

RIGHT CHEMISTRY. RIGHT PEOPLE



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
 : Talc
 GRADE
 : IP

 BATCH NO.
 : TC-17E012023
 DATE
 : 23/02/2023

Date of MFG.: 17/01/2023 Date of EXP: 5 years from MFG

| PROPERTY | UNIT | SPECIFICATIONS | TEST VALUE |
|---|--------|--|------------------|
| Description | - | A white almost white powder, free from grittiness,readily adheres to the skin unctuous on touch odorless powder | Complies |
| | - | By infrared absorption spectrum of the substance being examined in potassium bromide dispersion should show absorption, bands at 3677cm,1018cm and at 669 cc | Passes |
| identification | | A white crystalline precipitate is formed with Di Sodium Hydrogen Phosphate The residue obtained in identification test B gives reaction of silicates | Passes |
| Acidity or Alkalinity | - | NMT 0.3 ml of 0.1M HCl required to make it acidic | Passes |
| Water Soluble Substance | mg | NMT 10 mg | 4 |
| Loss on Drying (180°C/1 hr) | % | NMT 1.0 | 0.18 |
| Chloride | ppm | NMT 250 | < 250 |
| Iron | ppm | NMT 10 | < 10 |
| Acid soluble substance | % | NMT 2.0 | 1.24 |
| Carbonate Test | - | No effervescence produced with diluted HCl | Passes |
| ()anic Compound | - | Colour of material after LOD NMT slight yellowish or gray | Passes |
| Total viable microbial count Fungi & Yeast | Cfu/ g | Total Aerobic count For cutaneous administration 100 cfu/gm max, For Oral administration 1000 cfu/gm max. Total Y & M Count-100 cfu/gm max, Salmonella &E.Coli- Absent | Passes Passes |

| Tested by Chemist | Checked by QA | Approved by Lab Head |
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| - Layrav - 23/02/23 | P. hmar 23/03/23 | UVIVO 23 OZAPPROVED O OCAPPROVED |
| Mr. Gaurav Sen | Mr. Prince Srivastava | Mr. Ujjval Tiwari |



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CERTIFICATE OF ANALYSIS

CUSTOMER: M/S

PRODUCT: Purified Talc

BATCH NO: TC-11D022023

Date of MFG: 11/02/2023

INVOICE: Sample

GRADE: BP

DATE: 28/02/2023

Date of EXP: 5 years from MFG

PROPERTY UNIT **SPECIFICATIONS** Results Light, homogeneous, white or almost Light, homogeneous, white or almost white **Appearance** white powder, powder, Practically insoluble in water, in ethanol (96%) **Passes Solubility** and in dilute solutions of acids, and alkali hydroxide By Infrared absorption spectrum of the substance Passes being examined in potassium bromide dispersion Identification A should show absorption, bands at 3677+2 cm⁻¹, at $1018 \pm 2 \, \text{cm}^{-1}$ and at $669 \pm 2 \, \text{cm}^{-1}$ A white, crystalline precipitated should be Passes Identification B formed. The residue obtained in identification test B Passes Identification C should give reaction of silicates. Max 0.3 ml of 0.01 M sodium hydroxide is 0.15 ml of 0.01 M sodium hydroxide **Acidity or Alkanity** required to change the colour of the indicator to is required to change the colour of pink. the indicator to pink. 0.02 Water-Soluble Substances % max 0.2 Aluminium % Max 2 0.73 Calcium % Max 0.44 0.9 Iron % max < 0.25 0.25 3.3 Lead ppm max 10 Magnesium 18.24 % 17.0 - 19.5Loss on ignition @1050°C-3.06 7 % max 1100°C If intended for cutaneous administration: TAMC 10^2 cfu/g max, cfu/gm Microbial Contamination If intended for oral administration: Complies With BP max TAMC 10³ cfu/g max, TYMC 10² cfu/gm max,

| Tested by Chemist | Checked by QA | Approved by Lab Head | |
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| Gaysa9- 28/02/23 | P. h. borato 28/02/23 | 1802123 EFRARMADILIS | |
| Mr. Gaurav Sen | Mr. Prince Srivastava | Mr. Ujjval Tiwari | |
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CERTIFICATE OF ANALYSIS

| CUSTOMER: M/S | INVOICE : Sample |
|---------------------------|-------------------------------|
| PRODUCT : Talc | GRADE : USP - 43 |
| BATCH NO. :TC-16E012023 | DATE : 28/02/2023 |
| Date of MFG. : 16/01/2023 | Date of EXP: 5 years from MFG |

