

## Pen peptide certificate of analysis (CoA)

<b>Product:</b>	<b>Epitalon</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>	25JAN24SEM
<b>Production:</b>	01/2025	<b>Expiry:</b>	01/2027
<b>Formulation:</b>	0.2 µm-filtered solution in 20mM glycine, 200mM Mannitol, 20mM NaH <sub>2</sub> PO <sub>4</sub> , pH 7.4; m-cresol 1 mg/ml, glycerol 2 mg/ml (when liquid)		
<b>Protein/peptide concentration per 0,88 ml cartridge:</b>	5 mg		

<b><u>Release Testing:</u></b>	<b><u>Specification</u></b>	<b><u>Lot Result</u></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 a Nb2-11 cell proliferation assay.

Purity was determined by SDS PAGE and coomassie stain (under reducing and non-reducing conditions).

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 was determined using fluorimetric assay.

### **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.