

WUHAN WUYAO PHARMACEUTICAL CO.,LTD



CERTIFICATE OF ANALYSIS

REC-QC-01075-01

Report Number: C1-190952

Product Name: Metronidazole	Batch No: C04-190984
Test Standard: CEP CEP: R1-CEP 2007-083-Rev 02	Manufacturing Date: 2019.09.24
Packing: 25kg/drum	Report Date: 2019.10.01
Quantity: 25kg/drum×38drum+2.26kg	Retest Date: 2023.08

Item	Requirements	Result
【Appearance】:	White or yellowish, crystalline powder	slightly yellow crystalline powder
Solubility:	Slightly soluble in water, in acetone, in alcohol and in methylene chloride	Conforms
【Identification】:		
C. IR:	The sample spectrum complies with the reference standard spectrum	Conforms
【Tests】:		
Appearance of solution:	Not more than II	< II
Related Substances (HPLC):	Not more than GY6	< GY6
Impurity A:	Not more than 0.05%	0.01%
Any impurity:	Not more than 0.05%	0.02%
Total impurity	Not more than 0.2%	0.04%
Heavy metals:	Not more than 10 ppm	< 10ppm
Loss on drying:	Not more than 0.5%	0.1%
Sulfated ash:	Not more than 0.1%	0.05%
【Assay】		
(on dried basis):	99.3% to 101.0%	100.5%
【Residual solvent】:		
Epoxyethane:	Not more than 1 ppm	Not detected
Ethandiol:	Not more than 620 ppm	Not detected
【Microbial test】:		
Total aerobic microbial count:	Not more than 100 CFU/g	< 1CFU/g
Total yeasts and mould count:	Not more than 100 CFU/g	< 1CFU/g
Pseudomonas aeruginosa:	Absent	Not detected
Staphylococcus aureus:	Absent	Not detected
Escherichia coli:	Absent	Not detected
【Bacterial endotoxins】:	Not more than 0.35 EU/mg	< 0.33EU/mg

Conclusion: The above product complies with the standard CEP

Approved by: 王洪 2019.10.01 Checked by: 李华 2019.10.01 Prepared by: 王洪 2019.10.01

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