

TIANJIN JINJIN PHARMACEUTICAL CO., LTD. CERTIFICATE OF ANALYSIS

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| Report No.: | 2023-074 | 以於专届意识cateNo.: | 2023-08-13 | Page 1 of 1 |
|----------------------------|---|-----------------|---|-------------|
| Product Name: | Hydrocortison | Colonia Colonia | i de la | |
| Batch No.: | Hydrocortison TA0588 Hydrocartison Date: | | 2023.08.16 | |
| Quantity: | 25Kg | Retest Date: | 2026.08.15 | |
| Package: | drum or carton | Report Date: | 2023.09.09 | |
| Items | Requirements | | Results | |
| Appearance | a white or practically white, crystalline powder | | White crystalline powder | |
| Solubility(annual) | very slightly soluble in water and in ether; sparingly soluble in acetone and in alcohol; slightly soluble in chloroform. | | Complies | |
| Identification | | | | |
| A.IR -spectrum | meets the requirement | | Complies | |
| B. UV Absorption | meets the requirement | | Complies | |
| Specific rotation | between +150° and +156° | | +153.8° | |
| Loss on drying | | | | |
| | not more than 1.0 | % | 0.08% | |
| Residue on ignition | | | | |
| | not more than 0.59 | % | 0.00% | |
| Chromatographic purity | | | | |
| Any individual impurity | not more than 0.5% | | 0.14% | |
| Sum of impurities | not more than 2.0% | | 0.37% | |
| Assay | | | | |
| | between 97.0% and | 1 102.0% | 100.5% | |
| Residual solvent(In-house) | | | | |
| Methanol | not more than 3000 | opm | 105ppm | |
| Ethanol | not more than 2000ppm | | not detect out | |
| Acetone | not more than 5000] | | not detect out | |
| DMF | not more than 880ppm | | not detect out | |
| Methylene chloride | not more than 600ppm | | not detect out | |
| Particle size(In-house) | | | | |
| | 90% not more than | 15 microns | Complies | |

CONCLUSION: THE PRODUCT CONFORMS TO USP41

Responsible Person: 34, 25, 25, 26, 28

Checker: **M B**Date: **223**, **9**, 28