



FACI STEARATES:
the excipient solution
for tableting process



FACI is a global Group of Companies, active in the production and marketing of bio-based oleo chemical additives from renewable feedstock since 1943.

The continuous desire and propensity for finding the best balance between quality, competitiveness and sustainability is the driver of our daily activities and has existed in the company's culture since its foundation.

Pharmaceutical grade products - excipients

The key to our success are: continuous technical development, close attention to the quality standards of our chemicals and their production process, an open-minded approach to local and international markets and a

close cooperation with our customers.

The Pharmaceutical excipients derived from stearic acid (both of animal and vegetable origin) are part of our specialties.

Their production respects the principals and recommendations stated in the IPEC – PQG Guidelines 2017;

“The Joint Good Manufacturing Practice Guide for Pharmaceutical Excipients”.

All our production sites have an ISO 9001 certification that is the basis of our quality policy.





FACI Guaranteed Quality, Respect for the Environment

FACI Group pharmaceutical excipients

The FACI Group is strongly committed to working with the Pharmaceutical industries and we are producing Pharmaceutical excipients in three of our seven production units (Italy, Spain and Singapore). FACI can provide a wide range of possibilities for any need. The list of all available Pharmaceutical excipients is below:

- Calcium stearate
- Magnesium stearate
- Sodium stearate
- Zinc stearate
- Glyceryl monostearate type I & II
- Glycerine
- Stearic Acid type 50 & 70

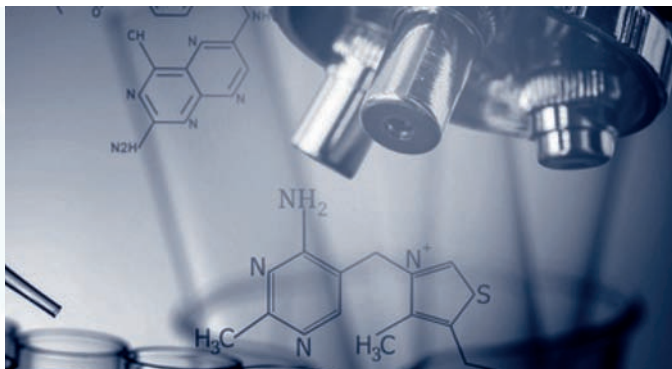


Excipients Product Range

| Excipient | Conformity | FACI SpA Italy | FACI Metalest Spain | FACI Asia Pacific Singapore |
|--|--------------------------------------|----------------|---------------------|-----------------------------|
| Magnesium Stearate Vegetable EUR PHAR | EP, USP/NF,JP,BP, ChP,FCC | • | - | - |
| Magnesium Stearate Tallow EUR PHAR | EP, USP/NF,JP,BP, ChP,FCC | • | - | - |
| Magnesium Stearate Vegetable M-125 NF | NF | - | • | - |
| Magnesium Stearate Vegetable HSEP | EP, USP/NF | - | • | - |
| Magnesium Stearate Vegetable MSEP | EP, USP/NF | - | • | - |
| Magnesium Stearate Vegetable XSEP* | EP, USP/NF | - | • | - |
| Magnesium Stearate Vegetable EUR PHAR | EP, USP/NF,JP,BP, ChP, Kosher, Halal | - | - | • |
| Calcium Stearate Vegetable EUR PHAR | EP, USP/NF,JP,BP, ChP,FCC | • | - | - |
| Calcium Stearate Tallow EUR PHAR | EP, USP/NF,JP,BP, ChP,FCC | • | - | - |
| Calcium Stearate vegetable M205 NF | NF | - | • | - |
| Calcium Stearate vegetable M205 EP | EP | - | • | - |
| Calcium Stearate Vegetable EUR PHAR | EP, USP/NF,JP, ChP, Kosher, Halal | - | - | • |
| Sodium Stearate Tallow Veg EUR PHAR | EP, USP/NF,JP,BP, ChP | • | - | - |
| Sodium Stearate Vegetable EUR PHAR | EP, USP/NF,JP,BP, ChP | • | - | - |
| Sodium Stearate Vegetable EUR PHAR | EP, USP/NF,JP,BP, ChP, Kosher, Halal | - | - | • |
| Zinc Stearate Vegetable EUR PHAR | EP, USP/NF,JP, ChP,FCC | • | - | - |
| Zinc Stearate Tallow EUR PHAR | EP, USP/NF,JP, ChP,FCC | • | - | - |
| Zinc Stearate Vegetable M303 NF | NF | - | • | - |
| Zinc Stearate Vegetable EUR PHAR | EP, USP/NF,JP, ChP, Kosher, Halal | - | - | • |
| Glycerol monostearate 40-55 type I & II Vegetable EUR PHAR | EP, USP/NF,JP,FCC | • | - | - |
| Glycerol monostearate 40-55 type I & II Vegetable EUR PHAR | EP, USP/NF,JP, ChP, Kosher, Halal | - | - | • |
| Glycerine 86.5% EUR PHAR | EP | • | - | - |
| Glycerine 99.5% EUR PHAR | EP | • | - | - |
| Glycerine 99.7% EUR PHAR | EP | • | - | - |
| Stearic Acid 50 & 70 | EP | • | - | - |

