VWR®
We Enable Science

NeoLiCy®
Analytical Methods' LifeCycle Assessment

NEOLICY SAVES YOU DAYS OR EVEN WEEKS OF WORK

Software for comprehensive statistical assessment of analytical methods during their complete life cycle
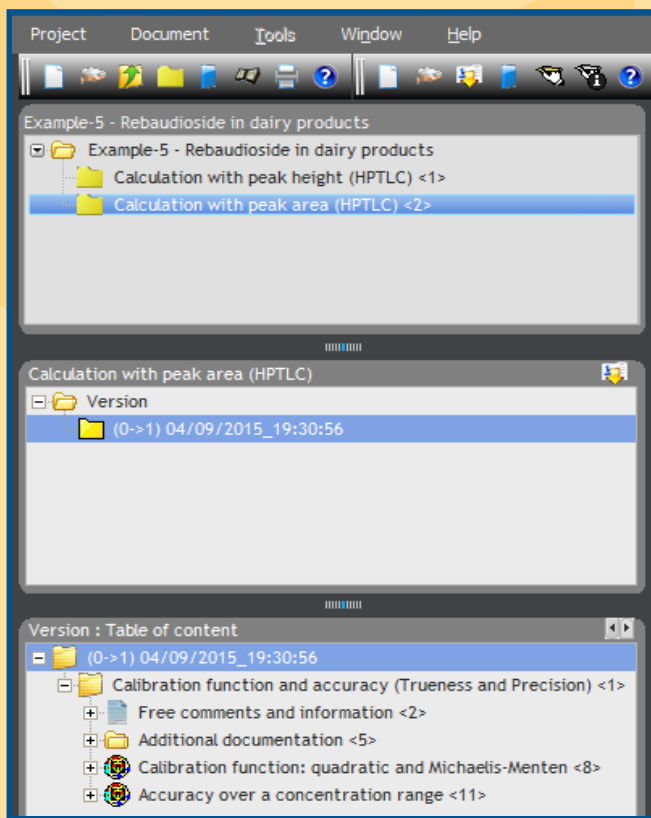
Figure 1:

NeoLiCy® project navigation pane showing project and file classification levels (upper), document, chapter and characteristic classification levels (middle and lower)

Take part in the NeoLiCy® project

When operating according to quality management systems (e.g. according to GxP or ISO guidelines), statistical assessment of the analytical procedures used is of the utmost importance.

This includes for instance validation of analytical methods, analytical stability studies, method robustness studies, estimation of measurement uncertainty, method transfer and many other assessment steps during the whole life cycle of the analytical method.

NeoLiCy® software project is designed to fulfill the requirements of all these steps according to proven and established recommendations and regulations. Each new release of **NeoLiCy®** shall address one or several more aspects of statistical assessment of analytical methods during their life cycle.

Release 1 of **NeoLiCy®** specifically addresses the statistical assessment for validation of analytical methods.

Universally accepted

NeoLiCy® is developed with regard to international recommendations and regulations on assessment of analytical methods. It is based on the ICH recommendations (ICH Q2(R1) on method validation, ICH Q8 on Quality by Design, …), EMA, FDA, USP, EP guidelines and ISO standards related to the subject.

