

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, Huanggang City, Hubei Province, China

ANALYTICAL REPORT

品名: 甲硝唑

Name of product: Metronidazole /

批号:

Batch Number: 20130555

生产日期:

Manufacturing Date: MAY.19, 2013

批重量:

Batch weight: 1000KGS

包装: 25 公斤/纸桶

Packing: in 25kg/drum

复检日期:

Re-test Date: MAY.18, 2017

Characteristics: a white or yellowish crystalline powder, slightly soluble in water, in acetone, in alcohol and in m: ethylene, chloride, very slightly soluble in ether.

Storage: store in a well-closed container, protected from light.

性状: 白色或淡黄色结晶性粉末, 微溶于水、丙酮、三氯甲烷、极微溶于乙醚。

COS NO.R0-CEP 2007-309-Rev 01

化验结果

RESULT OF ANALYSIS

项目 (ITEMS)	标准 (STANDARDS)	实测结果 (RESULTS)
鉴别 Identification	IR	COMPLY
熔点 Melting point	159-163°C	160.9-161.3°C
干燥失重 Loss on drying	0.5% MAX	0.16%
炽灼残渣 Sulphated ash	0.1% MAX	0.03%
溶液外观 Appearance of solution	SUSPENSION II AND SOLUTION GY6	COMPLY
堆积密度 Bulk density	≥0.7	Complies
重金属 Heavy Metal	20PPM MAX	<20PPM
有关物质 Related substances	Impurity: 0.1% MAX Total impurity: 0.2% MAX	0.02% 0.05%
微生物检测 Microorganism test	Total bacterium <1000 UFC/G Fungi and Mould <100 UFC/G	COMPLY
色谱纯度 Chromatographic purity	COMPLY	COMPLY
无碱性杂质 Non-basic substances	COMPLY	COMPLY
粒径 Particle size	40-60 MESH	COMPLY
吸收系数 Specific absorbance	365-395	377
含量 Assay	99.0%-101.0% C ₆ H ₉ N ₃ O ₃	99.6% C ₆ H ₉ N ₃ O ₃

结论: 本品符合药典 BP2011/USP34/EP7 版。

Conclusion: comply with the requirement of BP2011/USP34/EP7 standard.

主管 (Director):

化验 (Inspector):

质检员 06

Produced according to GMP No.: 鄂 J0356, issue date: 13/01/2009,

validity date: 12/01/2014, manufacturer: Hubei Hongyuan Pharmaceutical Co., Ltd

Batch production record checked and approved, no deviation, no reworking and reprocessing.