* Product development





OUR PROCESS

- Property know-how for the development of an optimized in-house process with selected raw materials for high quality and consistent products (selected and audited raw material suppliers, very low heavy metal content).
- The first production of Magnesium Stearate started in 1973 and the company has since succeeded in supplying specialties according to market requirement and change.
- The FACI Group provides support to a wide number of customers in the Pharmaceutical Industries with different kind of applications/productions.
- Dedicated equipment and lines used for each class of product.

FACI can supply excipients and Pharmaceutical products produced from the following raw materials:

- Vegetable based products: Palm oil origin.
- Available RSPO MB certified vegetable grade
- Tallow Based products: BSE/TSE FREE.

| Site - Manufacturer | Vegetable based | Animal based |
|---------------------|-----------------|--------------|
| FACI SpA | • | • |
| Metalest | • | - |
| FACI Asia Pacific | • | - |

FACI is producing its tallow products range exclusively from raw material EDQM CoS certified, Certificate of Suitability number RO-CEP 2000-269 rev00.

USES DESCRIPTION

FACI Group excipients find their use in the following applications:

- Tableting agent (tableting ease - tablet quality)
- Filler material and binder in drug tablets
- Lubricant
- Surfactant
- Emulsifier
- Processing aid (emulsion, stabilizer)
- anticaking agent (facilitate release from press)
- anticaking (blend uniformity)





MAGNESIUM STEARATE

Due to its particular crystalline structure, Magnesium Stearate gains particular interest in the Pharmaceutical industry:

Magnesium Stearate is a well-known excipient used as a tableting agent and is also considered a good hydrophobic agent. It can also retard the dissolution of a drug from a solid dosage form with the aim to help regulate the Drug release.

Magnesium Stearate contributes to the API uniform distribution and compatibility in the drug formulation. The correct dosage of different excipients could influence the API concentration.

Magnesium Stearate can improve the tableting

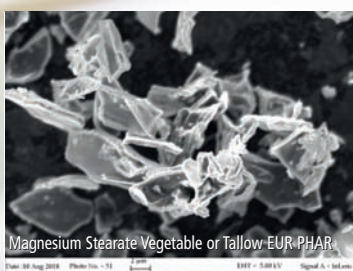
process on drying granulation; studies about Magnesium Stearate show its effect as a demolding agent, avoiding capping problems during production or at any other time when the tablet is stressed.

Magnesium Stearate is the primary anticaking agent used as anticaking in capsule production. Magnesium Stearate is also under study for uses in inhalation formulation.

Magnesium Stearate is generally recognized as safe by the FDA ^[1]

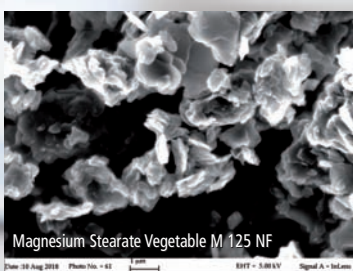
^[1] FDA's SCOGS database; Magnesium stearate, Report No. 60, 1979.; ID Code: 557-04-0;

