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Pen peptide certificate of analysis (CoA)

Product:	**AC-KPV-NH2**
Source:	Hybrid synthesis (recombinant using peptide secretion system and chemical synthesis)
Intended use:	For stability, viability and activity testing only.
Order number:	**Lot:** 25AUG 21KPV
Production:	08/2025 **Expiry:** 08 /2027
Formulation:	0.2 µm-filtered solution in 20mM glycine, 200mM Mannitol, 20mM NaH_2PO_4, pH 6.5; m-cresol 1 mg/ml, glycerol 2 mg/ml (when liquid)
Protein/peptide concentration per 3 ml cartridge:	15 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.

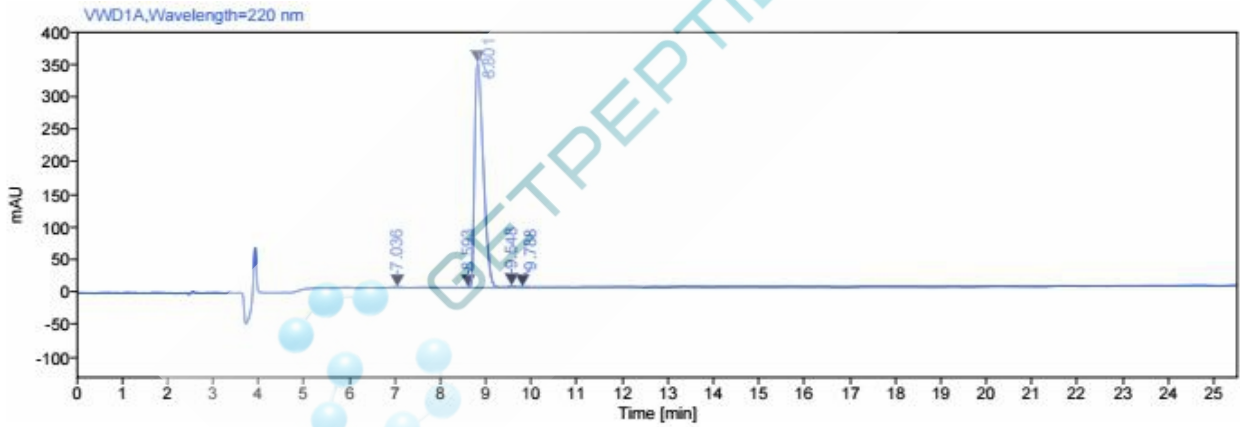
Storage and stability: Store material at +2 - +8^{0}C. **Do not freeze!**

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	:KPV
Lot. No	:202508
Sequence	:KPV
Column	: Agilent 5 HC-C18(2) 250*4.6mm
Buffer	: A: 0.1% TFA in Acetonitrile B: 0.1% TFA in H2O
Gradient	:5-30% in 25 min
Flow rate	:1.0ml/min
Wavelength	:220nm
Dissolution method	:100%H2O
Column temperature	： 35℃



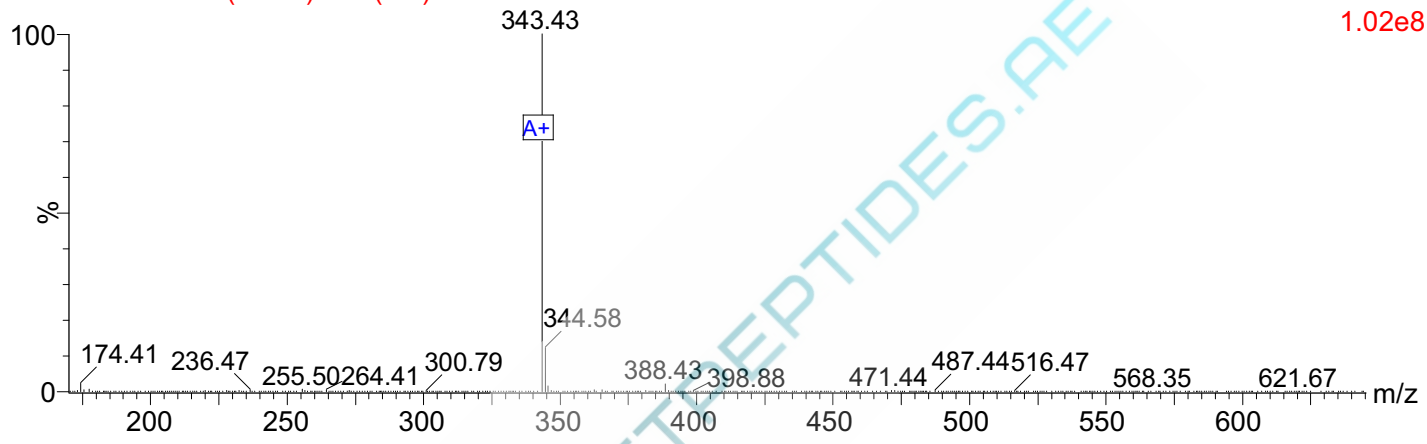
Signal: VWD1A,Wavelength=220 nm

RT [min]	Type	Width [min]	Area	Height	Area%	Name
7.036	MM m	0.21	3.69	0.68	0.08	
8.593	BM m	0.18	1.63	0.41	0.04	
8.801	MM m	0.77	4595.50	344.99	99.39	
9.548	MM m	0.33	18.23	2.25	0.39	
9.788	MM m	0.27	4.52	0.46	0.10	
		Sum	4623.58			

MS Spectrum

P250318-M148 9 (0.153) Cm (3:9)

Scan ES+
1.02e8



Dissolution	:0.1%HCOOH+ACN	Interface	:ESI	Prerod Bias	:+3.5kv
Date	:2025/08/21	Nebulizing Gas Flow	:500L/hr	Detector	:-0.2kv
Injection	9:44:24 :2.5ul	CDL Temp	:400C	T.Flow	:0.35ml/min
Block Temp	:150	CDL Volt	:+5v	B.conc	:50%H2O/50%MEOH

Product Name	:	KPV
Sequence	:	KPV
Lot.No	:	202508
Theoretical	:	342.43
Observed	:	342.43