

### 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 & Drug Administration – Govt. of Uttar Pradesh)

## **CERTIFICATE OF ANALYSIS**

CUSTOMER: M/s INVOICE: Sample

PRODUCT: KAOLIN (Heavy) GRADE: IP

BATCH NO.: KN-04C022023 DATE: 23/02/2023

Date of MFG.: 04/02/2023 Date of EXP: 5 years from MFG

<b>PROPERTY</b>	UNIT	SPECIFICATIONS	<b>TEST VALUE</b>
Description	-	Fine white or Grayish white soft,odorless powder	Complies
A Acidity	-	NMT 0.25ml of 0.01M NaOH soln. required for colour change of soln. to pink	Passes
Absorption Power	-	Test should be pass	Passes
Swelling Power	-	2g sample+2ml water, the mixture does not flow	Passes
Loss on Ignition	%	NMT 15	07.36
Identification	-	Test A	Passes
	×	Test B	Passes
Substance soluble in mineral acid	%	NMT 1.0.	0.34
Arsenic	ppm	2.0 max	< 2.0 ppm
Sulphates	ppm	750 max	< 750 ppm
Organic impurities	-	Test should be pass	Passes
Heavy Metal as Lead	ppm	NMT 50	< 50 ppm

Tested by Chemist	Checked by QA	Approved by Lab Head
Chausa v 23/02/23	1. Wmaso 23/02/23	Wild Day 2023 GARES PHARMADI
Mr. Gaurav Sen	Mr. Prince Srivastava	Mr. Ujjval Tiwari



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#### **CERTIFICATE OF ANALYSIS**

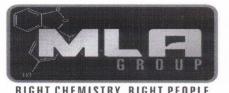
CUSTOMER: M/s INVOICE:
PRODUCT: KAOLIN (HEAVY) GRADE: BP

BATCH NO: KN-20E022023 DATE: 28/02/2023

Date of MFG: 20/02/2023 Date of EXP: 5 years from MFG

PROPERTY	UNIT	SPECIFICATIONS	TEST VALUE
Appearance	-	Fine white or Grayish white unctuous powder	Fine white or Grayish white unctuous powder
Solubility		Practically insoluble in water, and in organic solvents.	Passes
Identification -		Test A -Passes Test B - Sediment limit is NMT 5 ml, Test C-Passes	Passes the test Passes the test Passes the test
Acidity or Alkalinity	-	NMT 0.25 ml of 0.01M NaOH soln. required for colour change of indicator phenolphthalein.	Passes the test
Organic Impurities	-	After calcinations the residue is only slightly more colored than original substance.	Passes the test
Absorption power -		Test should passes	Passed
Swelling power -		Test should passes	Passed
Substance Soluble in dil. hcl	mg	NMT 10 mg	7
Chlorides	ppm max	250	< 250 ppm
Sulfates	%	0.1	Passes the test
Calcium	ppm max	250	< 250 ppm
Extractable Heavy Metal	ppm max	50	< 50 ppm
Microbial Contamination	CFU/g	TAMC -1000 cfu/gm, TYMC-100 cfu/gm	Passes the test

Tested by Chemist	Checked by QA	Approved by Lab He	ead
28/02/23	P. rumaso 28/02/23	University of the second of th	ES PHARMA OIL
Mr. Gaurav Sen	Mr. Prince Srivastava	Mr. Ujjval Tiwari	APPROVE Z
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#### CERTIFICATE OF ANALYSIS

CUSTOMER : M/s INVOICE Nill : KAOLIN (HEAVY) **PRODUCT GRADE** USP BATCH NO. : KNH-07A012023 DATE 28/02/2023 Date of MFG.: 07/01/2023 Date of EXP: 5 years from MFG

PROPERTY	UNIT	SPECIFICATIONS	TEST VALUE
Colour & Appearance	-	Fine white or Grayish white soft,odorless powder	Complies with USP
Identification	-	A gray residue remains on the filter, and the filtrate meets the requirements of the test.	Complies with USP
Loss on ignition	%	NMT 15.0 % . @550-600*c temp.	9.8
Lead	ppm	NMT 10.0 ppm	Complies with USP
Iron		Test should passes	Passes the test
Acid soluble substance	%	NMT 10 mg of residue	Complies with USP
Carbonate test -		No effervescence occurs	Passes the test
Microbial Contamination	-	Meets the requirement for the absence of E.Coli	E.Coli Absent

Tested by Chemist	Checked by QA	Approved by Lab Head
Caysard - 18/02/23	P. h. mas 28 02+28	Uijan Raliza RESPHARMADI
Mr. Gaurav Sen	Mr. Prince Srivastava	Mr. Ujjval Tiwari
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#### **CERTIFICATE OF ANALYSIS**

CUSTOMER: M/S	INVOICE : Sample
PRODUCT : KAOLIN , HEAVY	GRADE : EP
BATCH NO.: KN-28E012023	DATE : 01/03/2023
Date of MFG: 28/01/2023	Date of EXP: 5 years from MFG

