

Lot: 0J80717

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: QC17060115

REGISTER NO: ZLJL-0510-02

REGISTER NO: ZLJL-0510-02

PRODUCT	OMEPRAZOLE	PHARMACOPOEIA	EP9.0
BATCH NO.	A-20411705039-1250	GROSS WEIGHT	23.3Kg/Drum
BATCH QUANTITY	89.150Kg	NET WEIGHT	20Kg/Drum
MANUFACTURE DATE	JUN.01,2017	RETEST DATE	MAY.2019
ANALYSIS DATE	JUN.06,2017	REPORT DATE	JUN.16,2017
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%		Not detected
Any other individual impurity	Not more than 0.10%		0.01%
Total impurity	Not more than 0.5%		0.02%
Residual solvents:			
a)Acetone	Not more than 1500ppm		272ppm
b)Methylene chloride	Not more than 100ppm		Not detected (LOD=0.65ppm)
c)Methanol	Not more than 1000ppm		62ppm
d)Toluene	Not more than 300ppm		Not detected (LOD=0.37ppm)
e)Benzene	Not more than 1ppm		Not detected (LOD=0.24ppm)
Loss on drying	Not more than 0.2%(2.2.32)		0.07%
Sulphated ash	Not more than 0.1% (2.4.14)		0.03%
Assay% on dry basis	C ₁₇ H ₁₉ N ₃ O ₃ S conforms to 99.0%-101.0%(2.2.20)		100.2%
Results: The commodity meets the standard of EP9.0.			

Examiner:Zhao Guangtian

赵广田

Checker:Liu Xiaoping

刘小平

QA:Li Lianshu

李连书