A constant technological survey of these guidelines and recommendations is the core of the development specifications for **NeoLiCy®**.
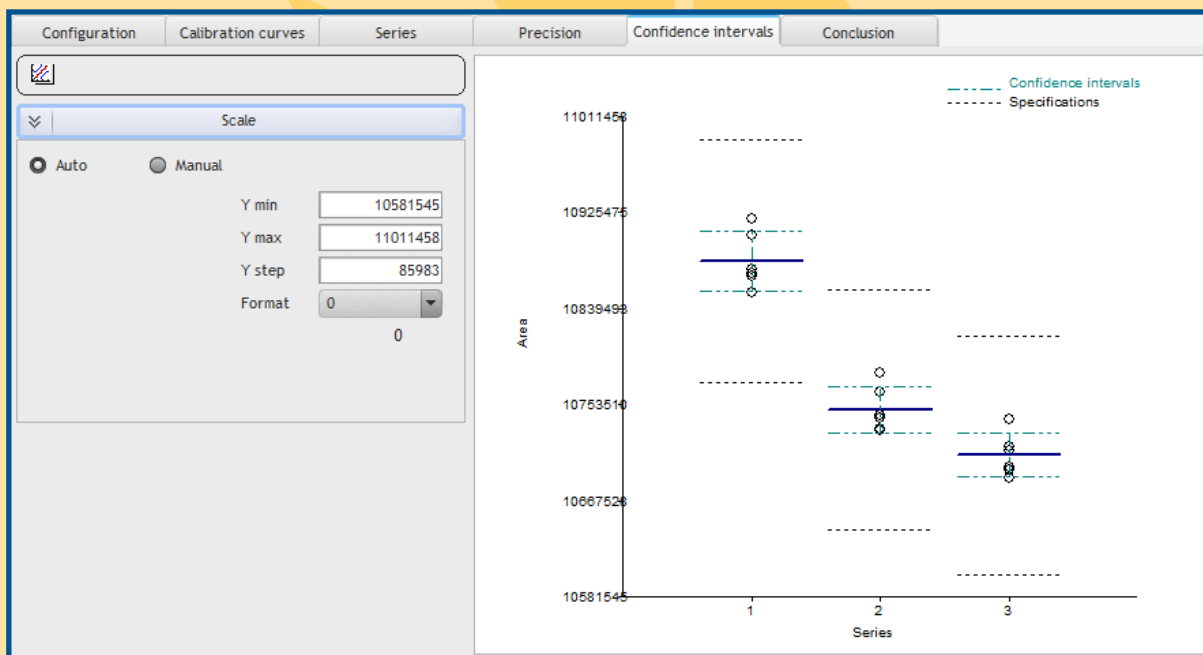
Figure 2: Precision results showing for each series its confidence interval and the chosen specifications

Versatile configuration

NeoLiCy® is a configurable software designed for statistical assessment of any kind of analytical method. It contains ready to use templates related to the configuration of the statistical tests and associated calculations. These templates comply with the guidelines and recommendations for pharmaceutical, cosmetic, agro-foodstuff, environmental and chemical industry. For ease of use these templates are pre-configured and additionally the user may create and save own templates. This high degree of versatility enables **NeoLiCy®** Release 1 to be used for the validation of all analytical procedures in any kind of industrial activity.

Powerful project management

NeoLiCy® database management allows creation of up to five classification levels. The project level is the main classification level; it contains all the data and revisions of the different files, documents and chapters related to the products or compounds in the products. The characteristic level is the final statistical assessment level, dedicated to evaluation of a single characteristic (e.g. a method validation characteristic as precision, accuracy, …).

As some of these classification levels are optional, **NeoLiCy®** provides a high level of flexibility in the content management of projects, allowing the study of several compounds in a single product or several products, the study of analytical methods related to several matrices and so on.

Even the list of characteristics to be assessed for a specific analytical method may be user defined or entered by use of chapter or document templates.

