

Lot-0120619

WUHAN WUYAO PHARMACEUTICAL CO.,LTD



CERTIFICATE OF ANALYSIS

REC-QC-01075-01

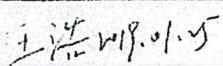
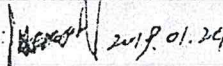
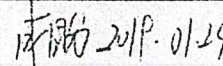
Report Number: C1-190047

Product Name:	Metronidazole	Batch No:	C04-190141
Test Standard:	CEP (CEP No.: R1-CEP 2007-083-Rev 02)	Manufacturing Date:	2019.01.15
Packing:	25kg/drum	Report Date:	2019.01.24
Quantity:	25kg/drum×35drum+9.44kg	Retest Date:	2022.12

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%	0.01%
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%	0.2%
Sulfated ash:	Not more than 0.1%	0.04%
【Assay】		
(on dried basis):	99.3% to 101.0%	100.1%
【Residual solvent】:		
Epoxyethane	Not more than 1 ppm	Not detected
Ethanedial	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:  2019.01.15 Checked by:  2019.01.24 Prepared by:  2019.01.24

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