



Hangzhou Peptidego Biotech Co.,Ltd

CERTIFICATION OF ANALYSIS

Bivalirudin Powder (Synthetic)	CAS: 128270-60-0
Product No.:800002	Batch No.: 17120007
Date of Mfg: Jan 13, 2018	Date of Exp: Jan 12, 2020
Sequence: DPhe-Pro-Arg-Pro-Gly-Gly-Gly-Gly-Asn-Gly-Asp-Phe-Glu-Glu-Ile-Pro-Glu-Glu-Tyr-Leu	

Test	Specification	Result
Appearance	White or off-white powder	White powder
Solubility	soluble in water	conforms
MS	2180.3 ± 1.0	2180.2
Amino acid analysis	Asp 1.80-2.20 Glu 3.60-4.40 Pro 2.60-3.20 Gly 4.50-5.50 Arg 0.90-1.10 Phe 1.80-2.20 Tyr 0.90-1.10 Ile 0.90-1.10 Leu 0.90-1.10 No more than the traces of the other amino acids are present.	Asp 2.0 Glu 3.9 Pro 2.8 Gly 5.1 Arg 1.0 Phe 1.9 Tyr 1.0 Ile 1.0 Leu 1.0 Conforms
Related Substances (purity)	Unspecified impurity for each impurity: NMT1.0% Total impurity: NMT 2.0%	0.14% (single largest impurity) 0.14%
Trifluoroacetate	NMT 12.0%	8.0%
Water Content(Karl Fischer)	NMT 7.0%	4.8%
Bacterial Endotoxins	Less than 5 IU/mg	conforms
Assay	95%-105% (anhydrous, and TFA-free substance)	98.7%

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Test	Specification	Result
Specific Optical Rotation	-110 to -120 (anhydrous, and TFA-free substance)	-112.8
Residual solvent Methanol Acetonitrile Triethylamine	NMT 3000ppm NMT 410 ppm NMT 320ppm	conforms

Storage: In an air tight container,protected from light at temperature 2-8°C.

Conclusion: the product complies with specification.

It is only supplied as chemical product.

Analysis :Janie.zhang
Date :2018.01.13

Approved by : Christ.zheng
Date :2018.01.13



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