

RIGHT CHEMISTRY, RIGHT PEOPLE



### M.L.A. Industries Pvt. Ltd. (Pharma Division)

Regd. Office: 111/230, HARSH NAGAR, KANPUR, Tel.: (0512)-2555292 Factory Address: D-7B, D-8 & D-16, Panki Industrial Area, Site-1, Kanpur, Uttar Pradesh 208022 Website:www.mlagroup.com, E-mail:sales@mlagroup.com

( Drug License No. UP78250000012)

(Food Safety & Drug Administration - Govt. of Uttar Pradesh)

#### **CERTIFICATE OF ANALYSIS**

CUSTOMER: M/s : Sample **INVOICE** PRODUCT : SODIUM STEARATE **GRADE** : BP BATCH NO. : SS-16F022023 DATE : 28/02/2023 Date of MFG: 16/02/2023 Date of EXP: 5 years from MFG

PROPERTY	UNIT	SPECIFICATIONS	TEST VALUE
Appearance	-	White Or yellowish , fine Powder ,Greasy To the touch	Complies with BP
Solubility	-	Practically insoluble in water and in anhydrous ethanol .	Complies with BP
Identification	-	Test A – Freezing Point-NLT 53°C  Test B- acid value is 195-210,  Test C –Passes  Test D- Sol . S Gives Reaction Of Sodium	A - 58°C B - Acid Value - 204 C - Passes D - Passes
Acidity or Alkalinity	-	NLT 0.60 ml And NMT 0.85 ml of 0.1 M Na(0H) $_{\rm 2}$ is req. to change the colour of the indicator .	Complies with BP
Chlorides	% Max	0.2	<0.2
Sulphates	% Max	0.3	<0.3
Nickel	ppm max	5	1.62
Loss on Drying	%	NMT 5.0 %	3.14
Microbial Contamination (A) TAMC	CFU/g	NMT 10 <sup>3</sup>	120
Microbial Contamination (B) TYMC	CFU/g	NMT 10 <sup>2</sup>	<10.0
Microbial Contamination (C) Escherichia Coli	-	Absent	Absent
Microbial Contamination (D) Salmonellae	-	Absent	Absent
Assay	%	7.4 – 8.5	7.98
Stearic Acid	-	NLT 40.0%	Complies with BP
Sum of Stearic acid and Palmitic acid	-	NLT 90.0%	Complies with BP

Tested by Chemist	Checked by QA	Approved by Lab Head	
28/02/23	P. Kimar 28/02/23	UNIVO 223 RESPHARMA OUT	
Mr. Gaurav Sen	Mr. Prince Srivastava	Mr. Ujjval Tiwari	



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#### **CERTIFICATE OF ANALYSIS**

CUSTOMER: M/s

PRODUCT: SODIUM STERATE

BATCH NO.: SS-23A012023

Date of MFG.: 23/01/2023

Date of EXP: 5 years from MFG

PROPERTY	UNIT	SPECIFICATIONS	TEST VALUE
Description	_	Appearance: white or yellowish, fine powder, greasy to the touch.	Complies to EP
Solubility	-	slightly soluble in water and in ethanol 96 %.	Complies to EP
Identification	7 =	A. Freezing point: minimum 53 °C B. Acid value: 195 to 210, C. Examine the chromatograms obtained in the assay of stearic acid and palmitic acid. D. Solution S gives reaction (b) of sodium	A - 57°C B - 203 C - Passes D - Passes
Acidity or alkalinity.		Not less than 0.60 ml and not more than 0.85 mL of 0.1 M sodium hydroxide is required to change the colour of the indicator.	Passes
Chloride	%	NMT 0.2	<0.2
Sulfates	%	NMT 0.3	< 0.3
Nickel	ppm	NMT 5.0	0.78
Loss on drying	%	NMT 5.0	2.76
Microbial contamination	CFU/g	TAMC: acceptance criterion 10 <sup>3</sup> CFU/g TYMC: acceptance criterion 10 <sup>2</sup> CFU/g Absence of Escherichia coli Absence of Salmonella	Passes
Assay	%	7.4 - 8.5	7.98
Stearic Acid and Palmitic acid			Complies to EP
1. Stearic Acid 2. Sum of Palmitic acid +St.Acid	%	For 1. NLT 40 For 2. NLT 90	

Tested by Chemist	Checked by QA	Approved by Lab Head
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Mr. Gaurav Sen	Mr. Prince Srivastava	Mr. Ujjval Tiwari
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#### **CERTIFICATE OF ANALYSIS**

INVOICE **CUSTOMER: M/s GRADE** USP PRODUCT : SODIUM STEARATE 28/02/2023 DATE BATCH NO.: SS-22A012023 Date of EXP: 5 years from MFG Date of MFG: 22/01/2023

PROPERTY	UNIT	SPECIFICATIONS	TEST VALUE
Colour & Appearance	-	White Free Flowing Powder	White Free Flowing Powder
Identification	-	Test A –Passes Test B- the solidification temperature of the fatty acids is not less than 54.	A - Complies with USP B - 57
Assay	%	Stearic Acid: NLT – 40.0 % Sum Of Stearic acid and palmitic acid: NLT - 90.0 %	Complies with USP
Acid value of fatty acids	-	between 196 and 211	204
Acidity		(between 0.28% and 1.2% as stearic acid).	Passes the test
Loss on Drying	%	NMT 5.0 %	3.0
Fats And Fixed Oil (Acid Value)	-	196 -210	204
Fats And Fixed Oil (Iodine Value)	-	NMT 4.0	0.89
Alcohol – insoluble substances	-	Test should passes	Passes the test

Tested by Chemist	Checked by QA	Approved by Lab Head		
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Mr. Gaurav Sen	Mr. Prince Srivastava	Mr. Ujjval Tiwari		

\* KANP