Pen peptide certificate of analysis (CoA)

Product:	**Tirzepatide**		
Source:	Hybrid synthesis (recombinant using peptide secretion system and chemical synthesis)		
Intended use:	For stability, viability and activity testing only.		
Order number:		**Lot:**	25AUG25TIR
Production:	08/2025	**Expiry:**	08/2027
Formulation:	0.2 µm-filtered solution in 20mM glycine, 200mM Mannitol, 20mM NaH_2PO_4, pH 6.6; m-cresol 1 mg/ml, glycerol 2 mg/ml (when liquid)		
Protein/peptide concentration per 3 ml cartridge:	30 mg		

Release Testing:	**Specification**	**Lot Result**
Purity:	≥ 97%	> 98%
Identity:	Complies	Complies
Sterility:	Sterile	Complies
Endotoxin level:	< 10 EU/mg	< 0.20 EU/mg
Host-cell DNA	≤ 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 vialed 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:

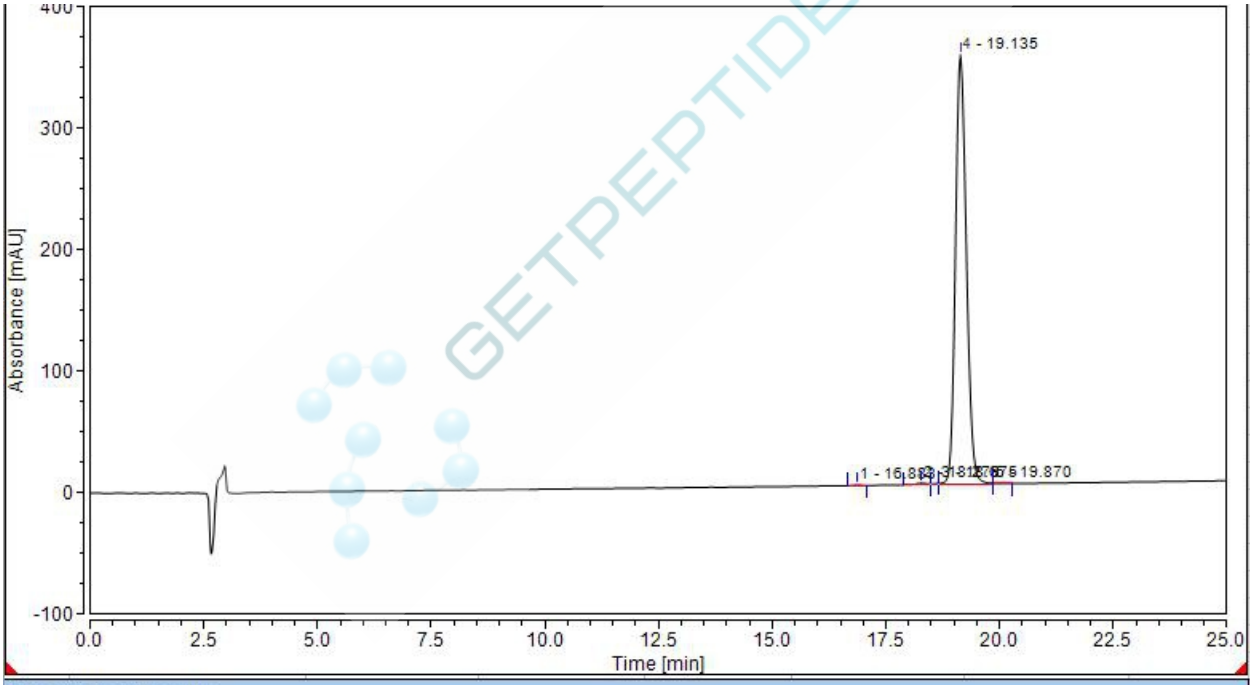
General usage:	Open cap, clean the rubber stopper with disinfectant napkin or other cleaning disinfection method / material. Puncture rubber stopper with sterile needle by screwing needle on. Remove the plastic protective cover. Set the index to physician prescribed position, remove the pink plastic 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^{0}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.

