

Lot: 0420320

寿光富康制药有限公司  
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CERTIFICATE OF ANALYSIS

REPORT NO: QC19120065

REGISTER NO: SMR-QC-018a0

PRODUCT	OMEPRAZOLE	PHARMACOPOEIA	EP9.0
BATCH NO.	A-20411912003	GROSS WEIGHT	23.3 Kg/Drum
BATCH QUANTITY	320Kg	NET WEIGHT	20Kg/Drum
MANUFACTURE DATE	DEC.02,2019	RETEST DATE	NOV.2021
ANALYSIS DATE	DEC.04,2019	REPORT DATE	DEC.07,2019
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
Impurity Fand G	The absorbance is not greater than 0.10 at 440nm (2.2.25)		0.018
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%		0.02%
Total impurity	Not more than 0.5%		0.08%
Residual solvents:			
a)Acetone	Not more than 1500ppm		372ppm
b)Methylene chloride	Not more than 100ppm		Not detected
c)Methanol	Not more than 1000ppm		19ppm
d)Toluene	Not more than 300ppm		4ppm
e)Benzene	Not more than 1ppm		Not detected
Loss on drying	Not more than 0.2%(2.2.32)		0.05%
Sulphated ash	Not more than 0.1% (2.4.14)		0.02%
Assay% on dry basis	C <sub>17</sub> H <sub>19</sub> N <sub>3</sub> O <sub>3</sub> S conforms to 99.0%-101.0%(2.2.20)		99.9%

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

Examiner: Zhang Yingchao

张迎超 2020.02.14

Checker: Ding Rongmei

丁荣梅 2020.02.14

QA: Tang Haiyan

唐海燕 2020.02.14