



TABRIZ PHARMA
Tabriz Chemical and Pharmaceutical Ind.

Date:
No:
Comment:

Quality Control Laboratory

Certificate of Analysis

Product: Magnesium Stearate USP41

Batch No.: MAS98-253

Quantity: 1000 kg

Packing: 20 kg

Ref:USP41-NF36

Lab No.: QC105

Mfg. date: 06/01/98

Exp. date:06/01/00

| 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 0.05ml 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 % | 2.8% |
| 11 | Microbial limits: | | |
| | Total viable aerobic count | 1000 cfu/g | 20cfu/g |
| | Total molds & yeasts | 500 cfu/g | Absent |
| | Salmonella & esherchiacoli | Absence of Salmonella & esherchiacoli | Absent |
| 12 | Assay (Magnesium) | 4.0- 5.0% | 4.2% |
| 13 | Relative content of Stearic & palmitic acid: | | |
| | Stearic acid | Min. 40.0 % | 45.3% |
| | Stearic acid & palmitic acid | Min. 90.0% | 99.2% |

Date of Sampling:07/01/98

Approved

Rejected

Date of Analysis:15/01/98

[Signature]
Chemical Analyst

Q.C.Manager

[Signature]
Microbial Analyst

Authorized by

We hereby certify that this product has been prepared under GMP regulation and tested according & conform to the requirements of USP41. The raw materials, manufacturing process and product do not contain any of the solvents listed in organic volatile impurities (USP<467>)