



# IVIVCPLUS™

GastroPlus® PBPK & PBBM was the first software program to offer “mechanistic deconvolutions,” which deconvolute, or fit, the *in vivo* dissolution vs. time along the gut lumen using the Weibull function (triple Weibull function options!).



## What is the IVIVCPlus™ module?

The IVIVCPlus™ Module is an optional add-on module that provides a convenient way to develop mechanistic and/or traditional correlations (IVIVC) between either *in vitro* release and *in vivo* release or *in vitro* release and absolute bioavailability. The formed correlation can then be used to predict plasma concentration-time profiles for formulations with different *in vitro* release rates or dose strengths to support internal research and regulatory applications (e.g., establish product specifications).

## IVIVCPlus offers five methods for deconvolution:

- ✓ Mechanistic Absorption Model (GastroPlus)
- ✓ Wagner-Nelson (1-compartment model)
- ✓ Loo-Riegelman (2-compartment model)
- ✓ Loo-Riegelman (3-compartment model)
- ✓ Numerical Deconvolution

## Run Convolutions:

The correlation function can be used to calculate an *in vivo* release or absolute bioavailability vs. time profile from a developed IVIVC for a new formulation exhibiting different *in vitro* release vs. time kinetics. A plasma concentration vs. time profile for the new formulation can then be constructed with the deconvoluted *in vivo* release-time or absolute bioavailability-time profile and the underlying PK, PBPK, PBBM model.

## Evaluate Validation Statistics:

After running a convolution, the IVIVCPlus™ module outputs the observed values, predicted values, prediction errors, and mean absolute percent prediction error for both  $C_{max}$  and AUC to validate the IVIVC.



## The Mechanistic Deconvolution Model

The Deconvolution method directly deconvolutes the *in vivo* release rate.

