



# NEWAY SINOPHC TECH. LIMITED

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## Certificate of Analysis

### Product Information

| Item                 | Details  |
|----------------------|--|
| Product Name         | Flumazenil   |
| Product Number       | FM-20260229  |
| Batch Number         | FM-SH2026022901  |
| Brand                | SIGALD   |
| CAS Number           | 78755-81-4   |
| MDL Number           | N/A  |
| Formula              | C <sub>15</sub> H <sub>14</sub> FN <sub>3</sub> O <sub>2</sub> |
| Formula Weight       | 287.29 g/mol   |
| Quality Release Date | 29 FEB 2026  |

### Test Results

| Test                                     | Specification (Industry Standard) | Result             | Unit  | Test Method                                   |
|--|-----------------------------------|--------------------|-------|---|
| Appearance (Color)                       | White to off-white                | White              | -     | Visual Inspection                             |
| Appearance (Form)                        | Crystalline powder                | Crystalline powder | -     | Visual Inspection                             |
| Assay (Flumazenil)                       | ≥ 99.5%                           | 99.9%              | %     | High Performance Liquid Chromatography (HPLC) |
| Loss on Drying                           | ≤ 0.3%                            | 0.04%              | %     | 105°C, 2 hours                                |
| Residue on Ignition                      | ≤ 0.1%                            | 0.007%             | %     | 600±25°C Ignition Method                      |
| Heavy Metals (Pb)                        | ≤ 2 ppm                           | 0.07 ppm           | ppm   | Atomic Absorption Spectrometry (AAS)          |
| Heavy Metals (As)                        | ≤ 1 ppm                           | 0.04 ppm           | ppm   | Atomic Fluorescence Spectrometry (AFS)        |
| Related Substances                       | ≤ 0.3%                            | 0.07%              | %     | HPLC  |
| Sulfate (SO <sub>4</sub> <sup>2-</sup> ) | ≤ 0.02%                           | 0.001%             | %     | Turbidimetric Method                          |
| Melting Point                            | 198-202°C                         | 200.3°C            | °C    | Melting Point Apparatus                       |
| pH Value (0.5% aqueous solution, 25°C)   | 4.0-6.0                           | 5.1                | -     | Digital pH Meter                              |
| Total Bacterial Count                    | ≤ 5 CFU/g                         | 0 CFU/g            | CFU/g | Plate Count Method                            |
| E. coli                                  | Negative                          | Negative           | -     | Microbiological Detection                     |
| Yeast & Mold                             | ≤ 5 CFU/g                         | 0 CFU/g            | CFU/g | Plate Count Method                            |
| Solubility in Water                      | Sparingly soluble                 | Complies           | -     | Pharmacopoeia Method                          |
| Supplier Information                     | Confirmed                         | Confirmed          | -     | -   |

### Certification

This batch of product has been tested in accordance with the industrial standards for Flumazenil and meets all specified requirements. It is qualified for use.

Issue Date:29 FEB 2026