

North-East of Dongwaihuan Road, Dongcheng Industrial Acras Shoriguang 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

PRODUCT BATCH NO.	OMEPRAZOLE	PHARMACOPOE I A	EP9.0
BATCH NO.			1
	A-20411705039-1250	GROSS WEIGHT	23.3 Kg/Drum
BATCH QUANTITY	89.150Kg	NET WEIGHT	20Kg/Drum
MANUFACTURE DATE	JUN.01,2017	EXPIRY DATE	MAY.2020
ANALYSIS DATE	JUN.06,2017	REPORT DATE	MAY.03,2018
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		0.007
	(2.2.25)		
Related substances(HPLC)	(2.2.29)		
Impurity D	Not more than 0.15%		Not detected
Е	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

赵二阳 218.5.3

Checker:Liu Xiaoping

QA:Li Lianshu

本北1853