



TABRIZ PHARMA
Tabriz Chemical and Pharmaceutical Ind.

Date:
No:
Comment:

Quality Control Laboratory

Certificate of Analysis

Product: Calamine - USP41

Batch No.: CAL00-107

Quantity: 1000 kg

Packing: 25 kg

Ref: USP41-NF36

Lab No.: QC607

Mfg. date: 20/11/00

Exp. Date: 20/11/02

| No. | Chemical Analysis | Specifications | Results |
|-----|---------------------------|--|--|
| 01 | Characteristics | Pink, odorless fine powder | Pink, odorless fine powder |
| 02 | Solubility | Insol. in water, practically completely sol. in mineral acid | Insol. in water, completely sol. in mineral acid |
| 03 | Identification A,B | According to USP requirements | Passes the tests |
| 04 | Acid-insoluble substances | Max. 2.0 % | 0.5 % |
| 05 | Alkaline substances | According to USP requirements | Conforms |
| 06 | Arsenic | Max. 8 ppm | < 8 ppm |
| 07 | Calcium | According to USP requirements | Conforms |
| 08 | Calcium or Magnesium | According to USP requirements | Conforms |
| 09 | Lead | According to USP requirements | No turbidity was produced |
| 10 | Assay | 98.0-100.5 % | 98.8 % |
| 11 | Loss on ignition | Max. 2.0 % | 0.2 % |
| 12 | Microbial limits | | |
| | Staphylococcus aureus | Absence of staphylococcus aureus | Absent |
| | Pseudomonas aeruginosa | Absence of pseudomonas aeruginosa | Absent |

Additional test:

| | | |
|----------------------------|------------|------------|
| Microbial limits | | |
| Total viable aerobic count | 100 cfu/g | 20cfu/g |
| Salmonella & esherchiacoli | Absent | Absent |
| Total molds & yeasts | < 10 cfu/g | < 10 cfu/g |

Date of Sampling: 20/11/00

Approved

Rejected

Date of Analysis: 28/11/00

Chemical Analyst

Microbial Analyst

Q.C. Manager

Technical Manager

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>)