Chemical-physical properties & morphology of excipients



| Excipient | Production site | PSD (µm) typical value | SSA (m ² /g) typical value | Bulk Density (g/l) |
|---|-----------------------------|---------------------------------|---------------------------------------|--------------------|
| Magnesium Stearate Vegetable or Tallow EUR PHAR | FACI SpA Italy | d10 3.0 d50 10.0 d90 25.6 | 2.5 – 5.5* | 140-200 |
| Magnesium Stearate Vegetable EUR PHAR | FACI Asia Pacific Singapore | | | |

* Customized and narrower SSA vales could be requested

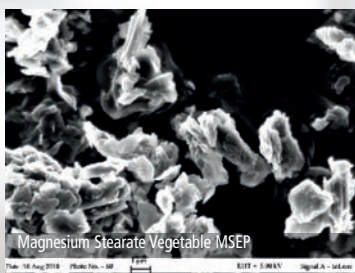


| Excipient | Production site | PSD (µm) typical value | SSA (m ² /g) typical value | Bulk Density (g/l) typical |
|-------------------------------------|---------------------|--------------------------------|---------------------------------------|----------------------------|
| Magnesium Stearate Vegetable 125 NF | FACI Metalest Spain | d10 1.6 d50 7.0 d90 23.0 | - | 300 |



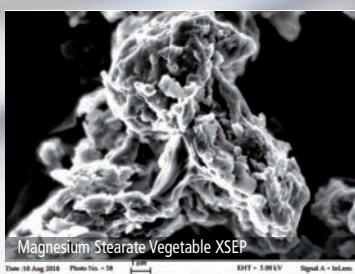
| Excipient | Production site | PSD (μm) typical value | SSA (m^2/g) | Bulk Density (g/l) typical value |
|-----------------------------------|---------------------|-------------------------------------|-------------------------------|--|
| Magnesium Stearate Vegetable HSEP | FACI Metalest Spain | d10 1.4 d50 6.0 d90 22.0 | ≥ 8.0 (12.0*) | 300 |

* Typical value



| Excipient | Production site | PSD (μm) typical value | SSA (m^2/g) | Bulk Density (g/l) typical value |
|-----------------------------------|---------------------|-------------------------------------|-------------------------------|--|
| Magnesium Stearate Vegetable MSEP | FACI Metalest Spain | d10 1.5 d50 9.0 d90 35.0 | 6.0-10.0 (8*) | 320 |

* Typical value



| Excipient | Production site | PSD (μm) typical value | SSA (m^2/g) | Bulk Density (g/l) typical value |
|-----------------------------------|---------------------|-------------------------------------|-------------------------------|--|
| Magnesium Stearate Vegetable XSEP | FACI Metalest Spain | d10 2.6 d50 4.4 d90 13.6 | 15 - 20 (16 *) | 300 |

* Typical value



CALCIUM STEARATE

Calcium Stearate is a possible alternative to magnesium stearate depending on the specific application. It finds uses as anti-adherent and lubricant agent in tableting processes for oral drug formulations. It is also reported as nontoxic and nonirritant. It is listed on the FDA^[2] Generally Regarded as Safe database

| Excipient | Production site | PSD (µm) typical value | SSA (m ² /g) typical value | Bulk Density (g/l) |
|-------------------------------------|-----------------------------|---------------------------------|---------------------------------------|--------------------|
| Calcium Stearate anim/Veg EUR PHAR | FACI SpA Italy | d10 3.2 d50 10.0 d90 25.0 | 2.5 – 5.5 (4.5*) | < 260 |
| Calcium Stearate Vegetable EUR PHAR | FACI Asia Pacific Singapore | | | |
| Calcium Stearate Vegetable M205 NF | FACI Metalest Spain | d10 2.0 d50 7.0 d90 22.0 | 10* | 270 * |
| Calcium Stearate Vegetable M205 EP | FACI Metalest Spain | | | |

* Typical value

^[2] FDA's SCOGS database; calcium stearate; SCOGS-Report Number: 59; Accessed April 9, 2012

SODIUM STEARATE

Sodium Stearate is mainly used as a pharmaceutical adjuvant in ointments, creams, and suppositories. In lotions it can be used as emulsion stabilizer.

| Excipient | Production site | Sieve Residue 100 mesh (150 µm) (Fines) | Bulk Density (g/l) |
|------------------------------------|-----------------------------|---|--------------------|
| Sodium Stearate anim/Veg EUR PHAR | FACI SpA Italy | 0.5% max | 200-320 |
| Sodium Stearate Vegetable EUR PHAR | FACI Asia Pacific Singapore | | |

