TABRIZ PHARMA
Tabriz Chemical and Pharmaceutical Ind.

Physico-Chemical and microbiological Specification Of Product

Magnesium stearate

Name / Internal code: Magnesium stearate (3201026)
Sampling SOP: SOP/QC -027
Precaution: SDS/PR-002
Testing SOP: SOP/QC-102
SOP/ML-050
Specification code: QC/MAS-035
Validity date: 1 years

No.	Chemical Analysis	Specifications	Reference
01	Characteristics	A white, very fine, light powder	USP2024
02	Identification A,B	According to USP requirements	USP2024
03	Solubility	Insoluble in water, in alcohol, and in ether	USP2024
04	Acidity or alkalinity	According to USP requirements	USP2024
05	Chlorides	Max. 0.1%	USP2024
06	Sulfates	Max. 1.0 %	USP2024
07	Limit of Cadmium	Max. 3ppm	USP2024
08	Limit of Nickel	Max. 5 ppm	USP2024
09	Limit of Lead	Max. 10 ppm	USP2024
10	Loss on drying	Max. 6.0 %	USP2024
11	Assay (Magnesium)	4.0- 5.0%	USP2024
12	Microbial limits:		USP2024
	Total viable aerobic count	1000 cfu/g	
	Total molds & yeasts	500 cfu/g	
	Salmonella & esherchiacoli	Absence	
13	Relative content of Stearic & palmitic acid		USP2024
	Stearic acid	Min. 40.0 %	
	Stearic acid & palmitic acid	Min. 90.0%	

Remark: Not Applicable

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

QC Manager : 18.03.2024 Tahmasebi

QA Manager: Faridi 18.03.2024

QA APPROVED
By: Shafiei
Date: 18.03.2024