscopy: 197K](#)▲ (CN 1-May-2020) ·

B: It meets the requirements of the test for [Tartrate \(191\)](#).

C: The retention time of the morantel peak in the chromatogram of the *Test solution* corresponds to that in the chromatogram of *Standard solution 1*, as obtained in the test for *Related compounds*.

MELTING TEMPERATURE (741): 167° to 172°.

pH (791): between 2.8 and 3.9.

Solution—Dissolve and dilute 0.25 g to 25.0 mL in carbon dioxide-free water.

LOSS ON DRYING (731)—Dry it at 100° to 105° to constant weight: it loses not more than 1.5% of its weight.

RESIDUE ON IGNITION (281): not more than 0.1%.

Related compounds—

[NOTE—Conduct this test without exposure to daylight, and with the minimum necessary exposure to artificial light.]

Mobile phase—Mix 3.5 mL of triethylamine and 850 mL of water. Adjust with phosphoric acid to a pH of 2.5. Add 50 mL of tetrahydrofuran and 100 mL of methanol, and mix.

Tartrate solution—Prepare a solution containing about 0.15 mg of tartaric acid per mL in *Mobile phase*.

Standard solution 1—Dissolve an accurately weighed quantity of [USP Morantel Tartrate RS](#) in *Mobile phase* to obtain a solution having a known concentration of about 5.0 µg per mL.

Standard solution 2—Dilute 2.0 mL of *Standard solution 1* to 100.0 mL with *Mobile phase*.

System suitability solution—Expose 10 mL of *Standard solution 1* to daylight for 15 minutes before injection.

Test solution—Dissolve an accurately weighed quantity of Morantel Tartrate in *Mobile phase* to obtain a solution having a concentration of about 0.5 mg per mL.

Chromatographic system (see [CHROMATOGRAPHY \(621\)](#))—The liquid chromatograph is equipped with a 226-nm detector and a 4.6-mm × 25-cm column that contains 5-µm packing L1. The flow rate is about 0.75 mL per minute. Chromatograph the *Tartrate solution*, *Standard solution 1*, and the *System suitability solution*, and record the peak areas as directed for *Procedure*: using the *System suitability solution*, the resolution, *R*, between morantel and its preceding peak ((Z)-isomer) is not less than 2. The relative retention times are about 0.8, 1.0, and 1.2 for the morantel (Z)-isomer, morantel, and the morantel 4-methyl isomer (1-methyl-2-[(E)-2-(4-methylthiophen-2-yl)ethenyl]-1,4,5,6 tetrahydropyrimidine), respectively.

Procedure—Separately inject equal volumes (about 20 µL) of the *Tartrate solution*, *Standard solution 1*, *Standard solution 2*, and the *Test solution* into the chromatograph, record the chromatograms, and measure the areas for the major peaks. Disregarding the tartrate peak and any peak in the chromatogram of the *Test solution* less than the area of the principal peak in the chromatogram of *Standard solution 2*,

calculate the area percentage of each impurity, relative to morantel, in the portion of Morantel Tartrate taken by the formula:

$$100(C_s/C_u)(r_i/r_s)$$

in which C_s and C_u are the concentrations of morantel tartrate, in mg per mL, of *Standard solution 1* and the *Test solution*, respectively; and r_i and r_s are the peak areas of each individual impurity and morantel obtained from the *Test solution* and *Standard solution 1*, respectively: not more than 3% of the morantel 4-methyl isomer is found; not more than 0.5% of any other individual impurity is found; and not more than 1% of total other individual impurities is found.

Assay—

Dissolve 0.280 g in 40 mL of anhydrous acetic acid. Titrate with 0.1 N perchloric acid VS, determining the endpoint potentiometrically (see [Titrimetry \(541\)](#)). One mL of 0.1 N perchloric acid is equivalent to 37.04 mg of $C_{12}H_{16}N_2S \cdot C_4H_6O_6$.

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

Topic/Question	Contact	Expert Committee
MORANTEL TARTRATE	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 32(6)

Current DocID: GUID-A12E18B1-B78F-41DC-9DF7-4245BD880E72_4_en-US

DOI: https://doi.org/10.31003/USPNF_M54780_04_01

DOI ref: [8o26r](#)

OFFICIAL