Package ‘T2EQ’

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Type Package

Title Functions for Applying the T^2-Test for Equivalence

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Description Contains functions for applying the T^2-test for equivalence.

The T^2-test for equivalence is a multivariate two-sample equivalence test.
Distance measure of the test is the Mahalanobis distance.
For multivariate normally distributed data the T^2-test for equivalence is exact and UMPI.
The function T2EQ() implements the T^2-test for equivalence according to Wellek (2010) <DOI:10.1201/ebk1439808184>.
The function T2EQ.dissolution.profiles.hoffelder() implements a variant of the T^2-test for equivalence according to Hoffelder (2016) <http://www.ecv.de/suse_item.php?suseId=Z|p1|8430> for the equivalence comparison of highly variable dissolution profiles.

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Description

Contains functions for applying the $T^2$-test for equivalence. The $T^2$-test for equivalence is a multivariate two-sample equivalence test. Distance measure of the test is the Mahalanobis distance. For multivariate normally distributed data the $T^2$-test for equivalence is exact and UMPI. The function T2EQ() implements the $T^2$-test for equivalence according to Wellek (2010). The function T2EQ.dissolution.profiles.hoffelder() implements a variant of the $T^2$-test for equivalence according to Hoffelder (2016) for the equivalence comparison of highly variable dissolution profiles.

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Author(s)

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References


Examples

## Not run: A recalculation of the example evaluation in Hoffelder et al. (2015)
can be done with the following code:
## End(Not run)

data(ex_data_JoBS)
REF_JoBS <- cbind(ex_data_JoBS[ which(ex_data_JoBS$Group=="REF"), ]
    [c("Diss_15_min","Diss_20_min","Diss_25_min")])
TEST_JoBS <- cbind(ex_data_JoBS[ which(ex_data_JoBS$Group=="TEST"), ]
    [c("Diss_15_min","Diss_20_min","Diss_25_min")])
equivalence_margin_JoBS <- 0.74^2
test_T2EQ_JoBS <- T2EQ(X=REF_JoBS,Y=TEST_JoBS,eq_margin = equivalence_margin_JoBS)

## Not run: A recalculation of the results underlying Figure 1 in Hoffelder (2016)
can be done with the following code:
## End(Not run)

data(ex_data_pharmind)
REF_pharmind <- cbind(ex_data_pharmind[ which(ex_data_pharmind$Group=="REF"), ]
    [c("Diss_10_min","Diss_20_min","Diss_30_min")])
TEST_pharmind <- cbind(ex_data_pharmind[ which(ex_data_pharmind$Group=="TEST"), ]
    [c("Diss_10_min","Diss_20_min","Diss_30_min")])
test_T2EQ.dissolution.profiles.hoffelder_pharmind <-
    T2EQ.dissolution.profiles.hoffelder(X=REF_pharmind,Y=TEST_pharmind)

---

ex_data_JoBS

Example dataset from Hoffelder et al. (2015)

Description

Multivariate example dataset of dissolution profiles. Dataset consists of two three-dimensional
samples. The names of the three variables are "Diss_15_min","Diss_20_min" and "Diss_25_min". Variable "Group" discriminates between first sample (Group == "REF") and second sample (Group == "Test"). Sample size is 12 per group.

Usage

data("ex_data_JoBS")

Format

A data frame with 24 observations on the following 4 variables.

Group  a factor with levels REF TEST
Diss_15_min  a numeric vector
Diss_20_min  a numeric vector
Diss_25_min  a numeric vector
Details

Example dataset from Hoffelder et al. (2015).

Source


References

URL: [http://dx.doi.org/10.1080/10543406.2014.920344](http://dx.doi.org/10.1080/10543406.2014.920344)

Examples

```r
data(ex_data_JoBS)
```

---

**ex_data_pharmind**

*Example dataset from Hoffelder (2016)*

Description

Multivariate example dataset of dissolution profiles. Dataset consists of two three-dimensional samples. The names of the three variables are "Diss_10_min"; "Diss_20_min" and "Diss_30_min". Variable "Group" discriminates between first sample (Group == "REF") and second sample (Group == "Test"). Sample size is 12 per group.

Usage

```r
data("ex_data_pharmind")
```

Format

A data frame with 24 observations on the following 4 variables.

- **Diss_10_min** a numeric vector
- **Diss_20_min** a numeric vector
- **Diss_30_min** a numeric vector
- **Group** a character vector

Details

Example dataset underlying Figure 1 in Hoffelder (2016).

