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Sulfamethazine Granulated

» Sulfamethazine Granulated contains Sulfamethazine mixed with suitable diluents, carriers, and inactive ingredients. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of sulfamethazine ($C_{12}H_{14}N_4O_2S$).

Packaging and storage—Preserve in well-closed containers. Avoid moisture and excessive heat.

Labeling—Label it to indicate that it is for veterinary use only. Label it also to indicate that it is for manufacturing, processing, or repackaging.

USP Reference standards ⟨11⟩—
USP Sulfamethazine RS

Identification—The chromatogram of the *Assay preparation* obtained as directed in the *Assay* exhibits a major peak for sulfamethazine, the retention time of which corresponds to that exhibited in the chromatogram of the *Standard preparation* obtained as directed in the *Assay.*

Loss on drying ⟨731⟩—Dry it in vacuum at 60° for 5 hours: it loses not more than 10% of its weight.

Powder fineness ⟨811⟩**:** not less than 95% passes a No. 20 sieve, and not more than 10% passes a No. 80 sieve.

Assay—

Mobile phase—Prepare a mixture of water, methanol, and glacial acetic acid (68:30:2). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Extractant—Prepare a mixture of 0.15 N hydrochloric acid and methanol (3:1).

Standard preparation—Prepare a solution of USP Sulfamethazine RS in *Extractant* having a known concentration of about 0.01 mg per mL.

Assay preparation—Transfer about 5 g of Sulfamethazine Granulated, accurately weighed, to a suitable container, add 250.0 mL of *Extractant*, and shake by mechanical means for 2 hours. Allow the mixture to settle, storing the mixture in a refrigerator if settling is allowed to continue overnight. Filter a portion of the supernatant, and transfer 10.0 mL of the clear filtrate to a 100-mL volumetric flask. Dilute with *Extractant* to volume, and mix. Transfer 5.0 mL of this solution to a 200-mL volumetric flask, dilute with *Extractant* to volume, and mix. Pass a portion of this solution through a filter having a 0.5-µm or finer porosity, and use the filtrate as the *Assay preparation*. This solution contains about 0.01 mg of sulfamethazine per mL.

Derivatizing reagent—Dissolve 6.0 g of dimethylaminobenzaldehyde in 200 mL of glacial acetic acid, add 120 mL of methanol and 80 mL of water, mix, and degas. Prepare this reagent daily.

Chromatographic system—The liquid chromatograph is equipped with a guard column that contains packing L1, a 4.6-mm × 25-cm analytical column that contains 10-µm packing L1, a separate pump to deliver the *Derivatizing reagent* via a T-junction installed immediately postcolumn, a postcolumn derivatization coil consisting of 3-m × 0.5-mm inside-diameter polytef tubing, a flow cell, and a 450-nm detector. The *Mobile phase* flow rate is about 2 mL per minute, and the *Derivatizing reagent* flow rate is about 1 mL per minute. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the capacity factor, *k'*, for the sulfamethazine peak is not less than 2.0; and the relative standard deviation for replicate injections is not more than 3.5%.

Procedure—Separately inject equal volumes (about 100 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the sulfamethazine peaks. Calculate the quantity, in mg, of sulfamethazine ($C_{12}H_{14}N_4O_2S$) in each g of the Sulfamethazine Granulated taken by the formula:

$$100{,}000(C/W)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Sulfamethazine RS in the *Standard preparation; W* is the quantity, in g, of Sulfamethazine Granulated taken to prepare the *Assay preparation;* and r_U and r_S are the sulfamethazine peak responses obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Topic/Question	Contact	Expert Committee
SULFAMETHAZINE GRANULATED	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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