

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

100% not more than 20 microns

pass

III. Result and Conclusion:

Complies with CURRENT USP

Responsible person:

周雪萍

Analyst:

罗勤 王明

Checker:

张明