

YANGZHOU PHARMACEUTICAL CO., LTD. CERTIFICATION OF ANALYSIS

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Report No: 003

SOPLHQC-CP016-01

Sample Name	Hydrocortisone	Sending Sample Unit	Workshop Two
Batch No.	QK20200003	Factory Name	Yangzhou pharmaceutical CO., LTD.
Specification	Pharmaceutical	Manufacturing Date	2019. 11. 30
Quantity	200kg	Report Date	2020. 01. 17
Package	Drum	Expiry Date	2023. 11. 29

DMF #4710

I. Analytical Method:	CURRENT USP	
II. Property Tested	Specification	Test Result
Characteristics:	A white or almost crystalline powder	pass
Identification: (A)	IR-by USP(197 M)	pass
(B)	UV-by USP(197 U)	pass
Specific rotation:	Between +150° and +156°	+153°
Loss on drying:	Not more than 1.0%	0.1%
Residue on ignition:	Not more than 0.5%	0.06%
Chromatographic purity:	(1) Individual impurities(not more than 0.5%)	0.186%
	(2) Total impurities(not more than 2.0%)	0.687%
Assay:	Between 97.0% and 102.0% (on the dried basis)	99.2%
Residual Solvent		
Methanol:	Not more than 1500ppm	314ppm
Micronization:	95% not more than 10 microns	
	99% not more than 16 microns	pass
	100% not more than 20 microns	

III. Result and Conclusion: Complies with CURRENT USP

Responsible person:

周雪萍

Analyst:

罗公勤 王明

Checker:

张明