

## **CERTIFICATE OF ANALYSIS**

## PRODUCT NAME: IRINOTECAN HYDROCHLORIDE

| SPECIFICATIONS      | CORPORATION STANDARD                    | ANALYSIS RESULT |
|---------------------|---|-----------------|
| Identification      | IR, HPLC Meet The Requirements          | Complies        |
| Solubility          | Sparingly Soluble In Methanol And Water | Complies        |
| Ph                  | 3.0~5.0                                 | 4.5             |
| Absorbance At 430nm | ≤0.7                                    | Complies        |
| Water               | 7.0~9.0%                                | 8.1%            |
| Chloride            | 3.0~5.5%                                | Complies        |
| Specific Rotation   | +60°~ +73°                              | +65°            |
| Residue On Ignition | ≤0.1%                                   | 0.08%           |
| Heavy Metals        | ≤20ppm                                  | Complies        |
| Total Impurities    | ≤1.00%                                  | 0.52%           |
| Individual Impurity | ≤0.50%                                  | 0.27%           |
| Assay               | 97.0%~103.0%                            | 100.88%         |