

寿光富康制药有限公司

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CERTIFICATE OF ANALYSIS

REPORT NO: A-50411407002

REGISTER NO: ZLJL-0510-02

PRODUCT		OMEPRAZOLE	PHARMACOPOEIA	REGISTER NO: ZLJL-0510-02
BATCH NO.		A-50411407002	GROSS WEIGHT	EP8.0
BATCH QUANTITY		360Kg	NET WEIGHT	18.3 Kg/Drum
MANUFACTURE DATE		JUL.04.2014	RETEST DATE	15Kg/Drum
ANALYSIS DATE		JUL.05.2014	REPORT DATE	JUN.2016
TEST ITEM		STANDARDS REQUIRED		JUL.07,2014
				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%			0.007%
E	Not more than 0.15%			0.004%
Any other individual impurity	Not more than 0.10%			0.04%
Total impurity	Not more than 0.5%			0.1%
Residual solvents:				
a)Acetone	Not more than 1500ppm			631ppm
b)Methylene chloride	Not more than 100ppm			Not detected (LOD=1.4ppm)
c)Methanol	Not more than 1000ppm			32ppm
d)Toluene	Not more than 300ppm			26ppm
e)Benzene	Not more than 1ppm			Not detected (LOD=0.2ppm)
Loss on drying	Not more than 0.2% (2.2.32)			0.07%
Sulphated ash	Not more than 0.1% (2.4.14)			0.05%
Assay% on dry basis	C ₁₇ H ₁₉ N ₃ O ₃ S conforms to 99.0%-101.0% (2.2.20)			99.7%
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





