

## Pen peptide certificate of analysis (CoA)

<b>Product:</b>	<b>Retatrutide</b>		
<b>Source:</b>	Hybrid synthesis (recombinant using peptide secretion system and chemical synthesis)		
<b>Intended use:</b>	For stability, viability and activity testing only.		
<b>Order number:</b>		<b>Lot:</b>	25AUG21RET
<b>Production:</b>	08/2025	<b>Expiry:</b>	08/2027
<b>Formulation:</b>	0.2 µm-filtered solution in 20mM glycine, 200mM Mannitol, 20mM NaH <sub>2</sub> PO <sub>4</sub> , pH 8.4; m-cresol 1 mg/ml, glycerol 2 mg/ml (when liquid)		
<b>Protein/peptide concentration per 3 ml cartridge:</b>	30 mg		

<b>Release Testing:</b>	<b>Specification</b>	<b>Lot Result</b>
<b>Purity:</b>	≥ 97%	> 98%
<b>Identity:</b>	Complies	Complies
<b>Sterility:</b>	Sterile	Complies
<b>Endotoxin level:</b>	< 10 EU/mg	< 0.20 EU/mg
<b>Host-cell DNA</b>	≤ 200 ng/mg	Complies (1.1 ng/mg)

Activity was determined using in vitro test.

Purity was determined by HPLC.

Identity was confirmed by end-of-production DNA sequencing and N-terminal protein sequencing.

Sterility test of vial product was performed according to Eur.Pharm. (Inoculation method).

Endotoxin was determined using the gel clot assay according to Eur.Pharm.

Host-cell DNA/RNA was determined using fluorimetric assay (if applicable).

### **Handling Instructions:**

**General usage:** Open cap, clean the rubber stopper with disinfectant napkin or other cleaning disinfection method / material. Puncture rubber stopper with sterile needle by screwing needle on. Remove the plastic protective cover. Set the index to physician prescribed position, remove the pink plastic cover and let out the air from the cartridge by several button presses into the air. Put on the plastic protective cover back.

**Using liquid product:** Liquid products are ready to use according to physician recommendations.

**Storage and stability:** Store material at +2 - +8°C. **Do not freeze!**

### **Quality Statement:**

This product is manufactured, tested and realized in compliance with the relevant GMP-guidelines. No animal- or human-derived materials were used during manufacturing. USP chapter <1043> “ancillary materials for cell, gene, and tissue-engineered product” has been considered in the design of this product.

## Stability report

### Retatrutide

#### Data Provided:

- Initial concentration of Retatrutide: **99,28%**.
- Concentration after 7 days at:
  - **+4°C: 98,63%**.
  - **+42°C: 98,83%**.

#### Analysis Plan:

- Use the Arrhenius equation to calculate the degradation rate constants.
- Determine the activation energy ( $E_a$ ) based on the temperature and degradation rates.
- Predict time to 90% stability at **+4°C**.

#### Summary of Results:

- **Activation Energy ( $E_a$ ): 10 kJ/mol.**
- **Time to 90% Stability at +4°C: 315 days.**





