

## Certificate of Analysis

### Ambroxol Hcl

|             |              |                  |              |
|-------------|--------------|------------------|--------------|
| CAS No      | 23828-92-4   | Code             | BIOJAMB001   |
| Batch No    | AMLH-250502  | Manufacture Date | May.20, 2025 |
| Retest date | May.19, 2030 | Quantity         | 1.5Kgs       |

| Testing Items   | Specifications   | Results  |
|---|--|--|
| Appearance  | White or yellowish crystalline powder  | Conforms   |
| Identification<br>First identification: B D<br>Second identification: A C D | A) Ultraviolet and visible absorption spectrophotometry  | Conforms   |
|   | B) Infrared absorption spectrophotometry   | Conforms   |
|   | C) Thin-layer chromatography   | Conforms   |
|   | D) Reaction of chlorides   | Conforms   |
| Solubility  | Sparingly soluble in water, soluble in methanol, practically insoluble in methylene chloride   | Conforms   |
| Appearance of solution  | Clear and not more intensely coloured than reference solution Y <sub>6</sub>   | Conforms   |
| pH  | 4.5~6.0  | 5.00   |
| Loss on drying  | ≤0.5%  | 0.20%  |
| Sulfated ash  | ≤0.1%  | 0.06%  |
| Heavy metals  | ≤20ppm   | <20ppm   |
| Related substances  | Impurity A ≤0.1%<br>Impurity B ≤0.1%<br>Impurity C ≤0.1%<br>Impurity D ≤0.1%<br>Impurity E ≤0.1%<br>Unspecified impurity ≤0.1%<br>Total impurities ≤0.3% | Conforms<br>Conforms<br>Conforms<br>Conforms<br>Conforms<br>0.02%<br>0.03% |
| Assay   | 99.0%~101.0%<br>(Calculated on the dried basis)  | 99.9%  |
| Conclusion  | This product conforms to EP10 standard   |  |

**\*Storage condition: Store below 25°C, Protect from moisture and light.**