



江苏凌云药业股份有限公司成品检验报告书

Certification of Analysis Jiangsu Lingyun Pharmaceutical Co., Ltd

报告书编号 Report No.: FP211103-01

品名 Product Name	托曲珠利 TOLTRAZURIL	批号 Batch No.	CP004-211001
数量 Quantity	205.40kg	规格 Packing Size	25kg/桶 25kg/drum
生产日期 Mfg.Date	2021.10.23	报告日期 Report Date	2021.11.03
检验依据 Test Standard	企业标准 QS-CP004-06 Enterprise Standard	有效期 Exp. Date	2024.10.22

项目/Test Items	标准规定/Specification	结果/Results
性状 Appearance	白色或类白色结晶性粉末 White or off white crystalline powder	白色结晶性粉末 White crystalline powder
鉴别 Identification	IR IR spectrum of sample corresponds to that of reference standard 供试品溶液主峰的保留时间与对照品主峰保留时间一致 HPLC The retention time of the main peak corresponds to that of reference standard	符合 Conform 符合 Conform
溶液的澄清度 Clarity	澄清 The solution is clear	符合 Conform
溶液色度 Degree of coloration	溶液与标准比色液 B7 比较, 不得更深 The solution is not more intensely than reference solution B7	符合 Conform
熔点/Melting point	192~196°C	193.0~194.0°C
干燥失重 Loss on drying	不得过 0.50% Not more than 0.50%	0.09%
硫酸灰分 Sulphated ash	不得过 0.10% Not more than 0.10%	0.03%
重金属 Heavy metals	不得过百万分之十 Not more than 10ppm	符合 Conform
单一最大杂质 Single max impurity	不得过 0.20% Not more than 0.20%	0.15%
总杂质 Total impurities	不得过 1.0% Not more than 1.0%	0.34%
含量 Assay (HPLC)	按干燥品计算, 应为 98.0%~102.0% It should be 98.0%~102.0% (Calculated with dried substance)	99.6%
残留溶剂 Residual solvent	甲醇, 不得过 3000ppm Methanol: Not more than 3000ppm	54ppm
结论 Conclusion	经检验, 该批产品符合规定! Complies specification	
检验/日期: Analyst/Date:	QC 复核日期: 2021.11.03 QC Checked/Date:	QA 批准/日期: QA Approved/Date:

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