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\*\*\* End of Report \*\*\*





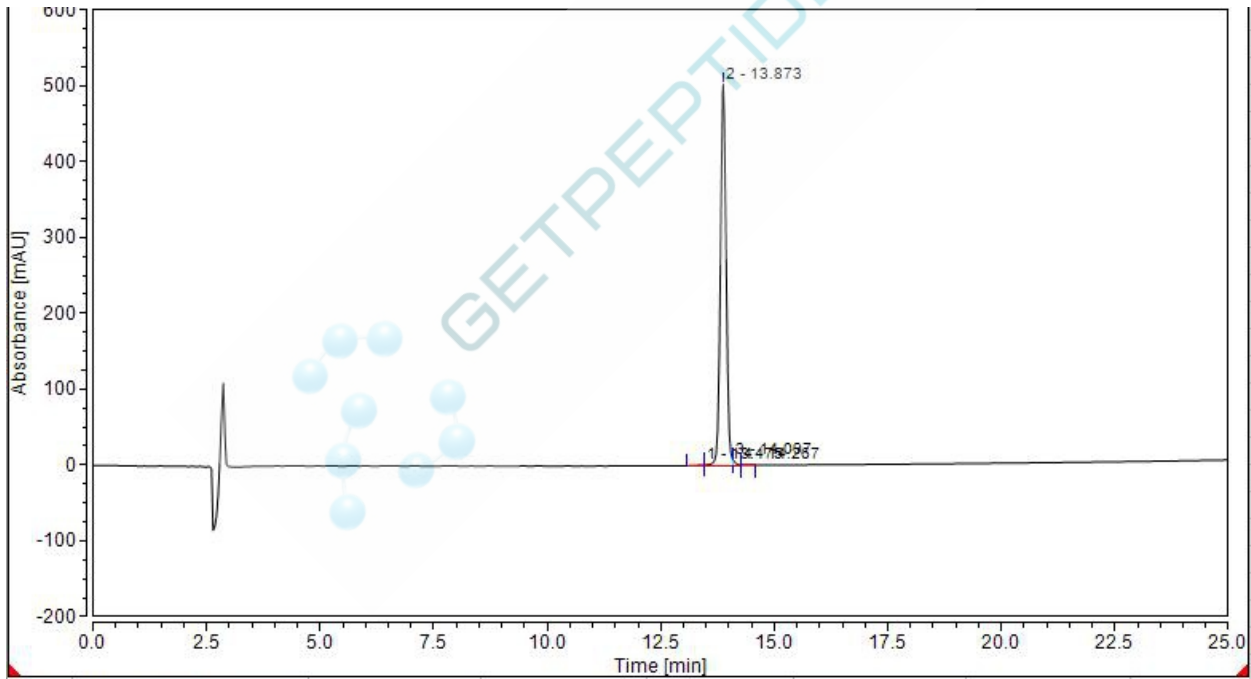


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\*\*\* End of Report \*\*\*

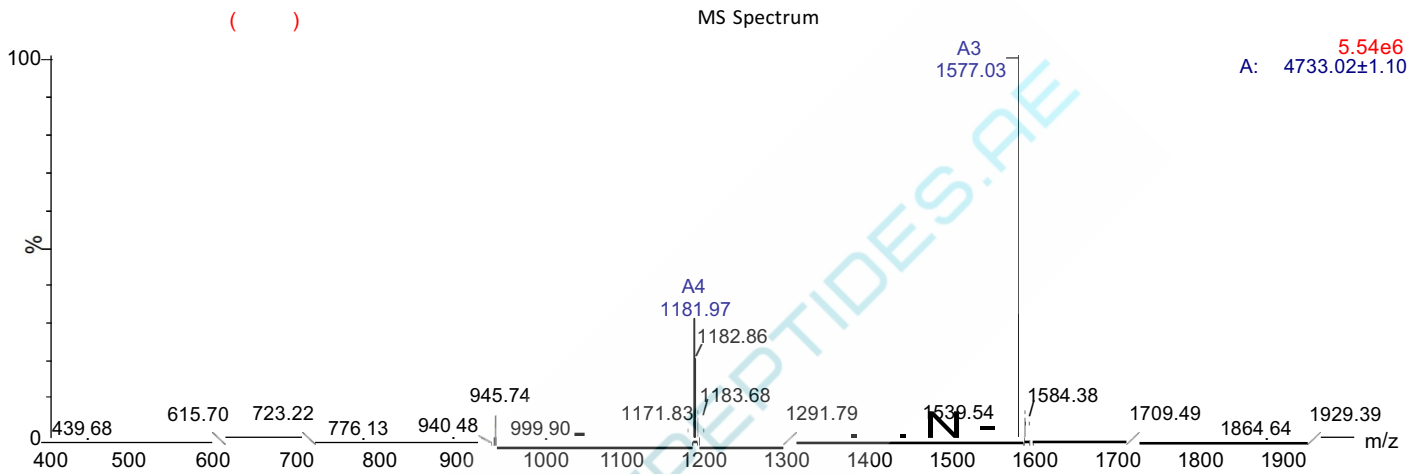


## Sample Information

Product Name : Retatrutide  
 Lot.No :  
 Sequence : Tyr- {Aib}-Gln-Gly-Thr-Phe-Thr-Ser-Asp-Tyr-Ser-Ile- { $\alpha$ -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  
 Column : Welch, XB-C18, (4.6mm i.d., 250 mm L)  
 Buffer : A: 0.1% TFA in Acetonitrile B: 0.1% TFA in H2O  
 Gradient : 40-65% in 25 min  
 Flowrate : 1.0ml/min  
 Wavelength : 220nm  
 Dissolution method : 100% H2O



Integration Results							
No.	Peak Name	Retention Time min	Area mAU*min	Height mAU	Relative Area %	Relative Height %	Amount n.a.
1		13.475	0.160	0.850	0.22	0.17	n.a.
2		13.873	72.924	502.311	99.18	98.40	n.a.
3		14.097	0.374	6.814	0.51	1.33	n.a.
4		14.267	0.066	0.480	0.09	0.09	n.a.
<b>Total:</b>			<b>73.524</b>	<b>510.454</b>	<b>100.00</b>	<b>100.00</b>	



5.54e6  
A: 4733.02±1.10

Dissolution	: 0.1% HCOOH + ACN	Interface	: ESI	Prerod Bias	: +3.5 kv
Date	: 2025/08/21	Nebulizing Gas Flow	: 500 L/hr	Detector	: -0.2 kv
Injection	: 20:18:45 : 2.5 µl	CDL Temp	: 400 C	T.Flow	: 0.35 ml/min
Block Temp	: 150	CDL Volt	: -45 V	B.conc	: 50% H <sub>2</sub> O / 50% MEOH

Product Name : Retatrutide

Sequence : Tyr-{Aib}-Gln-Gly-Thr-Phe-Thr-Ser-Asp-Tyr-Ser-Ile-  
 -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-Se  
 r-Ser-Gly-Ala-Pro-Pro-Pro-Ser-NH<sub>2</sub> α

Lot.No : 202508

Theoretical : 4731.33

Observed : 4731.92