



PEPTIVA BioHealth

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Certificate of analysis

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Product Name		Retatrutide	
Catalog No.		C6015	Batch No. AR0763RT4
Sequence		Tyr-{Aib}-Gln-Gly-Thr-Phe-Thr-Ser-Asp-Tyr-Ser-Ile-{a-Me-Leu}-Leu-Asp-Lys-{diacid-C20-gamma-Glu-(AEEA)-Lys}-Ala-Gln-{Aib}-Ala-Phe-Ile-Glu-Tyr-Leu-Leu-Glu-Gly-Gly-Pro-Ser-Ser-Gly-Ala-Pro-Pro-Ser-NH2	
Manufacturing Date		2025.04.17	Received Date 2025.04.17
Report Date		2025.04.18	Retest Date 2027.04.16
Test Reference		In-house specification/Protocol specification	
Test Items		Specification	Result
Appearance		White to off white powder or loose lump	Conforms
Solubility		Soluble in 50% aqueous acetonitrile	Conforms
Amino acid analysis		Tyr(2.4-3.2) Aib(1.6-2.4) Glu (4.0-6.0) Gly(3.2-4.8) Thr(1.6-2.4) Phe(1.6-2.4) Ser(4.0-6.0) Asp(1.6-2.4) Ile(1.6-2.4) Leu(2.4-3.6) Lys(1.6-2.4) Ala(2.4-3.6) Pro(3.2-4.8) AEEA(0.8-1.2)	Tyr(3.1) Aib(2.0) Glu(4.3) Thr(1.9) Phe(1.6-2.4) Ser(5.3) Asp(2.1) Ile(2.0) Leu(3.1) Lys(1.9) Ala(3.2) Pro(4.2) AEEA(1.0)
Identification	HPLC	The principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution	The principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution
	MS	4731.33±1.0	4731.92
Clarity and color of solution		Clear and colorless	Conforms
Water		≤10.0%	4.1%
pH		6.0~9.0	6.50
Acetic acid		≤0.5%	N.D





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Test Items	Specification	Results
Trifluoroacetate ion	$\leq 0.1\%$	N.D
Sodium ion	$\leq 3.0\%$	1.6%
Related Substances (HPLC)	Any individual impurity: $\leq 1.0\%$ Total impurity: $\leq 2.0\%$	0.28% 0.62%
Purity	$\geq 98\%$	99.38%
Residual solvents	Methanol: $\leq 0.3\%$ Isopropanol: $\leq 0.5\%$ Acetonitrile: $\leq 0.041\%$ Methylene chloride: $\leq 0.06\%$ N,N-Dimethylformamide: $\leq 0.088\%$ Triethylamine: $\leq 0.032\%$ Tert-butyl methyl ether: $\leq 0.5\%$	Methanol: N.D Isopropanol: N.D Acetonitrile: 0.021% Methylene chloride: N.D N,N-Dimethylformamide: N.D Triethylamine: N.D Tert-butyl methyl ether: N.D
Bacterial endotoxin	$< 10\text{EU/mg}$	Conforms
Microbiological Examination	TAMC: NMT 100cfu/g	Less than 10cfu/g
	TYMC: NMT 50cfu/g	Less than 10cfu/g
	Escherichia coli: Absent	Absent
Peptide Assay	$\geq 80.0\%$	93.69%
Packaging and storage	Store at a temperature of $2\sim 8^{\circ}\text{C}$, protected from light.	
Conclusion	The test results comply with the requirements of in-house specification.	
Remark	This analysis applies to the active pharmaceutical ingredient (API) incorporated in Alluvi's 40mg and 20mg Retatrutide pre-filled injection pens. The product is aseptically filled, sealed under sterile conditions, and packaged for controlled distribution.	

