



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

品名	甲硝唑	批号	
PRODUCT	METRONIDAZOLE EP8	BATCH NO	C04-160234
数量		生产日期	
QUANTITY	150KG	PRODUCTION DATE	FEB.22.2016
包装		有效日期	
PACKING	25KG/DRUM	EXPIRY DATE	JAN.2020

项目 ITEMS	标准 SPECIFICATIONS	结果 RESULT
外观 APPEARANCE	WHITE OR YELLOWISH, CRYSTALLINE POWDER	PASS
溶解度 SOLUBILITY	SLIGHTLY SOLUBLE IN WATER, IN ACETONE, IN ALCOHOL AND IN METHYLENE CHLORIDE	PASS
鉴别 IDENTIFICATION	A) MELTING POINT: BETWEEN 159°C AND 163°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 C) INFRARED SPECTRUM SHOULD COMPLY WITH THE SPECTRUM OBTAINED WITH METRONIDAZOLE CRS D) THE SOLUTION GIVES THE REACTION OF PRIMARY AROMATIC AMINES	PASS
溶液澄清度与颜色 APPEARANCE OF SOLUTION	SAMPLE SOLUTION SHOULD NOT BE MORE OPALESCENT THAN REFERENCE SUSPENSION II AND NOT MORE INTENSELY COLOURED THAN REFERENCE SOLUTION GY6	PASS
重金属 HEAVY METAL	NMT 20 PPM	PASS
有关物质 RELATED SUBSTANCES (HPLC)	2-METHYL-5-NITRO-IMIDAZOL: NOT MORE THAN 0.05% m/m ANY IMPURITY: NOT MORE THAN 0.05% m/m TOTAL NOT MORE THAN 0.2% m/m	0.01% m/m 0.01% m/m 0.03% m/m
干燥失重 LOSS ON DRYING	NOT MORE THAN 0.5% M/M	0.3% m/m
残留溶剂 RESIDUAL SOLVENTS	ETHYLENE OXIDE NMT 1 PPM	PASS
灰分 SULPHATED ASH	NOT MORE THAN 0.1% m/m	0.03% m/m
含量 ASSAY (ON DRIED BASIS)	BETWEEN 99.0% m/m AND 101.0% m/m	99.6% m/m

CONCLUSION: THE ABOVE PRODUCT COMPLIES WITH THE

INSPECTOR: CHENRONGRONG

REINSPECTOR: LU HUIJUN

CEP NO: R1-CEP2007-083-Rev 01

APPROVAL DATE: FEB.24.2016

TEST DATE: FEB. 24. 2016

QD MANAGER LU SHI

050 060 070 080 090 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 250

Authorized Signature

NOTE ACOFARLS 160625

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Compliance to USP <467> Residual Solvents /
ICH guidance Q3C Impurities: Residual Solvents
(Reference attached residual solvent limit tables)

Material Name: metronidazole

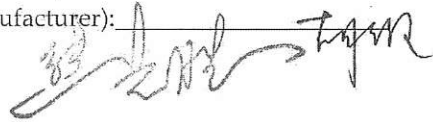
- Class 2 solvents likely to be present above Option 1 limit:

Solvent Name	Method	Limit
EPOXYETHANE		<1PPM

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Completed by: WUHAN WUYAO PHARMACEUTICAL CO., LTD.

Signature indicates authorization as a representative of (manufacturer):



Authorized Signature