The **NeoLiCy®** user management provides tools to adapt the rights given to each user in project management tasks.
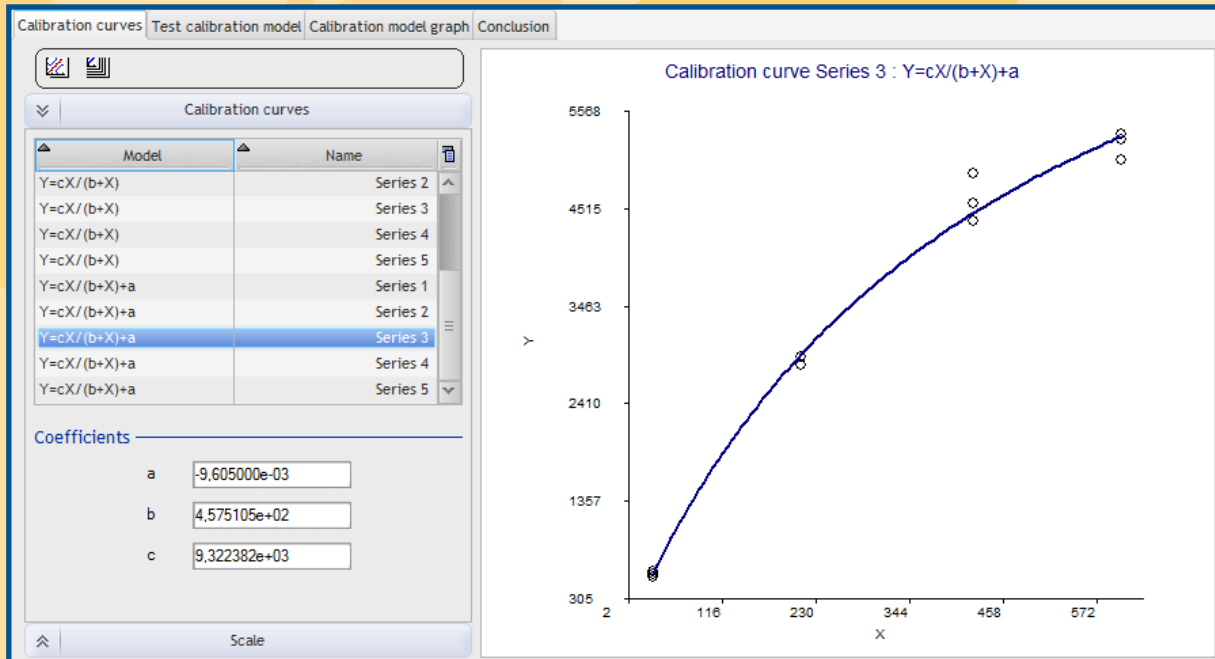
Figure 3: Non-linear response function (here: Michaelis-Menten): assessment of each calibration series

Easy creation of projects and documents

Once a project has been created, the user may apply ready to use document templates containing a set of characteristics to be assessed. Wizards are provided to help the user in building his project. Tables of content may be adapted or modified in order to comply with specific regulations or to the company's procedures for statistical assessment and design of experiments.

Easy data input

Data input in **NeoLiCy®** may be done manually - for security this right is part of the user administration configuration. Moreover, any data can be copied from Microsoft® Excel™ tables.

