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Certificate of Analysis 检测报告单		
Product Name: Elacestrant dihydrochloride 产品名称: 依拉司群双盐酸盐		Batch No: 批号: RD16832308
Production Date: 生产日期: 2023.12.19	Test Date: 检测日期: 2023.12.25	Quantity: 数量: 10.00g
Retest Date: 复检期至: 2024.12.18		Certificate No: 报告单号: XY1116424006
Recommended storage conditions: Ordinary temperature 建议储存条件: 常温(10-30°C)		CAS No: CAS 号: 1349723-93-8
Test Items 检测项目	Specification 标准	Test Result 检测结果
Appearance 外观	White to yellow to gray solid 白色至黄色至灰色固体	White solid 白色固体
Identity(HPLC) 鉴别(高效液相)	RT confirmation with that of standard 与标准品保留时间一致	Conforms 符合
Identity(IR) 鉴别(红外)	The IR spectrum should be concordant with the standard spectrum 供试品谱图与参照谱图一致	Conforms 符合
Assay 含量	97.0%~103.0%	99.54%
Purity 纯度	≥98.0%	99.66%
Impurity A 杂质 A	≤0.10%	Not detected 未检出
Impurity B 杂质 B	≤0.10%	0.026%
Impurity C 杂质 C	≤0.10%	0.019%
Any unknown single impurity 任意未知单杂	≤0.10%	0.055%
Total impurities 总杂	≤2.0%	0.34%
Chiral purity 手性纯度	≥99.0%	99.77%
Water content(Karl Fischer) 水分(卡尔费休法)	≤5.0%	0.43%
Melting point 熔点	Report result 实际测量值	227.2~227.6°C
Polymorphic Form 多晶型	Form I	Conforms 符合
Conclusion 结论: Qualified 合格		

