Research compound · Certificate of Analysis

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: —
Production: **03/2026** Expiry: **03/2028**
Formulation: 0.2 µm-filtered solution in 20mM glycine, 200mM Mannitol, 20mM NaH_2PO_4, pH 7.4; m-cresol 1 mg/ml, glycerol 2 mg/ml
Concentration: 10 mg / 3 ml cartridge
LOT: **25091726MAR09ACK**
Batch size: 500 units

Test	Specification	Lot Result	Method
ANALYSIS DATA			
Purity	≥ 96.0%	98.9%	
Appearance	Clear solution	Complies	
Color	Colourless to pale	Complies	
pH	6.8 – 7.6	7.29	
Identity	Complies	Complies	
Sterility	Sterile	Complies	
Endotoxin level	< 10 EU/mg	< 0.11 EU/mg	
Host-cell DNA	≤ 200 ng/mg	Complies (2.7 ng/mg)	
CHEMICAL CONTROL			
Heavy metals	≤ 10 ppm	Conforms	
Arsenic (As)	≤ 1 ppm	0.005 ppm	
Mercury (Hg)	≤ 2 ppm	Not detected	
Cadmium (Cd)	≤ 2 ppm	Not detected	
Lead (Pb)	≤ 1 ppm	0.003 ppm	
MICROBIOLOGICAL CONTROL			
Total plate count	≤ 10000 cfu/g	< 100 cfu/g	
Yeast and mold	≤ 300 cfu/g	< 10 cfu/g	
E. coli	Neg / 10 g	Negative	
Salmonella	Neg / 25 g	Negative	
S. aureus	Neg / 10 g	Negative	

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 +4 / +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.