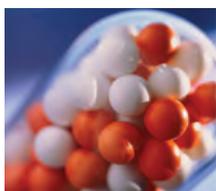


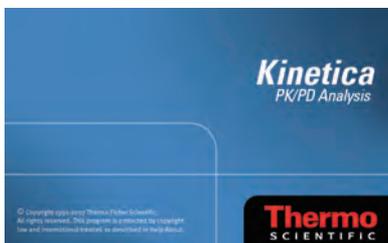
For Scientists involved in pharmacokinetic studies who wish to rapidly turn around high-quality analyses and reports, Kinetica is a high-throughput, template-driven pharmacokinetic analytical solution that allows rapid analysis of data and ensures consistencies between analyses and analysts. Kinetica has a unique template format that users can reuse and share.

Thermo Scientific Kinetica

Pharmacokinetic/Pharmacodynamic (PK/PD) data analysis, simulation and reporting system.



Thermo Scientific Kinetica - the analytical data solution that simplifies data analysis and safely enables multiple analysts to share study templates.



The Goal of PK/PD Analysis

One of the critical aspects of drug development is the determination of ultimate dosage for a new drug substance. Analysis via PK/PD processes determines the dose-response behavior of a drug, i.e., how much of a drug is good and how much is toxic or potentially lethal. PK/PD analyses also play an important role in drug labeling, providing indicators for populations at risk or potentially intolerant of the drug (pediatrics or geriatrics) or populations that have conditions that should prohibit use of the drug (kidney malfunction, heart disease or compromised immune systems). PK/PD analysis will determine the optimized dosage of a particular drug, before the drug is considered for costly Phase III trials.

How does Kinetica help the PK/PD process?

Kinetica has been designed with multiple standardized settings so that each PK analyst has a set of pre-defined templates. With this standardization, Kinetica eliminates the need to hire additional QA personnel to review all the PK data in a study report. Additionally, this standardization saves time for laboratory and study managers who would have to double-check all subordinates' findings. The results are more consistent and reviewing those results is less time consuming.

Benefits of Kinetica Standardization of PK Studies

- Reduction in manual transcription error from transferring data
- Seamless transition of data from Thermo Scientific Watson LIMS™ saving analysts significant time in data transfer
- Non-compartment, standard compartment and population PK/PD bioequivalence, graphs and reports in a single application
- Templates provide consistencies and standardization, customizable to specific corporate SOP
- Pre-set options and settings provide consistency of analysis and reporting across multiple analysts
- Template format allows analysts to apply the same analysis to multiple datasets
- Single file for graphics, tables, raw data and analysis results means time saved in searching for applicable formats and compiling computation specifications
- Unit Management feature provides complete set of mass, volume, and time combinations, plus molarity and pharmacokinetic parameter outputs

The Kinetica Solution

For scientists involved in pharmacokinetic studies, a primary challenge is to be able to process bioanalytical data into meaningful parameters for dose optimization and decision-making processes. The Kinetica solution is an easy-to-use application that allows user to seamlessly import data from Watson LIMS, as well as other data sources, perform computations, and graph and create tables in a single application.

Kinetica in Action

Kinetica comes with predefined templates for any type of pharmacokinetic analyses from non-compartment through to population pharmacokinetics. To access these predefined templates, (1) click File then New from the menu. A dialog box will appear showing various folders for these templates. The folders are separated according to the type of analysis these templates perform. For example, the non compartmental folder will contain pre-defined templates for the three main routes of administration and an additional template for steady state profile. (2) The second step is to select the folder for the type of analysis and then select the template itself. Notice that on the lower right hand corner there is a box that allows you to open with data. If you are not familiar with what the template is doing, open it with data. It will show you what the methods do and where the results go. (3) Click OK when ready.

The Kinetica Solution

Challenge

Process bioanalytical data into meaningful parameters for dose optimization and decision-making processes

Solution

Easy-to-use purpose-built application that allows users to import data from Watson LIMS and other sources, compute, graph and create tables in a single application

Product Description

Automated calculation of pharmacokinetics with predefined templates and methods
Supports Excel, ASCII, Watson LIMS, Oracle, P-Pharm data import

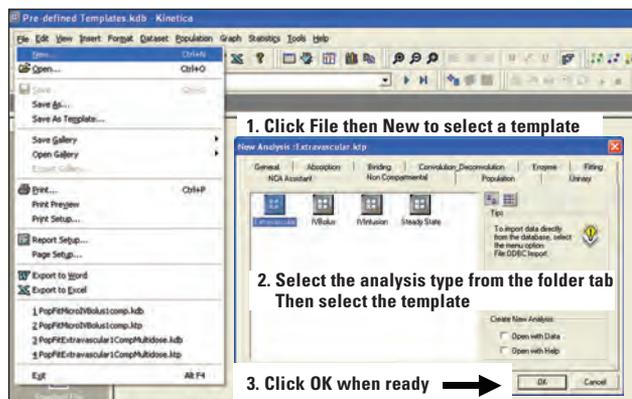
Able to perform all types of analyses in a single package

Ability to perform from non-compartmental through to population analysis, bioequivalence, graphs, table script

More than one analysis method can be performed at a time

Includes more than 60 different validated templates to support wide range of pharmacokinetics/toxicokinetics calculations

- Noncompartmental & compartmental analyses
- Population PK analysis
- Bioequivalence
- Predefined Table scripts
- Enzyme kinetics
- Protein binding



Thermo Scientific Kinetica

Single File Format Simplifies Data System for Drug Submission

As data and analyses from years of research and drug development will eventually be used for drug submission and filing, users need a simple way of storing and retrieving data. Kinetica provides the convenience of storing your raw data, analysis information, method and options, table scripts and graphical output in a single file. So that every time you run an analysis, you can have confidence when the time for filing comes, that you only need to retrieve one single file.

Scripting Language to Automate Workflow

Kinetica comes with a visual basic scripting language for user to create macros and methods. The basic scripting language offers customization to automate workflow, import and export. Kinetica customers have utilized this tool to create their own templates equipped with the ability to send data to SAS. First, go to the Macro Editor or Method Editor and start creating your macro. Save the macro you have created by selecting Tools, then Macro, then Save Macro in Kinetica File. If you select Macro, instead of Save Macro in Kinetica File, a dialog box appears to let you run, edit or rename a specific macro. As you can see, even the macro is saved along with the file.

The Kinetica Solution

Challenge	Solution	Product Description
As data and analysis from years of research will eventually be used for drug submission and filing, a need for simplicity of storing and retrieving data	All data and analysis information are stored in a single file, including method information, algorithms, graphs and report setting Can also be saved as template for user to import data from other studies and use the same option settings	All information from the analysis stored as a single .kdb file

