

SPECIFICATION

Product Name: Magnesium Stearate USP Grade
Chemical Formula: C ₃₆ H ₇₀ MgO ₄
CAS Number: 557-04-0
Molecular Weight: 591.27 g/mol
Appearance: A Very Fine, Light, White Powder
Odor: Odorless

Chemical Composition

Parameter	Unit	Typical Value	Specification (Min/Max)
Identification: (A) Freezing Point (B) Acid Value (C) Fatty Acid Composition (D) Reaction on Magnesium	°C - - -	56°C Complies Complies Complies	Not Less Than 53° C The Acid Value of the fatty acid is 195 to 210 As Per IP Solution A gives the reaction of magnesium
Appearance of solution	-	Complies	Solution A is not more intensely colored than reference solution YS6
Appearance of solution of the fatty acids	-	Complies	The solution is clear, and not more intensely colored than reference solution YS5
Acidity of Alkalinity	ml	0.004 ml of 0.1 M HCl is Required	NMT 0.05 ml of 0.1M HCl or 0.1 M NaOH is required to change the color of the solution

Acid value of the fatty acids	-	208.2	195 to 210
Free Stearic acid	%	1.41%	NMT 3 %
Zinc Stearate	-	Complies	No violet Precipitate is formed
Lead	PPM	Complies	Max 10 PPM
Chlorides	%	Complies	<0.1%
Sulphates	%	0.7%	Not more than 1.0%
Loss on Drying at 105OC, 1.0 g	%	2.86%	NMT 6.0%
Cadium	PPM	Complies	NMT 3 PPM
Assay	%	4.75%	4.0% - 5.0% Mg on the Dried Basis
The relative contain of stearate	%	Complies	NLT 40.0%
Sum of stearic acid and palmitic acid	%	Complies	NLT 90.0%
TAMC	Cfu/g	<1000 Cfu/g	Acceptance criterion 203 Cfu/g
TYMC	Cfu/g	<500 Cfu/g	Acceptance criterion 500 Cfu/g
Escherichia coli	-	Absent	Absent
Salmonella	-	Absent	Absent
Particle size	%	95%	< 100um
Nickel	PPM	2 PPM	NMT 5 PPM

Mercury	PPM	Complies	NMT 3 PPM
Arsenic	%	Complies	NMT 1.5%
Specific surface area	%	<90%	NLT 90% (6.0 – 12.0) m ² /g

Physical Properties

- Solubility: Practically insoluble in water. Practically insoluble in ethanol. Slightly soluble in ether.

Shelf Life & Storage

- Shelf Life: 5 years from date of manufacture under recommended storage.
- Storage Conditions: Store in a tightly closed container. Keep in a cool, dry place. Protect from moisture and humidity. Avoid exposure to heat and direct sunlight. Keep away from strong oxidizing agents.

Applications

- Use: Reduces friction during compression and ejection. Prevents sticking to punches, dies, and equipment. Improves powder flowability. Ensures smooth release of tablets from molds. Used as an inactive ingredient in solid dosage forms.
- Dosage: Depends on formulation type, compression process, and other excipients used.

Packaging

- Standard Packing: 25 kg woven PP bags with inner liner, 1 kgs and 100 grams, or as per customer requirement.
- Labeling: Product name, batch number, net weight, manufacture date, expiry date, and manufacturer details.

* Specifications are based on the manufacturer's provided specifications.