

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

111/230, HARSH NAGAR, KANPUR, Tel. : (0512)-2555292

Website: www.mlagroup.com, E-mail: sales@mlagroup.com

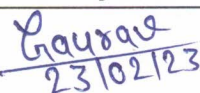
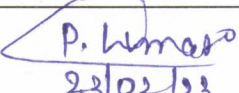
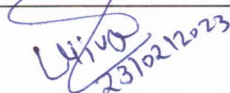
( Drug License No. UP78250000012 )

(Food Safety &amp; Drug Administration – Govt. of Uttar Pradesh)

**CERTIFICATE OF ANALYSIS**

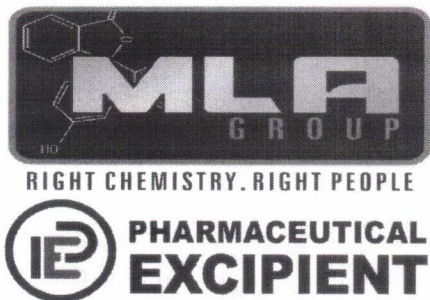
<b>CUSTOMER : M/s</b>	<b>INVOICE : Sample</b>
<b>PRODUCT : MAGNESIUM STEARATE</b>	<b>GRADE : IP (PRM)</b>
<b>BATCH NO. : MG-09E012023</b>	<b>DATE : 23/02/2023</b>
<b>Date of MFG : 09/01/2023</b>	<b>Date of EXP : 5 years from MFG</b>

PROPERTY	UNIT	SPECIFICATIONS	TEST VALUE
Description	-	A very fine light, White powder, Odourless or very faint odour of stearic acid, Unctuous and free from grittiness.	A very fine light, White powder, Odourless or very faint odour of stearic acid, Unctuous and free from grittiness.
Identification	-	Test A – Passes, Freezing Point-NLT 53°C Test B- Passes, acid value is 195-210, Test C- Passes, Test D-Aquos soln. should gives reaction of Mg	A - 58°C B - Acid Value - 204 C – Passes D – Passes
Purity (Assay)	%	3.8 -5 % on dried basis	4.32
Appearance of Sol.	-	Sol. A is not more than YS6	Passes
Appearance of Sol. of the fatty acid	-	0.5 ml Of + 10 ml chloform Sol. is clear. Reference YS5	Passes
Acidity or Alkalinity	-	NMT 0.05 mL of 0.1 N hydrochloric acid or 0.1 N sodium hydroxide is required to change the color of the indicator.	Test passes
Acid Value of the fatty acid	-	195-210	204
Free St. Acid	%	1 Gm Sample + 50 ML Chloform Filter Evaporation + Phenolphthalein indicator. Titrate with 0.1 m Naoh. (Not more 3.0 %)	0.84
Zinc stearate	-	Passes	Pass As per IP
Heavy Metal as Pb	-	Not More than 20 ppm	< 20
Chloride	-	Not More than 250 ppm	< 250
Sulphates	%	Not More than 0.6 %	< 0.6
Loss on Drying	%	Not More than 6 %	3.28
Fatty Acid Composition 1. Stearic Acid 2. Sum of Palmitic acid +St.Acid	%	For 1. NLT 40% For 2. NLT 90%	Pass As per IP

<b>Tested by Chemist</b>	<b>Checked by QA</b>	<b>Approved by Lab Head</b>
 23/02/23	 23/02/23	 23/02/23
Mr. Gaurav Sen	Mr. Prince Srivastava	Mr. Ujjval Tiwari







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## CERTIFICATE OF ANALYSIS

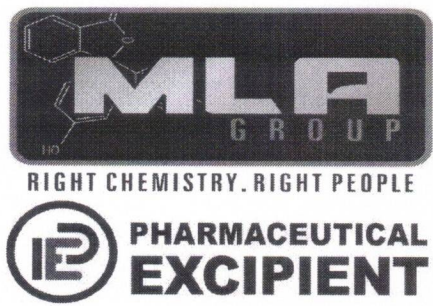
<b>CUSTOMER : M/s</b>	<b>INVOICE :</b>
<b>PRODUCT : MAGNESIUM STEARATE</b>	<b>GRADE : BP</b>
<b>BATCH NO. : MG-19E012023</b>	<b>DATE : 28/02/2023</b>
<b>Date of MFG : 19/01/2023</b>	<b>Date of EXP : 5 years from MFG</b>

