

**Certificate of Analysis**

| | |
|----------------|-------------------------------------|
| Product | Dibasic Calcium Phosphate Dihydrate |
| Grade | IP |

| | | | | | | |
|-------------------|------------------|-------------------|------------------|------------------|-----------------|---------------------|
| Report No. | Batch No. | Batch Qty. | Mfg :Date | Exp: Date | Quantity | Drug lic no. |
| #76/23-24 | #76/23-24 | 3000 kg | March-2023 | 5 Years | 100 gm | G- 1498 |

General Characteristics

| | | |
|-------------------|---|----------|
| Appearance | White or almost white, crystalline granules | Complies |
| Taste | Tasteless | Complies |
| Odor | Odorless | Complies |
| Solubility | Practically insoluble in water and in ethanol(96 percent) | Complies |
| | It Dissolve in dilute hydrochloric acid and in dilute nitric acid | Complies |

CHEMICAL ANALYSIS

| Properties | Unit | Mini | Maxi | Result |
|--|------|-------------------------------------|--------------|----------|
| Identification A, B & C | -- | -- | -- | Complies |
| Acid insoluble substances | % | -- | 0.1 | 0.074 |
| Carbonates | -- | No effervescence should be produced | With hcl | Complies |
| Chlorides | % | -- | 0.25 | <0.125 |
| Fluorides | Ppm | -- | 50 | 21 |
| Sulphates | % | -- | 0.5 | <0.5 |
| Arsenic | Ppm | -- | 3.0 | <3.0 |
| Barium | -- | No turbidity should | Be produced | Complies |
| Heavy metals (as Pb) | Ppm | -- | 40 | <40 |
| Iron | Ppm | -- | 400 | <400 |
| Loss on ignition(800°C to 825°) | % | 24.5 | 26.5 | 25.94 |
| Nitrate | -- | To Pass Test | To Pass Test | Complies |
| Reducing Substances | -- | To Pass Test | To Pass Test | Complies |
| Protenous Impurities | -- | To Pass Test | To Pass Test | Complies |
| Mono Calcium and Tri Calcium Phosphate | ml | 11.0 | 12.5 | 11.6 |
| Assay(Dihydrate) | % | 98.0 | 105 | 100.71 |

Microbiological Analysis

| | In House | Cfu/gm | -- | 1,000 | Complies |
|------------------------------------|----------|-----------------------|----|----------|----------|
| Total Aerobic microbial count | | Cfu/gm | -- | 100 | Complies |
| Total yeast and mold count | | Absent/g | -- | Absent/g | Complies |
| Escherichia Coli | | Absent/g | -- | Absent/g | Complies |
| Salmonella | | Absent | -- | Absent | Complies |
| Pathogens | | Meets the requirement | -- | Meets | Complies |
| O V I (ORGANIC VOLATILE IMPURITES) | | Absent | -- | Absent | Complies |
| B S E / TSE | | | | | |

OPINION: The above product is declared as standard quality.

| | Analyzed by | Checked by | Approved by |
|------------------|-------------------------------------|------------------------------|-------------------------------|
| Signature | Gaurang Patel <i>G. M. Patel</i> | Kiran Mistry <i>Kiran</i> | Rushil Barot <i>Rushil</i> |