

## CERTIFICATE OF ANALYSIS

Standard product specification — applicable to all consignments of this product and grade supplied by Scapex Exports Pvt. Ltd., manufacturer and supplier of quality chemicals.

|                   |                            |
|-------------------|----------------------------|
| Product Name      | Tribasic Calcium Phosphate |
| C.A.S. Number     | 7758-87-4                  |
| Molecular Formula | —                          |
| Molecular Weight  | —                          |
| Grade / Standard  | IP/BP/USP/EP               |
| Physical Form     | White amorphous powder     |
| Product Category  | Pharmaceutical Excipients  |
| Country of Origin | India                      |

### ANALYTICAL RESULTS

| S. No. | Test Parameter                                  | Specification                      | Result           | Method                        |
|--------|-------------------------------------------------|------------------------------------|------------------|-------------------------------|
| 1      | Description                                     | White amorphous powder             | Complies         | Visual                        |
| 2      | Identification (A) — Infrared absorption        | Concordant with reference spectrum | Complies         | IR Spectrophotometry          |
| 3      | Identification (B) — Chemical / chromatographic | Positive for the substance         | Complies         | As per monograph              |
| 4      | Solubility                                      | As per specification               | Complies         | Visual / Monograph            |
| 5      | Assay (on dried basis)                          | 98.0 – 102.0 % w/w                 | 99.04            | HPLC / Titrimetry (Monograph) |
| 6      | pH (aqueous dispersion)                         | As per monograph                   | 6.2              | Potentiometry                 |
| 7      | Bulk Density                                    | As per specification               | 0.40 g/mL        | USP <616>                     |
| 8      | Tapped Density                                  | As per specification               | 0.68 g/mL        | USP <616>                     |
| 9      | Particle Size (d50)                             | As per specification               | 62 µm            | Laser diffraction             |
| 10     | Loss on Drying                                  | Not more than 1.0 % w/w            | 0.31             | Gravimetry (Monograph)        |
| 11     | Sulphated Ash / Residue on Ignition             | Not more than 0.1 % w/w            | 0.057            | Gravimetry (Monograph)        |
| 12     | Heavy Metals                                    | Not more than 20 ppm               | Less than 10 ppm | ICP-OES / Limit test          |
| 13     | Related Substances — any individual impurity    | Not more than 0.10 %               | 0.051            | HPLC                          |
| 14     | Related Substances — total impurities           | Not more than 0.50 %               | 0.174            | HPLC                          |
| 15     | Residual Solvents                               | Complies with ICH Q3C limits       | Complies         | Headspace GC                  |
| 16     | Total Aerobic Microbial Count                   | Not more than 1000 cfu/g           | 33 cfu/g         | IP / USP <61>                 |
| 17     | Total Yeast & Mould Count                       | Not more than 100 cfu/g            | 8 cfu/g          | IP / USP <61>                 |
| 18     | Escherichia coli                                | Absent in 1 g                      | Absent           | IP / USP <62>                 |

| S. No. | Test Parameter     | Specification                   | Result          | Method        |
|--------|--------------------|---------------------------------|-----------------|---------------|
| 19     | Salmonella species | Absent in 10 g                  | <b>Absent</b>   | IP / USP <62> |
| 20     | Structure          | Conforms to reference structure | <b>Complies</b> | FTIR / NMR    |

**Remarks**

Material supplied against this specification is analysed on every production lot and **conforms** to the limits stated above in all tested parameters. Results shown are the typical values obtained for this grade.

Retained samples are held against every export consignment. Store in tightly closed original packing, in a cool, dry, well-ventilated place away from incompatible materials and direct sunlight.

**Checked and Approved by****Prem Panchal**

Quality Assurance  
Scapex Exports Pvt. Ltd.

This document sets out the standard specification for the product named above and applies to all consignments of this grade. It is issued by Scapex Exports Pvt. Ltd. as manufacturer and supplier. Refer to the Material Safety Data Sheet (MSDS) before handling.