

## 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      | Levocetirizine Dihydrochloride           |
| C.A.S. Number     | 130018-77-8                              |
| Molecular Formula | —                                        |
| Molecular Weight  | —                                        |
| Grade / Standard  | EP                                       |
| 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 (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                                | 99.47            | HPLC / Titrimetry (Monograph) |
| 6      | Clarity & Colour of Solution                    | Clear; not more intensely coloured than reference | Complies         | Visual (Monograph)            |
| 7      | pH (1 % w/v aqueous solution)                   | As per monograph                                  | 5.1              | Potentiometry                 |
| 8      | Water Content (Karl Fischer)                    | Not more than 0.5 % w/w                           | 0.25             | Karl Fischer titration        |
| 9      | Melting Range / Point                           | As per monograph                                  | Complies         | Capillary method              |
| 10     | Particle Size (d90)                             | As per specification                              | 89 µm            | Laser diffraction             |
| 11     | Sulphated Ash / Residue on Ignition             | Not more than 0.1 % w/w                           | 0.026            | 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 %                              | 0.025            | HPLC                          |
| 14     | Related Substances — total impurities           | Not more than 0.50 %                              | 0.101            | HPLC                          |
| 15     | Residual Solvents                               | Complies with ICH Q3C limits                      | Complies         | Headspace GC                  |
| 16     | 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.