

Certificate of Analysis

Product: Magnesium Stearate USP43

Batch No.: MAS01-101

Quantity: 1000 kg

Packing: 20 kg

Ref: USP43-NF38

Lab No.: QC126

Mfg. date: 18/01/01

Exp. date: 18/01/03

No.	Chemical Analysis	Specifications	Results
01	Characteristics	A white, very fine, light powder	Fine white powder
02	Identification A,B	According to USP requirements	Passes the tests
03	Solubility	Practically insoluble in water and in ethanol	Conforms
04	Acidity or alkalinity	According to USP requirements	The test sol. consumed 0.03ml of HCl 0.1 M
05	Chlorides	Max. 0.1%	< 0.1 %
06	Sulfates	Max. 1.0 %	< 1.0 %
07	Limit of Cadmium	Max. 3ppm	< 3 ppm
08	Limit of Nickel	Max. 5 ppm	< 5 ppm
09	Limit of Lead	Max. 10 ppm	< 10 ppm
10	Loss on drying	Max. 6.0 %	3.4%
11	Microbial limits:		
	Total viable aerobic count	1000 cfu/g	20cfu/g
	Total molds & yeasts	500 cfu/g	Absent
	Salmonella & esherchiacoli	Absence	Absent
12	Assay (Magnesium)	4.0- 5.0%	4.3%
13	Relative content of Stearic & palmitic acid:		
	Stearic acid	Min. 40.0 %	68.8%
	Stearic acid & palmitic acid	Min. 90.0%	99.0%

Date of Sampling: 20/01/01

Approved

Rejected

Date of Analysis: 27/01/01

Chemical Analyst

Q.C. Manager

Microbial Analyst

Authorized by

We hereby certify that this product has been prepared under GMP regulation and tested according & conform to the requirements of USP43. The raw materials, manufacturing process and product do not contain any of the solvents listed in organic volatile impurities (USP<467>)