* Typical value

Sodium Stearate EUR PHAR is also available in microbeads physical form (Bulk Density 220 - 420 g/l)

ZINC STEARATE

Zinc Stearate as Magnesium and Calcium Stearate is used in the tableting process. It has also interesting applications as a water-repellent, a lubricant in cosmetic formulations to improve texture and smoothness and a protective agent in powders and ointments in the treatment of skin diseases, related to its antiseptic, astringent and topical protective properties.

| Excipient | Production site | Sieve Residue 200 mesh (75 µm) | SSA (m ² /g) typical value | Bulk Density (g/l) |
|----------------------------------|-----------------------------|--------------------------------|---------------------------------------|--------------------|
| Zinc Stearate anim/Veg EUR PHAR | FACI SpA Italy | 0.5% max | d10 2.0 d50 11.0 d90 29.0 | 260-360 |
| Zinc Stearate Vegetable EUR PHAR | FACI Asia Pacific Singapore | | | |
| Zinc Stearate Vegetable M205 NF | FACI Metalest Spain | <1.0% 325 mesh* | d10 1.5 d50 5.0 d90 14.0 | 260 |

* Typical value



CALCIUM STEARATE
 SODIUM STEARATE
 ZINC STEARATE
 GLYCEROL MONOSTEARATE
 STEARIC ACID
 GLYCERIN

GLYCEROL MONOSTEARATE

Glycerol Monostearate finds uses in the pharmaceutical industry as emulsifier, typically to emulsify water and oil products.

Available in powder and pastilles.

| Excipient | Production site |
|---|-----------------------------|
| Glycerol monostearate 40-55 type I & type II Veg EUR PHAR | FACI SpA Italy |
| Glycerol monostearate 40-55 type I & type II Veg EUR PHAR | FACI Asia Pacific Singapore |

Type I: stearic acid 40 – 60%; sum of stearic & palmitic acid >90%

Type II: stearic acid 60 – 80%; sum of stearic & palmitic acid >90%

STEARIC ACID

Stearic acid is a possible alternative to Magnesium Stearate in particular formulations. It is a product of high purity, with a possibility of two different types of fatty acid composition and available in three physical forms powder, microbeads.

Stearic Acid 50: stearic acid 40 – 60%; sum of stearic & palmitic acid >90%

Stearic Acid 70: stearic acid 60 – 80%; sum of stearic & palmitic acid >90%

GLYCERIN

Glycerol has a wide variety of applications and is one of the most valuable and versatile chemical substances in nature. It can be used as an emollient, a solvent and a sweetening agent, alongside use in pharmaceutical formulations, cosmetics, foodstuffs and toiletries. It is very stable and can be easily stored under normal temperature. It is non-irritating and has no adverse impact to the environment.

Available at different concentration range, EP-USP/NF conforming.

| |
|--------------------------|
| Glycerine 86.5% EUR PHAR |
| Glycerine 99.5% EUR PHAR |
| Glycerine 99.7% EUR PHAR |





PALM OIL POSITION PAPER

The FACI Group identifies the urgent need to protect habitat for wildlife threatened by unsustainable palm oil production and believes that the palm oil industry plays an important role in employment and economic growth for developing countries.

Unsustainable palm oil production results in massive deforestation, rapid biodiversity loss in tropical ecosystems and significant greenhouse gas emissions. Global consumption of palm oil and its derivatives is increasing, requiring strong conservation action to save species.

Additionally, the commitment of political and business leaders at the regional and local level could

evolve into a successful and sustainable development plan for the palm oil industry.

It is critical that the agents involved in the palm oil supply chain will collaborate and work in an environmentally sustainable and responsible way.

