

# 寿光富康制药有限公司

## SHOUGUANG FUKANG PHARMACEUTICAL CO., LTD

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### CERTIFICATE OF ANALYSIS

REPORT NO: A-20411306004

REGISTER NO: ZLJL-0510-02

PRODUCT	OMEPRAZOLE	PHARMACOPOEIA	EP7.7
BATCH NO.	A-20411306004	GROSS WEIGHT	18.3 Kg/Drum
BATCH QUANTITY	320Kg	NET WEIGHT	15Kg/Drum
MANUFACTURE DATE	JUN.06,2013	RETEST DATE	MAY.2015
ANALYSIS DATE	JUN.08,2013	REPORT DATE	JUN.10,2013
TEST ITEM	STANDARDS REQUIRED	TEST RESULTS	
Characters	A white or almost white powder	almost white powder	
Identification			
IR	IR Conforms to the CRS (2.2.24)	Complies	
Test			
Appearance of solution	Solution S is clear (2.2.1)	Clear	
Absorbance	The absorbance is not greater than 0.10 at 440nm (2.2.25)	0.03	
Related substances(HPLC)	(2.2.29)		
Impurity D	Not more than 0.15%	Not detected	
E	Not more than 0.15%	0.006%	
Any other individual impurity	Not more than 0.10%	0.08%	
Total impurity	Not more than 0.5%	0.1%	
Residual solvents:			
a)Acetone	Not more than 1500ppm	607ppm	
b)Methylene chloride	Not more than 100ppm	Not detected (LOD=1.4ppm)	
c)Methanol	Not more than 1000ppm	72ppm	
d)Toluene	Not more than 300ppm	17ppm	
e)Benzene	Not more than 1ppm	Not detected (LOD=0.2ppm)	
Loss on drying	Not more than 0.2% (2.2.32)	0.08%	
Sulphated ash	Not more than 0.1% (2.4.14)	0.07%	
Assay% on dry basis	C <sub>17</sub> H <sub>19</sub> N <sub>3</sub> O <sub>3</sub> S conforms to 99.0%-101.0% (2.2.20)	100.1%	
Particle Size	100% pass 10 microns	Complies	

Results: The commodity meets the standard of EP7.7.

Examiner: Zhang Guoqiang

Checker: Liu Xiaoping

QA: Sun Wei

张国强

刘小平

孙伟