

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,
 LUOTIAN COUNTY, HANGANG CITY, HUBEI PROVINCE, CHINA

CERTIFICATE OF ANALYSIS

品名: 甲硝唑
 Name of product: Metronidazole
 批号:
 Batch Number.: 01220150155
 生产日期:
 Manufacturing Date: JAN.2015
 储藏条件: 避光、密封保存
 Storage: store in a well-closed container, protected from light.
 GMP CERTIFICATE NO.: J0356
 REACH NO.: 05-2114324659-41-0000

批重量:
 Batch Size: 1000KGS
 包装: 25 公斤/纸桶
 Packing: in 25kg/drum
 保质日期: Expiry Date: JAN.2019
 DATE OF RELEASE: JAN.2015

COS NO.R0-CEP 2007-309-Rev 02

化验结果
RESULT OF ANALYSIS

项目 (ITEMS)	标准 (STANDARDS)	实测结果 (RESULTS)
外观 Appearance	White or yellowish crystalline powder	COMPLY
溶解度 Solubility	Slightly soluble in water, acetone, 96% alcohol and in methylene chloride	COMPLY
鉴别 Identification	A:IR B:UV	COMPLY
熔点 Melting point	159-163 °C	160.4-160.7 °C
干燥失重 Loss on drying	0.5% MAX	0.18%
炽灼残渣 Residue on ignition	0.1% MAX	0.06%
溶液外观 Appearance of solution	SUSPENSION II AND SOLUTION GY6	COMPLY
残留溶剂 Residual solvents	EPOXYETHANE ≤ 620PPM	NOT DETECTED
重金属 Heavy Metal	20PPM MAX	<20PPM
微生物检测 Microbiological purity	Total count of bacteria and fungi (sum): NMT 100 CFU/g Enterobacteria: Absent in 1 g Pseudomonas aeruginosa: Absent in 1 g Staphylococcus aureus: Absent in 1 g	COMPLY
有关物质 Related substances	Any impurity: 0.1% MAX Any other impurities: 0.05% MAX Total impurity: 0.2% MAX	0.01% 0.01% 0.02%
硫酸灰份 Sulphated ash	≤ 0.10%	0.06%
粒径 Particle size	40-80MESH	COMPLY
含量 Assay	99.0%-101.0% C ₆ H ₉ N ₃ O ₃	99.9% C ₆ H ₉ N ₃ O ₃

结论: 本品符合药典 BP2010/USP35/EP8/ND to the registration certificate ΦC-000035-241210 and Amendments 2,3,4,5 版。

Conclusion: Comply with the requirement of BP2010/USP35/EP8/and registered Normative Documentation ΦC-000035-241210 and Amendments 2,3,4,5 .

主管 (Director):

李伟群

化验 (Inspector):

张红霞