

# UMARHA 145

### Mfg. Bulk Drug

Block No. 263, SANTEJ
Ta. Kalol, Dist. Gandhinagar.
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## **CERTIFICATE OF ANALYSIS**

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

| Report No. | Batch No. | Batch Quantity | Mfg :Date  | Exp: Date | Quantity | Drug lic no. |
|------------|-----------|----------------|------------|-----------|----------|--------------|
| #04/23-24  | #04/23-24 | 5000 kg        | April-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       | %    |                 | 0.2%            | 0.070%   |
| Carbonates                      |      | To Confirm Test | To Confirm Test | Complies |
| Chlorides                       | Ppm  | 00              | 2500            | 750      |
| Fluorides                       | Ppm  |                 | 50              | 21       |
| Sulphates                       | %    |                 | 0.5             | 0.4      |
| Arsenic                         | Ppm  |                 | 3               | Complies |
| Barium                          |      | To Confirm Test | To Confirm Test | Complies |
| Heavy metals (as Pb)            | Ppm  |                 | 40              | 32       |
| Iron                            | Ppm  |                 | 400             | 260      |
| Loss on ignition(800°C to 825°) | %    | 6.6%            | 8.5%            | 7.70%    |
| Mono Calcium & Tri Calcium      | ml   | 11              | 12.5            | 11.6     |
| Phosphate                       |      |                 |                 |          |
| Assay                           | %    | 98              | 105             | 100.81   |

#### Microbiological Analysis

| Total Aerobic microbial count | In House | Cfu/gm   | <br>1,000    | Complies |
|-------------------------------|----------|----------|--------------|----------|
| Total yeast and mold count    |          | Cfu/gm   | <br>100      | Complies |
| Escherichia Coli              |          | Absent/g | <br>Absent/g | Complies |
| Salmonella                    |          | Absent/g | <br>Absent/g | Complies |

OPINION: The above product is declared as standard quality.

|           | Analyzed by   | Checked by   | Approved by            |
|-----------|---------------|--------------|------------------------|
| Signature | Gaurang Patel | Kiran Mistry | Rushil Barot<br>RUShil |
|           | Co.M. Purce   | Trus         | Nonij                  |