

JINAN HONG KONGDA CHEMICAL CO.,LTD

济南鸿康达化工有限公司

CERTIFICATE OF ANALYSIS

成品检验报告单

产品名称 Product Name	氟维司群 Fulvestrant	CAS No.	129453-61-8
产品批号 Batch No.	25031501	生产日期 Mfg. Date	2025.03.15
报告日期 Report Date	2025.03.22	有效期至 Exp. Date	2027.03.14
数量 Quantity	10kg	检验依据 Quality Standard	企业标准 Enterprise Standard
检验项目 Tests	标准规定 SPECIFICATIONS		检验结果 RESULTS
外观 Appearance	白色至类白色粉末 White to off-white powder		类白色粉末 Off-white powder
鉴别 Identification	Conform with standard IR/HPLC		Complies
比旋度 Specific Rotation	+108°~+115°		+110.8°
灼烧残渣 Residue on ignition	≤0.1%		0.06%
干失 Loss on drying	≤0.5%		0.45%
有关物质 Related substances	杂质 A Impurity A≤0.1%		Not Detected
	杂质 B Impurity B ≤0.2%		Not Detected
	杂质 C Impurity C≤0.3%		0.06%
	杂质 D Impurity D≤0.6%		Not Detected
	杂质 E Impurity E≤0.1%		Not Detected
	杂质 F Impurity F≤0.15%		Not Detected
	最大未知单一杂质 Max unknown single impurity ≤0.1%%		0.03%
	总杂 Total impurities ≤1.0%		0.30%
氟维司群 A Fulvestrant A	42%~48%		43.6%
氟维司群 B Fulvestrant B	52%~58%		56.4%
溶剂残留 Solvent Residue	四氢呋喃 THF≤0.072%		Not Detected 未检出
	二氯甲烷 dichloromethane≤0.06%		Not Detected 未检出
	甲醇 methyl alcohol≤0.3%		0.12%
	乙酸乙酯 ethyl acetate≤0.5%		0.44%



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含量 Assay	97.0%~102.0%	99.7%
结论 Conclusion	本品按企业标准检验，结果符合规定。 The results conform to the Enterprise standard	

