



**TABRIZ PHARMA**  
Tabriz Chemical and Pharmaceutical Ind.

Date:  
No:  
Comment:

## Quality Control Laboratory

### Certificate of Analysis

**Product: Calamine - USP41**

**Batch No.: CAL98-106**

**Quantity: 1000 kg**

**Packing: 25 kg**

**Ref: USP41-NF36**

**Lab No.: QC467**

**Mfg. date: 24/05/98**

**Exp. Date: 24/05/00**

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 %	0.7 %
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 %	99.2 %
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	10cfu/g
Salmonella & esherchiacoli	Absent	Absent
Total molds & yeasts	< 10 cfu/g	< 10 cfu/g

**Date of Sampling: 24/05/98**

**Approved**

**Rejected**

**Date of Analysis: 31/05/98**

*[Signature]*  
**Chemical Analyst**

*[Signature]*  
**Microbial Analyst**

*[Signature]*  
**Q.C. Manager**

*[Signature]*  
**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>)