Package 'NonCompart'

December 21, 2016

Date	2016-12-20
Title	Noncompartmental Analysis for Pharmacokinetic Data
Descr	ription Conduct a noncompartmental analysis as closely as possible t
	mercial software for pharmacokinetic analysis, i.e. 'Phoenix(R) Winl

to the most widely used com-

lin(R)' https://www.certara.com/software/pkpd-modeling-and-simulation/phoenix-winnonlin/>. Some features include:

1) Use CDISC SDTM PP domain terms.

Version 0.2.5

- 2) Automatic slope selection with the same criterion of WinNonlin(R)
- 3) Support both 'linear-up linear-down' and 'linear-up log-down' method
- 4) Calculate partial(interval) AUC with 'linear' or 'log' interpolation method

For more details on noncompartmental analysis, see the reference: Gabriels-

- son J, Weiner D. Pharmacokinetic and Pharmacodynamic Data Analysis Concepts and Applications. 5th ed. 2016. (ISBN:9198299107)
- *) Acknowledgement: Author thanks for the careful review and valuable input of Dr. Jee Eun Lee.

Depends R (>= 2.0.0) Author Kyun-Seop Bae Maintainer Kyun-Seop Bae <k@acr.kr> Copyright 2016, Kyun-Seop Bae License GPL-3 NeedsCompilation no LazyLoad yes Repository CRAN

URL https://cran.r-project.org/package=NonCompart

R topics documented:

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Slope

NonCompart-package

Noncompartmental Analysis for Pharmacokinetic Data

Description

It conducts a noncompartmental analysis(NCA) as closely as possible to the most widely used commercial pharmacokinetic analysis software.

Details

The main functions are

```
NCA to perform NCA for many subjects.

IndiNCA to perform NCA for one subject.
```

Acknowledgement

Author thanks for the careful review and valuable input of Dr. Jee Eun Lee.

Author(s)

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References

- 1. Gabrielsson J, Weiner D. Pharmacokinetic and Pharmacodynamic Data Analysis Concepts and Applications. 5th ed. 2016.
- 2. Shargel L, Yu A. Applied Biopharmaceutics and Pharmacokinetics. 7th ed. 2015.
- 3. Rowland M, Tozer TN. Clinical Pharmacokinetics and Pharmacodynamics Concepts and Applications. 4th ed. 2011.
- 4. Gibaldi M, Perrier D. Pharmacokinetics. 2nd ed. revised and expanded. 1982.

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```
"Theoph_Log_CoreOutput.txt")
writeLines(NCA(Indometh, "Subject", "time", "conc", Dose=25, AdmMode="Bolus", Report="Text"),
           "Indometh_Bolus_Linear_CoreOutput.txt")
writeLines(NCA(Indometh, "Subject", "time", "conc", Dose=25, AdmMode="Bolus", Method="Log",
           Report="Text"), "Indometh_Bolus_Log_CoreOutput.txt")
writeLines(NCA(Indometh, "Subject", "time", "conc", Dose=25, AdmMode="Infusion", TimeInfusion=0.25,
           Report="Text"), "Indometh_Infusion_Linear_CoreOutput.txt")
writeLines(NCA(Indometh, "Subject", "time", "conc", Dose=25, AdmMode="Infusion", TimeInfusion=0.25,
           Method="Log", Report="Text"), "Indometh_Infusion_Log_CoreOutput.txt")
IndiNCA(Theoph$Subject==1, "Time"], Theoph[Theoph$Subject==1, "conc"], Dose=320)
IndiNCA(Indometh[Indometh$Subject==1, "time"], Indometh[Indometh$Subject==1, "conc"], Dose=25,
        AdmMode="Bolus")
IndiNCA(Indometh[Indometh$Subject==1, "time"], Indometh[Indometh$Subject==1, "conc"], Dose=25,
        AdmMode="Infusion", TimeInfusion=0.25)
IndiNCA(Theoph[Theoph$Subject==1,"Time"], Theoph[Theoph$Subject==1, "conc"], Dose=320,
        Report="Text")
IndiNCA(Indometh[Indometh$Subject==1, "time"], Indometh[Indometh$Subject==1, "conc"], Dose=25,
        AdmMode="Bolus", Report="Text")
IndiNCA(Indometh[Indometh$Subject==1, "time"], Indometh[Indometh$Subject==1, "conc"], Dose=25,
        AdmMode="Infusion", TimeInfusion=0.25, Report="Text")
iAUC = data.frame(Name=c("AUC[0-12h]", "AUC[0-24h]"), Start=c(0,0), End=c(12,24)); iAUC
IndiNCA (The oph [The oph $Subject == 1, "Time"], \ The oph [The oph $Subject == 1, "conc"], \ Dose = 320, \\
        iAUC=iAUC)
IndiNCA(Indometh[Indometh$Subject==1, "time"], Indometh[Indometh$Subject==1, "conc"], Dose=25,
        AdmMode="Bolus", iAUC=iAUC)
IndiNCA(Indometh[Indometh$Subject==1, "time"], Indometh[Indometh$Subject==1, "conc"], Dose=25,
        AdmMode="Infusion", TimeInfusion=0.25, iAUC=iAUC)
```

AUC

Calculate Area Under the Curve (AUC) and Area Under the first Moment Curve (AUMC) in a table format

Description

Calculate Area Under the Curve(AUC) and the first Moment Curve(AUMC) in two ways; 'linear trapezoidal method' or 'linear-up and log-down' method. Return a table of cumulative values.

Usage

