



## TECHNICAL DATA SHEET

010697-TDS-ENG-2023

<b>MAGNESIO ESTEARATO EP</b>		
DESCRIPTION DCI: MAGNESIUM STEARATE		DESCRIPTION DOE: MAGNESIO ESTEARATO
CAS Nº: 292-967-2	EC Nº: 91031-63-9	AEMPS CODE: ---
MOL. WEIGHT: 563.19	MOL. FORMULA: C <sub>34</sub> H <sub>66</sub> MgO <sub>4</sub>	ARTICLE CODE: 010697

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, very fine, light powder, greasy to the touch
Solubility	Practically insoluble in water and in anhydrous ethanol
Identification C	Complies
Identification D	Complies
Acidity or alkalinity	=< 0.05 mL 0.1 M HCl or NaOH
Chlorides	=< 0.1 %
Sulfates	=< 1.0 %
Cadmium	=< 3 ppm
Lead	=< 10 ppm
Nickel	=< 5 ppm
Loss on drying	=< 6.0 %
Microbial contamination	
TAMC	=< 1000 CFU/g
TYMC	=< 100 CFU/g
Escherichia coli	Absence
Salmonella	Absence
Assay	
Magnesium	4.0 - 5.0 %
Stearic acid in the fatty acid fraction	=> 40.0 %
Sum of stearic acid and palmitic acid in the fatty acid fraction	=> 90.0 %

### COMPLIES WITH

European Pharmacopoeia 11.0

### STORAGE

Store tightly closed in a dry and cool place.

### REMARKS

Magnesium Stearate is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.