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VALIDAT 2005 / Bioassays

Biological Assay Analysis according to Ph. Eur. 4, chapter 5.3

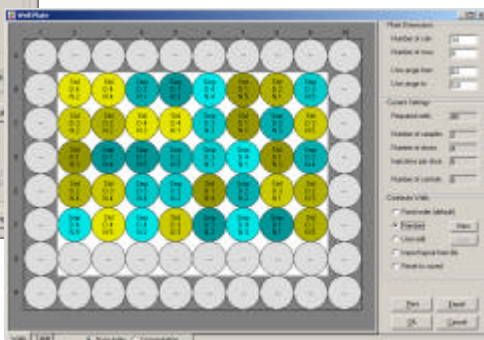
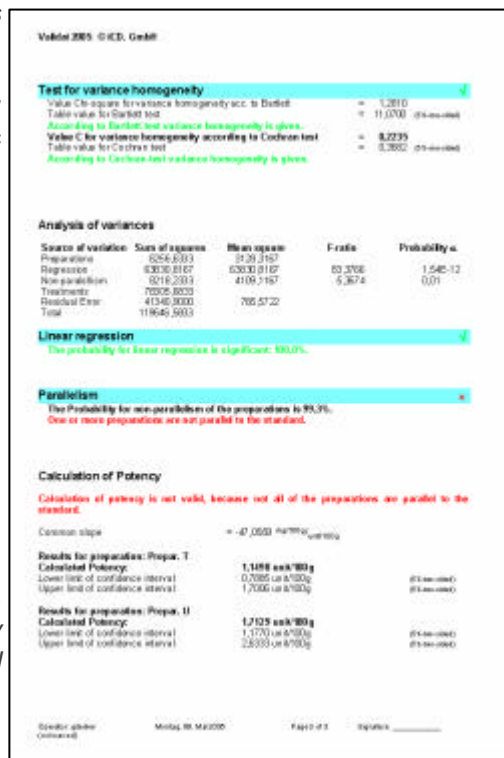
From a well plate layout to a complete report, the **Bioassays** module for **VALIDAT 2005** supports you in planning and executing analysis of parallel line assays. Otherwise extensive tasks are now completed efficiently with the help of a few concise dialogs. Additionally, all advantages from the basic **VALIDAT 2005**, like templates, report layouts, versioned database repository, or a complete audit trail are available to the user.

With little effort, a report reviewing all important requirements from Ph. Eur. 4, chap. 5.3 is created:

- test on normal distribution (Shapiro-Wilk)
- test on homogeneity of variances (Bartlett, Cochran)
- linearity
- parallelism.

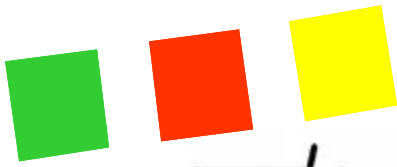
Of course all important values and probabilities, as well as a complete analysis of variances are shown in the report. Common slope, potency and corresponding confidence intervals based on a *completely randomized design* or a *randomized block design* are calculated for every preparation.

If linearity is not given, **VALIDAT 2005** can find a maximum linear range of doses where valid potencies might be calculated. Parameters like a minimum number of doses and inclusion of the 50% response value (central value of the total range of values) are simply adjusted in the planning dialog.



A graphical interface for planning well plate layouts allows a fast random or manual distribution of treatments and doses to wells. For later reuse all layouts can be exported and imported. Even control samples can be included in planning.

Bioassays for **VALIDAT 2005** supports creating a controlled environment for biological assay analysis with reliable results while reducing time, costs and efforts.



Results

Guidelines and regulations

- Analysis of biological assays and tests according to Ph. Eur. 4, chap. 5.3:
- Parallel line assays with completely randomized design
 - Parallel line assays with randomized block design

Tests

- test on normal distribution (Shapiro-Wilk)
- test on variance homogeneity (Bartlett and Wilcoxon)

Calculations

- Analysis of variances as described in Ph. Eur. 4, chap. 5.3: linearity, parallelism, linear regression, blocks (for randomized block design), treatments, preparations, residual error
- mean and coefficients of variation for all doses and preparations
- calculation of common slope and relative potency
- confidence intervals
- configurable levels of significance (95% / 99%) for linearity, parallelism and regression
- configurable confidence intervals (1% two sided / 5% two sided)
- configurable tests on normal distribution and variance homogeneity (1% one sided / 5% one sided)
- automatic determination of a linear range of doses with optional inclusion of 50% response.

Documentation

Reporting

- Output of all input data with optional control samples
- Output of calculation, including mean, coefficients of variation, common slope, relative potency, confidence intervals
- Enable or disable output of analysis of variances, variance homogeneity, test on normal distribution
- optional graphic in report
- optional output of well plate layouts
- comments, header data, footer, report header and layouts as known from **VALIDAT 2005**

Graphics

- all values and linear regressions with a logarithmic X-axis
- graphical display of well plate layout

Formulas

Optionally, the whole set of used formulas can be attached to the report for documentation purposes.

Integration

Complete integration as a new checkpoint in **VALIDAT 2005** with the following benefits:

- **Security:** user management; login; digital Signatures; complete audit trail; document management system; database servers; etc.
- **Versatility:** English and German reports; several layouts; export to Microsoft Word, RTF, HTML or PDF; comments; data input manual, by clipboard and directly from an Excel or text file; etc.
- **Flexibility:** configurable calculations and reporting; adaptation of corporate identity; data can be stored in local files, on Oracle or MS-SQL database servers; installation in networks and for terminal server; etc.

User Interface

- Graphical planning dialog for well plate: random distribution, manual edit, import/export.
- Concise planning dialog: Standard and preparations with titles, units, individual header data, number of doses and treatments, dilution ratio, design typ, etc.
- data input in Excel like data grid with clip board and import functionality