

## 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      | Alendronate Sodium                       |
| C.A.S. Number     | 121268-17-5                              |
| Molecular Formula | —                                        |
| Molecular Weight  | —                                        |
| Grade / Standard  | ≥99% Pure                                |
| Physical Form     | White crystalline powder                 |
| Product Category  | Active Pharmaceutical Ingredients (APIs) |
| Country of Origin | India                                    |

### ANALYTICAL RESULTS

| S. No. | Test Parameter                | Specification                                     | Result   | Method                    |
|--------|-------------------------------|---------------------------------------------------|----------|---------------------------|
| 1      | Description                   | White crystalline powder                          | Complies | Visual                    |
| 2      | Identification                | Conforms to the structure of the substance        | Complies | FTIR / Chemical test      |
| 3      | Solubility                    | As per specification                              | Complies | Visual / Monograph        |
| 4      | Assay                         | Not less than 99.0 % w/w                          | 99.45    | Titrimetry / Instrumental |
| 5      | Clarity & Colour of Solution  | Clear; not more intensely coloured than reference | Complies | Visual (Monograph)        |
| 6      | pH (1 % w/v aqueous solution) | As per monograph                                  | 6.5      | Potentiometry             |
| 7      | Water Content (Karl Fischer)  | Not more than 0.5 % w/w                           | 0.15     | Karl Fischer titration    |
| 8      | Melting Range / Point         | As per monograph                                  | Complies | Capillary method          |
| 9      | Particle Size (d90)           | As per specification                              | 66 µm    | Laser diffraction         |
| 10     | 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.