Automatic calculation

After configuration of the assessment of method characteristics, the user has simply to input his specifications on results, according to the company procedure or any regulation to be applied. Calculations are carried out by a simple click and statistically checked with regard to the applied procedures. The final conclusion on each of the assessed characteristics is proposed to the user by **NeoLiCy®**, providing large spaces for any comments or decisions depending on the calculated results. According to the user rights, the final conclusion on each characteristic can be modified and justified by the user separately.
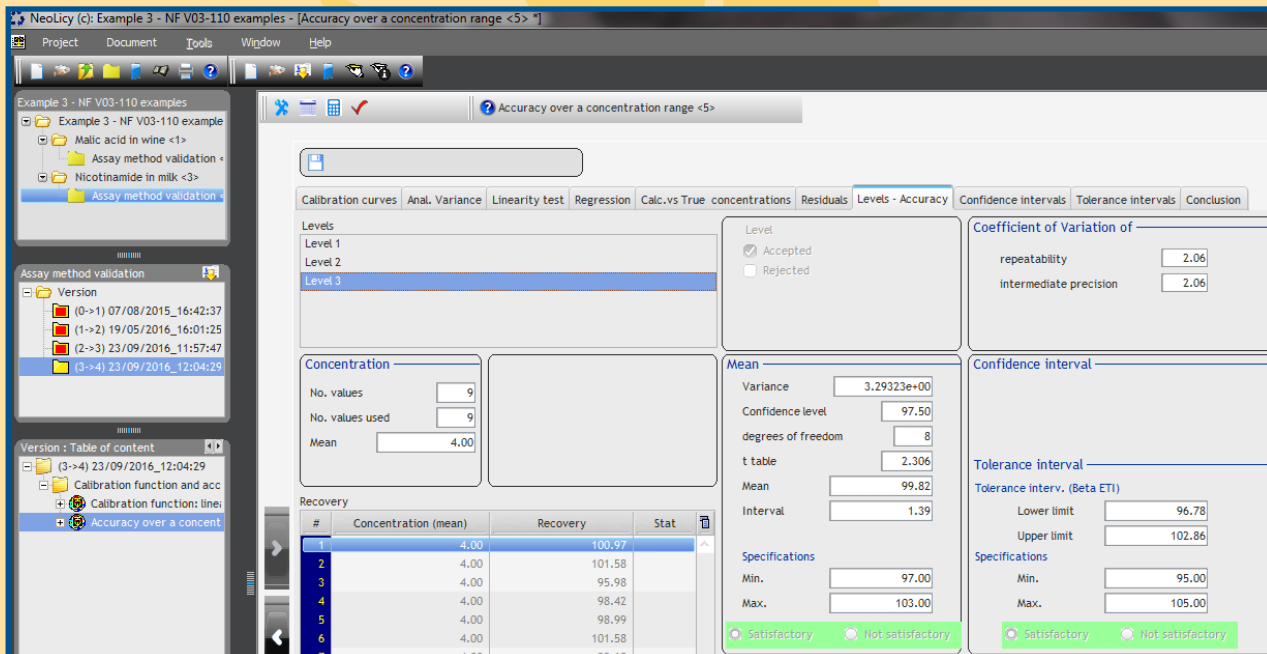
Figure 4: Accuracy over a concentration range: one of the result screens

Automatic report compilation

After input of the comments and decisions, the statistical assessment report is created with only a mouse click. The report may contain data and results from a single characteristic up to results of a full project. Optionally a detailed description of the statistical procedures used can be added. **NeoLiCy®** provides the user with five different ways to create the report:

- A write protected standard NeoLiCy® report
- An Adobe® Acrobat™ pdf file
- A protected Adobe® Acrobat™ pdf file
- A rtf format file, which may be used in any word processor software (text and pictures can be added)
- A html format file

Compliant with international standards

Whatever is the characteristic to be assessed, **NeoLiCy®** has been designed for full compliance with international standards and industry recommendations and regulations. **NeoLiCy®** Release 1 provides statistical assessment of the following characteristics:

