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Trimethobenzamide Hydrochloride Capsules

» Trimethobenzamide Hydrochloride Capsules contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{21}H_{28}N_2O_5 \cdot HCl$.

Packaging and storage—Preserve in well-closed containers.

USP REFERENCE STANDARDS (11)—

[USP Trimethobenzamide Hydrochloride RS](#)

Identification—

A: The UV absorption spectrum of the solution employed for measurement of absorbance in the Assay exhibits maxima and minima at the same wavelengths as that of the Standard solution.

B: Transfer a portion of the contents of Capsules, equivalent to about 20 mg of trimethobenzamide hydrochloride, to a suitable vessel, dissolve in 15 mL of 0.1 N hydrochloric acid, and filter. Transfer the filtrate to a separator, and add 5 mL of 1 N sodium hydroxide. Extract with 15 mL of chloroform, filtering the chloroform extract through anhydrous sodium sulfate into a suitable vessel, and evaporate to dryness. Allow to cool to room temperature, add a small portion of ether, and evaporate at room temperature to dryness. Dry the residue at 60° for 1 hour: the IR absorption spectrum of a potassium bromide dispersion of the residue so obtained exhibits maxima only at the same wavelengths as that of a similar preparation of [USP Trimethobenzamide Hydrochloride RS](#).

C: Place a portion of the contents of Capsules, equivalent to about 25 mg of trimethobenzamide hydrochloride, in a 10-mL volumetric flask, add methanol to volume, mix, and filter: the filtrate so obtained responds to the [Thin-layer Chromatographic Identification Test \(201\)](#), a solvent system consisting of a mixture of ethyl acetate, alcohol, and ammonium hydroxide (90:10:5) being used.

DISSOLUTION (711)—

Medium: water; 900 mL.

Apparatus 1: 100 rpm.

Time: 45 minutes.

Procedure—Determine the amount of $C_{21}H_{28}N_2O_5 \cdot HCl$ dissolved from UV absorbances at the wavelength of maximum absorbance at about 258 nm of filtered portions of the solution under test, suitably diluted with Medium, if necessary, in comparison with a Standard solution having a known concentration of [USP Trimethobenzamide Hydrochloride RS](#) in the same Medium.

Tolerances—Not less than 75% (Q) of the labeled amount of $C_{21}H_{28}N_2O_5 \cdot HCl$ is dissolved in 45 minutes.

UNIFORMITY OF DOSAGE UNITS (905): meet the requirements.

Assay—Transfer, as completely as possible, the contents of not less than 20 Capsules to a suitable tared container, and determine the average weight per Capsule. Mix the combined contents, and transfer an accurately weighed portion of the powder, equivalent to about 50 mg of trimethobenzamide hydrochloride, to a 100-mL volumetric flask. Add 50 mL of dilute hydrochloric acid (1 in 120), shake the mixture for several minutes, then add dilute hydrochloric acid (1 in 120) to volume, and mix. Filter through small retentive filter paper, discarding the first 20 mL of the filtrate. Transfer 4.0 mL of the subsequent filtrate to a 100-mL volumetric flask, add dilute hydrochloric acid (1 in 120) to volume, and mix. Concomitantly determine the absorbances of this solution and a Standard solution of [USP Trimethobenzamide Hydrochloride RS](#) in the same medium having a known concentration of about 20 μ g per mL, in 1-cm cells at the wavelength of maximum absorbance at about 258 nm, with a suitable spectrophotometer, using dilute hydrochloric acid (1 in 120) as the blank. Calculate the quantity, in mg, of $C_{21}H_{28}N_2O_5 \cdot HCl$ in the portion of Capsules taken by the formula:

$$2.5C(A_u/A_s)$$

in which C is the concentration, in μ g per mL, of [USP Trimethobenzamide Hydrochloride RS](#) in the Standard solution, and A_u and A_s are the absorbances of the solution from the Capsules and the Standard solution, respectively.

Topic/Question	Contact	Expert Committee
TRIMETHOBENZAMIDE HYDROCHLORIDE CAPSULES	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](#)

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