

天津市津津药业有限公司检验报告单

TIANJIN JINJIN PHARMACEUTICAL CO., LTD. CERTIFICATE OF ANALYSIS

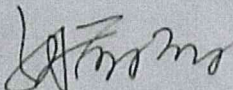
No.8, Jingfu Road, Industrial Zone of Zhangjiawo Town, Xiqing district, Tianjin, China


Tel: +86 22 87982602 Fax: +86 22 87982950

Report No.:	2017-007	Analytical No.:	2017-5-3	Page 1 of 1
Product Name:	Hydrocortisone Acetate			
Batch No.:	HC0067	Manuf. Date:	2017.5.6	
Quantity:	30Kg	Retest Date:	2020.5.5	
Package:	drum or carton	Report Date:	2017.5.17	

Items	Requirements	Results
Appearance	a white or almost white, crystalline powder	White crystalline powder
Solubility(annual)	Practically insoluble in water, slightly soluble in anhydrous ethanol and in methylene chloride	Complies
Identification		
A. IR -spectrum	meets the requirement	Complies
B. HPLC	meets the requirement	Complies
Specific optical rotation		
	between +158° and +167°	+161.4°
Loss on drying		
	not more than 0.5%	0.06%
Related substances		
impurity A RRT 0.4	not more than 0.5%	0.06%
impurity B RRT 0.7	not more than 0.3%	ND
impurity C RRT 0.9	not more than 0.6%	0.11%
impurity D RRT 1.2	not more than 0.3%	ND
impurity G RRT 1.8	not more than 0.15%	ND
impurity E RRT 2.3	not more than 0.3%	ND
Any unspecified impurity	not more than 0.10%	Complies
Total	not more than 1.5%	0.18%
Assay		
	between 97.0 % and 102.0 %	100.5%
Residual solvent (In-house)		
Ethanol	not more than 2000ppm	287ppm
DMF	not more than 880ppm	not detect out
Particle size (In-house)		
	90% not more than 20 microns	Complies

CONCLUSION : THE PRODUCT CONFORMS TO Ph.Eur.9(R1-CEP 2008-085-Rev 00)

Responsible Person : 

Checker: 

Date: 2017.8.31

Date: 2017.8.31