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Sulfadimethoxine Tablets

» Sulfadimethoxine Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of sulfadimethoxine ($C_{12}H_{14}N_4O_4S$).

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

Labeling—Label the Tablets to indicate that they are for veterinary use only.

USP REFERENCE STANDARDS (11).—
[USP Sulfadimethoxine RS](#)

Identification—Shake a quantity of finely powdered Tablets, equivalent to about 1 g of sulfadimethoxine, with 5 mL of diluted hydrochloric acid and 10 mL of water. Filter, and to the filtrate add 2.5 N sodium hydroxide dropwise until a precipitate forms and redissolves. Add diluted hydrochloric acid dropwise until a precipitate forms. Collect the filtrate on a very fine filter, and wash it with water and with ether: the sulfadimethoxine so obtained meets the requirements for the *Identification* tests under [Sulfadimethoxine](#).

DISINTEGRATION (701): 30 minutes.

UNIFORMITY OF DOSAGE UNITS (905): meet the requirements.

Assay—

Mobile phase, Standard preparation, and Chromatographic system—Proceed as directed in the Assay under [Sulfadimethoxine](#).
Assay preparation—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 50 mg of sulfadimethoxine, 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. Filter if necessary to obtain a clear solution. Protect this solution from light.
Procedure—Proceed as directed in the Assay under [Sulfadimethoxine](#). Calculate the quantity, in mg, of sulfadimethoxine ($C_{12}H_{14}N_4O_4S$) in the portion of Tablets taken by the formula:

$$250C(r_u/r_s)$$

in which the terms are as defined therein.

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

Topic/Question	Contact	Expert Committee
SULFADIMETHOXINE TABLETS	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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