B: A filtered solution of Tablets, equivalent to magnesium salicylate solution (1:20), responds to the test for *Magnesium* ⟨191⟩.

Dissolution ⟨711⟩—

Medium: water; 900 mL.

Apparatus 2: 50 rpm.

Time: 120 minutes.

Procedure—Determine the amount of $C_{14}H_{10}MgO_6$ dissolved from UV absorbances at the wavelength of maximum absorbance at about 296 nm of filtered portions of the solution under test, suitably diluted with water, in comparison with a Standard solution having a known concentration of USP Salicylic Acid RS in the same medium, using water as the blank. Calculate the quantity of magnesium salicylate ($C_{14}H_{10}MgO_6$), dissolved by the formula:

$$(298.54 / 276.24)(900C)(A_U / A_S)$$

in which the terms are as defined in the *Assay*.

Tolerances—Not less than 80% *(Q)* of the labeled amount of $C_{14}H_{10}MgO_6$ 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 $C_{14}H_{10}MgO_6$ in the portion of Tablets taken by the formula:

$$(298.54 / 276.24)(L / D)(C)(A_U / A_S)$$

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 A_U and A_S are the absorbances of the solution from the Tablets and the Standard solution, respectively.

Magnesium Sulfate

$MgSO_4 \cdot xH_2O$

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

Magnesium sulfate (1:1) monohydrate [14168-73-1].	138.36
Magnesium sulfate (1:1) heptahydrate [10034-99-8].	246.47
Anhydrous [7487-88-9].	120.37

DEFINITION

Magnesium Sulfate, rendered anhydrous by ignition, contains NLT 99.0% and NMT 100.5% of $MgSO_4$.

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*

Titrimetric 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. Caclulate the percentage of $MgSO_4$ in the portion of the ignited Magnesium Sulfate taken:

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

V = *Sample* titrant volume (mL)
N = titrant molarity (mmol/mL)
F = equivalency factor, 120.36 mg/mmol
W = 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 B* 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 best fitting the three plotted points. From the graph, determine the iron content, *C*, in µg, of the *Sample solution*.
Calculate the content, in µg/g, of iron in the portion of Magnesium Sulfate taken:

$$\text{Result} = C/W$$

C = content of iron in the *Sample solution* in µg, determined from the graph
W = weight of Magnesium Sulfate in the *Sample solution* (g)

Acceptance criteria: NMT 0.5 µg/g

- **SELENIUM ⟨291⟩**
Test solution: 200 mg in 50 mL of 0.25 N nitric acid
Acceptance criteria: NMT 30 µg/g
- **HEAVY METALS ⟨231⟩**
Sample solution: 2 g in 25 mL of water
Acceptance criteria: NMT 10 ppm

SPECIFIC TESTS
- **PH ⟨791⟩**
Sample solution: 50 mg/mL
Acceptance criteria: 5.0–9.2
- **LOSS ON DRYING ⟨731⟩:** Dry a sample at 105° for 2 h: the anhydrous form loses NMT 2% of its weight.
- **LOSS ON IGNITION ⟨733⟩**
Sample: 1 g
Analysis: Weigh the *Sample* in a crucible, heat at 105° for 2 h, then ignite in a muffle furnace at 450 ± 25° to constant weight.
Acceptance criteria
Monohydrate: Loses 13.0%–16.0% of its weight
Dried form: Loses 22.0%–28.0% of its weight
Heptahydrate: Loses 40.0%–52.0% of its weight

ADDITIONAL REQUIREMENTS
- **PACKAGING AND STORAGE:** Preserve in well-closed containers.
- **LABELING:** The label states whether it is the monohydrate, the dried form, or the heptahydrate. Magnesium Sulfate intended for use in preparing parenteral dosage forms is so labeled. Magnesium Sulfate not intended for use in preparing parenteral dosage forms is so labeled. In addition, it may be labeled also as intended for use in preparing nonparenteral dosage forms.

Magnesium Sulfate Injection

» Magnesium Sulfate Injection is a sterile solution of Magnesium Sulfate in Water for Injection. It contains magnesium sulfate equivalent to not less than 93.0 percent and not more than 107.0 percent of the labeled amount of $MgSO_4 \cdot 7H_2O$.

Packaging and storage—Preserve in single-dose or multiple-dose containers, preferably of Type I glass.

Labeling—The label states the total osmolar concentration in mOsmol per L. Where the contents are less than 100 mL, or where the label states that the Injection is not for direct injection but is to be diluted before use, the label alternatively may state the total osmolar concentration in mOsmol per mL.

USP Reference standards ⟨11⟩**—**
USP Endotoxin RS

Identification—It responds to the tests for *Magnesium* ⟨191⟩ and for *Sulfate* ⟨191⟩.

Bacterial endotoxins ⟨85⟩**—**It contains not more than 0.09 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 TS, 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 $MgSO_4 \cdot 7H_2O$.

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 ($MgSO_4 \cdot 7H_2O$) and not less than 90.0 percent and not more than 110.0 percent of the labeled amount of dextrose ($C_6H_{12}O_6 \cdot H_2O$).

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 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 $C_6H_{12}O_6 \cdot H_2O$, 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*.