

金坛市中兴医药化工有限公司
JINTAN ZHONGXING
PHARMACEUTICAL AND CHEMICAL CO., LTD.
检验分析报告

CERTIFICATION OF ANALYSIS

产品名称 Product Name:	克霉唑 CLOTRIMAZOLE		批号 Batch No.:	20121002
数量 Quantity:	1000	kgs	生产日期 Manufacturing Date:	2012.10.02
包装 Packing:	25	kg/桶 kg/Drum	有效期 Expiry Date:	2016.10.02
项目 Specifications		标准 Standard		结果 Results
特性 Description		白色或灰黄色结晶性粉末，难溶于水，溶于醚 A white or pale yellow crystalline powder, practically insoluble in water, soluble in ethanol(96%) and methyl chloroide.		符合要求 Complies
鉴别 Identification	红外光谱 IR spectrum	与标准物光谱相似 similar to the standard.		符合要求 Complies
	薄板层析 Test TLC	基本斑点的位置和大小与对比液相似 Principal spot of test solution is similar in position and size to the reference solution.		符合要求 Complies
相关物质 (HPLC) Related Substances (HPLC)	杂质 A, B Impurities A, B	不大于 0.2% Not more than 0.2%		0.15%
	杂质 D, E Impurities D, E	不大于 0.2% Not more than 0.2%		0.14%
	杂质 F Impurities F	不大于 0.1% Not more than 0.1%		0.05%
	单个不明杂质 Unspecified	不大于 0.1% Not more than 0.1%		0.05%
	杂质总量 Total Impurities	不大于 0.5% Not more than 0.5%		0.39%
	熔点 Melting point	141 to 145°C		143-144°C
干燥失重 Loss on drying		不大于 0.5% Not more than 0.5%		0.14%
硫酸盐灰份 Sulphated ash		不大于 0.1% Not more than 0.1%		0.06%
残留溶剂 Residual solvent		甲苯: 残留不大于 890ppm Toluene: 890ppm max 丙酮: 残留不大于 5000 ppm ACETONE: 5000 ppm		No found 830ppm
含量 Assay		不得低于 98.5%; 不得高于 100.5% Not less than 98.5% and not more than 100.5%		99.3%
结论 Conclusion:		本品符合 EP7.5 标准要求 UPTO THE EP7.5 STANDARD		

分析员 王小力
Analyzer:

校核员 薛军强
Re-checker:

2012.10.05

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