

佳尔科生物科技南通有限公司

Jiaerke Biotechnology Nantong Co., Ltd.

No. 10, 2 Haibin Road, Rudong Coastal Economic Development Zone, Nantong City, Jiangsu Province 226407, China. Tel:0086-513-84811816 Fax:0086-513-84811066

Certificate of Analysis

No.: P01-2304002

Product name:	Prednisolone	Batch No.:	P01-230303(M)
Quantity:	50kg	Packaging:	25kg/drum
Manuf. date:	Mar. 04, 2023	Sampling date:	Apr. 04, 2023
Re-test date:	Mar. 03, 2026	Report date:	Apr. 06, 2023
Standard:	EP10		
Items	Specifications		Results
1.Appearance	White or almost white crystalline powder		White crystalline powder
2.Identification	IR spectrum of sample corresponds to with that of reference standard.		Complies
	In the chromatogram of the content determination, the retention time and the peak area of the major peak in the chromatogram of the sample is similar to that in the chromatogram of the reference standard.		Complies
3.Specific optical rotation (dried substance)	+113° ~ +119°		+116°
4.Loss on drying	≤1.0%		0.21%
5.Related substances	Impurity F(RRT≈0.7): ≤0.5%		<0.05%
	Impurity B(RRT≈0.9): ≤0.3%		<0.05%
	Impurity A(RRT≈1.05): ≤1.0%		0.48%
	Impurity J(RRT≈1.5): ≤0.3%		<0.05%
	Impurity C(RRT≈1.7): ≤0.3%		ND
	Unspecified impurity: ≤0.10%		<0.05%
	Total impurities: ≤1.5%		0.48%
6.Assay (dried substance)	96.5% ~ 102.0%		99.4%
7.Residual solvents	Benzene: ≤2ppm Dichloromethane: ≤600ppm Methanol: ≤3000ppm		ND 19ppm 62ppm
8*.Particle size	90% <30μm		Complies
Conclusion:	The above product conforms to EP10		

Reported by: 徐佳华

Approved by:

