



coreychem®

Career Henan Chemical Co. Certificate of Analysis

Product Name	Hydrocortisone Acetate		CAS:50-03-3
Batch No.	FS25-180401W	Testing Time	2018.4.7
Manu Date	2017.12.13	Retest Date	2020.11
Quantity	144.48kg	Testing procedure	EP7/USP39

Tests	Specification		Results	
	EP7	USP39	EP7	USP39
Appearance	White or almost white crystalline powder	White or almost white crystalline powder	Almost white crystalline powder	Almost white crystalline powder
Identification	A:IR	A:IR	Conforms	Conforms
	B:TLC	B:UV	Conforms	Conforms
Specific Rotation	+158° ~ +167°	+158° ~ +167°	+162.78	+162.78
Melting point	≥220°	/	222°	/
Loss on Drying	≤0.5%	≤1.0%	≤0.12%	≤0.12%
Residue on ignition	/	100mg Negligible	/	Conforms
Related Substances	Any individual Impurity ≤1.0%	Any individual Impurity ≤1.0%	Any individual Impurity 0.14%	Any individual Impurity 0.14%
	Total impurity ≤1.5%	Total impurity ≤2.0%	Total impurity 0.51%	Total impurity 0.93%
	≥0.5% impurity ≤1	/	0	/
Residue Solvents	methanol ≤3000ppm	methanol ≤3000ppm	ND	ND
	Chloroform ≤60pp	Chloroform ≤60pp	ND	ND
	Pyridine ≤200ppm	Pyridine ≤200ppm	ND	ND
	DMF ≤880ppm	DMF ≤880ppm	549ppm	549ppm
Assay On dried basis	97.0%-103.0%	97.0%-102.0%	99.03%	101.75%/
Particle size	≤20um. ≥90%	≤20um. ≥90%	Conforms	Conforms
Packing and storage	Stored protected from light			
conclusion	Conform to the current EP7/USP39 monograph			

Quality control: Dr Lian

Inspector: Xu