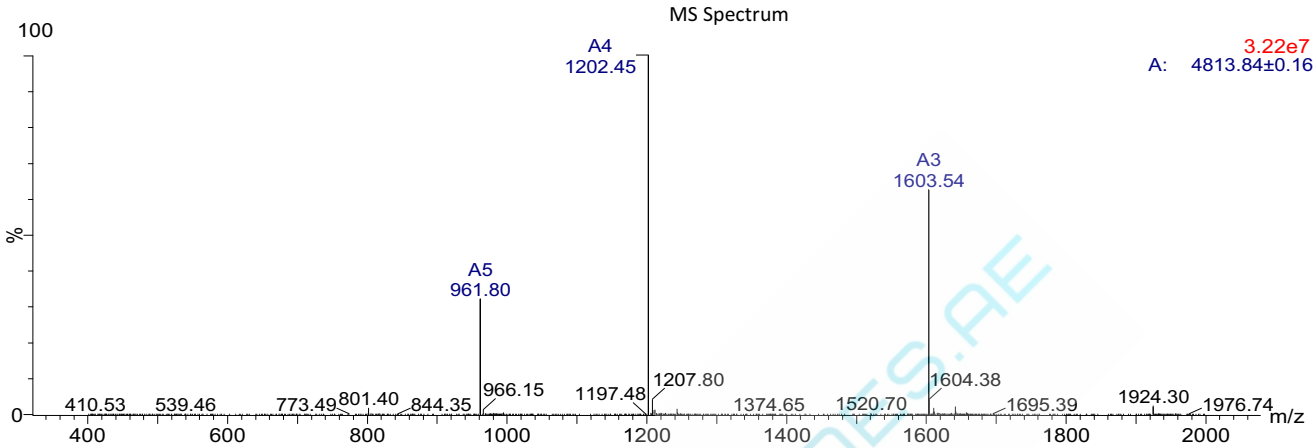
Sample Information

Product Name	: Tirzepatide
Lot. No	:
Sequence	: Tyr-{Aib}-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Tyr-Ser-Ile-{Aib}-Leu-Asp-Lys-Ile-Ala-Gln-{diacid-gamma-Glu-(AEEA)2-Lys}-Ala-Phe-Val-Gln-Trp-Leu-Ile-Ala-Gly-Gly-Pro-Ser-Ser-Gly-Ala-Pro-Pro-Pro-Ser-NH2
Column	: Welch,XB-C18,(4.6mm i.d.,3um,250 mm L)
Buffer	: A: 0.1% TFA in Acetonitrile B: 0.1% TFA in H2O
Gradient	: 43-55.5% in 25 min
Flow rate	: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		16.883	0.102	0.570	0.10	0.16	n.a.
2		18.278	0.363	1.206	0.37	0.34	n.a.
3		18.675	0.123	0.844	0.12	0.24	n.a.
4		19.135	98.095	353.700	99.33	99.16	n.a.
5		19.870	0.070	0.364	0.07	0.10	n.a.
Total:			**98.753**	**356.684**	**100.00**	**100.00**	



Dissolution	:0.1%HCOOH+ACN	Interface	:ESI	Prerod Bias	:+3.5kv
Date	:2025/08/25 18:29:31 :2.5u	Nebulizing Gas Flow	:500L/hr	Detector	:-0.2kv
Injection	:150	CDL Temp	:400C	T.Flow	:0.35ml/min
		CDL Volt	:-15v	B.conc	:50%H2O/50%MEOH

Product Name : Tirzepatide

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Lot.No e-Val-Gln-Trp-Leu-Ile-Ala-Gly-Gly-Pro-Ser-Ser-Gly-Ala-Pro-Pro-Pro-Ser-NH2 :

Theoretical : 4813.45

Observed : 4813.68