

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.:	2010-002	Analytical No.:	2010-4-1	Page 1 of 1
Product Name:	Hydrocortisone Acetate			
Batch No.:	HC0004	Manuf. Date:	2010.3.27	
Quantity:	5Kg	Test Date:	2013.3.26	
Package:	drum or carton	Report Date:	2010.4.26	

Items	Requirements	Results
Characters	a white or almost white, crystalline powder	White crystalline powder
Solubility	Practically insoluble in water, sparingly soluble in ethanol and in methylene chloride	Complies
Melting point(Ph.Eur.)	about 220°C	223°C
Identification		
A. IR -spectrum(Ph.Eur.)	meets the requirement	Complies
B. TLC(Ph.Eur.)	meets the requirement	Complies
A. IR -spectrum(USP)	meets the requirement	Complies
B. UV Absorption(USP)	meets the requirement	Complies
Specific rotation		
(Ph.Eur.)	between +158° and +167°	+161.2°
(USP)	between +158° and +165°	+161.2°
Loss on drying		
(Ph.Eur.)	not more than 0.5%	0.17%
(USP)	not more than 1.0 %	0.06%
Residue on ignition(USP)	negligible, from 100mg	Complies
Related substances(Ph.Eur.)		
Any individual impurity	not more than 1.0%	0.15%
	not more than one such peak has area greater than 0.5%	Complies
Sum of impurities	not more than 1.5%	0.33%
Chromatographic purity(USP)		
Any individual impurity	not more than 1.0%	0.09%
Sum of impurities	not more than 2.0%	0.47%
Residual solvent (In-house)		
Ethanol	not more than 2000ppm	475ppm
DMF	not more than 880ppm	not detect out
Assay		
(Ph.Eur.)	between 97.0 % and 103.0 %	101.2%
(USP)	between 97.0 % and 102.0 %	99.8%
Particle size (In-house)	90% not more than 20 microns	Complies

CONCLUSION : THE PRODUCT CONFORMS TO Ph.Eur.6 /USP 32

Responsible Person: 董能书

Checker: 孙志

Analyst: 夏士田

Date: 2011.2.16

Date: 2011.2.16

Date: 2011.2.16