



# *In vitro* Subcutaneous Injection Site Simulation

Pion Analytical Services offers the ability to compare, de-risk, and design your subcutaneous drug candidates *in vitro* using the SCISSOR technique.

## SUBCUTANEOUS INJECTION SITE SIMULATOR (SCISSOR) ASSAY

SCISSOR is an instrument developed by Pion that mimics the physiological properties of the subcutaneous tissue *in vitro* reducing the need for animal testing. Our technique is used to rank order subcutaneous formulations by relating their release kinetics and physical behavior upon injection providing critical data that helps scientists “de-risk” formulation candidates, increasing the likelihood of success in advancing these to the next stage of development.

At Pion, we offer a custom-made service using our SCISSOR technique coupled with our unparalleled expertise, tailoring the experiments to your individual application, from mAbs to small molecules, simple solutions to complex *in-situ* forming gels—we’re here to help.

## EXPERIMENT OVERVIEW

To simulate the injection site, a cartridge - which houses two customized dialysis membranes - is filled with our Pion-made artificial extracellular matrix (ECM) which simulates the subcutaneous tissue. This is suspended within a chamber containing a bicarbonate buffer which is under sink conditions, representing the systemic circulation. A subcutaneous formulation is then injected into the cartridge forming a bolus or depot, before migrating through the artificial ECM and out of the customized dialysis membranes, into the chamber simulating ‘uptake’ to the blood and lymphatics. Post-injection, optical density is monitored to detect potential instabilities like precipitation or aggregation.

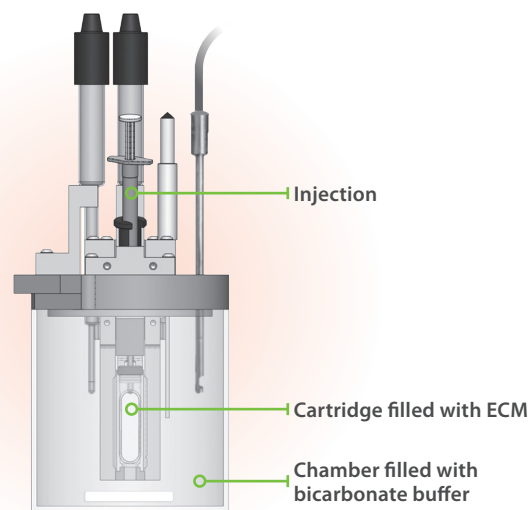
Photographic images are captured at various time points to further assess drug performance during and after injection. A pH electrode is placed at the simulated injection site to observe changes in local pH caused by the formulation and to measure the time it takes for the site to return to homeostasis.

The amount of API (Active Pharmaceutical Ingredient) that diffuses from the simulated injection site through dialysis membranes into the systemic circulation chamber is quantified in real-time using our sophisticated Rainbow *in-situ* UV-Vis platform, producing concentration/release profiles. Alternatively, aliquots can be automatically collected from the bicarbonate buffer in the chamber at predetermined intervals for quantification using off-line methods like HPLC.



### Why Use Pion

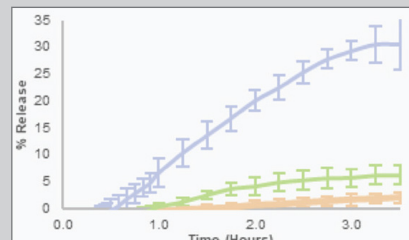
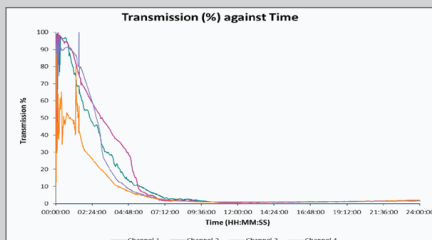
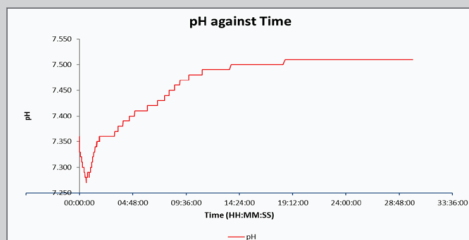
The SCISSOR technology, originally developed and validated primarily using mAbs, and now backed by 10+ years of experience in *in vitro* subcutaneous testing, is designed to mimic the human subcutaneous environment—enabling researchers to compare drug release kinetics and potential immunogenicity risk in a controlled setting. By providing insights into how a drug behaves post-injection, SCISSOR aids in optimizing formulations and predicting clinical outcomes without relying on animal testing.





## KEY DELIVERABLES

The collected data is compiled to provide an understanding of the formulation or drug's overall performance during *in vitro* subcutaneous injection, allowing for a comparison of the product's behavior against other candidates. A full study report will be provided in PDF format including concentration vs time profiles, pH and turbidity graphs, as well as photographic images taken throughout the assay duration. Our experts are also on hand to discuss any findings post-analysis in a follow-up call.



## ANALYTICAL SERVICES PART NUMBERS

SCISSOR analysis is customized and tailored to meet your specific needs. Contact us today for a consultation with our experts to design an assay suited to your unique samples!

### SCISSOR Analytical Services Part Numbers

Analysis	Part #	Details
Gold Standard SCISSOR	1810101	SCISSOR experiment up to 6 hours with Rainbow analytics
Platinum Standard SCISSOR	1810111	Experiment up to 24 hours with Rainbow release analytics
Extended Assay Runtime	1801811	Extra time charge for experiments over 24 hours (price per day)
with HPLC Analysis	1801802	Extra charge for HPLC analysis



**With analysis that can be tailored to your specific application, Pion's Analytical Services provides the vital information missing from your research.**



## VALIDATION STUDIES FOR SCISSOR

[1] Kinnunen HM, Sharma V, Contreras-Rojas LR, Yu Y, Alleman C, Sreedhara A, Fischer S, Khawli L, Yohe ST, Bumbaca D, Patapoff TW, Daugherty AL, Mrsny RJ. J Control Release. 2015; 214:94-102. [2] Bown HK, Bonn C, Yohe S, Yadav DB, Patapoff TW, Daugherty A, Mrsny RJ. J Control Release. 2018; 273:13-20. **Biomolecule inclusion in simulated human ECM** [3] Gomes CG, Gridley K, Anastasiou I, Sinkó B, Mrsny R. European Journal of Pharmaceutics and Biopharmaceutics. 2024; 199:114308