The purpose of this paper is to define the FACI Group position on those issues and to describe better the achievement through its own supply chain and through its business activities, regarding:

- ZERO DEFORESTATION
- ROUNDTABLE ON SUSTAINABLE PALM OIL (RSPO)
- TRACEABILITY
- HUMAN RIGHTS INCLUDING LABOR RIGHTS





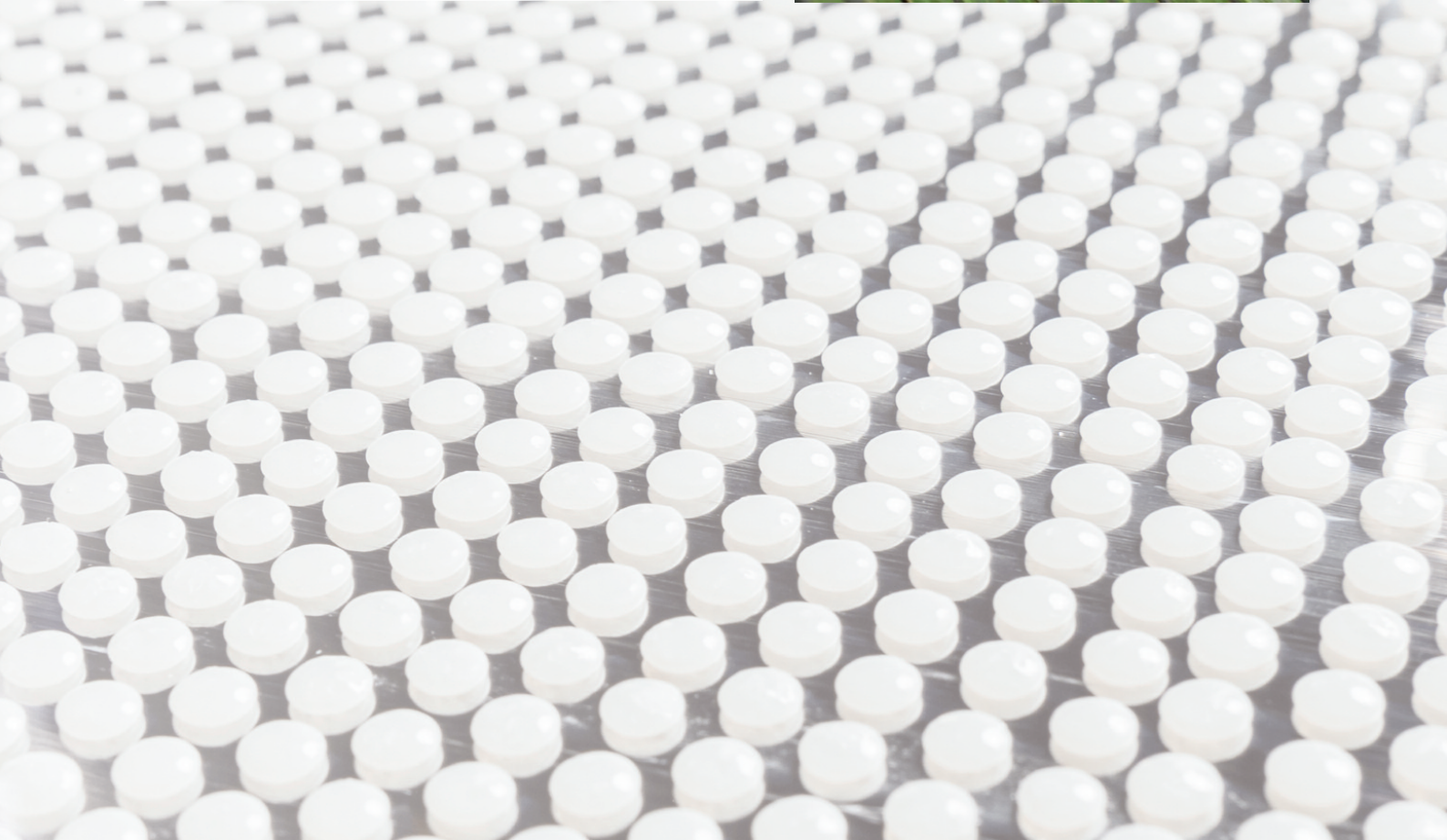
RSPO Mass Balance and Segregated Certified Products

Available vegetable RSPO scheme certified products:
FACI S.p.A.: RSPO Mass Balance 172226-2015-AQ-ITA-ASI
released 10/02/2015

FACI Asia Pacific Ltp: RSPO Mass Balance & segregated
2-0341-12-000-00

FACI Metalest: RSPO Mass Balance 186045-2015-AQ-IBE-ASI
released 15/09/2015

RSPO segregated new certification just obtained, waiting
for official registration number



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