



## Magnesium Stearate

### Specifications

This material conforms to the specifications for magnesium stearate in the National Formulary, Food Chemicals Codex, and applicable supplements as of the date of manufacture. It also conforms to the specifications in the European Pharmacopeia, DAB 10, British Pharmacopeia 1998, and Codex X.

#### **Analytical Details**

##### **Identification**

##### **Physical Appearance:**

##### **Assay (as Mg):**

##### **Assay (as MgO):**

##### **Fatty Acid Soluble Temperature:**

##### **Solidification Temperature:**

##### **Chloride:**

##### **Sulfate:**

##### **Acidity/Alkalinity:**

##### **Cadmium:**

##### **Nickel:**

##### **Lead:**

##### **Heavy Metals:**

##### **Stearic Acid/Palmitic Acid:**

##### **C18:**

##### **C16 + C18:**

##### **Water, Alcohol & Ether Solubles:**

##### **Through 200 Mesh:**

##### **Loss on Drying:**

##### **Microbiological Limits:**

##### **Aerobic Count:**

##### **Molds & Yeast:**

##### **Salmonella & E. Coli:**

##### **Residual Solvents:**

#### **Specifications**

Conforms

Fine white powder

4.0-5.0%

6.8-8.3%

Min 54°C

Min 54°C

< 0.1%

< 0.3%

Conforms

Max 3 ppm

Max 5 ppm

Max 5.0 ppm

Max 20.0 ppm

Conforms

Min 40%

> 90.0 %

None

Min 98%

Max 4.0%

< 1000 cfu/g

< 500 cfu/g

Absent

This product is not tested for the presence of the residual solvents <467> listed in the US Pharmacopeia since based on knowledge of the manufacturing process and controlled handling and storage of this material, there is no potential for these toxic solvents to be present. The material if tested, will comply with these established standards.

**Shelf Life:** 24 months with the exception of microbiological data which are guaranteed until the date of shipment.

**Date:** 11/05/2015

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