| PROPERTY | UNIT | SPECIFICATIONS | TEST VALUE |
|---------------------------------------|---------------|--|-------------------|
| DEFINITION | | Talc is a powdered, selected, natural, hydrated magnesium silicate. Pure talc has the formula MgSiO(OH). It may contain variable amounts of associated minerals among which chlorites (hydrated aluminum and magnesium silicates), magnetite (magnesium carbonate), calcite (calcium carbonate), and dolomite (calcium and magnesium carbonate) are predominant. | Complies With USP |
| Appearance | | A white almost white powder, free from grittiness, readily adheres to the skin unctuous on touch odorless powder | Complies With USP |
| Solubility | | Practically insoluble in water, in ethanol (96%) and in dilute solutions of acids | Complies With USP |
| | | A- The IR spectrum of a potassium bromide dispersion of it exhibits maxima at 3677 ± 2 cm, at 1018 ± 2 cm, and at 669 ± 2 cm. | Complies With USP |
| Identification | | B- A white, crystalline precipitate of magnesium ammonium phosphate is formed. | Complies With USP |
| , | | C - Within a short time, a white ring is rapidly formed around the drop of water. | Complies With USP |
| Assay | % | 17.0 -19.5 | 18.22 |
| Impurities (Water soluble substances) | mg | NMT 5 | 2 |
| Iron | % | NMT 0.25 % | 0.02 |
| Lead | ppm | NMT 10.0 | 4.85 |
| Calcium | % | NMT 0.9 % | 0.3 |
| Aluminium | % | NMT 2.0 % | 0.85 |
| Asbestos | - | Absent | Complies With USP |
| Microbial Enumeration Tests | cfu/gm max | For Tropical Administration= TAMC- NMT 100 cfu/gm & TYMC- 50 cfu/gm max For Oral Administration= TAMC-NMT 1000 cfu/gm & TYMC-100 cfu/gm | Complies With USP |
| ACIDITY AND ALKALINITY | - | NMT 0.4 mL of 0.01 N hydrochloric acid is required to change the color of the bromothymol blue indicator. NMT0.3 mL of 0.01 N sodium hydroxide is required to change the color of the phenolpthalein indicator to pink. | Complies With USP |
| Loss on Ignition@1075°C± 25 | % | NMT 7.0 % | 3.45 |

| Tested by Chemist | Checked by QA | Approved by Lab Head |
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| Laura 9 - 28/02/23 | 2. 102128 | Jily Boards THARMADINGS |
| Mr. Gaurav Sen | Mr. Prince Srivastava | Mr. Ujjval Tiwari |

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CERTIFICATE OF ANALYSIS

CUSTOMER: M/s INVOICE: Sample
PRODUCT: TALC GRADE: EP

BATCH NO.: TC-22C022023 DATE: 03/01/2023
Date of MFG.: 22/02/2023 Date of EXP: 5 years from MFG

| PROPERTY | UNIT | SPECIFICATIONS | TEST VALUE |
|--------------------------|-------|---|----------------|
| Description | - | Appearance: light, homogeneous, white or almost white powder, greasy to the touch (non abrasive) | Complies to EP |
| Solubility | | practically insoluble in water, in ethanol (96 percent) and in dilute solutions of acids and alkali hydroxides. | Complies to EP |
| Identification | - | A. Infrared absorption spectrophotometry Absorption bands: at 3677 ± 2 cm-1, 1018 ± 2 cm-1 and 669 ± 2 cm-1. | Passes |
| | | B. To the filtrate add 1 mL of disodium hydrogen phosphate solution R. A white, crystalline precipitate is formed. | Passes |
| | | C.The residue obtained in identification test B gives the reaction of silicates. | Passes |
| Acidity or alkalinity | - | not more than 0.3 mL of 0.01 M sodium hydroxide is required to change the colour of the indicator to pink. | Passes |
| Water Soluble substances | % | NMT 0.2 | 0.07 |
| Aluminium | % | NMT 2.0 | <2.0 |
| Calcium | % | NMT 0.9 | <0.9 |
| Iron | % | NMT 0.25 | 0.17 |
| Lead | ppm | NMT 10 | 4.9 |
| Magnesium | % | 17.0- 19.5 | 18.24 |
| Loss on Ignition | % | NMT 7.0 | 3.74 |
| Microbial contamination | CFU/g | If intended for cutaneous administration TAMC: acceptance criterion:10 ² CFU/g | |
| | | If intended for oral administration TAMC: acceptance criterion:10 ³ CFU/g TYMC: acceptance criterion:10 ² CFU/g | Complies to EP |

| Tested by Chemist | Checked by QA | Approved by Lab Head | |
|-------------------|-------------------------|----------------------|---------------|
| Gausas - 0/103/23 | p.klimaro 01/03/2023 | Tipo 123 | THARMA DIVISO |
| Mr. Gaurav Sen | Mr. Prince Srivastava | Mr. Ujjval Tiwari | |





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CERTIFICATE OF ANALYSIS

| CUSTOMER: | INVOICE: |
|---------------------------|-------------------------------|
| PRODUCT : TALC | GRADE: JP |
| BATCH NO. : TC- 20A022023 | DATE: 01/03/2023 |
| Date of MFG.: 20/02/2023 | Date of EXP: 5 years from MFG |

| PROPERTY | UNIT | SPECIFICATIONS | TEST VALUE |
|--|------|--|------------------|
| Description | - | Talc occurs as a white to grayish white, fine, crystalline powder. It is odorless and tasteless. It is unctuous, and adheres readily to the skin. | Complies to JP |
| solubility | - | It is practically insoluble in water, in ethanol (95) and in diethyl ether. | Complies to JP |
| Identification | - | Test A – precipitate is blue in color. Test B- a white, crystalline precipitate is produced. | Passes Passes |
| Acid-soluble substances | % | Not more than 2.0 % | 1.66 |
| Acid or alkali, and water- soluble substances | mg | Not more than 4.0 mg | 2 mg |
| Water-soluble iron | - | Make 10 mL of the filtrate obtained in (2) weakly acidic with hydrochloric acid, and add drop wise potassium hexacyanoferrate (11) TS: the liquid does not acquire a blue color. | Passes |
| Arsenic | ppm | Not more than 4 ppm | Passes |
| Loss on drying | % | Not more than 5.0% (1 g, 450-550*C, 3 hours). | 1.20 |

| Tested by Chemist | Checked by QA | Approved by Lab Head | |
|-------------------|-----------------------|------------------------|--|
| Gaysas - 01/03/23 | P.hamap 01/03/28 | OTO 123 STRES PHARMADO | |
| Mr. Gaurav Sen | Mr. Prince Srivastava | Mr. Ujjval Tiwari | |

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