

SINOWAY INDUSTRIAL CO.,LTD,

16/F, HUICHENG COMM.COMPLEX 839 XIAHE ROAD, XIAMEN,CHINA.

TEL: 0086-592-5854962

POSTCODE: 361004

FAX: 0086-592-5854960

E-MAIL: sale3@china-sinoway.com

Certificate of analysis by Manufacturer

1/2

NAME OF PRODUCT:HYDROCORTISONE MIC

BATCH NO:T3017

MANUF DATE:DEC. 5, 2014

RETEST DATE: DEC. 4, 2017

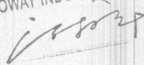
QUANTITY:25KG

ISSUE DATE:FEB. 06, 2015

LC NO: 0221MLCS15000039

ITEMS	REQUIREMENTS	RESULTS
APPEARANCE (PH. EUR.)	A WHITE OR ALMOST WHITE, CRYSTALLINE POWDER	WHITE CRYSTALLINE POWDER
SOLUBILITY (PH. EUR.)	PRACTICALLY INSOLUBLE IN WATER, SPARINGLY SOLUBLE IN ACETONE AND IN ALCOHOL, SLIGHTLY IN METHYLENE CHLORIDE	COMPLIES
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 OPTICAL ROTATION		
(PH. EUR)	BETWEEN+150° AND +156°	+153.6°
(USP)	BETWEEN+150° AND +156°	+153.4°
LOSS ON DRYING		
(PH. EUR)	NOT MORE THAN 1.0%	0.05%
(USP)	NOT MORE THAN 1.0%	0.06%
RESIDUE ON IGNITION (USP)	NOT MORE THAN 0.5%	0.00%
RELATED SUBSTANCES (PH. EUR)		
ANY INDIVIDUAL IMPURITY	NOT MORE THAN 0.5%	0.18%
SUM OF IMPURITIES	NOT MORE THAN 1.5%	0.70%
CHROMATOGRAPHIC PURITY (USP)		
ANY INDIVIDUAL IMPURITY	NOT MORE THAN 0.5%	0.16%
SUM OF IMPURITIES	NOT MORE THAN 2.0%	0.76%
ASSAY		
UV ABSORPTION (PH. EUR.)	BETWEEN 97.0% AND 103.0%	100.3%
HPLC (USP)	BETWEEN 97.0% AND 102.0%	99.9%
RESIDUAL SOLVENT (IN-HOUSE)		
METHANOL	NOT MORE THAN 500PPM	NOT DETECT OUT
ETHANOL	NOT MORE THAN 2000PPM	341PPM
METHYLENE CHLORIDE	NOT MORE THAN 600PPM	NOT DETECT OUT

SINOWAY INDUSTRIAL CO.,LTD.



SINOWAY INDUSTRIAL CO.,LTD,

16/F, HUICHENG COMM.COMPLEX 839 XIAHE ROAD, XIAMEN,CHINA.

TEL: 0086-592-5854962

POSTCODE: 361004

FAX: 0086-592-5854960

E-MAIL: sale3@china-sinoway.com

Certificate of analysis by Manufacturer

2/2

NAME OF PRODUCT:HYDROCORTISONE MIC

BATCH NO:T3017

MANUF DATE:DEC. 5, 2014

RETEST DATE: DEC. 4, 2017

QUANTITY:25KG

ISSUE DATE:FEB. 06, 2015

LC NO: 0221MLCS15000039

ITEMS	REQUIREMENTS	RESULTS
CHLOROFORM	NOT MORE THAN 60PPM	NOT DETECT OUT
PARTICLE SIZE(IN-HOUSE)	90% NOT MORE THAN 15 MICRONS	COMPLIES
CONCLUSION:THE PRODUCT CONFORMS TO PH.EUR.6/USP37		

RESPONSIBLE PERSON: ZHANG LI

CHECKER: LIU CHUANYU

ANALYST: WANG XIU RU

Manufacturer: SINOWAY INDUSTRIAL CO LTD

SINOWAY INDUSTRIAL CO.,LTD.

