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Salsalate Tablets

» Salsalate Tablets 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

Identification—Transfer a quantity of finely powdered Tablets, 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 so obtained exhibits maxima only at the same wavelengths as that of a similar preparation of USP Salsalate RS.

Dissolution ⟨711⟩—

Test 1: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 1*.

Medium: 0.25 M pH 7.4 phosphate buffer, prepared by mixing 5.175 g of monobasic sodium phosphate and 30.17 g of anhydrous dibasic sodium phosphate with water to obtain 1000 mL of solution, and adjusting by the dropwise addition of 50% sodium hydroxide solution to a pH of 7.40 ± 0.05; 900 mL.

Apparatus 2: 50 rpm.

Time: 60 minutes.

Procedure—Determine the amount of $C_{14}H_{10}O_5$ dissolved from UV absorbances at the wavelength of maximum absorbance at about 308 nm of filtered portions of the solution under test, suitably diluted with *Medium,* in comparison with a Standard solution having a known concentration of USP Salsalate RS in the same *Medium*.

Tolerances—Not less than 70% *(Q)* of the labeled amount of $C_{14}H_{10}O_5$ is dissolved in 60 minutes.

Test 2: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

Medium: 0.05 M, pH 7.5 phosphate buffer; prepared by mixing 40.83 g of monobasic potassium phosphate and 120 mL of 2 N sodium hydroxide with water to obtain 6 L of solution, and adjusting by the dropwise addition of 2 N sodium hydroxide or phosphoric acid to a pH of 7.50 ± 0.05; 900 mL.

Apparatus 2: 100 rpm.

Time and *Procedure*—Proceed as directed for *Test 1*.

Tolerances—Not less than 70% *(Q)* of the labeled amount of $C_{14}H_{10}O_5$ is dissolved in 60 minutes.

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 solution—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 50-mL volumetric flask, dilute with *Diluent* to volume, and mix. This solution contains about 0.03 mg per mL.

Test solution—Use the *Assay stock preparation* 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 solution* and the *Test solution.* Calculate the percentage of salicylic acid ($C_7H_6O_3$) in the portion of Tablets 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 solution;* O_T is the quantity, in mg, of salsalate in the portion of Tablets taken based on the labeled amount; and r_U and r_S are the salicylic acid peak responses obtained from the *Test solution* and the *Standard solution,* respectively: not more than 3.0% is found.

Assay—

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

Assay stock preparation—Weigh and finely powder not fewer than 20 Tablets. 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. Pass a portion of this solution through a suitable filter of 0.5-µm or finer porosity. Use the clear filtrate.

Assay preparation— Transfer 2.0 mL of the *Assay stock preparation* to a 100-mL volumetric flask, dilute with *Diluent* to volume, and mix.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Salsalate.* Calculate the quantity, in mg, of $C_{14}H_{10}O_5$ in the portion of Tablets 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 TABLETS	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

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