

# 台州恒丰医药化工有限公司

TAIZHOU HENGFENG PHARMACEUTICAL & CHEMICAL CO., LTD.

## CERTIFICATE OF ANALYSIS

Lot: 0010211

|                |              |                |            |
|----------------|--------------|----------------|------------|
| PRODUCT NAME   | ISOTRETINOIN |                |            |
| BATCH No       | 20110102     | DATE OF MANUF. | 2011/01/06 |
| QTY.           | 2kg          | DATE OF EXPIRY | 2013/01/05 |
| TEST BASED ON: | EP5          |                |            |

| ITEMS                     | SPECIFICATION                                                                                                      | RESULTS                   |
|---------------------------|--------------------------------------------------------------------------------------------------------------------|---------------------------|
| Description               | Yellow to light-orange crystalline powder                                                                          | Yellow crystalline powder |
| Identification: A         | UV                                                                                                                 | Complies                  |
| B                         | IR                                                                                                                 | Complies                  |
| Related substances:       |                                                                                                                    |                           |
| Tretinoin                 | 2.0% MAX                                                                                                           | 0.1%                      |
| Total of other impurities | 0.5% MAX                                                                                                           | 0.3%                      |
| Heavy metals              | Not more than 0.002%                                                                                               | 20ppm                     |
| Loss on drying            | Not more than 0.5%                                                                                                 | 0.3%                      |
| Sulphated ash             | Not more than 0.1%                                                                                                 | 0.03%                     |
| Assay                     | 98.0~102%MIN                                                                                                       | 99.5%                     |
| Packaging and storage     | Preserve in tight containers, preferably under an atmosphere of nitrogen, protected from light, stored at 25°C±2°C |                           |

### CONCLUSION:

Test results confirm with EP5

CHECKER:

ANALYST:

APPROVAL:

