

## 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      | Ergocalciferol (Vitamin D2)          |
| C.A.S. Number     | 50-14-6                              |
| Molecular Formula | —                                    |
| Molecular Weight  | —                                    |
| Grade / Standard  | USP/EP Oily/Powder Grade             |
| Physical Form     | White crystalline powder/oily liquid |
| Product Category  | Vitamins, Minerals & Amino Acids     |
| Country of Origin | India                                |

### ANALYTICAL RESULTS

| S. No. | Test Parameter                                  | Specification                        | Result            | Method                        |
|--------|-------------------------------------------------|--------------------------------------|-------------------|-------------------------------|
| 1      | Description                                     | White crystalline powder/oily liquid | 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      | Assay (on dried basis)                          | 98.0 – 102.0 % w/w                   | 100.35            | HPLC / Titrimetry (Monograph) |
| 5      | Specific Optical Rotation                       | As per monograph                     | Conforms          | Polarimetry                   |
| 6      | Loss on Drying                                  | Not more than 0.5 % w/w              | 0.26              | Gravimetry                    |
| 7      | Residue on Ignition                             | Not more than 0.1 % w/w              | 0.042             | Gravimetry                    |
| 8      | Chloride                                        | Not more than 0.05 %                 | 0.0128            | Turbidimetry                  |
| 9      | Lead (Pb)                                       | Not more than 3 ppm                  | Less than 0.5 ppm | ICP-MS                        |
| 10     | Heavy Metals                                    | Not more than 20 ppm                 | Less than 10 ppm  | ICP-OES / Limit test          |
| 11     | Related Substances — any individual impurity    | Not more than 0.10 %                 | 0.022             | HPLC                          |
| 12     | Related Substances — total impurities           | Not more than 0.50 %                 | 0.094             | HPLC                          |
| 13     | Residual Solvents                               | Complies with ICH Q3C limits         | Complies          | Headspace GC                  |
| 14     | Total Aerobic Microbial Count                   | Not more than 1000 cfu/g             | 125 cfu/g         | IP / USP <61>                 |
| 15     | Total Yeast & Mould Count                       | Not more than 100 cfu/g              | 11 cfu/g          | IP / USP <61>                 |
| 16     | Escherichia coli                                | Absent in 1 g                        | Absent            | IP / USP <62>                 |
| 17     | Salmonella species                              | Absent in 10 g                       | Absent            | IP / USP <62>                 |

| S. No. | Test Parameter | Specification                   | Result   | Method     |
|--------|----------------|---------------------------------|----------|------------|
| 18     | Structure      | Conforms to reference structure | Complies | 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.