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Salicylic Acid Topical Foam

» Salicylic Acid Topical Foam contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_7H_6O_3$.

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩—

USP Salicylic Acid RS

Identification—The retention time of the salicylic acid peak of the *Assay preparation* observed in the chromatogram obtained in the *Assay* corresponds to the retention time of the salicylic acid peak of the *Standard preparation.*

pH ⟨791⟩: between 5.0 and 6.0.

Assay—

Mobile phase—To 225 mg of tetramethylammonium hydroxide pentahydrate add 700 mL of water, 150 mL of methanol, 150 mL of acetonitrile, and 1.0 mL of glacial acetic acid, mix, filter, and degas.

Internal standard solution—Dissolve benzoic acid in methanol to obtain a solution having a concentration of about 8 mg per mL.

Standard preparation—Transfer about 20 mg of USP Salicylic Acid RS, accurately weighed, to a 100-mL volumetric flask, add 10.0 mL of *Internal standard solution*, dilute with *Mobile phase* to volume, and mix.

Assay preparation—Transfer an accurately weighed portion of Topical Foam, equivalent to about 20 mg of salicylic acid, to a 100-mL volumetric flask, add 10.0 mL of *Internal standard solution*, dilute with *Mobile phase* to volume, and mix. Cool in an ice bath to below room temperature and filter, discarding the first few mL of the filtrate.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 280-nm detector and a 4-mm × 30-cm column that contains packing L1. The flow rate is about 2 mL per minute. Chromatograph four replicate injections of the *Standard preparation*, and record the peak responses as directed for *Procedure:* the relative standard deviation is not more than 3.0%, the resolution factor between salicylic acid and benzoic acid is not less than 3.0, and the tailing factors for the salicylic acid and benzoic acid peaks are not more than 2.0.

Procedure—Separately inject equal volumes (about 5 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. The retention times are about 2.5 minutes for salicylic acid and 5.5 minutes for benzoic acid. Calculate the quantity, in mg, of $C_7H_6O_3$ in the portion of Topical Foam taken by the formula:

$$(100C)(R_U/R_S)$$

in which C is the concentration, in mg per mL, of USP Salicylic Acid RS in the *Standard preparation*, and R_U and R_S are the ratios of the peak responses for salicylic acid to the peak responses for benzoic acid obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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

Topic/Question	Contact	Expert Committee
SALICYLIC ACID TOPICAL FOAM	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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