ALLUVI HEALTH CARE

ALLUVI Health Care
Website: www.Alluvi.org
Email: Research@Alluvi.org

Certificate of analysis

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-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**		**Results**
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(l.6-2.4) Phe(l.6-2.4) Ser(4.0-6.0) Asp(l.6-2.4) Ile(l.6-2.4) Leu(2.4-3.6) Lys(l.6-2.4) Ala(2.4-3.6) Pro(3.2-4.8) AEEA(0.8-1.2)		Tyr(3.l) Aib(2.0) Glu(5.4) Gly(4.3) Thr(l.9) Phe(2.1) Ser(5.3) Asp(2.l) Ile(2.0) Leu(3.l) Lys(l.9) Ala(3.2) Pro(4.2) AEEA(l.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

ALLUVI HEALTH CARE

ALLUVI Health Care
Website: www.Alluvi.org
Email: Research@Alluvi.org

Test Items	Specification	Results
Trifluoroacetate ion	≤0.1%	N.D
Sodium ion	≤3.0%	1.6%
Related Substances (HPLC)	Any individual impurity: ≤1.0% Total impurity: ≤2.0%	0.28% 0.62%
Purity	≥98%	99.38%
Residual solvents	Methanol: ≤0.3% Isopropanol: ≤0.5% Acetonitrile: ≤0.041% Methylene chloride: ≤0.06% N,N-Dimethylformamide: ≤0.088% Triethylamine: ≤0.032% Tert-butyl methyl ether: ≤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	<l0EU/mg	Conforms
Microbiological Examination	TAMC: NMT I00cfu/g	Less than I0cfu/g
	TYMC: NMT 50cfu/g	Less than 10cfu/g
	Escherichia coli: Absent	Absent
Peptide Assay	≥80.0%	93.69%
Packaging and storage	Store at a temperature of 2~8°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.