USP Salicylic Acid RS in the same medium, using water as the blank. Calculate the quantity of magnesium salicylate (C₁₄H₁₀MgO₆), dissolved by the formula:

\[(298.54 / 276.24)(900)(A_0 / A_1)\]

in which the terms are as defined in the Assay.

Tolerances—Not less than 80% (Q) of the labeled amount of C₁₄H₁₀MgO₆ is dissolved in 120 minutes.

**Uniformity of dosage units (905):** meet the requirements.

**Assay**—Weigh and finely powder not fewer than 20 Tablets. Weigh accurately a portion of the powder, equivalent to about 500 mg of magnesium salicylate, and transfer to a 250-mL volumetric flask. Dilute with water to volume, mix, and filter, discarding the first 20 mL of the filtrate. Dilute an accurately measured portion of the filtrate quantitatively and stepwise, if necessary, to obtain a final concentration of about 20 μg per mL. Dissolve an accurately weighed quantity of USP Salicylic Acid RS in water, and dilute quantitatively and stepwise, if necessary, with water to obtain a Standard solution having a known concentration of about 18 μg per mL. Concomitantly determine the absorbances of both solutions in 1-cm cells at the wavelength of maximum absorbance at about 296 nm, with a suitable spectrophotometer, using water as the blank. Calculate the quantity, in mg, of C₁₄H₁₀MgO₆ in the portion of Tablets taken by the formula:

\[(298.54 / 276.24)(L / D)(C)(A_0 / A_1)\]

in which 298.54 is the molecular weight of anhydrous magnesium salicylate; 276.24 is twice the molecular weight of salicylic acid; L is the labeled quantity, in mg, of magnesium salicylate in each Tablet; D is the concentration, in mg per mL, of magnesium salicylate in the solution from the Tablets, based on the labeled quantity per Tablet and the extent of dilution; C is the concentration, in mg per mL, of USP Salicylic Acid RS in the Standard solution; and A₀ and A₁ are the absorbances of the solution from the Tablets and the Standard solution, respectively.

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**Magnesium Sulfate**

MgSO₄·xH₂O

Sulfuric acid magnesium salt (1:1), hydrate;

MgSO₄ (1:1) monohydrate 138.36

[14168-73-1].

MgSO₄ (1:1) heptahydrate 246.47

[10034-99-8].

Anhydrous 120.37

[7487-88-9].

**DEFINITION**

Magnesium Sulfate, rendered anhydrous by ignition, contains NLT 99.0% and NMT 100.5% of MgSO₄.

**IDENTIFICATION**

* A. **IDENTIFICATION TESTS—GENERAL, Magnesium (191) and Sulfate (191)**

Sample solution: 50 mg/mL

Acceptance criteria: Meets the requirements

**ASSAY**

* **PROCEDURE**

Sample: 250 mg of the ignited Magnesium Sulfate obtained in the test for Loss on Ignition

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**Titrmetric system**

**Mode:** Direct titration

**Titrant:** 0.05M edetate sodium VS

**Endpoint detection:** Colorimetric

**Analysis:** Dissolve the Sample in 100 mL of water and the minimum amount of 3 N hydrochloric acid required for a clear solution. Adjust the reaction of the solution (using pH indicator paper; see Reagents, Indicators, and Solutions—Reagents—Indicator and Test Papers) with 1 N sodium hydroxide to a pH of 7, add 5 mL of ammonia–ammonium chloride buffer TS and 0.15 mL of eriochrome black TS, and titrate with the Titrant to a blue endpoint. Calculate the percentage of MgSO₄ in the portion of the ignited Magnesium Sulfate taken:

\[\text{Result} = [\frac{V \times N \times F}{100}] / W\]

- \(V = \text{Sample titrant volume (mL)}\)
- \(N = \text{titrant molarity (mmol/mL)}\)
- \(F = \text{equivelancy factor, 120.36 mg/mmol}\)
- \(W = \text{weight of Sample (mg)}\)

**Acceptance criteria:** 99.0%–100.5% on the anhydrous by ignition basis

**IMPURITIES**

- **LIMIT OF CHLORIDE (221)**

Sample: 1.0 g

Acceptance criteria: The Sample shows no more chloride than corresponds to 0.20 mL of 0.020 N hydrochloric acid (0.014%).

- **LIMIT OF IRON (241)**

Magnesium Sulfate intended for use in preparing nonparenteral dosage forms

Sample solution: Dissolve 0.50 g in 40 mL of water.

Analysis: Proceed as directed in the test for Iron (241).

Acceptance criteria: NMT 20 μg/g

Magnesium Sulfate intended for use in preparing parenteral dosage forms

[NOTE—Rinse all glassware used in this test with Dilute hydrochloric acid.]

**Dilute hydrochloric acid:** 1 mL of hydrochloric acid diluted with water to 1000 mL

**Solution A:** 500 mg/mL of ammonium acetate in water

**Solution B:** 13.4 mg/mL of ascorbic acid in water

[NOTE—Use this solution on the day prepared.]

