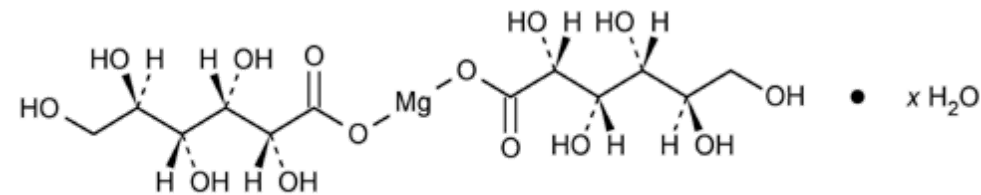


U.S. PHARMACOPEIA

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Magnesium Gluconate


 $C_{12}H_{22}MgO_{14} \cdot xH_2O$ (anhydrous) 414.60

D-Gluconic acid, magnesium salt (2:1), hydrate.

Magnesium D-gluconate (1:2) hydrate.

Magnesium D-gluconate (1:2) dihydrate 450.64 [59625-89-7].

Anhydrous [3632-91-5].

» Magnesium Gluconate contains not less than 98.0 percent and not more than 102.0 percent of $C_{12}H_{22}MgO_{14}$, calculated on the anhydrous basis.

Packaging and storage— Preserve in well-closed containers.

USP Reference standards [〈 11 〉](#) — [USP Potassium Gluconate RS](#).

Identification—

A: A solution (1 in 10) responds to the tests for *Magnesium* [〈 191 〉](#).

B: It responds to *Identification* test *B* under [Calcium Gluconate](#).

pH [〈 791 〉](#): between 6.0 and 7.8, in a solution (1 in 20).

Water, Method 1b [〈 921 〉](#): between 3.0% and 12.0%, 30 minutes being allowed for solubilization of the specimen and for the reaction to reach completion, and a blank determination being performed with the same volume of *Reagent* but without the specimen. Calculate the water content of the specimen, in mg, taken by the formula:

$$F(X_b - X)R,$$

in which X_b is the volume, in mL, of standardized *Water-Methanol Solution* required to neutralize the unconsumed *Reagent* in the blank determination; and the other terms are as defined therein.

Chloride [〈 221 〉](#)— A 1.0-g portion shows no more chloride than corresponds to 0.70 mL of 0.020 N hydrochloric acid (0.05%).

Sulfate [〈 221 〉](#)— A 2.0-g portion shows no more sulfate than corresponds to 1.0 mL of 0.020 N sulfuric acid (0.05%).

Heavy metals [〈 231 〉](#)— Dissolve 1.0 g in 10 mL of water, add 6 mL of 3 N hydrochloric acid, and dilute with water to 25 mL: the limit is 0.002%.

Reducing substances— Transfer 1.0 g to a 250-mL conical flask, dissolve in 10 mL of water, and add 25 mL of [alkaline cupric citrate TS](#). Cover the flask, boil gently for 5 minutes, accurately timed, and cool rapidly to room temperature. Add 25 mL of 0.6 N acetic acid, 10.0 mL of 0.1 N iodine VS, and 10 mL of 3 N hydrochloric acid, and titrate with 0.1 N sodium thiosulfate VS, adding 3 mL of [starch TS](#) as the endpoint is approached. Perform a blank determination, omitting the specimen, and note the difference in volumes required. Each mL of the difference in volume of 0.1 N sodium thiosulfate consumed is equivalent to 2.7 mg of reducing substances (as dextrose): the limit is 1.0%.

Organic volatile impurities, Method I [〈 467 〉](#): meets the requirements.

Residual solvents [〈 467 〉](#): meets the requirements.

(Official January 1, 2007)

Assay— Weigh accurately about 800 mg of Magnesium Gluconate, dissolve in 20 mL of water, add 5 mL of ammonia-ammonium chloride buffer TS and 0.1 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 20.73 mg of $C_{12}H_{22}MgO_{14}$.

Auxiliary Information— *Staff Liaison* : [Lawrence Evans, III, Ph.D., Scientist](#)

Expert Committee : (DSN05) Dietary Supplements - Non-Botanicals

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