



JINAN JIULONG PHARMACEUTICAL TECHNOLOGY CO.,LTD

济南久隆医药科技有限公司

检验报告单

Certificate of Analysis

品名 Product Name	利伐沙班 Rivaroxaban	批号 Batch No	20230901
生产日期 MFG Date	20230911	有效期 EXP Date	20260910
检验日期 Date of Analysis	20230913	检验依据 Standard	欧洲药典 European Pharmacopoeia
检验项目 Analysis Item	标准 Standard	检测结果 Result	检测结果 Result
性状 Properties	本品为白色或淡黄色粉末 white or yellowish powder		白色粉末 white powder
鉴别 Identification	本品与对照品有相同的红外吸收光谱 This product has the same infrared absorption spectrum as the rivaroxaban CRS 对映异构体检查项下, 供试品溶液与对照品溶液对映异构体有相同的保留时间 Under the enantiomer check, the enantiomer peak in the test solution and the reference solution has the same retention time		符合要求 Conforms
溶解度 Solubility	本品在二甲基亚砷中易溶, 在水、无水乙醇、正庚烷中几乎不溶 practically insoluble in water, freely soluble in dimethyl sulfoxide, practically insoluble in anhydrous ethanol and in heptane		符合要求 Conforms
熔点 Melting Range	228~235°C		230~233°C
水分 Water	≤0.5%		0.22%
炽灼残渣 Sulfated ash	≤0.1%		0.05%
残留溶剂 Residual solvent	二甲基亚砷 Dimethyl Sulfoxide ≤0.5% 二氯甲烷 Dichloromethane ≤0.06% 甲醇 Methanol ≤0.3%		符合要求 Conforms
对映异构体 Enantiomeric purity	≤0.5%		0.2%
有关物质 Related substances	单杂 Individual Impurities ≤0.1% 总杂 Total Impurities ≤0.3%		符合要求 Conforms
含量 Assay	以无水物计算, 含 C ₁₉ H ₁₈ CIN ₃ O ₅ S 应为 98.0%~102.0% 98.0 percent to 102.0 per cent (anhydrous substance)		99.46%
结论 Conclusion	本品符合欧洲药典 Comply with European Pharmacopoeia		

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