

lot: 0121214

寿光富康制药有限公司

SHOUGUANG FUKANG PHARMACEUTICAL CO., LTD

North-East of Dongwailuan 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: A-20411409023

REGISTER NO: ZLJL-0510-02

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PRODUCT	OMEPRAZOLE	PHARMACOPOEIA	EP8.0
BATCH NO.	A-20411409023	GROSS WEIGHT	18.3 Kg/Drum
BATCH QUANTITY	360Kg	NET WEIGHT	15Kg/Drum
MANUFACTURE DATE	SEP.17.2014	RETEST DATE	AUG.2016
ANALYSIS DATE	SEP.18.2014	REPORT DATE	DEC.08.2014
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)	0.02	
Related substances(HPLC)	(2.2.29)		
Impurity D	Not more than 0.15%	0.006%	
E	Not more than 0.15%	0.003%	
Any other individual impurity	Not more than 0.10%	0.03%	
Total impurity	Not more than 0.5%	0.06%	
Residual solvents:			
a)Acetone	Not more than 1500ppm	870ppm	
b)Methylene chloride	Not more than 100ppm	Not detected (LOD=1.4ppm)	
c)Methanol	Not more than 1000ppm	39ppm	
d)Toluene	Not more than 300ppm	12ppm	
e)Benzene	Not more than 1ppm	Not detected (LOD=0.2ppm)	
Loss on drying	Not more than 0.2% (2.2.32)	0.1%	
Sulphated ash	Not more than 0.1% (2.4.14)	0.03%	
Assay% on dry basis	C ₁₁ H ₁₀ N ₂ O ₅ S conforms to 99.0%-101.0% (2.2.20)	100.2%	
Particle Size	100% pass 10 microns	Complies	
Results: The commodity meets the standard of EP8.0.			

Examiner: Huang Shanshan

Checker: Li Baoxing

QA: Zheng Panpan