NO CHANGE
Effective Date 11/06/2022
Next review Date 10/06/2025
Sign./Date 11/06/2022

MASTER COPY
Sign/Date (QA)

NITIKA
PHARMACEUTICAL SPECIALITIES PVT. LTD.
WHO - GMP & ISO CERTIFIED

12/06/2019

NITIKA PHARMACEUTICAL SPECIALITIES PVT. LTD., NAGPUR

FINISHED PRODUCT SPECIFICATIONS

PRODUCT NAME:TABLUBE® MAGNESIUM STEARATE (USP37/NF32)	GRADE:RSPO (MB) VEGETABLE GRADE (GENERICHEM CUSTOMISED – III) (As per GENERICHEM)	Page: 1 of 2
	RSPO CERTIFICATE NUMBER:- 268468-2018-AQ-IND-ASI	

Reference	: USP37/NF32	Specification No.	: QAD/FP/SPEC/ABG/MGST0C/02
Code	: MGST0	Review Date.	: 11/06/2022
Effective Date	: 12/06/2019	Retest Periodicity	: 60 Months
Shelf Life	: 60 Months	Supersedes	: QAD/FP/SPEC/ABG/MGST0C/01

SN	TESTS	SPECIFICATIONS
1. *	Description	Very, fine, light, white powder, slippery to touch.
2.	Solubility	Insoluble in water, in alcohol, and in ether.
3.	Identification	
	Test A: Test for Magnesium	The sample solution meets the requirement.
	Test B:	As Per USP
4. *	Assay (Calculated on the dried basis)	4.0 % - 5.0 % of Mg,
5.	Test for Calcium	No precipitate is formed
6.	Limit of chloride	Max. 0.1 %
7.	Limit of sulfate	Max. 1.0 %
8.	Limit of Lead	Max. 2 ppm
9.	Limit of cadmium	Max. 3 ppm
10.	Limit of nickel	Max. 5 ppm
11. *	Microbial enumeration tests and tests for specified microorganisms.	
	i) The total aerobic microbial count	NMT 1000 CFU/g
	ii) The total combined molds and yeasts count	NMT 200 CFU/g
	iii) Salmonella species	Absent
	iv) Escherichia coli.	Absent
	v) Total Coliform Test	NMT 50 cfu/g
	vi) Staphylococcus aureus	None detected
	vii) Standard Plate Count	NMT 3000 cfu/g
12.	Specific Surface Area	NLT 3- 13 m^2/g.
13.	Acidity or alkalinity	NMT 0.05 ml of 0.1 N HCl or 0.1 N NaOH is required to change the color of the indicator.
14. *	Loss on drying at 105^0	NMT 6.0 % of its weight.
15. *	Relative content of Stearic acid and palmitic acid	i) NLT 40 % for the stearate peak ii) The sum of the stearate and palmitate peaks is not less than 90 % of the total peak area of all fatty acid.
16.	Residual Solvents	Meets the requirement <467>

	Name	Designation	Signature/Date
Prepared By	Miss Pallavi Bhoyar	QA Chemist	12/06/2019
Checked By	Mrs. Ranjana Samrutwar	QCManager	12/06/2019
Approved By	Mr. M. K. Sharnagat	QA Manager	12/06/2019

NITIKA
PHARMACEUTICAL SPECIALITIES PVT. LTD.
WHO - GMP & ISO CERTIFIED

NITIKA PHARMACEUTICAL SPECIALITIES PVT. LTD., NAGPUR

FINISHED PRODUCT SPECIFICATIONS

PRODUCT NAME:TABLUBE® MAGNESIUM STEARATE (USP37/NF32)	GRADE:RSPO (MB) VEGETABLE GRADE (GENERICHEM CUSTOMISED – III) (As per GENERICHEM) RSPO CERTIFICATE NUMBER:- 268468-2018-AQ-IND-ASI	Page: 2 of 2

Reference	: USP37/NF32	Specification No.	: QAD/FP/SPEC/ABG/MGST0C/02
Code	: MGST0	Review Date.	: 11/06/2022
Effective Date	: 12/06/2019	Retest Periodicity	: 60 Months
Shelf Life	: 60 Months	Supersedes	: QAD/FP/SPEC/ABG/MGST0C/01

17.	Fineness (In-house)	Min 95 % Passing through 200 #
18.	Bulk Density (In-house)	0.10 to 0.30 g/cc
19.	Whiteness Index	Above 85

Note: Asterisk mark (*) test shall be Retest Analysis
NMT:-Not More Than, NLT:-Not Less Than, Max: - Maximum,
Min: - Minimum

Storage & Packing Condition: Preserve in tight Container.
Sampling Plan: 100 %
Sample Quantity: 80 g
Control Sample Quantity:250g

 # Revision History:

Revision Number	Review Date	CC No.	Reason for Revision
00	---	----	First time prepared
01	16/02/2019	CC/19-014	Inclusion of RSPO Number.
02	12/06/2019	CC/19-059	Upgradation of RSPO Certificate number Instead of Registration number.

GENERICHEM CORP
www.generichem.com
info@generichem.com

	Name	Designation	Signature/Date
Prepared By	Miss Pallavi Bhoyar	QA Chemist	12/06/2019
Checked By	Mrs. Ranjana Samrutwar	QCManager	12/06/2019
Approved By	Mr. M. K. Sharnagat	QA Manager	12/06/2019