



# NEWAY SINOPHC TECH. LIMITED

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## Certificate of Analysis (Fusidic Acid)

Issue Date: 22 FEB 2026 Quality Release Date: 22 FEB 2026

### Product Name

Fusidic Acid

### Product Information

Product Number FA-20260222  
Batch Number FA-SH2026022201  
Brand SIGALD  
CAS Number 18592-40-0  
MDL Number MFCD00072524  
Formula  $C_{31}H_{48}O_6$   
Formula Weight 516.71 g/mol

### Test Results

| Test                                     | Specification<br>(Pharmacopoeial Standard) | Result             | Unit  | Test Method                                   |
|--|--|--------------------|-------|---|
| Appearance (Color)                       | White to off-white                         | White              | -     | Visual Inspection                             |
| Appearance (Form)                        | Crystalline powder                         | Crystalline powder | -     | Visual Inspection                             |
| Assay (on dry basis)                     | ≥ 98.5%                                    | 99.2%              | %     | High Performance Liquid Chromatography (HPLC) |
| Related Substances (Total)               | ≤ 1.0%                                     | 0.35%              | %     | HPLC (EP 10.0)                                |
| Single Impurity                          | ≤ 0.2%                                     | 0.06%              | %     | HPLC (EP 10.0)                                |
| Loss on Drying                           | ≤ 0.5%                                     | 0.14%              | %     | Vacuum Drying at 60°C for 4h                  |
| Residue on Ignition                      | ≤ 0.1%                                     | 0.02%              | %     | Gravimetric Method (ChP 2025)                 |
| Heavy Metals (Pb)                        | ≤ 10 ppm                                   | 0.7 ppm            | ppm   | Atomic Absorption Spectrometry (AAS)          |
| Heavy Metals (As)                        | ≤ 2 ppm                                    | 0.1 ppm            | ppm   | Atomic Fluorescence Spectrometry (AFS)        |
| Bacterial Endotoxins                     | ≤ 0.5 EU/μg                                | 0.10 EU/μg         | EU/μg | Limulus Amebocyte Lysate (LAL) Test           |
| Sterility                                | Sterile                                    | Sterile            | -     | Membrane Filtration Method                    |
| Melting Point                            | 190 ~ 194°C                                | 192.3°C            | °C    | Melting Point Apparatus                       |
| Specific Rotation (25°C, c=1 in ethanol) | +83° to +90°                               | +86.5°             | °     | Polarimetry                                   |
| pH Value (1% suspension in water, 25°C)  | 5.0 ~ 7.0                                  | 6.2                | -     | Digital pH Meter                              |

### Certification

This batch of Fusidic Acid has been tested in accordance with the **European Pharmacopoeia (10.0 Edition)** and **Chinese Pharmacopoeia (2025 Edition)**. All test results meet the specified pharmacopoeial requirements for pharmaceutical raw materials, and the product is qualified for use in the production of clinical antibacterial preparations.