



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

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化验报告书

CERTIFICATE OF ANALYSIS

品名	甲硝唑	批号	
PRODUCT	METRONIDAZOLE EP8/CEP	BATCH NO	C04-160808
数量	R1-CEP 2007-083-Rev 01	生产日期	
QUANTITY	900KG	PRODUCTION DATE	AUG. 11, 2016
包装		有效日期	
PACKING	25KG/DRUM	EXPIRY DATE	JULY 2020

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	160°C~161°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	379
	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%	0.02%
LOSS ON DRYING	≤0.6%	0.1%
SULPHATED ASH	≤0.1%	0.04%
ASSAY (ON DRIED BASIS)	99.0%~101.0%	100.2%
RESIDUAL SOLVENT	EPOXYETHANE: NOT MORE THAN 1 PPM	NOT DETECTED
MICROORGANISMS	TAMC: NOT MORE THAN 1000CFU/G	<1CFU/G
	TYMC: NOT MORE THAN 100CFU/G	<1CFU/G
	PSEUDOMONAS AERUGINOSE: ABSENT	NOT DETECTED
	STAPHYLOCOCCUS AUREUS: ABSENT	NOT DETECTED
	ENTEROCOCCUS FAECIUM: ABSENT	NOT DETECTED
BACTERIAL ENDOTOXINS	NOT MORE THAN 0.35 EU/MG	<0.33EU/MG

CONCLUSION: THE ABOVE PRODUCT COMPLIES WITH THE EP8/CEP

REVIEWER: QU CHANGBIN

CHECKER: XIONG QIONG

ANALYST: GUO MINGHUI

Authorized Signature