

CERTIFICATE OF ANALYSIS

Product Name	Rivaroxaban
CAS No.	366789-02-8
QUSNTITY	
BATCH NO	
MANUFACTRE DATE	
INSPECTION DATE	
REPORT DATE	
RETEST DATE	

Chemical Composition	Standard	Specimen
Appearance	White or off-white crystalline powder	White crystalline powder
Identification	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.	Conforms
	IR absorption spectrum of sample should be consistent with spectrum of reference standard.	Conforms
Specific optical rotation	-39°~-42°	-41.4°
Loss on drying	≤0.5%	0.06%
Residue on ignition	≤0.1%	0.02%
Heavy metals	≤20ppm	<20ppm
Impurity A	≤0.10%	0.01%
Related substances	(Impurity B) ≤0.1%	N.D
	(Impurity C) ≤0.1%	N.D
	(Impurity E) ≤0.1%	N.D
	(Impurity F) ≤0.1%	0.005%
	(Impurity G) ≤0.1%	N.D

	(Impurity J)≤0.1%	0.003%
	(K1 and K2)(Impurity K)≤0.10%	N.D
	(Impurity D)≤0.10%	N.D
	(Unspecified impurity)≤0.10%	0.03%
	(Total impurities)≤0.50%	0.06%
Residual solvents	(Acetone)≤0.5%	N.D
	(Ethanol)≤0.5%	0.0004%
	(Methylbenzene)≤0.089%	N.D
	(N,N-dimethyl formamide)≤0.088%	N.D
	(Acetic acid)≤0.5%	N.D
Assay	98.0%~102.0% (Calculated on the dried basis)	100.7%
Conclusion	PASSED	