



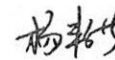
**Zhejiang Xianju Pharmaceutical Co., Ltd**  
**(Taizhou Xianju Site)**  
**Certificate of Analysis**




Product	PREDNISONONE	Batch No.	F-04.1091-251106
Amounts	47.84kg	Manufacture Date	2025-10-20
According To	USP 2025 And In-house, Customer Standard	Retest Date	2030-10-20

【ITEM】	【SPECIFICATION】	【RESULT】
Appearance	White or almost white crystalline powder	White crystalline powder
Identification	(1) Conforms by IR	Conforms
Identification	(2) Should be positive	Conforms
Specific Rotation	+167° to +175°	+170°
Related Substances	Prednisone acetate ≤ 0.25%	0.08%
Related Substances	Cortisone ≤ 0.25%	0.08%
Related Substances	Individual unknown impurity ≤ 0.10%	0.05%
Related Substances	Total impurities ≤ 0.75%	0.30%
Water	Not more than 1.0%	0.1%
Residue On Ignition	Negligible, from 100mg	Conforms
Residual Solvents	Methanol is not more than 3000ppm	808ppm
Residual Solvents	Cyclohexane is not more than 3880ppm	Not detected
Assay	It should contain 97.0% to 102.0% of C <sub>21</sub> H <sub>26</sub> O <sub>5</sub> calculated on the anhydrous basis	99.2%
Particle Size	Dv99 < 20μm	6μm

**Conclusion:** The Product Conforms To USP 2025(Official as of 2020-05-01) And In-house, Customer Standard.

Report:   
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