



Certificate of Analysis

Rivaroxaban

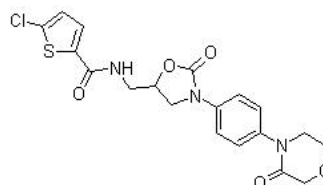
Brand Name :Biochempartner

M.Wt: 435.88

Formula: C₁₉H₁₈ClN₃O₅S

CAS No.: 366789-02-8

Batch NO: 20200515



Item	Specification	Result
外观 Appearance	白色或类白色结晶性粉末 White or off-white crystalline powder	白色结晶性粉末 White crystalline powder
溶解性 Solubility	本品在 N,N-二甲基甲酰胺、二甲基亚砷中溶解，在无水乙醇或水中几乎不溶 Soluble in N,N-dimethyl formamide and in dimethyl sulfoxide, practically insoluble in absolute ethyl alcohol or water.	符合规定 Conforms
比旋度 Specific optical rotation	-39° ~ -42°	-40.1°
有关物质 Related substances	杂质 B (Impurity B) ≤0.1% 杂质 C (Impurity C) ≤0.1% 杂质 E (Impurity E) ≤0.1% 杂质 F (Impurity F) ≤0.1% 杂质 G (Impurity G) ≤0.1% 杂质 J (Impurity J) ≤0.1% 杂质 K(L 与折)(Impurity K) ≤10% 杂质 D (Impurity D) ≤0.10% 其他单杂 (Unspecified impurity) ≤0.10% 总杂质(Total impurities)≤0.50%	0.004% 0.002% 未检出 N.D 未检出 N.D 未检出 N.D 0.001% 未检出 N.D 0.01% 0.02% 0.04%
杂质 A Impurity A	≤0.1%	0.01%

干燥失重 Loss on drying	≤0.50%	0.13%
炽灼残渣 Residue on ignition	≤0.1%	0.04%
重金属 Heavy Metals	≤20ppm	<20ppm
残留溶剂 Residual solvents	丙酮(Acetone) ≤0.5% 乙醇(Ethanol) ≤0.5% 甲苯(Methylbenzene) ≤0.089% N, N-二甲基甲酰胺 (N,N-dimethyl formamide) ≤0.088% 醋酸(Acetic acid) ≤0.5%	未检出 N.D 0.01% 未检出 N.D 未检出 N.D 未检出 N.D
含量 Assay	98.0% ~ 102.0% (按干燥品计算) (Calculated on the dried basis)	99.7%
Conclusion	Analyzed, this product complies with Enterprise Standard	

Conclusion: Complies with In-house standard.

QA manager :kexianxun

For and on behalf of
SHANGHAI BIOCHEMPARTNER CO., LIMITED

.....
Authorized Signature(s)

Kevin

