OPTCEUTICS
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The need to determine the stability of protein-based medicines

Protein-based medicines (e.g.antibodies) have revolutionized the treatment of blinding diseases.

Chronic conditions such as AMD require long-term treatment. Longer acting dosage forms are being developed to reduce the frequency of dosing patients with intravitreal injections.

Proteins are inherently sensitive and are typically stored at 4˚C before use. They readily aggregate and lose their biological function.

The stability of protein based medicines that are designed to reside in the vitreous cavity at body temperature for weeks or months must be determined during preclinical development.

Stability studies with the PK-Eye™ are easily conducted

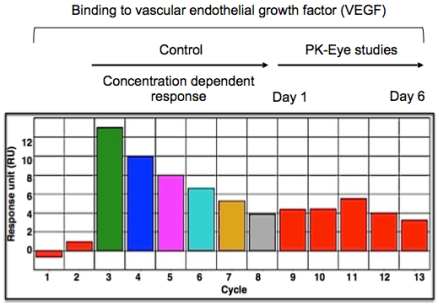
The use of animals to conduct stability studies of therapeutic proteins for intraocular use is challenging because the protein must be isolated from the animal eye at each time point. The protein needs to be extracted from the eye which can negatively impact protein stability resulting in difficulties estimating protein stability in a candidate formulation.

Determining the stability of proteins is easy with the PK-Eye. Stability estimates can be made efficiently for candidate formulations without need of extraction to determine the optimal formulation for detailed *in vivo* studies that might be necessary.

The PK-Eye evaluates therapeutic protein candidates at body temperature using simulated vitreous to conduct physico-chemical studies of protein stability. *Ex-vivo* studies can also be conducted with the PK-Eye that can determine protein stability in the presence of specific vitreous components (e.g. enzymes).

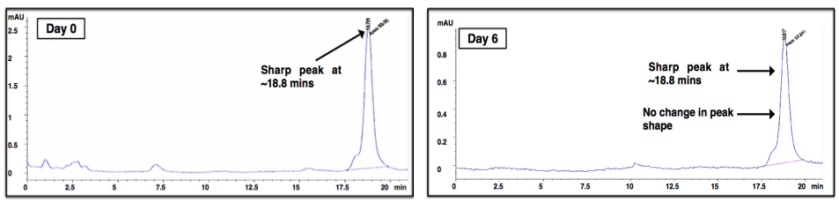
The PK-Eye™ for stability studies

- Surface plasmon resonance (SPR) to observe protein binding.
- Size exclusion chromatography (SEC) to observe protein aggregation.



SPR

Example: 1 week stability of bevacizumab (1.25 mg, 50 uL) in the PK-Eye



SEC

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