

Package ‘stab’

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Title data analysis of drug stability for shelf life estimation

Author Hsin-ya Lee, Yung-jin Lee <mobilePK@gmail.com>

Maintainer Yung-jin Lee <mobilePK@gmail.com>

Depends R (>= 2.10.0), stats4, MASS, reshape

Description data analysis of drug stability (shelf life estimation) based on ICH Q1E guideline.

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URL <http://pkpd.kmu.edu.tw/stability>

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bye

The final step Menu

Description

Try again or Leave stab package.

decisiontree

*Decision Tree for Data Evaluation for Retest Period os Shelf Life Es-
timation*

Description

Decision Tree for Data Evaluation for Retest Period os Shelf Life Estimation for Drug Substances or Product (excluding Frozen)

demostability

Demo file for three batch

Description

This is a demo file. First, the stability data is fitted with ANCOVA. The result in this example shows that the test rejects the hypothesis of equality of slopes (there is a significant difference in slopes among batches).

go

List of Stability Menu

Description

You can start a new project or see the demo file.

MultipleAnalyze

Data Analysis for Multiple Batches

Description

The following steps will be conducted as follows:

step1. ANCOVA can be employed to test the difference in slopes and intercepts of the regression lines among factors and factor combinations. step2. Based on the statistical results, it can divide into three parts. -> slope ($P \geq 0.25$) and intercept ($P \geq 0.25$) The tests for equality of slopes and equality of intercepts do not result at a level of significance of 0.25 (there is no significant difference in slope and intercepts among the batches). The data from all batches can be combined. -> slope ($P \geq 0.25$) and intercept ($P < 0.25$) The test rejects the hypothesis of equality of intercepts but fails to reject that the slopes are equal (there is a significant difference in intercepts but no significant difference in slopes among the batches). The data can be combined for the purpose of estimating the common slope. -> (slope ($P < 0.25$) and intercept ($P \geq 0.25$)) or (slope ($P < 0.25$) and intercept ($P < 0.25$)) The result in this example shows that the test rejects the hypothesis of equality of slopes (there is a significant difference in slopes among batches). It is not considered appropriate to combine the data from all batches. step3. The shelf life will be estimated.

MultipleBatchcsv

choose separator and decimal type

Description

Separator : comma, semicolon ,white space. Decimal: comma, point.

MultipleBatchmenu

Menu for Data input for Multiple Batches

Description

Input assay data for Data Analysis for Multiple Batches

SingleAnalyze

Data Analysis for a Single Batch

Description

This function is to estimate the shelf life for a Single Batch.

SingleBatchcsv	<i>choose separator and decimal type</i>
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Description

Separator : comma, semicolon ,white space. Decimal: comma, point.

SingleBatchmenu	<i>Menu for Data input for a single Batch</i>
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Description

Input assay data for Data Analysis for a single Batch

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Description

List of Stability Menu

statistical	<i>Menu for Data Analysis for a Single Batch or Data Analysis for multiple Batches</i>
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Description

Menu for Data Analysis for a Single Batch or Data Analysis for multiple Batches

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