



Your software for  
bioequivalence studies

**noraymet**  
**BioEquiv**

# main features

## What is BioEquiv?

BioEquiv is a specific software to manage and analyse bioequivalence studies. Pharmacokinetics calculations and statistical tests required by the FDA and GxP to perform bioequivalence studies are implemented in the software with no need of programming.

BioEquiv enables the user to work on pharmacokinetics and statistics at the same time, using a single software. Thanks to its user-friendly environment, BioEquiv does not require any specific computing knowledge and allows the user to save time in the analysis of bioequivalence studies.

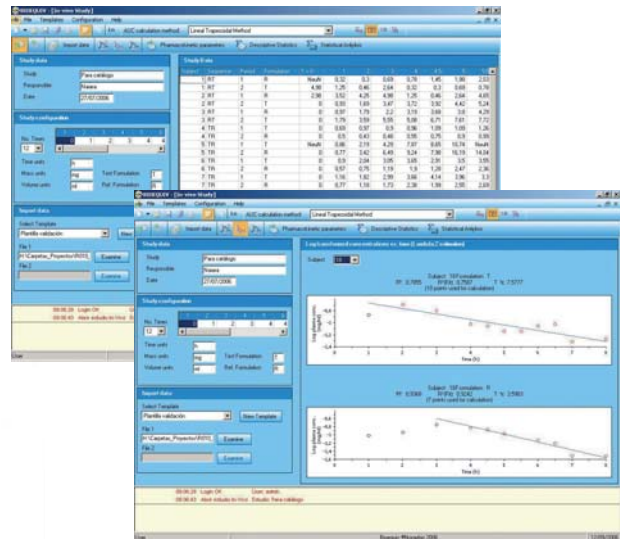
BioEquiv also includes an *in vitro* module to manage and analyse *in vitro* bioequivalence studies. From the dissolution profiles of two formulations, the software compares both dissolution profiles based on f1 and f2 factors calculations.



## How does it work?

BioEquiv allows the user to conduct 2x2 Crossover designs for average bioequivalence studies. Among different designs for assessing bioequivalence, the standard 2x2 Crossover design appears to be the most common one for assessing average bioequivalence between two formulations of a drug product.

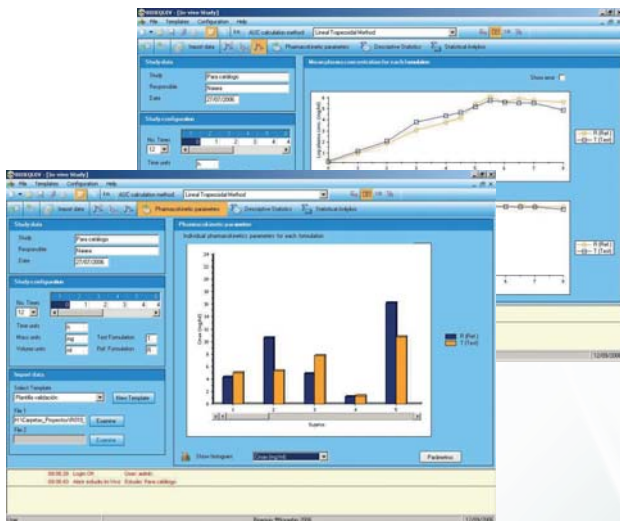
As data are directly imported from a previous Excel sheet, the time-consuming task of building new tables is avoided. BioEquiv calculates relevant pharmacokinetic parameters such as AUC (0-t), AUC (0-∞), C<sub>max</sub>, T<sub>max</sub>, λ<sub>z</sub>, T<sub>1/2</sub>... from drug plasma concentrations of subjects. The approach used to calculate these parameters involves non-compartmental analysis. The areas can either be calculated by means of lineal trapezoidal rule or Log/lineal trapezoidal method.



All of these calculations are depicted in helpful graphs which show both a general view of the behaviour of compared compounds, as well as pharmacokinetic parameters for each subject and for the whole population, both for reference compound/formulation and test compound/formulation.

Once pharmacokinetics parameters have been calculated, the software provides a complete descriptive statistics and a series of parametric and non parametric statistical analysis to evaluate the presence of bioequivalence between two compounds or formulations. The statistical tests implemented in the software include:

- ANOVA
- Classic Confidence Interval
- Westlake Symmetric Confidence Interval
- Schuirmann Test
- Wilcoxon-Mann-Whitney Test



## How does BioEquiv make your bioequivalence analysis easier?

BioEquiv has been developed using validated and accepted methods for pharmacokinetics and statistical analysis.

With just one click, the software generates a complete set of results including pharmacokinetics for each subject and for the whole sample and an extensive range of statistical approaches necessary to conclude bioequivalence. The user has not to lose time thinking about the type of design or selecting different pharmacokinetic or statistical methods through several windows, just enter data and click results .

Bioequiv helps researcher with an automatically generated report that incorporates all the results tables and graphs required by regulatory agencies for the registration of new generic drugs. This report includes both pharmacokinetics and statistical analysis obtained from the bioequivalence study built in a standard format, allowing the researcher to print and send it to regulatory agencies without losing time in elaborating the report.

The software has been developed in compliance with the GxP guidelines in terms of data management, user control and electronic records.

BioEquiv is bilingual; it is available both in Spanish and English.

## Support

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NorayBio is always looking for its client satisfaction and the usability of its products. Our mission is to be innovative and to enhance working practices in pharmaceutical companies. For this reason, the company offers a support for advice, technical assistance, possible customizations and problem solving, building quality into all software we design. Personal attention and individual solutions are the key aspects of the collaboration with our customers.

## Technical features

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Noraymet BioEquiv™ works locally installed or as client/server application.

### Server requirements:

- Minimum:
  - Windows: NT, 2000 or 2003
  - Intel Pentium III or AMD Athlon 800MHz
  - 260MB RAM
  - 200 MB of free space in the Hard Disk
- Recommended:
  - Windows: 2000 or 2003
  - Intel Pentium IV or AMD XP 1.8GHz
  - 512MB RAM
  - 2GB of free space in the Hard Disk
  - Net Ethernet 100Mb

### Workstation requirements:

- Minimum:
  - Windows: NT, 2000 or XP
  - Intel Pentium 500MHz
  - 128MB RAM
  - 100 MB of free space in the Hard Disk
- Recommended:
  - Windows: 2000 or XP
  - Intel Pentium III 1GHz
  - 512MB RAM
  - 150MB of free space in the Hard Disk
  - Net Ethernet 100Mb
  - Screen resolution: 1024 x 768



## Contact information

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## Request a videodemo

To see how BioEquiv can help you with bioequivalence studies, request a videodemo of the software in [info@noraybio.com](mailto:info@noraybio.com).