TABRIZ PHARMA
Tabriz Chemical and Pharmaceutical Ind.

Physico-Chemical and Microbiological Specification Of Product

Calamine (USP)

Name / Internal code: Calamine (3203005)
Sampling SOP: SOP/QC-027
Precaution: SDS/PR-018
Testing SOP: SOP/QC-090
SOP/ML-048
Specification code: QC/CAL-004
Validity date: 1 year

No.	Chemical Analysis	Specifications	Reference
01	Characteristics	Pink, odorless, practically tasteless, fine powder	USP2024
02	Solubility	Soluble in mineral acids; insoluble in water	USP2024
03	Identification A,B	According to USP requirements	
04	Acid-insoluble substances	Max. 2.0 %	USP2024
05	Alkaline substances	According to USP requirements	USP2024
06	Arsenic	Max. 8 ppm	USP2024
07	Calcium	According to USP requirements	USP2024
08	Calcium or Magnesium	According to USP requirements	USP2024
09	Lead	According to USP requirements	USP2024
10	Assay	98.0-100.5%	USP2024
11	Loss on ignition	Max. 2.0%	USP2024
12	Microbial limits		
	Staphylococcus aureus	Absence of staphylococcus aureus	USP2024
	Pseudomonas aeruginosa	Absence of pseudomonas aeruginosa	USP2024

Additional test:

No.	Chemical Analysis	Specifications	Reference
01	Total viable aerobic count	Max.100 cfu/g	In-house
02	Total molds & yeasts	Max. 10 cfu/g	In-house

Remark: Not applicable

Packing and storage: Keep in well-closed container & dry place

QC Manager: 09.05.2024

QA Manager: 09.05.2024

QA APPROVED
By:
Date: 09.05.2024

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