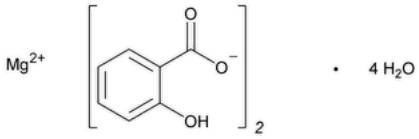
Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-EB58E31D-9262-4151-9264-73E7C9A8FEC9_4_en-US
DOI: https://doi.org/10.31003/USPNF_M46940_04_01
DOI Ref: rf7gr

Magnesium Salicylate



$C_{14}H_{10}MgO_6 \cdot 4H_2O$ 370.59
$C_{14}H_{10}MgO_6$ 298.54

Magnesium, bis(2-hydroxybenzoato-*O*[1],*O*[2])-, tetrahydrate;

Magnesium salicylate (1:2), tetrahydrate CAS RN®: 18917-95-8; UNII: 41728CY7UX.

Anhydrous CAS RN®: 18917-89-0; UNII: JQ69D454N1.

DEFINITION

Magnesium Salicylate contains NLT 98.0% and NMT 103.0% of magnesium salicylate ($C_{14}H_{10}MgO_6 \cdot 4H_2O$).

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**▲ (CN 1-May-2020)

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

• **C.** **Identification Tests—General, *Magnesium* ⟨191⟩:** Meets the requirements

ASSAY

• **Procedure**

Mobile phase: Methanol, phosphoric acid, and water (40:0.1:60), prepared by adding 1 mL of phosphoric acid to a solution containing 400 mL of methanol and 600 mL of water

Standard solution: 0.5 mg/mL of USP Magnesium Salicylate RS, in *Mobile phase*

Sample solution: 0.5 mg/mL of Magnesium Salicylate, in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 236 nm

Column: 4.6-mm × 10-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 1.10%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of magnesium salicylate ($C_{14}H_{10}MgO_6 \cdot 4H_2O$) in the portion of Magnesium Salicylate taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

C_U = concentration of Magnesium Salicylate in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–103.0%

IMPURITIES

• **Organic Impurities**

Mobile phase: Methanol, phosphoric acid, and water (40:0.1:60), prepared by adding 1 mL of phosphoric acid to a solution containing 400 mL of methanol and 600 mL of water

Standard stock solution: 0.25 mg/mL of USP Magnesium Salicylate RS, 0.25 mg/mL of USP Salicylic Acid Related Compound A RS, 0.125 mg/mL of USP Salicylic Acid Related Compound B RS, and 0.05 mg/mL of USP Phenol RS, in *Mobile phase*

Standard solution: 0.005 mg/mL of USP Magnesium Salicylate RS, 0.005 mg/mL of USP Salicylic Acid Related Compound A RS, 0.0025 mg/mL of USP Salicylic Acid Related Compound B RS, and 0.001 mg/mL of USP Phenol RS, in *Mobile phase* prepared from *Standard stock solution*

Sample solution: 5 mg/mL of Magnesium Salicylate, in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 212 nm

Column: 4.6-mm × 10-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 2.0 between any two peaks

Relative standard deviation: NMT 3% for each peak

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of salicylic acid related compound A, salicylic acid related compound B, and phenol in the portion of Magnesium Salicylate taken:

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

r_U = peak response of salicylic acid related compound A, salicylic acid related compound B, or phenol from the *Sample solution*

r_S = peak response of salicylic acid related compound A, salicylic acid related compound B, or phenol from the *Standard solution*

C_S = concentration of USP Salicylic Acid Related Compound A RS, USP Salicylic Acid Related Compound B RS, or USP Phenol RS in the *Standard solution* (mg/mL)

C_U = concentration of Magnesium Salicylate in the *Sample solution* (mg/mL)

Calculate the percentage of any other individual impurity in the portion of Magnesium Salicylate taken:

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

r_U = peak response of any other individual impurity from the *Sample solution*

r_S = peak response of salicylic acid related compound B from the *Standard solution*

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

C_U = concentration of Magnesium Salicylate in the *Sample solution* (mg/mL)

Acceptance criteria: See *Table 1*.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Salicylic acid related compound A	0.3	0.1
Phenol	0.4	0.02
Salicylic acid related compound B	0.6	0.05

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Salicylic acid	1.0	—
Any other individual impurity	—	0.05
Total impurities	—	0.2

SPECIFIC TESTS

• **Magnesium Content**

Sample solution: Transfer 800 mg of Magnesium Salicylate to a 200-mL volumetric flask. Dissolve in and dilute with water to volume. Stir the solution continuously for 15 min, and filter, discarding the first 10 mL of the filtrate, into a flask.

Titrimetric system

Mode: Direct titration

Titrant: 0.05 M edetate disodium VS

Endpoint detection: Visual

Analysis: Transfer 50.0 mL of the *Sample solution* to a 250-mL conical flask. Add 50 mL of water, 5 mL of ammonia–ammonium chloride buffer TS, and 0.15 mL of eriochrome black TS. Titrate with *Titrant* to a blue endpoint. Each mL of *Titrant* is equivalent to 1.215 mg of magnesium.

Acceptance criteria: 6.3%–6.7% of magnesium

• **Water Determination, *Method I* ⟨921⟩:** 17.5%–21.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Store in tight containers at controlled room temperature.

• **USP Reference Standards ⟨11⟩**

USP Magnesium Salicylate RS

USP Phenol RS

USP Salicylic Acid Related Compound A RS

4-Hydroxybenzoic acid.

$C_7H_6O_3$ 138.12

USP Salicylic Acid Related Compound B RS

4-Hydroxyisophthalic acid.

$C_8H_6O_5$ 182.13

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

Topic/Question	Contact	Expert Committee
MAGNESIUM SALICYLATE	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 40(1)

Current DocID: GUID-EB58E31D-9262-4151-9264-73E7C9A8FEC9_4_en-US

DOI: https://doi.org/10.31003/USPNF_M46940_04_01

DOI ref: rf7gr