

检验报告书

Certificate of Analysis

产品名称 Product Name	甲磺酸达拉非尼 Dabrafenib Mesylate		
化学名称 Chemical name	N-{3-[5-(2-amino-4-pyrimidinyl)-2-(1,1-dimethylethyl)-1,3-thiazol-4-yl]-2-fluorophenyl}-2,6-difluorobenzenesulfonamide methanesulfonic acid		
批号 Batch No.	23041301	CAS No.	1195768-06-9
生产日期 Manu. Date	2023.04.13	复验日期 Retest Date	2025.04.12
贮存条件 Storage Condition	遮光, 密封, 在干燥处保存。 Shade, seal and store in a dry place.		

检验项目 Testing Items	标准限度 Specification	检验结果 Results	
性状 Characters	类白色至白色粉末 Off-white to white powder	类白色粉末 Off-white powder	
鉴别 Identification	IR 法 The IR spectrum similar with that of reference standard.	符合规定 Complies	
	HPLC 法 The retention time of the major peak in the chromatogram of the sample solution corresponds to that of the standard solution as obtained in the Assay.	符合规定 Complies	
检查 Check Items	有关物质 Related Substance		
	最大单杂 Single Maximum Impurity NMT 0.1%	0.09%	
	总杂 Total Impurities NMT 1.0%	0.23%	
	水分 Water Content	≤1.0%	0.41%
	炽灼残渣 Residue on ignition	≤0.5%	0.28%
残留溶剂 Residue solvents	异丙醇 Isopropanol ≤0.5%	0.14%	
	乙醇 Ethyl alcohol ≤0.5%	0.18%	
	二氯甲烷 Dichloromethane ≤0.06%	N.A.	
	甲醇 Methyl alcohol ≤0.3%	0.08%	
	乙酸乙酯 Ethyl acetate ≤0.5%	N.A.	
	N,N-二甲基乙酰胺 N, N-dimethylacetamide ≤0.109%	N.A.	
	四氢呋喃 Tetrahydrofuran ≤0.072%	N.A.	

甲磺酸含量 Methylsulfonic acid Content	14.0% - 17.2%	15.8%
含量 Assay	98.0% - 102.0%	99.6%
结论 Conclusion	符合企业标准 Complies with Enterprise Standard	

	检验人员 Reported By	复核人员 Checked By	批准人员 Approved By
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