PROPERTY	UNIT	SPECIFICATION	TEST VALUE
<b>Color / Appearance</b>	-	White or Almost white very fine, light powder greasy to the touch.	Passes
<b>Solubility</b>	-	Practically insoluble in water and in anhydrous ethanol .	Passes
<b>Identification</b>	-	Test A –Freezing Point-NLT 53°C Test B- acid value is 195-210 Test C- Passes Test D- Passes	A - 58°C B - Acid Value - 203 C – Passes D – Passes
<b>Acidity or Alkalinity</b>	-	NMT 0.05 ml of 0.1M HCL or 0.1 M NaOH req. for the change of indicator color	0.03
<b>Acid Value of the fatty acid</b>	-	195-210	203
<b>Chloride</b>	%	0.1 max.	< 0.1
<b>Sulfates</b>	%	1.0 max.	<1.0
<b>Cadmium</b>	ppm	3.0 max.	0.18
<b>Lead</b>	ppm	10 max.	3.64
<b>Nickel</b>	ppm	5 max.	0.38
<b>Loss on Drying</b>	%	Not More than 6.0	2.94
<b>Microbial Contamination</b>	CFU/g	TAMC-NMT 10 <sup>3</sup> , TYMC-NMT 10 <sup>2</sup> , Salmonella & Escherichia Coli-Absent	Complies with USP
<b>Assay (mg on dried basis)</b>	%	4.0 - 5.0	4.39
<b>Fatty Acid Composition</b>			
1. Stearic Acid	%	For 1. NLT 40.0	Complies with BP
2. Sum of Palmitic acid +St.Acid	%	For 2. NLT 90.0 NLT=Not Less Than	
<b>Particle Size</b>	%	99.0 % Particle Passes From 325 mesh	99.9
<b>Specific Surface Area</b>	M <sup>2</sup> /gm	3M <sup>2</sup> /gm-14M <sup>2</sup> gm	10.38
<b>Thermogravimetry</b>	-	passes	Complies with BP

<b>Tested by Chemist</b>	<b>Checked by QA</b>	<b>Approved by Lab Head</b>
<i>Gaurav Sen</i> 28/02/23	<i>P. Prince</i> 28/02/23	<i>Ujjval Tiwari</i> 28/02/23
<b>Mr. Gaurav Sen</b>	<b>Mr. Prince Srivastava</b>	<b>Mr. Ujjval Tiwari</b>







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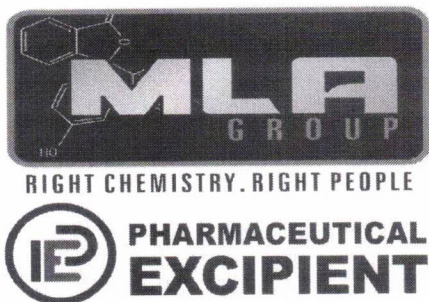
CUSTOMER : M/s	INVOICE :
PRODUCT : MAGNESIUM STEARATE	GRADE : USP - 43
BATCH NO. : MG- 28A012023	DATE : 28/02/2023
Date of MFG : 28/01/2023	Date of EXP : 5 years from MFG

PROPERTY	UNIT	SPECIFICATIONS	TEST VALUE
Colour & Appearance	-	White Free Flowing Powder	White Free Flowing Powder
Identification	-	<b>Test A</b> – Passes, solution responds to the test for Magnesium. <b>Test B</b> - The retention times of the peaks corresponding to stearic acid and palmitic acid of the Sample solution correspond to those of the System suitability solution, as obtained in the test for Relative Content of Stearic Acid and Palmitic Acid.	Test A = passes  Test B=passes
Assay (Mg Content)	%	4 - 5 % on dried basis	4.34
Chloride	% max	0.1 %	< 0.1
Sulfate	% max	1.0 %	<1.0
Cadmium	ppm max	3.0	0.7
Lead	ppm max	10.0	4.2
Nickel	ppm max	5.0	1.6
Microbial Contamination	CFU/g	TAMC-NMT 10 <sup>3</sup> ,TYMC-NMT 5x10 <sup>2</sup> , Salmonella & Escherichia Coli-Absent	Complies with USP
Acidity or Alkalinity	-	NMT 0.05 mL of 0.1 N hydrochloric acid or 0.1 N sodium hydroxide is required to change the color of the indicator.	Test passes
Specific Surface Area	M <sup>2</sup> /gm	3M <sup>2</sup> /gm-14M <sup>2</sup> gm	9.46
Loss on Drying	% Max	6.0	3.68
Fatty Acid Composition	%		
1.Stearic Acid	%	For 1. NLT 40%	
2. sum of the Stearate and palmitate peaks		For 2. NLT 90% NLT=Not Less Than	Complies with USP

