

Lot: 0030219

寿光富康制药有限公司
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CERTIFICATE OF ANALYSIS

REPORT NO: QC18120169

REGISTER NO: ZLJL-0510-02

PRODUCT	OMEPRAZOLE	PHARMACOPOEIA	EP9.0
BATCH NO.	A-20411811027	GROSS WEIGHT	23.3 Kg/Drum
BATCH QUANTITY	360Kg	NET WEIGHT	20Kg/Drum
MANUFACTURE DATE	NOV.26,2018	RETEST DATE	OCT.2020
ANALYSIS DATE	DEC.02,2018	REPORT DATE	DEC.04,2018
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 (2.2.25)	0.024	
Related substances(HPLC)	(2.2.29)		
Impurity D	Not more than 0.15%	0.005%	
E	Not more than 0.15%	0.008%	
Any other individual impurity	Not more than 0.10%	0.03%	
Total impurity	Not more than 0.5%	0.11%	
Residual solvents:			
a)Acetone	Not more than 1500ppm	753ppm	
b)Methylene chloride	Not more than 100ppm	Not detected	
c)Methanol	Not more than 1000ppm	36ppm	
d)Toluene	Not more than 300ppm	Not detected	
e)Benzene	Not more than 1ppm	Not detected	
Loss on drying	Not more than 0.2%(2.2.32)	0.09%	
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)	99.7%	
Results: The commodity meets the standard of EP9.0.			

Examiner: Zhang Song

张松 2018.12.6

Checker: Jiang Xuan

江璇 2018.12.6

QA: Yuan Zhenlong

袁振龙 2018.12.6