Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-Dec-2015
Document Type: USP Monographs
DocId: GUID-737FF171-7801-48B3-A4BA-EBCB0260D73C_1_en-US
DOI: https://doi.org/10.31003/USPNF_M46950_01_01
DOI Ref: j81kz

Magnesium Salicylate Tablets

DEFINITION

Magnesium Salicylate Tablets contain an amount of magnesium salicylate ($C_{14}H_{10}MgO_6 \cdot 4H_2O$) equivalent to NLT 95.0% and NMT 105.0% of the labeled amount of anhydrous magnesium salicylate ($C_{14}H_{10}MgO_6$).

IDENTIFICATION

• **A.** The IR absorption spectrum of a potassium bromide dispersion of a quantity of finely powdered Tablets exhibits maxima at the same wavelengths as those of a similar preparation of USP Magnesium Salicylate RS.

• **B.** **Identification Tests—General**, *Magnesium* ⟨191⟩

Sample solution: Prepare a 50-mg/mL magnesium salicylate solution from Tablets, and filter.

Acceptance criteria: Meet the requirements

• **C.** 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**

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

Standard solution: 0.05 mg/mL of anhydrous USP Magnesium Salicylate RS in *Mobile phase*

Sample stock solution: Nominally 0.5 mg/mL of anhydrous magnesium salicylate from NLT 20 finely powdered Tablets in *Mobile phase* prepared as follows. Transfer a suitable amount of the powder to a suitable volumetric flask. Add 75% of the flask volume of *Mobile phase*, and sonicate for 10 min. Allow the solution to cool to room temperature and then dilute with *Mobile phase* to volume.

Sample solution: Nominally 0.05 mg/mL of anhydrous magnesium salicylate in *Mobile phase*, from the *Sample stock solution*. Pass through a suitable filter of 0.20-µm pore size, discarding the first 2–3 mL of the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 212 nm

Column: 2.1-mm × 5-cm; 1.7-µm packing L1

Column temperature: 30°

Flow rate: 0.2 mL/min

Injection volume: 2 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: 0.8–1.8

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of anhydrous magnesium salicylate ($C_{14}H_{10}MgO_6$) in the portion of Tablets 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 anhydrous USP Magnesium Salicylate RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of anhydrous magnesium salicylate in the *Sample solution* (mg/mL)

Acceptance criteria: 95.0%–105.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: Water; 900 mL

Apparatus 2: 50 rpm

Time: 120 min

Standard solution: USP Salicylic Acid RS in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter, and dilute with *Medium* if necessary.

Instrumental conditions

Mode: UV

Analytical wavelength: Maximum wavelength at about 296 nm

Blank: Water

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of anhydrous magnesium salicylate ($C_{14}H_{10}MgO_6$) dissolved:

$$\text{Result} = (A_U/A_S) \times (1/L) \times (M_{r1}/M_{r2}) \times C_S \times V \times 100$$

A_U = absorbance from the *Sample solution*

A_S = absorbance from the *Standard solution*

L = nominal concentration of anhydrous magnesium salicylate in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of anhydrous magnesium salicylate, 298.54

M_{r2} = twice the molecular weight of salicylic acid, 276.24

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

V = volume of *Medium*, 900 mL

Tolerances: NLT 80% (Q) of the labeled amount of anhydrous magnesium salicylate ($C_{14}H_{10}MgO_6$) is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

IMPURITIES

• **Organic Impurities**

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

System suitability solution: 0.5 mg/mL of USP Magnesium Salicylate RS, 0.5 µg/mL of USP Salicylic Acid Related Compound A RS, 0.5 µg/mL of USP Salicylic Acid Related Compound B RS, and 0.5 µg/mL of USP Phenol RS, in *Mobile phase*

Standard solution: 2.5 µg/mL of anhydrous USP Magnesium Salicylate RS in *Mobile phase*

Sample solution: Nominally 2.5 mg/mL of anhydrous magnesium salicylate from NLT 20 finely powdered Tablets in *Mobile phase* prepared as follows. Transfer a suitable amount of the powder to a suitable volumetric flask. Add 80% of the flask volume of *Mobile phase*, and sonicate for 15 min. Allow the solution to cool to room temperature and then dilute with *Mobile phase* to volume. Centrifuge the solution, and use the supernatant.

Chromatographic system

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

Mode: LC

Detector: UV 212 nm

Column: 2.1-mm × 5-cm; 1.7-µm packing L1

Column temperature: 30°

Flow rate: 0.2 mL/min

Injection volume: 2 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 2.0 between any two peaks, *System suitability solution*

Relative standard deviation: NMT 3%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of any individual unspecified impurity in the portion of Tablets taken:

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

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

r_S = peak response of magnesium salicylate from the *Standard solution*

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

C_U = nominal concentration of anhydrous 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	—[a]
Phenol	0.4	—[a]
Salicylic acid related compound B	0.6	—[a]
Salicylic acid	1.0	—
Any individual unspecified impurity	—	0.10
Total impurities	—	1.0

[a] These are process impurities, which are included in the table for identification only. These impurities are controlled in the drug substance. They are not to be reported for the drug product and should not be included in the total impurities.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers.
- **USP Reference Standards** ⟨11⟩

USP Magnesium Salicylate RS

USP Phenol RS

USP Salicylic Acid 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

Topic/Question	Contact	Expert Committee
MAGNESIUM SALICYLATE 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

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 40(4)

Current DocID: GUID-737FF171-7801-48B3-A4BA-EBCB0260D73C_1_en-US
DOI: https://doi.org/10.31003/USPNF_M46950_01_01
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