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Salicylic Acid Plaster

DEFINITION

Salicylic Acid Plaster is a uniform mixture of Salicylic Acid in a suitable base, spread on paper, cotton cloth, or other suitable backing material. The plaster mass contains NLT 90.0% and NMT 110.0% of the labeled amount of salicylic acid ($C_7H_6O_3$).

IDENTIFICATION

• **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Solution A: Methanol and 2% (v/v) phosphoric acid in water (1:1)

Solution B: Methanol

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)	Flow Rate (mL/min)
0	100	0	1.0
5.5	100	0	1.0
5.6	0	100	2.0
7.1	0	100	2.0
7.2	100	0	2.0
9.4	100	0	2.0
9.5	100	0	1.0
10.0	100	0	1.0

Diluent: Tetrahydrofuran and hydrochloric acid (99:1)

Standard solution: 0.2 mg/mL of USP Salicylic Acid RS prepared as follows. Transfer USP Salicylic Acid RS to a suitable volumetric flask, and add *Diluent* equivalent to 12.5% of the final volume to dissolve. Dilute with *Solution A* to volume. Protect from light.

Sample solution: Transfer Plaster (scrape it from the fabric if needed), equivalent to 40 mg of salicylic acid, to a 200-mL volumetric flask, and add 25 mL of *Diluent* to dissolve. Sonicate if necessary to facilitate dissolution. Dilute with *Solution A* to volume. Mix, filter, and discard the first few mL. Protect from light.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 306 nm

Column: 4.6-mm × 15-cm; 5-µm packing L11

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of salicylic acid ($C_7H_6O_3$) in the portion of Plaster taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak area from the *Sample solution*

r_S = peak area from the *Standard solution*

C_S = concentration of USP Salicylic Acid RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of salicylic acid in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers. Store between 20° and 25°.
- **USP Reference Standards** ⟨11⟩
  USP Salicylic Acid RS

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

Topic/Question	Contact	Expert Committee
SALICYLIC ACID PLASTER	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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