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Sulfadimethoxine Sodium

$C_{12}H_{13}N_4NaO_4S$ 332.31

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

N^1-(2,6-Dimethoxy-4-pyrimidinyl)sulfanilamide monosodium salt CAS RN®: 1037-50-9; UNII: 49DG2B481W.

» Sulfadimethoxine Sodium contains not less than 98.0 percent and not more than 102.0 percent of $C_{12}H_{13}N_4NaO_4S$, 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—

A: To about 100 mg, add 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.

B: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay.*

C: Dissolve 10 mg 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.

pH ⟨791⟩: between 8.0 and 9.5, in a solution (1 in 20).

Loss on drying ⟨731⟩—Dry it at 125° for 3 hours: it loses not more than 5.0% of its weight.

Assay—

Mobile phase, *Standard preparation*, and *Chromatographic system*—Proceed as directed in the *Assay* under *Sulfadimethoxine*.

Assay preparation—Transfer about 60 mg of Sulfadi methoxine Sodium, accurately weighed, to a 250-mL volumetric flask, add about 200 mL of *Mobile phase*, and swirl to dissolve. Dilute with *Mobile phase* to volume, and mix. Protect this solution from light.

Procedure—Proceed as directed in the *Assay* under *Sulfadimethoxine*. Calculate the quantity, in mg, of $C_{12}H_{13}N_4NaO_4S$ in the portion of Sulfadimethoxine Sodium taken by the formula:

$$(332.31/310.34)(250C)(r_U/r_S)$$

in which 332.31 and 310.34 are the molecular weights of sulfadimethoxine sodium and sulfadimethoxine, respectively; and the other terms are as defined therein.

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

Topic/Question	Contact	Expert Committee
SULFADIMETHOXINE SODIUM	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

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