

## **CERTIFICATE OF ANALYSIS**

## DAUNARUBICIN HYDROCHLORIDE

| ITEMS                  | SPECIFICATIONS                              | RESULTS  |
|------------------------|---|----------|
| Appearance             | Orange Red Crystalline Hygroscopic Powder   | Conforms |
| Identification         | IR, HPLC, Deposition From Silver<br>Nitrate | Conforms |
| Ph                     | 4.5~6.5                                     | 5.5      |
| Water                  | ≤3.0%                                       | 0.95%    |
| Related Substance      |   |          |
| Any Other Impurity     | ≤1.5%                                       | 1.05%    |
| Total Impurities       | ≤3.0%                                       | 2.10%    |
| Residual Solvents      |   |          |
| Both Methanol &Ethanol | ≤0.2%                                       |          |
| Butyl Alcohol          | ≤1.0%                                       | Conforms |
| Acetone                | ≤0.5%                                       |          |
| Chloroform             | ≤0.006%                                     |          |
| Bacterial Endotoxins   | ≤4.3USP EU/Mg                               | Conforms |
| Assay (HPLC)           | 98.0~102.0%                                 | 99.5%    |