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Chlorpropamide Tablets

» Chlorpropamide Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{10}H_{13}ClN_2O_3S$.

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩—

USP Chlorpropamide RS

Identification—Shake a quantity of finely powdered Tablets, equivalent to about 100 mg of chlorpropamide, with 20 mL of 1 N hydrochloric acid, and extract with 50 mL of chloroform. Filter the chloroform through chloroform-washed cotton into a suitable beaker, and evaporate the chloroform on a steam bath with the aid of a current of dry air to dryness. Dry the residue at 105° for 1 hour: the residue so obtained responds to the *Identification* tests under *Chlorpropamide*.

Dissolution ⟨711⟩—

Medium: water; 900 mL.

Apparatus 2: 50 rpm.

Time: 60 minutes.

Procedure—Determine the amount of $C_{10}H_{13}ClN_2O_3S$ dissolved from UV absorbances at the wavelength of maximum absorbance at about 230 nm of filtered portions of the solution under test, suitably diluted with 0.1 N hydrochloric acid in comparison with a Standard solution having a known concentration of USP Chlorpropamide RS in 0.1 N hydrochloric acid. [Note—A volume of alcohol not exceeding 10% of the final volume of the Standard solution may be used to dissolve the USP Chlorpropamide RS.]

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_{10}H_{13}ClN_2O_3S$ is dissolved in 60 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Assay—

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

Assay preparation—Weigh and finely powder not less than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 50 mg of chlorpropamide, to a 100-mL volumetric flask. Add *Mobile phase* to volume, mix, and filter, discarding the first 10 mL of the filtrate. Pipet 10 mL of the filtrate into a second 100-mL volumetric flask, add *Mobile phase* to volume, and mix.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Chlorpropamide*. Calculate the quantity, in mg, of $C_{10}H_{13}ClN_2O_3S$ in the portion of Tablets 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 TABLETS	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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