

WITHDRAWAL-TIME CALCULATION PROGRAM

WT1.4

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1 Introduction

The program WT1.4 was developed in order to provide a users-friendly tool for using the statistical method for the calculation of withdrawal-times as developed by Germany and adopted by CVMP. For a detailed description of that method, reference is made to the EU Note of Guidance entitled: “Considerations on establishing withdrawal periods” (1996).

The program WT1.4 is merely a computer-translation of the method described in this Note of Guidance, and is not a new method of its own.

This newest release of the program is an upgrade to a 32-bits version. This upgrade was necessary in order meet the requirements of the newer 32-bits systems (e.g. windows 2000/windows XP). Although nothing was changed in the calculation-algorithm, the graphical design is renewed. A minor bug in the printing routines was also corrected.

2 Program installation

1. Run Setup.exe this will install the program and necessary files into a directory on your harddisk(e.g. C:\WT1)
2. Double click on the WT1.4 icon to start the program

3 Abbreviations and symbols

GTOT	total number of groups
NTOT	total number of animals
SSPE	sum of squares due to variability within the groups ($MSPE=SSPE/(NTOT-GTOT)$)
SSREG	sum of squares due to regression
SSLOF	sum of squares due to lack of fit ($MSLOF= SSLOF/(GTOT-2)$)
SXY	residual error
EXP(CPT)	calculated concentration at time =zero (intercept of the regression-line)
LK	calculated slope of the regression-line
CORR	calculated correlation coefficient
F-test	test for log-linearity of the data-set ($p>0.05$ indicates the validity of the used model)
Cochran-test	test for homogeneity of variances ($p>0.05$ indicates the validity of the used model)
Bartlett-test	test for homogeneity of variances ($p>0.05$ indicates the validity of the used model)
Shapiro/Wilk	test for normality of the calculated residuals ($p>0.10$ indicates the validity of the used model)
MRL	maximum residue limit
WT	withdrawal-time

4 Running the program

4.1 start/ exit

After double-clicking on the WT1.4 icon the program starts and the opening-screen will appear.

To continue: press the *continue*-button

After using the program exiting the program is possible via selecting *file > exit* from the menu-bar in the results-screen.

4.2 making/saving a new data set

- Select *file-> newfile* from the menu-bar (the first input screen will appear)
- Enter the appropriate data (number groups=2-7 / animals/group=2-15)
- Check the data (by simply clicking on the appropriate box and then altering the data)
- press **OK** (The next input screen will appear)
- Enter the times and concentrations (a zero or less concentration is not allowed)
- Check the data (by simply clicking on the appropriate box and then altering the data)
- Press **OK**
- Save the data-file under a name of choice (the extension must be “.WT”)

4.3 opening an existing data-set

As examples you did copy a number of data-sets (BGFAT.WT, BGLIV.WT, BGINJ.WT and TOTAL.WT) into your working-directory.

- Select *file-> open file* from the menu-bar (a list box with available data-sets will appear)
- Browse to and double click on the data-set of your choice
- The data-file will be read and the data will appear on your preview screen.

4.4 analysing a data set

- create a new data-set or open a existing data-set
- click on the **Set> MRL**-menu option and enter the appropriate value of the MRL
- chose a confidence interval (standard setting 95%) by clicking on the level of choice
- click on the **Analyse**-menu option (the results of the analysis will appear on your screen)
- next you can make various plots appear by clicking on the appropriate menu option.
 - 1- **Show >plot graph** provides a concentration.-time plot (semi-logarithmical), showing the data-points, the regression-line, the line of upper-confidence (95% or 99%), and the withdrawal-time.
 - 2- **Show >plot dev** provides a plot of the residuals (standardised by the residual error SXY) versus time.
 - 3- **Show >prob plot** provides a plot of the ordered residuals (standardised by the residual error SXY) versus their cumulative frequency on a normal probability scale

note 1:

If you want to re-analyse the data-set with another MRL and/or another confidence-level you only have to adjust the values (by pressing set MRL and/or confidence) and then analyse the data-set again (MRL-values of zero or less will not be accepted).

note 2:

If a value for Withdrawal time of -1 is displayed (indicating that the WT > 30) you have to adjust the TMAX value by selecting TMAX from the menu-bar and entering the new value of your choice, and then analysing the data-set again (TMAX values of zero or smaller will not be accepted)

note 3:

*If you want to return from a plot-screen to the results-screen, simply press **BACK** on the menu-bar*

4.5 show/change dataset

4.5.1 show/print data set

In order to print a data-set on your printer select *print>print file* on the menu-bar of the results-screen (if necessary) from the menu-bar select **PRINT > PRINT SETUP** for selecting the printer of your choice

In order to show and/or change the current data-set :

-create a new data-set or open a existing data-set

-select *file > show/change file* from the menu-bar in the results-screen (the data-input screen will appear)

-press the **OK**-button or the **CANCEL**-button (saving is not needed) for returning to the results-screen

Note

In the input screen you may change data if necessary (do not forget to save the data-set after changing)

4.5.2 delete animal/delete group

In order to delete an entire group of just an animal:

-create a new data-set or open a existing data-set

-select *file > show/change file* from the menu-bar in the results-screen (the data-input screen will appear)

- from the menu-bar select **DELETE DATA > DELETE GROUP** or **DELETE ANIMAL**

- enter the group number (**DELETE GROUP**) or group number and in the next inputbox the animal number (**DELETE ANIMAL**) (the data-set will be modified on screen)

-after checking the data press **OK**-button to save (you may save the modified data-set under a different name).

-the program will return to the results-screen

4.5.3 add animal/add group

In order to add an entire group of just an animal:

- create a new data-set or open a existing data-set
- select **file** > **show/change file** from the menu-bar in the results-screen (the data-input screen will appear)
- from the menu-bar select **ADD DATA> ADD GROUP** or **ADD ANIMAL**
- enter group number (**ADD ANIMAL**) (the data-set will be modified on screen)
- enter the appropriate data
- after checking the data press **OK**-button to save (you may save the modified data-set under a different name).
- the program will return to the results-screen

4.5.4 change titles

In order to change the titles of a data-set (EXP NO: DATE etc):

- open a existing data-set
- select **file** > **change titles** from the menu-bar in the results-screen (the titles-input screen will appear)
- enter the changed titles in the appropriate boxes
- after checking the data press **OK**-button to save .
- the program will return to the results-screen

4.6 adjusting/printing plots

- For printing of a plot simply select **print** on the menu-bar of the appropriate plot-screen

4.6.1 adjusting the x/y-axis of the plot-graph and the x-axis of the plot-devs

- select **SCALES** > **x-max** or, **y-max** from the menu-bar of the appropriate plot-screen
- enter the new value of xmax or ymax

(note: the ymax value must be given as the 10 log of the maximum concentration, since the scale is a logarithmical one)

4.6.2 adding text to the plot-graph

- select **TEXT** > *text x-axis, text y-axis or text centre* from the menu-bar of the appropriate plot-screen
- enter the text

4.7 printing reports

- A report of the analysis can be printed by simply selecting **print** > *print report* from the menu-bar in the results- screen.

5 References

1. CVMP note of Guidance: Considerations on establishing withdrawal periods (1996)