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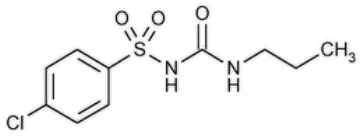
Chlorpropamide



$C_{10}H_{13}ClN_2O_3S$ 276.74

Benzenesulfonamide, 4-chloro-*N*-[(propylamino)carbonyl]-.

1-[(*p*-Chlorophenyl)sulfonyl]-3-propylurea CAS RN®: 94-20-2; UNII: WTM2C3IL2X.

» Chlorpropamide contains not less than 97.0 percent and not more than 103.0 percent of $C_{10}H_{13}ClN_2O_3S$, calculated on the dried basis.

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩—

USP Chlorpropamide RS

Identification—

Change to read:

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

B: It responds to the *Thin-Layer Chromatographic Identification Test* ⟨201⟩. Prepare the test solution by dissolving an accurately weighed quantity of Chlorpropamide in acetone to obtain a solution containing 1 mg per mL. Develop the chromatogram in a solvent system consisting of a mixture of methylene chloride, methanol, cyclohexane, and ammonium hydroxide (100:50:30:10).

Melting range ⟨741⟩: between 126° and 129°.

Loss on drying ⟨731⟩—Dry it in vacuum at 60° for 2 hours: it loses not more than 1.0% of its weight.

Residue on ignition ⟨281⟩: not more than 0.4%.

Selenium ⟨291⟩: 0.003%.

Assay—

Mobile phase—Prepare a filtered and degassed mixture of equal volumes of acetonitrile and dilute glacial acetic acid (1 in 100). [Note—Do not exceed 50% of acetonitrile.] Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Dissolve an accurately weighed quantity of USP Chlorpropamide RS in *Mobile phase*, and dilute quantitatively, and stepwise if necessary, with *Mobile phase* to obtain a solution having a known concentration of about 0.05 mg per mL.

Assay preparation—Transfer about 50 mg of Chlorpropamide, accurately weighed, to a 100-mL volumetric flask, add *Mobile phase* to volume, and mix. Transfer 10 mL of this solution to a second 100-mL volumetric flask, add *Mobile phase* to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 240-nm detector and a 4.6-mm × 25-cm column that contains packing L1. The flow rate is about 1.5 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed under *Procedure*: the tailing factor for the analyte peak is not more than 1.5, and 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 $C_{10}H_{13}ClN_2O_3S$ in the portion of Chlorpropamide taken by the formula:

$$1000C(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Chlorpropamide 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
CHLORPROPAMIDE	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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