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寿光富康制药有限公司
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CERTIFICATE OF ANALYSIS

REPORT NO: A-20411509020

REGISTER NO: ZLJL-0510-02

PRODUCT	OMEPRAZOLE	PHARMACOPOEIA	EP8.0
BATCH NO.	A-20411509020	GROSS WEIGHT	20.0 Kg/Drum
BATCH QUANTITY	320Kg	NET WEIGHT	24.5Kg/Drum
MANUFACTURE DATE	SEP.17,2015	RETEST DATE	AUG.2017
ANALYSIS DATE	SEP.18,2015	REPORT DATE	SEP.21,2015
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		0.02
	(2.2.25)		
Related substances(HPLC)	(2.2.29)		
Impurity D	Not more than 0.15%		0.006%
E	Not more than 0.15%		Not detected
Any other individual impurity	Not more than 0.10%		0.05%
Total impurity	Not more than 0.5%		0.06%
Residual solvents:			
a)Acetone	Not more than 1500ppm		759ppm
b)Methylene chloride	Not more than 100ppm		Not detected (LOD=1.4ppm)
c)Methanol	Not more than 1000ppm		164ppm
d)Toluene	Not more than 300ppm		61ppm
e)Benzene	Not more than 1ppm		Not detected (LOD=0.2ppm)
Loss on drying	Not more than 0.2% (2.2.32)		0.06%
Sulphated ash	Not more than 0.1% (2.4.14)		0.04%
Assay% on dry basis	C ₁₇ H ₁₉ N ₃ O ₃ S conforms to 99.0%-101.0% (2.2.20)		100.3%
Particle Size	100% pass 10 microns		Complies

Results: The commodity meets the standard of EP8.0.

Examiner: Ma Qi

Checker: Zhang Guoqiang

QA: Sun Wei

Ma Qi

Zhang Guoqiang

Sun Wei