Tested by Chemist	Checked by QA	Approved by Lab Head
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## CERTIFICATE OF ANALYSIS

CUSTOMER : M/s	INVOICE : Sample
PRODUCT : MAGNESIUM STERATE	GRADE : EP
BATCH NO. : MG-14B022023	DATE : 01/03/2023
Date of MFG. : 14/02/2023	Date of EXP : 5 years from MFG

PROPERTY	UNIT	SPECIFICATIONS	TEST VALUE
Appearance	-	White or almost white , very fine, light powder, greasy to the touch,	Complies with EP
solubility	-	practically insoluble in water and in Anhydrous ethanol.	Complies with EP
Identification	-	A. freezing point not lower than 53 °C. B. acid value of the fatty acids is 195 to 210 C. passes D. 1 ml of solution S gives the reaction of magnesium)	A - 58°C. B - 204 C - Passes D - Passes
Acidity or alkalinity.	-	Not more than 0.5 ml of .1 m hcl or 0.01 M sodium hydroxide is required to change the colour of the indicator .	Passes
Chloride	%	0.1	< 0.1
Sulfates	%	NMT 0.5	< 0.5
Cadmium	ppm	NMT 3.0	0.62
Lead	ppm	NMT 10.0	5.38
Nickel	ppm	NMT 5.0	0.80
Loss on drying	%	NMT 6.0	2.69
Microbial contamination	CFU/g	TAMC: acceptance criterion 10 <sup>3</sup> CFU/g TYMC: acceptance criterion 10 <sup>2</sup> CFU/g E.coli & Salmonella- Absent	Complies with EP
ASSAY	%	4.0 - 5.0	4.34
Stearic acid and Palmitic acid	%	Stearic Acid in the fatty acid fraction minimum 40.0 % Sum of stearic acid and palmitic acid in the fatty acid fraction minimum 90.0 %	Complies with EP
Specific Surface Area	M <sup>2</sup> /g	3.0 - 14.0	10.48

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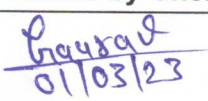
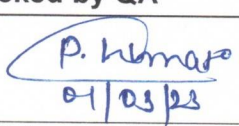
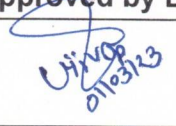


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**CERTIFICATE OF ANALYSIS**

CUSTOMER :	INVOICE : Sample
PRODUCT : MAGNESIUM STEARATE	GRADE : JP
BATCH NO. : MG- 17B012023	DATE : 01/03/2023
Date of MFG. : 17/01/2023	Date of EXP: 5 years from MFG

PROPERTY	UNIT	SPECIFICATIONS	TEST VALUE
Description	-	Magnesium Stearate occurs as a white, light, bulky powder. It is smooth to the touch and sticky to the skin. It has no odor or a faint, characteristic odor.	Complies to JP
solubility	-	It is practically insoluble in water and in ethanol (95).	Complies to JP
Identification	-	Test A - the sample solution responds to the Qualitative Tests for magnesium.  Test B – passes as per JP	Passes  Passes
Acid or alkali	-	add exactly 0.05 mL of 0.1 mol/L hydrochloric acid VS or 0.1 mol/L sodium hydroxide VS: the color of the solution changes.	Passes
Chloride	%	not more than 0.10%	<0.1
Sulfate	%	not more than 1.0%.	<1.0
Heavy metals	ppm	Not more than 20 ppm	<20.0
Relative content of stearic acid and palmitic acid	%	The relative standard deviation of the ratios of the peak area of methyl palmitate to methyl stearate is not more than 1.0%.	Passes
Loss on drying	%	Not more than 6.0% (2 g, 105°C, constant mass).	3.65
Microbial limit		Total viable aerobic microbial count is not more than 1000 per g, and the total count of fungi and yeasts is not more than 500 per g. Salmonella and Escherichia coli should not be observed.	Complies to JP
Assay	%	not less than 4.0% and not more than 5.0% of magnesium.	4.76

Tested by Chemist	Checked by QA	Approved by Lab Head
 01/03/23	 01/03/23	 01/03/23
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