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寿光富康制药有限公司

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CERTIFICATE OF ANALYSIS

REPORT NO: QC20060734

REGISTER NO: SMR-QC-018a0

REGISTER NO.: SMR-GC-0108

PRODUCT	OMEPRAZOLE	PHARMACOPOEIA	EP10.0
BATCH NO.	A-10412004008	GROSS WEIGHT	23.3 Kg/Drum
BATCH QUANTITY	340Kg	NET WEIGHT	20Kg/Drum
MANUFACTURE DATE	APR.06,2020	RETEST DATE	MAR.2022
ANALYSIS DATE	APR.08,2020	REPORT DATE	JUN.26,2020
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
Impurity Fand G	The absorbance is not greater than 0.10 at 440nm (2.2.25)		0.021
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%		Not detected
Total impurity	Not more than 0.5%		Not detected
Residual solvents:			
a)Acetone	Not more than 1500ppm		431ppm
b)Methylene chloride	Not more than 100ppm		Not detected
c)Methanol	Not more than 1000ppm		77ppm
d)Toluene	Not more than 300ppm		1ppm
e)Benzene	Not more than 1ppm		Not detected
Loss on drying	Not more than 0.2%(2.2.32)		0.08%
Sulphated ash	Not more than 0.1% (2.4.14)		0.02%
Assay% on dry basis	C ₁₇ H ₁₉ N ₃ O ₃ S conforms to 99.0%-101.0%(2.2.20)		99.5%
Results: The commodity meets the standard of EP10.0.			

Examiner: Hu Yue

胡悦 2020.07.30

Checker: Huang Shasha

黄莎莎 2020.07.30

QA: Tang Haiyan

唐海彦 2020.07.30



扫描全能王 创建