Source

T2EQ

References
URL: http://www.ecv.de/suse_item.php?useId=Z|pi|8430

Examples

```r
data(ex_data_pharmind)
```

**T2EQ**

Function for applying the $T^2$-test for equivalence

**Description**

The function T2EQ() implements the $T^2$-test for equivalence (see Wellek, 2010 or Hoffelder et al., 2015). The $T^2$-test for equivalence is a multivariate two-sample equivalence test. Distance measure of the test is the Mahalanobis distance.

**Usage**

T2EQ(X, Y, eq_margin, alpha = 0.05, print.results = TRUE)

**Arguments**

- `X`: numeric data matrix of the first sample. The rows of `X` contain the individual observations of the sample, the columns contain the variables/components of the multivariate sample.
- `Y`: numeric data matrix of the second sample. The rows of `X` contain the individual observations of the sample, the columns contain the variables/components of the multivariate sample.
- `eq_margin`: numeric (>0). The equivalence margin of the test.
- `alpha`: numeric (0<alpha<1). The significance level of the $T^2$-test for equivalence. Usually set to 0.05 which is the default.
- `print.results`: logical; if TRUE (default) summary statistics and test results are printed in the output. If NO no output is created.

**Details**

For multivariate normally distributed data the $T^2$-test for equivalence is exact and UMPI.

**Value**

- a data frame; three columns containing the results of the test
  - `p.value`: numeric; the p-value of the $T^2$-test for equivalence
  - `testresult.num`: numeric; 0 (null hypothesis of nonequivalence not rejected) or 1 (null hypothesis of nonequivalence rejected, decision in favor of equivalence)
  - `testresult.text`: character; test result of the $T^2$-test for equivalence in text mode
Author(s)

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References


Examples

```r
## Not run: A recalculation of the example evaluation in Hoffelder et al. (2015)
can be done with the following code:
## End(Not run)

data(ex_data_JOBS)
REF_JOBS <- cbind(ex_data_JOBS[ which(ex_data_JOBS$Group=='REF' ), ]
[c("Diss_15_min","Diss_20_min","Diss_25_min")])
TEST_JOBS <- cbind(ex_data_JOBS[ which(ex_data_JOBS$Group=='TEST' ), ]
[c("Diss_15_min","Diss_20_min","Diss_25_min")])
equivalence_margin_JOBS <- 0.74^2
test_T2EQ_JOBS <- T2EQ(X=REF_JOBS,Y=TEST_JOBS,eq_margin = equivalence_margin_JOBS)
```

Description

The function T2EQ.dissolution.profiles.hoffelder() implements a variant of the $T^2$-test for equivalence analyses of highly variable dissolution profiles (see Hoffelder, 2016). It is a multivariate two-sample equivalence procedure. Distance measure of the test is the Mahalanobis distance.

Usage

```
T2EQ.dissolution.profiles.hoffelder(X, Y, alpha = 0.05, print.results = TRUE)
```

Arguments

- **X** numeric data matrix of the first sample (REF). The rows of X contain the individual observations of the REF sample, the columns contain the variables/components of the multivariate sample. More precisely, the variables are the measured dissolution time points and the rows contain the individual dissolution profiles.
Y numeric data matrix of the second sample (TEST). The rows of Y contain the individual observations of the TEST sample, the columns contain the variables/components of the multivariate sample. More precisely, the variables are the measured dissolution time points and the rows contain the individual dissolution profiles.

alpha numeric (0<alpha<1). The significance level of the test. Usually set to 0.05 which is the default.

print.results logical; if TRUE (default) summary statistics and test results are printed in the output. If NO no output is created

Details
This function implements a variant of the $T^2$-test for equivalence suggested in Hoffelder (2016): The equivalence margin of the test is a compromise between the suggestions of Tsong et al. (1996) and EMA (2010) requirements. See Hoffelder (2016) for a discussion on that equivalence margin.

Value
a data frame; three columns containing the results of the test

p.value numeric; the p-value of the equivalence test according to Hoffelder (2016)
testresult.num numeric; 0 (null hypothesis of nonequivalence not rejected) or 1 (null hypothesis of nonequivalence rejected, decision in favor of equivalence)
testresult.text character; test result of the test in text mode

Author(s)
Thomas Hoffelder <thomas.hoffelder at boehringer-ingelheim.com>

References


Examples
## Not run: A recalculation of the results underlying Figure 1 in Hoffelder (2016)
can be done with the following code:
## End(Not run)
data(ex_data_pharmind)

REF_pharmind <- cbind(ex_data_pharmind[ which(ex_data_pharmind$Group=='REF'), ]

TEST_pharmind <- cbind(ex_data_pharmind[ which(ex_data_pharmind$Group=='TEST'), ]

test_T2EQ.dissolution.profiles.hoffelder_pharmind <-
T2EQ.dissolution.profiles.hoffelder(X=REF_pharmind, Y=TEST_pharmind)
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