

Sucralose Assay (FCCIV) by HPLC

Mobile Phase Add 150mL of HPLC-grade acetonitrile that has been filtered through a 0.45 μ m filter to 850mL of glass-distilled water that also has been filtered through a 0.45 μ m filter. Mix and degas thoroughly

Standard Preparation Transfer about 25mg of Sucralose Standard for analytical use accurately weighed, into a 25mL volumetric flask. Dissolve in and dilute to volume with Mobile Phase. Filter the solution through a 0.45 μ m filter.

Sample Preparation Transfer about 25mg of sample accurately weighed, into a 25mL volumetric flask. Dissolve in and dilute to volume with Mobile Phase. Filter the solution through a 0.45 μ m filter.

Chromatographic System Fit a high-performance liquid chromatographic system, operated at room temperature, with an 8-mm \times 10-cm, 5 μ m RadPakC18 reverse-phase column. Maintain the Mobile Phase a pressure and flow rate (typically 1.5mL/min) capable giving the required elution time. Use a refractive index detector.

System Suitability Test Obtain chromatograms of duplicate 20 μ L injections of the standard preparation. Ensure that the retention time of Sucralose is approximately 9 min. It may be necessary to adjust the Mobile composition to obtain the desired retention time. Ensure that the relative standard deviation($100 \times$ standard deviation/mean peak area) does not exceed 2.0%.

Procedure Analyze the Standard Preparation and Sample Preparation under the conditions described above. Making duplicate 20 μ L injections and calculate the mean peak areas.

Calculation Calculate the percent of Sucralose from the peak areas of the Sample Preparation (A_u) and Standard Preparation (A_s) According to the following formula:

$$100(A_u W_s)/(A_s W_u),$$

in which W_s is the weight, in milligrams, of the Sucralose Standard, and W_u is the weight, in milligrams, of the sample