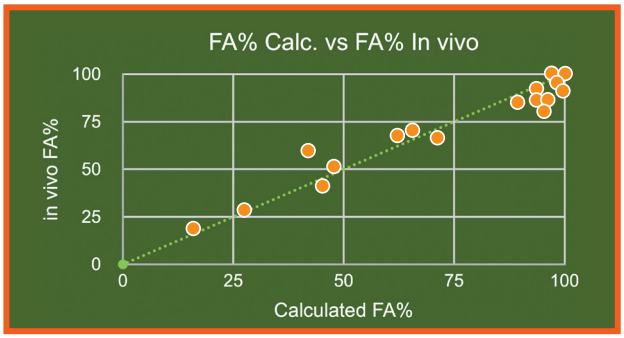
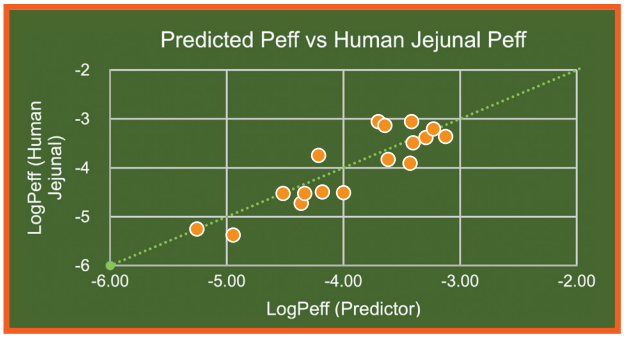
Predictor Software

Predict the *in vivo* effective permeability and the fraction of a dose absorbed using only *in vitro* flux data from the most biorelevant systems on the market.

Combine, analyze and compare dissolution, supersaturation-precipitation, and flux experiments from AuPRO and Rainbow quickly and effectively.

Visualize and understand the rate limiting step of oral absorption to control the performance of your APIs or formulations.





*Predictor™ applies the mechanisms of the GUT Framework to covert **in vitro** flux data to predictions of **in vivo** oral absorption.*

Handle large collections of AuPRO data efficiently with the *Predictor™* **Data Module**. Apply in-built calculations to determine dissolution rates, IDR, solubility, precipitation rates, induction times, and flux values for up to 16 concentration vs time profiles simultaneously.

Take flux data even further with the add-on **FA Module**. The *Predictor™* FA Module predicts the fraction absorbed (FA) of APIs or formulated drug and determines the rate limiting step to drug absorption, all from *in vitro* data acquired using Pion's line of FLUX apparatus.

Data module:
Concentration vs time profiles acquired using AuPRO software can be imported into *Predictor™*, enabling complete flexibility in compiling datasets for analysis and generating reports, from multiple source AuPRO files. User-friendly and intuitive data handling options allow for straightforward data refinements, including simple data point exclusion/inclusion, customizable units, and one-click exports of .pdf, Word, or Excel reports.

In-built data analysis functions for AuPRO concentration vs time data.

Powder Dissolution: Exponential curve fitting for use with µDISS powder dissolution results. Reports API solubility, dissolution rate, intrinsic dissolution rate, and estimated mean particle size for compatible data sets.

Disc Dissolution (Disc IDR): Linear fit for use with Disc IDR assay data. Calculates the intrinsic dissolution rate of an API for compatible data sets.

Dissolution (Noyes-Whitney): First-order fit for use with dissolution data from any source. Reports dissolution rate and API solubility.

Equilibrium Solubility: The observed equilibrium solubility of the API component, extrapolated to infinite time.

Average Concentration: The average concentration of the API component across a fixed time interval.

Area Under the Curve (AUC): The area under the concentration vs time profile over a user-defined time interval.

Precipitation Rate: The measured precipitation rate of the API, extrapolated back to the induction point of precipitation.

Induction Time: The induction time prior to the occurrence of precipitation of the API component, or the observed duration of the API component in a supersaturated state.

