

Lot: 0150719

寿光富康制药有限公司

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CERTIFICATE OF ANALYSIS

REPORT NO: QC19060001

REGISTER NO: ZLJL-0510-02

PRODUCT	OMEPRazole	PHARMACOPeIA	EP9.0
BATCH NO.	A-20411905024	GROSS WEIGHT	23.3 Kg/Drum
BATCH QUANTITY	360Kg	NET WEIGHT	20Kg/Drum
MANUFACTURE DATE	MAY.30,2019	RETEST DATE	APR.2021
ANALYSIS DATE	JUN.01,2019	REPORT DATE	JUN.04,2019
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)	0.023	
Related substances(HPLC)	(2.2.29)		
Impurity D	Not more than 0.15%	Not detected	
E	Not more than 0.15%	Not detected	
Any other individual impurity	Not more than 0.10%	0.04%	
Total impurity	Not more than 0.5%	0.04%	
Residual solvents:			
a)Acetone	Not more than 1500ppm	852ppm	
b)Methylene chloride	Not more than 100ppm	Not detected	
c)Methanol	Not more than 1000ppm	25ppm	
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)	0.03%	
Assay% on dry basis	C ₁₇ H ₁₉ N ₃ O ₃ S conforms to 99.0%-101.0%(2.2.20)	100.1%	

Results: The commodity meets the standard of EP9.0.

Examiner: Huang Shasha

黄沙沙 2019.06.25

Checker: Ding Rongmei

丁荣梅 2019.06.25

QA: Tang Haiyan

唐海燕 2019.06.25