



XIANJU  
PHARMA

# Zhejiang Xianju Pharmaceutical Co., Ltd (Taizhou Xianju Site)

## Certificate of Analysis

Name	Hydrocortisone	Number of COA	04.1219-2112-4
Batch No.	F-04.1219-211202	Test Date	2021-12-25
Amounts (kg)	52.42	Manufacture Date	2021-12-05
According To	USP 2020-05-01 and customer standard	Retest Date	2024-12-05

【ITEM】	【SPECIFICATION】	【RESULT】
Appearance	White to almost white crystalline powder	White crystalline powder
Identification	A. IR: The IR spectrum of the sample should conform to that of the reference standard B. Ultraviolet absorption: $\Delta E/E \leq 2.5\%$	Conforms 0.3%
Specific optical rotation	+150° To +156°	+154.4°
Loss on drying	$\leq 1.0\%$	0.2%
Residue on ignition	$\leq 0.5\%$	0.31%
Related substances	Individual impurity $\leq 0.5\%$ Total impurities $\leq 2.0\%$	0.12% 0.49%
Residual solvents	Methanol is not more than 3000ppm Cyclohexane is not more than 3880ppm	186ppm Not detected
Assay	Contains 97.0%~102.0% of $C_{21}H_{30}O_5$ , calculated on dried basis	100.4%
Particle size	Dv90 < 10 $\mu$ m	3.6 $\mu$ m

### CONCLUSION

**THE PRODUCT CONFORMS TO USP 2020-05-01 AND CUSTOMER STANDARD**

Analyst :

Checker :

Supervisor :

Date : 2021-12-29

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2021-06-01