Lte: 0110221

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: QC20090884 REGISTER NO:SMR-QC-018a0

PRODUCT	OMEPRAZOLE	PHARMACOPOEIA	EP10.0
BATCH NO.	A-50412009037	GROSS WEIGHT	23.3 Kg/Drum
BATCH QUANTITY	320Kg	NET WEIGHT	20Kg/Drum
MANUFACTURE DATE	SEP.27,2020	RETEST DATE	AUG.2022
ANALYSIS DATE	SEP.29,2020	REPORT DATE	NOV.12,2020

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
Impurity Fand G	The absorbance is not greater than 0.10 at 440nm (2.2.25)	0.006
Related substances(HPLC)	(2.2.29)	
Impurity D	Not more than 0.15%	Not detected
E	Not more than 0.15%	Not detected
Any other individual impurity	Not more than 0.10%	Not detected
Total impurity	Not more than 0.5%	Not detected
Residual solvents:		
a)Acetone	Not more than 1500ppm	394ppm
b)Methylene chloride	Not more than 100ppm	Not detected
c)Methanol	Not more than 1000ppm	147ppm
d)Toluene	Not more than 300ppm	0ppm
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)	100.2%

Results: The commodity meets the standard of EP10.0.

Examiner: Huang Shasha 2020.11.12 Checker: Hu Yue 2020.11.12 QA: Liu Yongxiang 2020.11.12