Magnesium Stearate

1 Nonproprietary Names

BP: Magnesium Stearate
JP: Magnesium Stearate
PhEur: Magnesium Stearate
USP–NF: Magnesium Stearate

2 Synonyms

Cecavon MG 51; Dibasic magnesium stearate; *Kemilub EM-F*; magnesium distearate; magnesii stearas; magnesium octadecanoate; octadecanoic acid, magnesium salt; stearic acid, magnesium salt; *Synpro 90*.

3 Chemical Name and CAS Registry Number

Octadecanoic acid magnesium salt [557-04-0]

4 Empirical Formula and Molecular Weight

$C_{36}H_{70}MgO_4$ 591.24

The USP 40–NF 35 S1 describes magnesium stearate as a compound of magnesium with a mixture of solid organic acids that consists chiefly of variable proportions of magnesium stearate and magnesium palmitate ($C_{32}H_{62}MgO_4$). The fatty acids are derived from edible sources. It contains not less than 4.0% and not more than 5.0% of Mg, calculated on the dried basis.

The PhEur 9.2 describes magnesium stearate as a mixture of magnesium salts of different fatty acids consisting mainly of stearic (octadecanoic) acid [$(C_{17}H_{35}COO)_2Mg$; M_r 591.3] and palmitic (hexadecanoic) acid [$C_{15}H_{31}COO)_2Mg$; M_r 535.1] with minor proportions of other fatty acids. It contains not less than 4.0% and not more than 5.0% of Mg (A_r 24.30), calculated with reference to the dried substance. The fatty acid fraction contains not less than 40.0% of stearic acid and the sum of stearic and palmitic acid is not less than 90.0%.

5 Structural Formula

$[CH_3(CH_2)_{16}COO]_2Mg$

6 Functional Category

Tablet and capsule lubricant.

7 Applications in Pharmaceutical Formulation or Technology

Magnesium stearate is widely used in cosmetics, foods, and pharmaceutical formulations. It is primarily used as a lubricant in capsule and tablet manufacture at concentrations between 0.25% and 5.0% w/w. It is also used in barrier creams.

See also Section 18.

8 Description

Magnesium stearate is a very fine, light white, precipitated or milled, impalpable powder of low bulk density, having a faint odor of stearic acid and a characteristic taste. The powder is greasy to the touch and readily adheres to the skin.

9 Pharmacopeial Specifications

The pharmacopeial specifications for magnesium stearate have undergone harmonization of many attributes for JP, PhEur, and USP–NF.

See Table I. *See also* Section 18.

10 Typical Properties

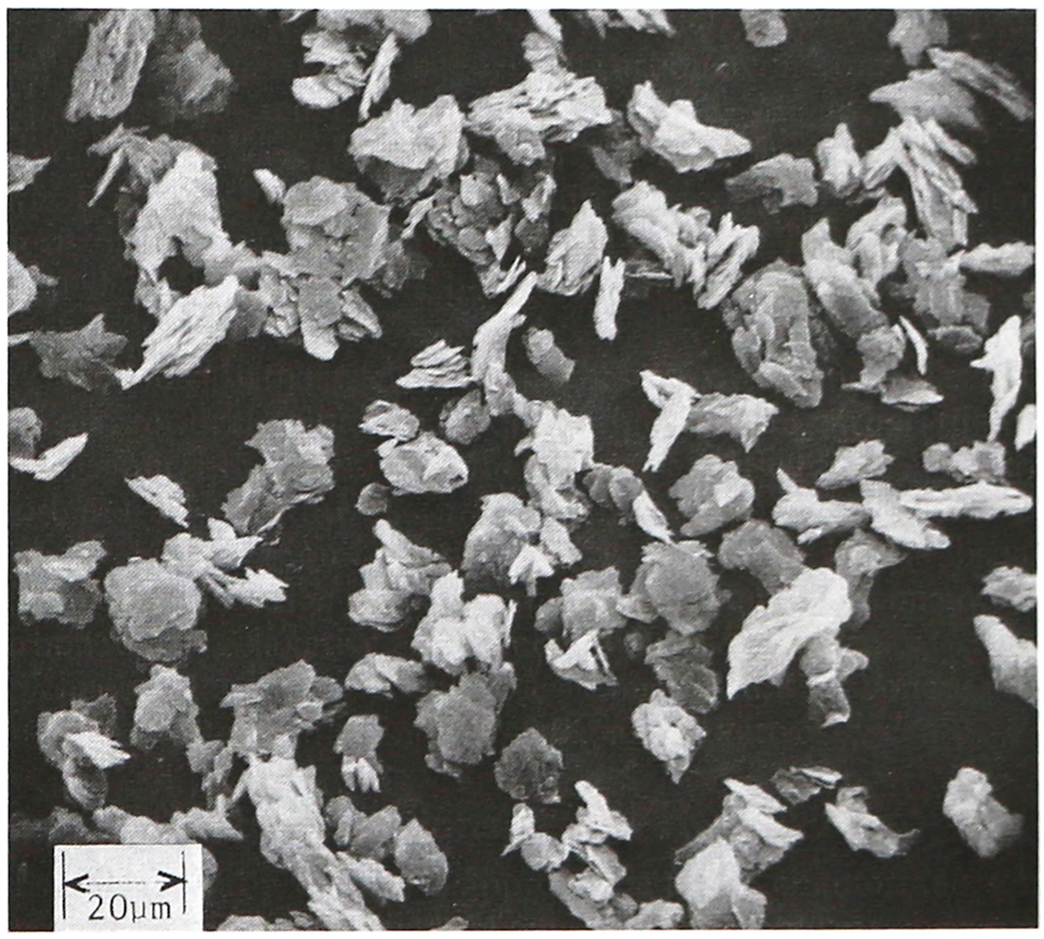
Crystalline forms High-purity magnesium stearate has been isolated as a trihydrate, a dihydrate, and an anhydrate.
Density (bulk) 0.159 g/cm^3
Density (tapped) 0.286 g/cm^3
Density (true) 1.092 g/cm^3
Flash point 250°C
Flowability Poorly flowing, cohesive powder.
Melting range

117–150°C (commercial samples);

126–130°C (high purity magnesium stearate).

Solubility Practically insoluble in ethanol, ethanol (95%), ether and water; slightly soluble in warm benzene and warm ethanol (95%).

SEM 1: Excipient: magnesium stearate; magnification: 600×.



SEM 2: Excipient: magnesium stearate; magnification: 2400×.