

Lot Number: 161743



武汉武药制药有限公司 WUHAN WUYAO PHARMACEUTICAL CO., LTD.

No.18 Wangfen Road, Fuchi Town, Yangxin County,

Huangshi City, Hubei Province, China

TEL: 0086-27-83824083/83310632/83822224

FAX: 0086-27-83310632/83832657

化验报告书

CERTIFICATE OF ANALYSIS

品名	甲硝唑	批号	C04-160725
PRODUCT	METRONIDAZOLE EP8/CEP	BATCH NO	
数量	R1-CEP 2007-083-Rev 01	生产日期	JULY 15, 2016
QUANTITY	600KG	PRODUCTION DATE	
包装		有效期	JUNE 2020
PACKING	25KG/DRUM	EXPIRY DATE	

ITEMS	SPECIFICATIONS	RESULT
APPEARANCE	WHITE OR YELLOWISH, CRYSTALLINE POWER	CONFORMS
SOLUBILITY	SLIGHTLY SOLUBLE IN WATER, IN ACETONE, IN ALCOHOL AND IN METHYLENE CHLORIDE	CONFORMS
IDENTIFICATION	A) MELTING POINT: 159°C TO 163°C	161°C~162°C
	B) THE SOLUTION SHOWS AN ABSORPTION MAXIMUM AT 277 NM AND A MINIMUM AT 240NM, THE SPECIFIC ABSORBANCE AT THE MAXIMUM IS 365 TO 395	381
	C) INFRARED SPECTRUM COMPLY WITH THE REFERENCE	CONFORMS
	D) THE SOLUTION GIVES THE REACTION OF PRIMARY AROMATIC AMINES	CONFORMS
APPEARANCE OF SOLUTION	REFERENCE SUSPENSION II, GY6	CONFORMS
HEAVY METAL	NOT MORE THAN 10 PPM	< 10 PPM
RELATED SUBSTANCES (HPLC)	2-METHYL-5-NITRO-IMIDAZOL: NOT MORE THAN 0.05%	0.01%
	ANY IMPURITY: NOT MORE THAN 0.05%	0.01%
	TOTAL IMPURITY: NOT MORE THAN 0.2%	0.03%
LOSS ON DRYING	≤ 0.5%	0.2%
SULPHATED ASH	≤ 0.1%	0.06%
ASSAY (ON DRIED BASIS)	99.0%~101.0%	100.5%
RESIDUAL SOLVENT	EPOXYETHANE: NOT MORE THAN 1 PPM	NOT DETECTED
MICROORGANISMS	TAMC: NOT MORE THAN 1000 CFU/G	< 1 CFU/G
	TYMC: NOT MORE THAN 100 CFU/G	4 CFU/G
	PSEUDOMONAS AERUGINOSA: ABSENT	NOT DETECTED
	STAPHYLOCOCCUS AUREUS: ABSENT	NOT DETECTED
BACTERIAL ENDOTOXINS	ESCHERICHIA COLI: ABSENT	NOT DETECTED
	NOT MORE THAN 0.35 EU/MG	< 0.35 EU/MG

CONCLUSION: THE ABOVE PRODUCT COMPLIES WITH THE EP8/CEP
 REVIEWER: QU CHANGBIN CHECKER: XIONG QIONG ANALYST: GUO MINGHUI