**Color reagent:** 3.8 mg/mL of 3-(2-pyridyl)-5,6-di-(2-furyl)-1,2,4-triazine-5′,5″-disulfonic acid, disodium salt in Solution A. Shake by mechanical means if necessary. Use this solution on the day prepared.

**Standard stock solution:** 1.0 μg/mL of iron, from Standard Iron Solution in Dilute hydrochloric acid

**Standard solutions:** To three separate 50-mL volumetric flasks transfer 2.0, 5.0, and 10.0 mL of Standard stock solution, and dilute each with Dilute hydrochloric acid to 35 mL. These solutions contain 2.0, 5.0, and 10.0 μg of iron, respectively.

**Sample solution:** Transfer 10.0 g of Magnesium Sulfate to a 50-mL volumetric flask, add Dilute hydrochloric acid to 35 mL, and sonicate, if necessary, to dissolve.

**Blank:** Transfer 35 mL of Dilute hydrochloric acid to a 50-mL volumetric flask.

**Instrumental conditions**

(See Spectrophotometry and Light-Scattering (851).)

**Mode:** UV-Vis

**Analytical wavelength:** 594 nm

**Analysis**

Samples: Standard solutions, Blank, and Sample solution

To each of the flasks containing the Standard solutions, the Sample solution, and the Blank add 5 mL of Solution A and 5 mL of Color reagent. Dilute each solution with Dilute hydrochloric acid to volume, mix, and allow to stand for 10 min. Plot the absorbance values of the Standard solutions versus their iron contents in μg and draw the straight line.
Magnesium Sulfate Injection

Magnesium Sulfate Injection is a sterile solution of Magnesium Sulfate in Water for Injection. It contains not less than 93.0 percent and not more than 107.0 percent of the labeled amount of MgSO₄ · 7H₂O.

Packaging and storage—Preserve in single-dose glass or plastic containers. Glass containers are preferably of Type 1 or Type II glass.

USP Reference standards (11)—
USP Endotoxin RS
Identification—It responds to the Identification test under Dextrose, and to the tests for Magnesium (191).
Bacterial endotoxins (85)—It contains not more than 0.039 USP Endotoxin Unit per mg of magnesium sulfate.

pH (791): between 5.5 and 7.0, when diluted to a concentration of 5% (w/v).

Particulate matter (788): meets the requirements for small-volume injections.

Other requirements—it meets the requirements under Injections (1).

Assay—Transfer to a beaker an accurately measured volume of Injection, equivalent to about 250 mg of anhydrous magnesium sulfate, and dilute with water to 100 mL. Adjust the reaction of the solution to a pH of 7 (using pH indicator paper; see Indicator and Test Papers under Reagents in the section Reagents, Indicators, and Solutions) with 1 N sodium hydroxide, add 5 mL of ammonia–ammonium chloride buffer TS and 0.15 mL of eriochrome black T, and titrate with 0.05 M edetate disodium VS to a blue endpoint. Each mL of 0.05 M edetate disodium is equivalent to 12.32 mg of MgSO₄ · 7H₂O.

Magnesium Sulfate in Dextrose Injection

Magnesium Sulfate in Dextrose Injection is a sterile solution of Magnesium Sulfate and Dextrose in Water for Injection. It contains not less than 93.0 percent and not more than 107.0 percent of the labeled amount of magnesium sulfate (MgSO₄ · 7H₂O) and not less than 90.0 percent and not more than 110.0 percent of the labeled amount of dextrose (C₆H₁₂O₆ · H₂O).

Packaging and storage—Preserve in single-dose glass or plastic containers. Glass containers are preferably of Type I or Type II glass.

USP Reference standards (11)—
USP Endotoxin RS
Identification—It responds to the Identification test under Dextrose, and to the tests for Magnesium (191).
Bacterial endotoxins (85)—It contains not more than 0.059 USP Endotoxin Unit per mg of magnesium sulfate.

pH (791): between 3.5 and 6.5.

Limit of 5-hydroxymethylfurfural and related substances—Dilute an accurately measured volume of Injection, equivalent to 1.0 g of C₆H₁₀O₅ · H₂O, with water to 500.0 mL. Determine the absorbance of this solution in a 1-cm cell at 284 nm with a spectrophotometer, using water as the blank; the absorbance is not more than 0.25.

Other requirements—it meets the requirements under Injections (1).

Assay for magnesium sulfate—Proceed with Injection as directed in the Assay under Magnesium Sulfate Injection.

Assay for dextrose—Proceed with Injection as directed in the Assay under Dextrose Injection.

Magnesium Trisilicate

2MgO · 3SiO₂ · xH₂O(anhydrous) 260.86
Silicic acid (H₄SiO₄), magnesium salt (1:2), hydrate. Magnesium silicate hydrate (Mg₃SiO₄ · xH₂O)
Anhydrous [14987-04-3].

Magnesium Trisilicate is a compound of Magnesium Oxide and silicon dioxide with varying proportions of water. It contains not less than