Status: Currently Official on 17-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-97788C59-F0CF-4BA4-8463-133C17F3400B_1_en-US
DOI: https://doi.org/10.31003/USPNF_M83880_01_01
DOI Ref: byb9q

Tolazamide Tablets

» Tolazamide Tablets contain not less than 95.0 percent and not more than 105.0 percent of the labeled amount of $C_{14}H_{21}N_3O_3S$.

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩—

USP Tolazamide RS

Identification—Triturate a quantity of Tablets, equivalent to about 250 mg of tolazamide, with 50 mL of chloroform, and filter. Evaporate the filtrate to dryness, and dry in vacuum at 60° for 3 hours: the residue so obtained responds to *Identification* test *A* under *Tolazamide*.

Dissolution ⟨711⟩—

Medium: 0.05 M Tris(hydroxymethyl)aminomethane, pH 7.6, adjusted, if necessary, with hydrochloric acid to a pH of 7.6; 900 mL.

Apparatus 2: 75 rpm.

Time: 30 minutes.

Procedure—Determine the amount of $C_{14}H_{21}N_3O_3S$ dissolved from UV absorbances at the wavelength of maximum absorbance at about 224 nm of filtered portions of the solution under test, suitably diluted with *Dissolution Medium*, in comparison with a Standard solution having a known concentration of USP Tolazamide RS in the same medium. [Note—Sonicate the Standard solution until the Reference Standard is dissolved.]

Tolerances—Not less than 70% *(Q)* of the labeled amount of $C_{14}H_{21}N_3O_3S$ is dissolved in 30 minutes.

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

Assay—

Internal standard preparation, *Mobile phase*, and *Standard preparation*—Prepare as directed in the *Assay* under *Tolazamide*.

Assay preparation—Weigh and finely powder not less than 10 Tablets. Weigh accurately a portion of the powder, equivalent to about 300 mg of tolazamide, and transfer to a suitable container. Add 100.0 mL of *Internal standard solution* and about 20 glass beads. Securely close the container, and shake vigorously for approximately 30 minutes. Centrifuge, and use the clear liquid as the *Assay preparation*.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Tolazamide.* Calculate the quantity, in mg, of $C_{14}H_{21}N_3O_3S$ in the portion of Tablets taken by the formula:

$$100C(R_U/R_S)$$

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
TOLAZAMIDE 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

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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