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湖北省宏源药业有限公司 HUBEI HONGYUAN PHARMACEUTICAL CO., LTD. NO.8 FENGSHAN ROAD, INDUSTRIAL AND ECONOMIC DEVELOPMENT ZONE, HUOTIAN COUNTY, HUBEI PROVINCE CHINA. HUANGGANG CITY, HUBEI PROVINCE CHINA.		
CERTIFICATE OF ANALYSIS		
品名: 甲硝唑 Name of product: Metronidazole 批号: Batch Number: 20130711 生产日期: Manufacturing Date: JUL.05,2013 性状: 白色或淡黄色结晶性粉末, 略溶于水 and 乙醇, 微溶于乙醚和三氯甲烷。 DESCRIPTION: White to pale yellow, odorous crystals or crystalline powder SOLUBILITY: Sparingly soluble in water and in nicotinic acid, slightly soluble in ether and in chloroform 包装: 内双膜厚膜袋包装, 外纸板桶包装, 净重 12.5 公斤。 Packing: Well-Closed fiber drum with sealed double polyethylene bag, net capacity 12.5kgs 储藏条件: 避光、密封保存 Storage: Preserve in a well-closed containers, protected from light. The goods have already passed microorganism test no any other extraneous matter	批重量: Batch weight: 500kgs 检测日期: Analysis date: JUL.05,2013 保质期: Expiry Date: JUL.04,2017	
化驗結果 RESULT OF ANALYSIS		
项目 (ITEMS)	标准 (STANDARDS)	实验结果 (RESULTS)
鉴别 Identification	A: IR B: UV	COMPLY
熔点 Melting range	159-163 °C	161.0-161.3 °C
干燥失重 Loss on drying	0.5% MAX	0.22%
炽灼残渣 Residue on ignition	0.1% MAX	0.06%
重金属 Heavy Metal	0.005% MAX	<0.005%
振打密度 Tapped density	0.50-0.75G/ML	0.57G/ML
有关物质 Related substances	Impurity A Impurity: 0.1 MAX Total impurity: 0.2 MAX	Not detected 0.02% 0.06%
无碱性杂质 Non-basic substances	A 1g portion dissolves completely in 10ml of dilute hydrochloric acid (1 in 2)	COMPLY
微生物检测 Microorganism test	Aerobic count: NMT 30 ufc/g Mold and yeast: NMT 10 ufc/g Pathogens: NO	COMPLY
色泽纯度 Chromatographic purity	COMPLY	COMPLY
粒径 Particle size	90% < 30 μm 10 % between 30 – 50 microns	COMPLY
残留溶剂 Residual solvents	Methylene oxide (LOD 0.15ppm) Formic acid (LOD 124ppm)	Not detected. Not detected
含量 Assay	99.0%-101.0% C ₆ H ₉ N ₃ O ₃	99.5% C ₆ H ₉ N ₃ O ₃
结论: 本品符合药典 USP33 版。 Conclusion: comply with the requirement of USP33 standard.		
主管 (Director):		化验 (Inspector):