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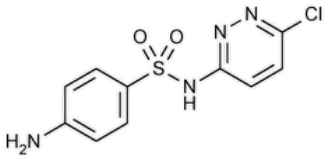
Sulfachlorpyridazine



$C_{10}H_9ClN_4O_2S$ 284.72

N^1-(6-Chloro-3-pyridazinyl)sulfanilamide CAS RN®: 80-32-0; UNII: P78D9P90C0.

» Sulfachlorpyridazine contains not less than 97.0 percent and not more than 103.0 percent of $C_{10}H_9ClN_4O_2S$, calculated on the dried basis.

Packaging and storage—Preserve in well-closed, light-resistant containers.

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

USP Reference standards ⟨11⟩—

USP Sulfachlorpyridazine RS

Identification—

Change to read:

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

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

Clarity and color of solution—Dissolve 1.0 g of it in 50 mL of 0.1 N methanolic hydrochloric acid prepared by diluting 8.6 mL of hydrochloric acid with methanol to obtain 1000 mL of solvent: a clear solution is produced that is not deeper in color than pale yellow.

Acidity—Prepare a suspension of 3.0 g of it in 150.0 mL of carbon dioxide-free water, and heat at 70° for 5 minutes, maintaining the suspension. Cool rapidly in an ice bath to 20 ± 0.5°, stirring by mechanical means. Filter the suspension using vacuum, and collect the filtrate. Titrate 25.0 mL of the clear filtrate with 0.1 N sodium hydroxide VS, using 2 drops of thymolphthalein TS as the indicator. Transfer a second 25.0-mL portion of the clear filtrate to a 250-mL conical flask, add 10 mL of hydrochloric acid, and cool in an ice bath to 15°. Add about 25 g of crushed ice, prepared from frozen purified water, and titrate with 0.1 M sodium nitrite VS, stirring vigorously, until the titrated solution produces an immediate, stable, blue color on starch-iodide paper. The volume of 0.1 N sodium hydroxide consumed in the titration of the first 25.0-mL portion of the filtrate does not exceed the volume of 0.1 M sodium nitrite consumed in the titration of the second 25.0-mL portion of the filtrate by more than 0.5 mL.

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—

pH 2.5 phosphate buffer—Dissolve 14 g of monobasic potassium phosphate in 1600 mL of water, adjust with phosphoric acid to a pH of 2.5 ± 0.1, dilute with water to 2000 mL, and mix.

Mobile phase—Prepare a filtered and degassed mixture of *pH 2.5 phosphate buffer* and methanol (700:300). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Prepare a stock solution of USP Sulfachlorpyridazine RS in methanol having a known concentration of about 0.5 mg per mL. Transfer 3.0 mL of this stock solution to a 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix. Filter this solution through a nylon filter having a porosity of 0.5 µm or finer, and use the filtrate as the *Standard preparation.* The *Standard preparation* contains about 15 µg of USP Sulfachlorpyridazine RS per mL.

Assay preparation—Transfer about 50 mg of Sulfachlor pyridazine, accurately weighed, to a 100-mL volumetric flask. Dissolve in and dilute with methanol to volume, and mix. Transfer 3.0 mL of this solution to a second 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix. Filter this solution through a filter having a porosity of 0.5 µm or finer, and use the filtrate as the *Assay preparation*.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 265-nm detector, a 4.6-mm × 25-cm analytical column containing 5-µm packing L1, and a guard column containing 5-µm packing L1, and is maintained at about 40°. The flow rate is about 1 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 20 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 $C_{10}H_9ClN_4O_2S$ in the portion of Sulfachlorpyridazine taken by the formula:

$$(10/3)(C)(r_U/r_S)$$

in which C is the concentration, in µg per mL, of USP Sulfachlorpyridazine RS in the *Standard preparation;* and r_U and r_S are the sulfachlorpyridazine peak area 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
SULFACHLORPYRIDAZINE	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. Information currently unavailable

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