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Sucralfate Tablets

» Sucralfate Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of sucralfate ($Al_8(OH)_{16}(C_{12}H_{14}O_{35}S_8)[Al(OH)_3]_x[H_2O]_y$) corresponding to not less than 30.6 percent and not more than 37.4 percent of sucrose octasulfate ($C_{12}H_{14}O_{35}S_8$).

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩—
USP Potassium Sucrose Octasulfate RS

[Note—Sucrosofate Potassium is USAN].

α-D-Glucopyranoside, 1,3,4,6-tetra-*O*-sulfo-β-D-fructofuranosyl, tetrakis (hydrogen sulfate), octapotassium salt, heptahydrate.

$C_{12}H_{14}K_8O_{35}S_8 \cdot 7H_2O$ 1413.64 CAS RN®: CAS-76578-81-9.

Anhydrous. $C_{12}H_{14}K_8O_{35}S_8$ 1287.53 CAS RN®: CAS-73264-44-5.

Identification—

A: The retention time of the sucrose octasulfate peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation*, as obtained in the *Assay*.

B: Shake a portion of finely powdered Tablets, equivalent to about 1 g of sucralfate, with 3 N hydrochloric acid, and filter: the solution so obtained meets the requirements of *Identification* test *C* under *Sucralfate*.

Disintegration ⟨701⟩: 15 minutes.

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

Acid-neutralizing capacity—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 250 mg of sucralfate, to a 250-mL screw-capped bottle, and proceed as directed in the test for *Acid-neutralizing capacity* under *Sucralfate*, beginning with "add 100.0 mL of 0.1 N hydrochloric acid": not less than 12 mEq of acid is consumed.

Assay—

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

Assay preparation—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 450 mg of sucralfate, to a 35-mL centrifuge tube, and shake at a moderate rate on a vortex mixer. Proceed as directed for *Assay preparation* in the *Assay* under *Sucralfate* beginning with "While shaking, add 10.0 mL."

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Sucralfate*. Calculate the quantity, in mg, of sucrose octasulfate ($C_{12}H_{14}O_{35}S_8$) in the portion of Tablets taken by the formula:

$$(974.75/1287.53)(25C)(r_U/r_S)$$

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
SUCRALFATE 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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