- Specificity, according to ICH Q2(R1) recommendations by means of comparison of analytical recordings.
- Precision (ICH Q2(R1) and ISO 5725 compliant), including repeatability, intermediate precision and/or reproducibility.
- LOD and LOQ estimation (ICH Q2(R1) and ISO 11843 compliant), by means of the S/N ratio or calibration curve data.
- Response function assessment: linear, linear through zero, weighted linear, linearized, quadratic or Michaelis-Menten models, by means of back calculated concentrations residuals and/or ANOVA (EMA guideline for Bionalytical Methods Validation, ISO 11843 and NF T90-210 compliant)
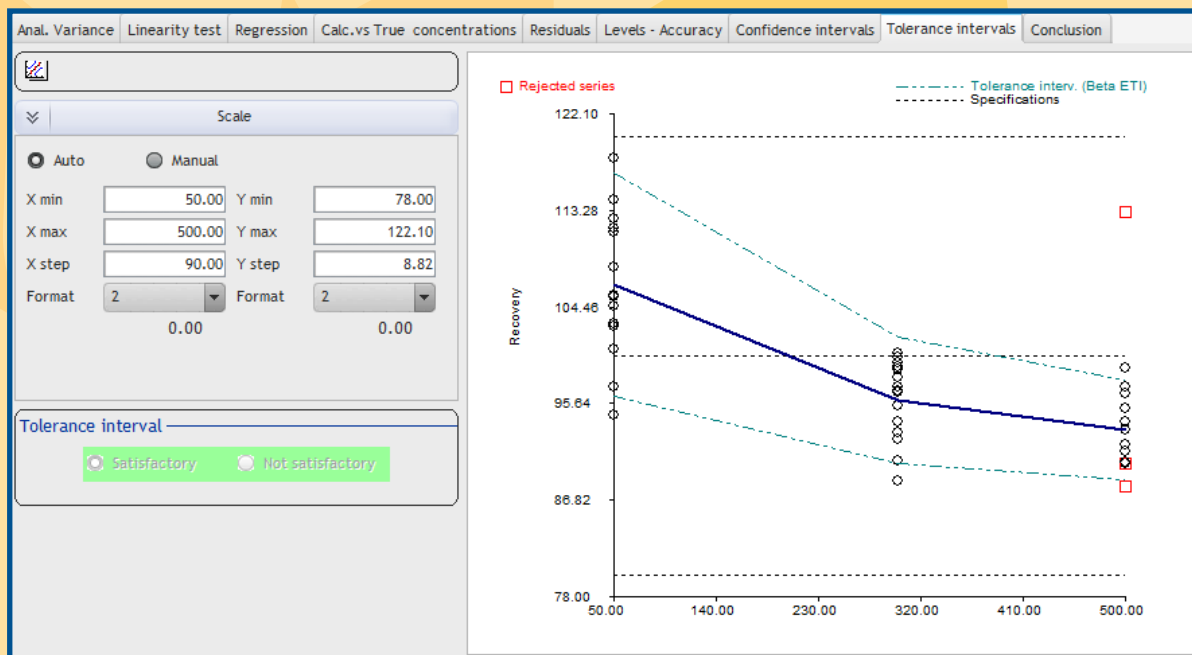
Figure 5: Use of the total error concept in accuracy assessment: calculation of the beta expectation tolerance intervals

- Linearity (ICH Q2(R1) and ISO 11095 or ISO 8466-1 compliant), including linear through zero model and assessment of relative residuals.
- Accuracy over a concentration range (ICH Q2(R1) compliant) by means of assessment of trueness and precision or use of the total error concept (beta expectation tolerance interval and/or ISO 16269-6 compliant).
- Accuracy at a target concentration (ICH Q2(R1) compliant) by means of assessment of trueness and precision or use of the total error concept (ISO 16269-6 compliant).
- Multi-series accuracy or interlaboratory trials (ICH Q2(R1) and ISO 5725 compliant) by means of assessment of trueness and precision.

Validated and fully FDA 21CFR part 11 and EU GMP Annex 11 compliant

NeoLiCy® is validated and the validation certificate is included in the software package. In addition to the operating system security layer, **NeoLiCy®** provides all functions necessary for full FDA 21CFR part 11 and EU GMP Annex 11 compliance:

