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Saccharin Sodium Tablets

» Saccharin Sodium Tablets contain the equivalent of not less than 95.0 percent and not more than 110.0 percent of the labeled amount of saccharin ($C_7H_5NO_3S$).

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩—

USP Saccharin RS

Completeness of solution—Place 5 Tablets in a 250-mL beaker containing 150 mL of water at 25°. Stir for 5 minutes: all of the Tablets dissolve to give a clear or practically clear solution.

Identification—

A: Dissolve a quantity of Tablets, equivalent to about 1 g of saccharin, in 10 mL of water, filter if necessary, and to the solution add 5 mL of 3 N hydrochloric acid: a white precipitate of saccharin is formed. Collect the precipitate on a filter, wash with small portions of cold water until the last washing is practically free from chloride, and dry it at 105° for 2 hours: the saccharin so obtained melts between 226° and 230°, the procedure for *Class I* being used (see *Melting Range or Temperature* ⟨741⟩).

[Note—Use the saccharin obtained in *Identification* test *A* for *Identification* tests *B* and *C*.]

B: Dissolve about 100 mg in 5 mL of sodium hydroxide solution (1 in 20), evaporate to dryness, and gently fuse the residue over a small flame until it no longer evolves ammonia. Allow the residue to cool, dissolve in 20 mL of water, neutralize with 3 N hydrochloric acid, and filter: the addition of a drop of ferric chloride TS to the filtrate produces a violet color.

C: Mix 20 mg with 40 mg of resorcinol, add 10 drops of sulfuric acid, and heat the mixture in a suitable liquid bath of 200° for 3 minutes. Allow it to cool, and add 10 mL of water and an excess of 1 N sodium hydroxide: a fluorescent green liquid results.

Limit of ammonium salts—Dissolve a quantity of powdered Tablets, equivalent to about 300 mg of saccharin, in 5 mL of water, and warm with 3 mL of 1 N sodium hydroxide: the odor of ammonia is not perceptible.

Assay—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 100 mg of saccharin, to a 100-mL volumetric flask, add about 50 mL of water, agitate until the Tablet material is dissolved or evenly dispersed, dilute with water to volume, and mix. Transfer 10.0 mL to a separator, add 2 mL of 3 N hydrochloric acid, and extract with five 20-mL portions of a solvent composed of chloroform and alcohol (9:1). Collect the combined extracts in a beaker, and evaporate on a steam bath to dryness with the aid of a current of air. Dissolve the residue in 10 mL of sodium hydroxide solution (1 in 250), transfer the solution with the aid of water to a 200-mL volumetric flask, dilute with water to volume, and mix. Concomitantly determine the absorbances of this solution and a Standard solution of USP Saccharin RS in the same medium having a known concentration of about 50 µg per mL, in 1-cm cells at the wavelength of maximum absorbance at about 269 nm, with a suitable spectrophotometer, using water as the blank. Calculate the quantity, in mg, of saccharin ($C_7H_5NO_3S$) in the portion of Tablets taken by the formula:

$$(2C)(A_U/A_S)$$

in which C is the concentration, in µg per mL, of USP Saccharin RS in the Standard solution; and A_U and A_S are the absorbances of the solution from the Tablets and the Standard solution, respectively.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
SACCHARIN SODIUM 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

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