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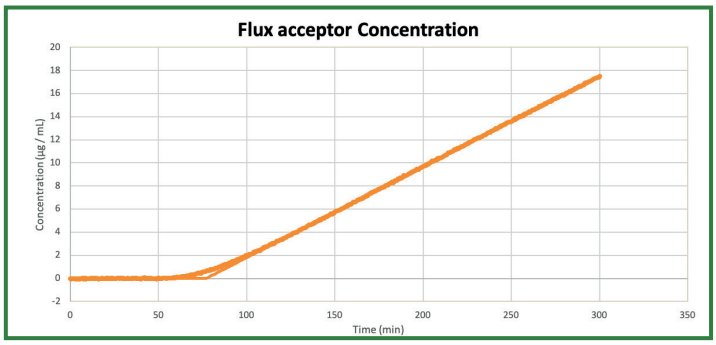
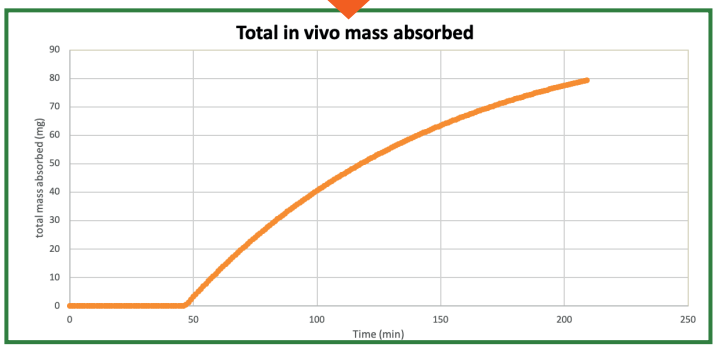
FA Module:
Based on the Gastrointestinal Unified Theoretical (GUT) Framework by Kiyohiko Sugano, PredictorTM directly applies in vitro flux data from Pion's FLUX line of dissolution-permeability testing apparatus to estimate the absorbed fraction of a dose in humans or other species using customizable physiological models. As well as predicting Fa%, *Predictor*™ can also produce exploratory BCS class predictions, and assess the rate limiting steps to the absorption of a drug by applying the Fraction Absorbed Classification System (FaCS).

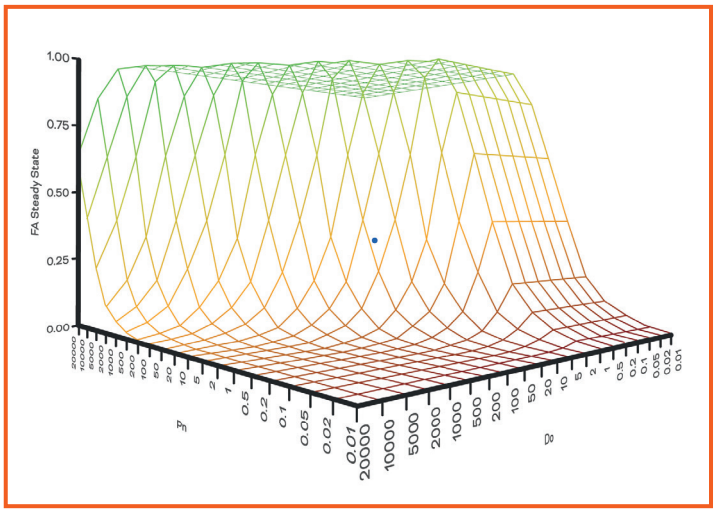
The Predictor™ FA Module converts acceptor chamber concentration vs time profiles obtained from flux experiments into flux vs time, and then scales up the values to in vivo magnitude. The mass of the drug absorbed is then given by the cumulative flux vs time. GUT Framework mechanisms are applied to simulate the permeation process for the intestinal physiology of the modelled species, and determine the surface area available for absorption in order to appropriately scale the flux, based on the permeability exhibited by the molecule in the in vitro assay.





Apply flux with *Predictor™* to understand where to target formulation improvements.

- *Predictor™* links flux measurements to the biopharmaceutical classification (BCS) and fraction absorbed classification (FaCS)
- *Predictor™* derives the dose (Do), dissolution (Dn) and permeability (Pn) numbers from flux assay results.
- 3D graphing visualizes how the absorbed fraction of a dose can change with respect to solubility (Do), dissolution performance (Dn), or permeability (Pn).
- Obtain exploratory predictions of the rate-limiting step to oral absorption of a drug for pure APIs or formulations.



Pion Predictor
Powered by the GUT Framework

Pion stands behind the science

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