

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:

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