- IQ and OQ procedures, installed together with the software
- User administration, based on defined user profiles (user rights)
- Audit trails
- Project management by revision
- Electronic signature
- Archiving
- Write protection of the software functions and calculation algorithms
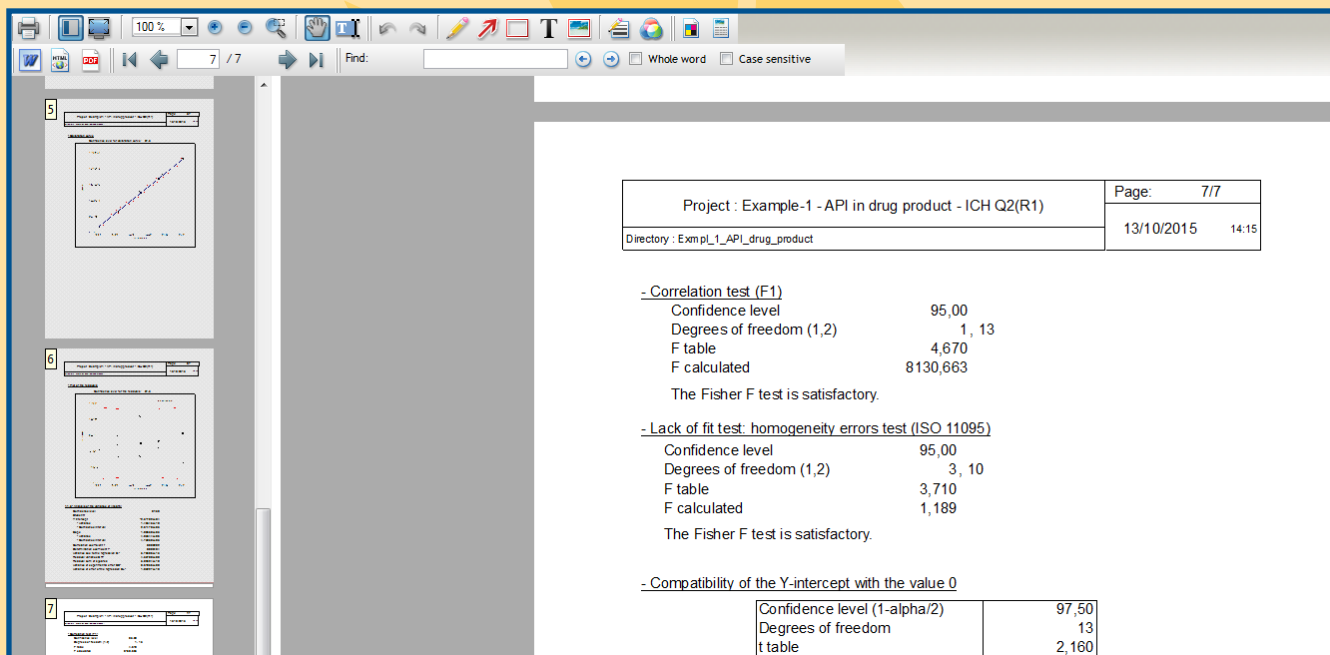- Write protection of the validation report

Figure 6: Report printout preview screen

Flexible installation

NeoLiCy® has been designed to operate in stand-alone or network environments. It supports single desktop/laptop installations, network installations with a database server or full network installations using a terminal server or a Citrix XenApp server.

Substantially time saving

As a comprehensive tool for statistical assessment of analytical methods during their life cycle, **NeoLiCy®** supports the user in the different steps of the statistical assessment procedure. Substantial time savings can be realized by the automatic calculations and compilation of the report.

NeoLiCy® - the time and cost saving tool for statistical assessment of analytical methods can save days or even weeks of work.

Description	Cat. No.
NeoLiCY single user license	908-0075
NeoLiCY multi-user first license	908-0076
NeoLiCy multi-user additional license	908-0077
NeoLiCy package single user software + SMA (1 year)	908-0078
NeoLiCy Support and Maintenance Agreement (1 year)	908-0079
NeoLiCy SMA multi-user first license (1 year)	908-0067
NeoLiCy SMA multi-user additional license (1 year)	908-0068
Update Validation Manager 3 to NeoLiCy single user	908-0069
Update Validation Manager 3 to NeoLiCy multi-user first license	908-0070
Update VM3 to NeoLiCy multi-user additional license	908-0071
NeoLiCy training	on request

NeoLiCy® is a registered trademark of Prof. M. Righezza and Dr. J.M. Roussel

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