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湖北省宏源药业有限公司
HUBEI HONGYUAN PHARMACEUTICAL CO.,LTD.

湖北省黄冈市罗田县工业经济开发区凤山大道8号
NO.8 FENGSHAN ROAD, INDUSTRIAL AND ECONOMIC DEVELOPMENT ZONE, LUOTIAN COUNTY,
HUANGGANG CITY, HUBEI PROVINCE CHINA.

CERTIFICATE OF ANALYSIS

品名: Name of product	甲硝唑 Metronidazole	批重量: Batch weight	500kg
批号: Batch Number	01220151124F	包装: Packing in	12.5kg/drum
生产日期: Manufacturing Date	NOV.10, 2015	报告日期 Report Date	NOV.18, 2015
有效期至 Expiry Date	OCT.2019	储藏条件 Storage	避光、密封保存 Store in a well-closed container, protected from light

化验结果

RESULT OF ANALYSIS

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项目 (ITEMS)	标准 (STANDARDS)	实测结果 (RESULTS)
性状 Characteristics	White to pale yellow, odorless crystals or crystalline powder, Sparingly soluble in water and in alcohol, slightly soluble in ether and chloroform.	COMPLY
鉴别 Identification	A:IR B:UV	A:COMPLY B:COMPLY
熔点 Melting range	159-163℃	160.1-160.2℃
有关物质 Related substances	Any other Impurity: ≤0.1%	0.02%
	Total impurity: ≤0.2%	0.03%
	Related compound A of Tinidazole: 0.1%MAX	Not detected
干燥失重 Loss on drying	≤0.5%	0.17%
硫酸盐灰分 sulfated ash	≤0.1%	0.06%
重金属 Heavy Metal	≤50PPM	<50PPM
含量 C ₆ H ₉ N ₃ O ₃ Assay	99.0%~101.0%	100.4%
※微生物检测 Microorganism test	Aerobic count: NMT 30 cfu/g Total combined molds and yeasts count: NMT 10 cfu/g Pathogens: NO	COMPLY
无碱性杂质 Non-basic substances	A 1g portion dissolves completely in 10ml of dilute chlorhydric acid (1 in 2)	COMPLY
色谱纯度 Chromatographic purity	COMPLY	COMPLY
※残留溶剂 Residual solvents	Formic acid (LOD 124ppm) Ethylene Oxide (LOD 0.15ppm)	Not detected
※吸收系数 Specific Absorbance	365-395	369
※粒径 Particle size	90%<30 μ m 10%<30 μ m ~50 μ m	COMPLY
※炽灼残渣 Residue on Ignition	0.1% MAX	COMPLY
结论: Conclusion;	comply with the requirement of USP37 standard.	
注: 带“※”为客户特殊需求的检测项目.		
化验员:史艳林		