寿光富康制药有限公司
SHOUGUANG FUKANG PHARMACEUTICAL CO., LTD
North-East of Dongwaihuan Road, Dongcheng Industrial Area, Shouguang City, Shandong Province, P.R.of China.
tel: 0086-536-5102364 fax: 0086-536-5101568
http://www.shouguangpharm.com e-mail: export@shouguangpharm.com

CERTIFICATE OF ANALYSIS

REPORT NO: QC18042302 REGISTER NO:ZLJL-0510-02

PRODUCT	OMEPRAZOLE	PHARMACOPOEIA	EP9.0
BATCH NO.	A-20411804033	GROSS WEIGHT	23.3 Kg/Drum
BATCH QUANTITY	320Kg	NET WEIGHT	20Kg/Drum
MANUFACTURE DATE	APR.21.2018	RETEST DATE	MAR.2020
ANALYSIS DATE	APR.24.2018	REPORT DATE	APR.26,2018

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)	0.007
Related substances(HPLC)	(2.2.29)	
Impurity D	Not more than 0.15%	Not detected
E	Not more than 0.15%	0.007%
Any other individual impurity	Not more than 0.10%	0.007%
Total impurity	Not more than 0.5%	0.02%
Residual solvents:		
a)Acetone	Not more than 1500ppm	349ppm
b)Methylene chloride	Not more than 100ppm	Not detected
c)Methanol	Not more than 1000ppm	85ppm
d)Toluene	Not more than 300ppm	1ppm
e)Benzene	Not more than 1ppm	Not detected
Loss on drying	Not more than 0.2%(2.2.32)	0.06%
Sulphated ash	Not more than 0.1% (2.4.14)	0.03%
Assay% on dry basis	$C_{17}H_{19}N_3O_3S$ conforms to 99.0%-101.0%(2.2.20)	99.9%

Results: The commodity meets the standard of EP9.0.

Examiner:Song Rongbing Checker: Liu Mingzheng QA:Li Lianshu