



Hangzhou Huarong Pharmaceutical Co., Ltd.

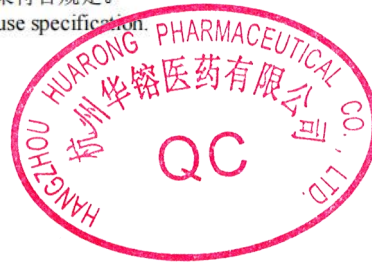
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名称 Product Name	奥拉帕利 Olaparib	产品批号 Batch No.	20220204-1C
生产日期 Mfg. Date	2022.02.16 Feb. 16, 2022	有效期至 Exp. Date	2024.02.15 Feb. 15, 2024
检验日期 Test Date	2022.02.16 Feb. 16, 2022	报告日期 Report Date	2022.02.18 Feb. 18, 2022
检验依据 Specification	In-house	批量 Batch Size	70kg
检验项目及结果 Tests and Results			
检验项目 Tests	标准 Acceptance Criteria	检验结果 Results	结论 Conclusion
外观 Appearance	淡黄色至白色粉末 Should be white to light yellow powder	白色粉末 White powder	符合规定 Complies
鉴别 Identification	HNMR 与标准图谱一致 The HNMR spectrum conforms to standard	一致 Conforms	符合规定 Complies
干燥失重 Loss on drying	不得过0.5% NMT 0.5%	0.27%	符合规定 Complies
炽灼残渣 Residue on ignition	不得过 0.1% NMT 0.1%	0.06%	符合规定 Complies
水分 Water	不得过1.0% NMT 1.0%	0.12%	符合规定 Complies
有关物质 Related substances	最大单杂≤0.15% 总杂质≤0.5% Unspecified impurity NMT 0.15% Total impurities NMT 0.5%	最大单杂: 0.07% 总杂质: 0.14% Unspecified impurity: 0.07% Total impurities: 0.14%	符合规定 Complies
溶剂残留 Residual solvents	异丙醇≤0.5%, 甲醇≤0.3% Isopropanol NMT 0.5%, Methanol NMT0.3%	Isopropanol: 0.06% Methanol: N.D.	符合规定 Complies
含量 Assay	不低于 99.0% NLT 99.0%	99.31%	符合规定 Complies
结论 Conclusion	本品按企业内控质量标准检验, 结果符合规定。 The test results comply with the in-house specification.		



*Means the document is under process
Product under patent is for R&D purpose.