PROPERTY	UNIT	SPECIFICATIONS	TEST VALUE
Description -		Appearance: fine, white or greyish-white, unctuous powder	Complies to EP
Solubility	-	practically insoluble in water and in organic solvents	Complies to EP
Identification -		A To 0.5 g in a metal crucible add 1 g of potassium nitrate R and 3 g of sodium carbonate R and heat until the mixture melts To the filtrate add 3 mL of ammonium chloride solution R. A gelatinous white precipitate is	Passes Passes
		formed.  B Add 2.0 g in 20 portions to 100 mL of a 10 g/L solution of sodium laurilsulfate R in a 100 mL graduated cylinder about 30 mm in diameter. The apparent volume of the sediment is not greater than 5 mL.	Passes
Acidity or	_	<ul><li>C 0.25 g gives the reaction of silicates.</li><li>0.01 M sodium hydroxide is required to change the colour</li></ul>	Passes
alkalinity		of the indicator to pink.	
Organic - impurities		The residue is only slightly more coloured than the original substance.	Passes
Adsorption power -		passes	Complies to EP
Swelling power.			Passes
Substances soluble in dilute % maximum 1 % hydrochloric acid		maximum 1 %	Passes
Chloride	ppm	NMT 250	< 250
Sulfates	%	NMT 0.1	<0.1
Calcium	ppm	NMT 250	<250
Extractable heavy metals	cractable heavy ppm Max. 50 ppm		<50.0
Microbial contamination	CFU/g	TAMC: acceptance criterion 10 <sup>3</sup> CFU/g TYMC: acceptance criterion 10 <sup>2</sup> CFU/g	Passes

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



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### **CERTIFICATE OF ANALYSIS**

CUSTOMER: M/s

PRODUCT: KAOLIN (LIGHT)

BATCH NO.: KN-09E012023

Date of MFG.: 09/01/2023

Date of EXP: 5 years from MFG

S.No.	PROPERTY	UNIT	SPECIFICATIONS	TEST VALUE
1.	Description	-	Light white powder free from grit particles, odourless free flowing powder	Complies
2.	Fine Particles	%	NLT 70 %	78 %
3.	Coarse Particles	, -	NMT 25 mg residue per 5 g sample	17 mg
4.	Identification	-	Test A	Passes
			Test B	Passes
5.	Soluble Matter	%	NMT 10mg residue per 2 g sample	3 mg
6.	Arsenic	ppm	2.0 max.	< 2.0
7.	Chloride	ppm	330 max.	< 330
8.	Loss on Drying	%	1.5 max.	0.36
Ó	Heavy metals	ppm	20 max	< 20
10.	Loss on Ignition (600°C)	%	15.0 max.	5.46

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**

CUSTOMER: M/s	INVOICE : Sample
PRODUCT : KAOLIN (LIGHT)	GRADE : BP-2022
BATCH NO : KN-15A022023	DATE : 28/02/2023
Date of MFG : 15/02/2023	Date of EXP: 5 years from MFG

PROPERTY	UNIT	SPECIFICATIONS	TEST VALUE
Description	-	Light, white powder free from gritty particles, odorless unctuous powder	Light, white powder free from gritty particles, odorless unctuous powder
Solubility		Practically insoluble in water and in mineral acids.	Complies
Coarse Particle	mg	NMT 25 mg residue per 5 gm of sample.	15
Identification	-	Test A -Passes Test B - Passes, TestC- Triturate 2 g with 2 mL of water. The resulting mixture flows.	A – Complies with BP B – Complies with BP C – Complies with BP
Coarse Particles	mg	NMT 25 mg residue per 5 g sample	15
Fine Particles	%	The wt of residue from the $2^{nd}$ portion is NLT 70 % of the wt of residue from the $1^{st}$ portion	79
Arsenic	ppm max	2.0	<2.0
HEAVY METAL (As Pb)	ppm max.	20.0	< 20.0
Chloride	ppm max	330	<330
LOD @ 105°C	% max	1.5	0.58
Loss on ignition (600*C)	%	15 % Max	8.14
soluble matter	mgm	NMT 10 mgm residue per 2 gm sample	6

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

CUSTOMER:	INVOICE:	
PRODUCT : KAOLIN	GRADE: JP	
BATCH NO. : KN- 21E022023	DATE : 01/03/2023	
Date of MFG.: 21/02/2023	Date of EXP: 5 years from MFG	

PROPERTY	UNIT	SPECIFICATIONS	TEST VALUE
Description	-	Kaolin occurs as white or nearly white, fragmentary masses or powder. It has a slightly clay-like odor. When moistened with water, it darkens and becomes plastic.	Complies to JP
solubility	-	It is practically insoluble in water, in ethanol (99.5) and in diethyl ether.	Complies to JP
Identification	-	Test A – Heat 1 g of Kaolin with 10 mL of water and 5 mL of sulfuric acid in a porcelain dish, and evaporate the mixture nearly to dryness. Cool, add 20 mL of water, boil for 2 to 3 minutes, and filter: the color of the residue is gray.  Test B - The filtrate obtained in (1) responds to the Qualitative	Passes
		Tests (1), (2) and (4) for aluminum salt.	
Acid or alkali	-	: the pH of the filtrate is between 4.0 and 7.5	6.22
Acid-soluble substances	g	residue is not more than 0.010 g	Passes
Carbonate	-	no effervescence occurs	Passes
Heavy metals As Pb	ppm	NMT 50 ppm	Passes
iron	ppm	NMT 500 ppm	Passes
Arsenic	ppm	NMT 2 ppm	Passes
Foreign matter	-	no sandy residue remains.	Passes
Loss on ignition	%	NMT 15.0% (1 g, 600*C, 5 hours).	8.45
Plasticity	-	The resultant mass has no remarkable fluidity.	Passes

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