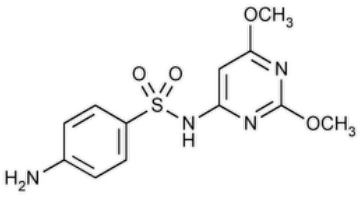
Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-13488704-6C08-468C-831E-F7CCA873C9AB_4_en-US
DOI: https://doi.org/10.31003/USPNF_M79011_04_01
DOI Ref: egc6h

Sulfadimethoxine



$C_{12}H_{14}N_4O_4S$ 310.33

Benzenesulfonamide, 4-amino-*N*-(2,6-dimethoxy-4-pyrimidinyl)-.

N^1-(2,6-Dimethoxy-4-pyrimidinyl)sulfanilamide CAS RN®: 122-11-2; UNII: 30CPC5LDEX.

» Sulfadimethoxine contains not less than 98.0 percent and not more than 102.0 percent of $C_{12}H_{14}N_4O_4S$, calculated on the dried basis.

Packaging and storage—Preserve in tight, light-resistant containers, and store at controlled room temperature.

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

USP Reference standards ⟨11⟩—

USP Sulfadimethoxine RS

Identification—

Change to read:

A: ▲*Spectroscopic Identification Tests* ⟨197⟩*, Infrared Spectroscopy: 197K*▲ (CN 1-May-2020) ·

Change to read:

B: ▲*Spectroscopic Identification Tests* ⟨197⟩*, Ultraviolet-Visible Spectroscopy: 197U*▲ (CN 1-May-2020) —

Solution: 1 in 100,000.

Medium: alcohol.

Absorptivities, calculated on the dried basis, at 272 nm do not differ by more than 3.0%.

C: To about 100 mg, add 3 mL of 2.5 N sodium hydroxide and 50 mL of water, mix until dissolved, and dilute with water to 100 mL. To about 5 mL of this solution, add 100 mg of phenol, and heat to boiling. Cool the solution, and add 0.5 mL of sodium hypochlorite TS and 3 drops of 2.5 N sodium hydroxide: a yellow color is produced.

D: To about 10 mg dissolved in 2 mL of diluted hydrochloric acid, add 3 drops of sodium nitrite solution (1 in 100), and dilute with water to 4 mL: the solution turns yellow. Add 1 mL of 2.5 N sodium hydroxide containing 10 mg of 2-naphthol: a red-orange precipitate is formed.

Melting range ⟨741⟩: between 197° and 202°.

Loss on drying ⟨731⟩: Dry it at 105° for 3 hours: it loses not more than 0.5% of its weight.

Residue on ignition ⟨281⟩: not more than 0.1%.

Assay—

Mobile phase—Dissolve 6 g of monobasic sodium phosphate in water to make 1000 mL. Adjust with 50% (w/v) sodium hydroxide solution to a pH of 7.0. Prepare a mixture of this solution and methanol (300:100). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Quantitatively dissolve an accurately weighed quantity of USP Sulfadimethoxine RS in *Mobile phase* to obtain a solution having a known concentration of about 0.2 mg per mL. Protect this solution from light.

Assay preparation—Transfer about 20 mg of Sulfadimethoxine, accurately weighed, to a 100-mL volumetric flask, add about 75 mL of *Mobile phase*, and swirl to dissolve. Dilute this solution with *Mobile phase* to volume, and mix. Protect this solution from light.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 4.6-mm × 25-cm column that contains packing L1. The flow rate is about 1 mL per minute. Chromatograph the *Standard preparation*, and record the peak

responses as directed for *Procedure:* the tailing factor is not more than 1.5; and the relative standard deviation for replicate injections is not more than 1.0%.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of $C_{12}H_{14}N_4O_4S$ in the portion of Sulfadimethoxine taken by the formula:

$$100C(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Sulfadimethoxine RS in the *Standard preparation;* and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
SULFADIMETHOXINE	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 28(6)

Current DocID: GUID-13488704-6C08-468C-831E-F7CCA873C9AB_4_en-US
DOI: https://doi.org/10.31003/USPNF_M79011_04_01
DOI ref: egc6h