

杭州东瑞医药科技有限公司
HANGZHOU DAWN RAY PHARMACEUTICAL CO.,LTD.

CERTIFICATE OF ANALYSIS

Hydrocortisone

| | |
|-------------------------------------|--------------------------------|
| Batch No.: DR20130103 | Quantity: 100kg |
| Manufacture Date: 2013.01.03 | Expiry Date: 2016.01.02 |

TESTS:

| Items | Specification | Results |
|------------------------|---|--------------------------|
| Appearance | White to practically white, crystalline powder. | White crystalline powder |
| Identification | A: IR B:UV | Conforms |
| Melting point | Melts at about , 215°C | 214°C |
| Solubility | Very slightly soluble in water and in ether; sparingly soluble in acetone and in alcohol; slightly soluble in chloroform. | Conforms |
| Specific rotation | +150° ~+ 156° | +152.4° |
| Loss on drying | ≤1.0% | 0.09% |
| Residue on ignition | Negligible | Conforms |
| Chromatographic purity | Any individual impurity ≤0.5% | 0.33% |
| | Total impurities ≤2.0% | 1.2% |
| Assay | 97.0%~102.0% | 101.5% |
| Storage | Preserve in well-closed containers. Store at 25 ° excursions permitted between 15 ° and 30 ° | |

Conclusion: The results conform with the USP32.



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