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Salsalate Capsules

» Salsalate Capsules contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{14}H_{10}O_5$.

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩—

USP Salsalate RS
USP Salicylic Acid RS
USP Trisalicylic Acid RS $C_{21}H_{14}O_7$ 378.34

Identification—Transfer a quantity of Capsule contents, equivalent to about 500 mg of salsalate, to a stoppered glass test tube. Add 20 mL of ether to the tube, close the tube tightly, shake by mechanical means for 10 minutes, and filter. Evaporate the filtrate to dryness using a stream of nitrogen: the IR absorption spectrum of a mineral oil dispersion of the residue thus obtained, exhibits maxima only at the same wavelengths as that of a similar preparation of USP Salsalate RS.

Disintegration ⟨701⟩: 30 minutes, simulated gastric fluid TS (without pepsin) being used.

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

Limit of salicylic acid—

Mobile phase, Diluent, Resolution solution, and *Chromatographic system*—Proceed as directed in the *Assay.*

Standard preparation—Dissolve an accurately weighed quantity of USP Salicylic Acid RS in *Diluent* to obtain a stock solution having a known concentration of about 0.5 mg per mL. Transfer 3.0 mL of this solution to a 100-mL volumetric flask, dilute with *Diluent* to volume, and mix. This solution contains about 0.015 mg per mL.

Test preparation—Use the *Assay stock solution* prepared as directed in the *Assay.*

Procedure—Proceed as directed for *Procedure* in the *Assay*, except to inject equal volumes (about 10 µL) of the *Standard preparation* and the *Test preparation*. Calculate the percentage of salicylic acid ($C_7H_6O_3$) in the portion of Capsules taken by the formula:

$$10{,}000(C/O_T)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Salicylic Acid RS in the *Standard preparation*, O_T is the quantity, in mg, of salsalate in the portion of Capsules taken based on the labeled amount, and r_U and r_S are the salicylic acid peak responses obtained from the *Test preparation* and the *Standard preparation*, respectively: not more than 1.5% is found.

Assay—

Mobile phase, *Diluent*, *Salsalate standard preparation*, *Resolution solution*, and *Chromatographic system*—Proceed as directed in the *Assay* under *Salsalate.*

Assay preparation—Transfer as completely as possible the contents of not less than 20 Capsules to a suitable tared container, and weigh. Mix, and transfer an accurately weighed portion of the powder, equivalent to about 100 mg of salsalate, to a 100-mL volumetric flask, dilute with *Diluent* to volume, and mix. Sonicate for about 10 minutes, and mix. Filter a portion of this solution through a suitable filter of 0.5 µm or finer porosity. Use the clear filtrate as the *Assay stock solution*. Transfer 2.0 mL of the *Assay stock solution* to a 100-mL volumetric flask, dilute with *Diluent* to volume, and mix (*Assay preparation*).

Procedure—Separately inject equal volumes (about 10 µL) of the *Salsalate standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the salsalate peaks. Calculate the quantity, in mg, of salsalate ($C_{14}H_{10}O_5$) in the portion of Capsules taken by the formula:

$$5000C(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Salsalate RS in the *Salsalate standard preparation*, and r_U and r_S are the responses of the salsalate peaks obtained from the *Assay preparation* and the *Salsalate standard preparation*, respectively.

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

Topic/Question	Contact	Expert Committee
SALSALATE CAPSULES	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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