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Magnesia Tablets

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click https://www.uspnf.com/rb-magnesia-tabs-20211119.

DEFINITION

Magnesia Tablets contain NLT 93.0% and NMT 107.0% of the labeled amount of magnesium hydroxide [$Mg(OH)_2$].

IDENTIFICATION

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

Sample solution: Crush several Tablets, and dissolve 1 g of the powder in 20 mL of 3 N hydrochloric acid.

Acceptance criteria: Meet the requirements

Delete the following:

▲• **B.** The retention time of the magnesium peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲ (RB 1-Dec-2022)

ASSAY

Change to read:

• **Procedure**

▲**Sample:** A portion of finely powdered Tablets (NLT 20), equivalent to about 250 mg of magnesium hydroxide.

Titrimetric system

Mode: Direct titration

Titrant: 0.05 M edetate disodium VS

Endpoint detection: Visual

Analysis: Transfer the *Sample* to a 100-mL volumetric flask. Dissolve in 10 mL of 3 N hydrochloric acid, and dilute with water to volume. Filter, if necessary, and transfer 25.0 mL of the filtrate to a beaker containing 75 mL of water. Adjust the reaction of the solution to a pH of 7 (using pH indicator paper; see *Reagents, Indicators, and Solutions—Indicator and Test Papers*) with 1 N sodium hydroxide, and add 5 mL of ammonia–ammonium chloride buffer TS and 0.15 mL of eriochrome black TS. Titrate with the *Titrant* to a blue endpoint. Each milliliter of the *Titrant* is equivalent to 2.916 mg of magnesium hydroxide [$Mg(OH)_2$].▲ (RB 1-Dec-2022)

Acceptance criteria: 93.0%–107.0%

PERFORMANCE TESTS

• **Disintegration ⟨701⟩**

Time: NMT 10 min

Analysis: Proceed as directed in the chapter, except substitute simulated gastric fluid TS instead of water.

Acceptance criteria: Meet the requirements

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

SPECIFIC TESTS

• **Acid-Neutralizing Capacity ⟨301⟩**

Analysis: Proceed as directed in the chapter.

Acceptance criteria: NLT 5 mEq of acid is consumed by the minimum single dose recommended in the labeling, and NLT the number of mEq calculated as follows:

$$\text{Result} = 0.8 \times (F_M \times M)$$

F_M = theoretical acid-neutralizing capacity of magnesium hydroxide [$Mg(OH)_2$], 0.0343 mEq/mg

M = quantity of magnesium hydroxide [$Mg(OH)_2$] in the sample tested, based on the labeled quantity (mg)

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

Delete the following:

▲• **USP Reference Standards** ⟨11⟩

USP Calcium Carbonate RS

USP Magnesium Hydroxide RS▲ (RB 1-Dec-2022)

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

Topic/Question	Contact	Expert Committee
MAGNESIA TABLETS	Documentary Standards Support	SM32020 Small Molecules 3

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