```
AUC(x, y, Method = "Linear")
```

Arguments

x vector values of independent variable, usually time
 y vector values of dependent variable, usually concentration
 Method either of "Linear" or "Log" to indicate the way to calculate AUC and AUMC

Details

Method="Linear" means linear trapezoidal rule with linear interpolation. Method="Log" means linear-up and log-down method.

4 BestSlope

Value

Table with two columns, AUC and AUMC; the first column values are cumulative AUCs and the second column values cumulative AUMCs.

Author(s)

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References

Rowland M, Tozer TN. Clinical Pharmacokinetics and Pharmacodynamics - Concepts and Applications. 4th ed. pp687-689. 2011.

See Also

LinAUC,LogAUC

Examples

```
AUC(Theoph[Theoph$Subject==1, "Time"], Theoph[Theoph$Subject==1, "conc"]) \# Default is "Linear" \\ AUC(Theoph[Theoph$Subject==1, "Time"], Theoph[Theoph$Subject==1, "conc"], Method="Log")
```

BestSlope

Choose best fit slope for the log(y) and x regression by the criteria of adjusted R-square

Description

It sequentially fits $(\log(y) \sim x)$ from the last point of x to the previous points with at least 3 points. It chooses a slope the highest adjusted R-square. If the difference is less then 1e-4, it chooses longer slope.

Usage

```
BestSlope(x, y, AdmMode = "Extravascular")
```

Arguments

x vector values of x-axis, usually time

y vector values of y-axis, usually concentration

AdmMode one of "Bolus" or "Infusion" or "Extravascular" to indicate drug adminis-

tration mode

Details

Choosing the best terminal slope (y in log scale) in pharmacokinetic analysis is somewhat challenging, and it could vary by analysis performer. Currently this function uses ordinary least square method(OLS) only.

IndiNCA 5

Value

R2	R-squared
----	-----------

R2ADJ adjusted R-squared

LAMZNPT number of points used for slope
LAMZ negative of slope, lambda_z
b0 intercept of regression line
CORRXY correlation of log(y) and x
LAMZLL earliest x for lambda_z
LAMZUL last x for lambda_z

CLSTP predicted y value at last point, predicted concentration for the last time point

Author(s)

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See Also

Slope

Examples

IndiNCA

Noncompartmental Analysis for an Individual

Description

It performs a noncompartmental analysis with one subject data

Usage

Arguments

x vector values of independent variable, usually timey vector values of dependent variable, usually concentration

Dose administered dose for the subject

Method either of "Linear" or "Log" to indicate the way to calculate AUC and AUMC AdmMode one of "Bolus" or "Infusion" or "Extravascular" to indicate drug adminis-

tration mode

TimeInfusion infusion duration for constant infusion, otherwise 0

RetNames character vector for the pharmacokinetic parameter names to be returned

Report either of "Table" or "Text" to specify the type of return value

iAUC data.frame with three columns, "Name", "Start", "End" to specify the invervals

for partial (interval) AUC

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Details

This performs a noncompartmental analysis for a subject. It returns practically the same result with the most popular commercial software.

Value

CMAX	maximum concentration, Cmax
CMAXD	dose normalized Cmax, CMAX / Dose, Cmax / Dose
TMAX	time of maximum concentration, Tmax
TLAG	time to observe the first non-zero concentration, for extravascular administration only
CLST	last positive concentration observed, Clast
CLSTP	last positive concentration predicted, Clast_pred
TLST	time of last positive concentration, Tlast
LAMZHL	half-life by lambda z, ln(2)/LAMZ
LAMZ	lambda_z negative of best fit terminal slope
LAMZLL	earliest time for LAMZ
LAMZUL	last time for LAMZ
LAMZNPT	number of points for LAMZ
CORRXY	correlation of log(concentration) and time
R2	R-squared
R2ADJ	R-squared adjusted
C0	back extrapolated concentration at time 0, for bolus intravascular administration only
AUCLST	AUC from 0 to TLST
AUCALL	AUC using all the given points, including trailing zero concentrations
AUCIFO	AUC infinity observed
AUCIFOD	AUCIFO / Dose
AUCIFP	AUC infinity predicted using CLSTP instead of CLST
AUCIFPD	AUCIFP / Dose
AUCPEO	AUC % extrapolation observed
AUCPEP	AUC % extrapolated for AUCIFP
AUCPBEO	AUC % back extrapolation observed, for bolus IV administration only
AUCPBEP	$AUC\ \%$ back extrapolation predicted with AUCIFP, for bolus IV administration only
AUMCLST	AUMC to the TLST
AUMCIFO	AUMC infinity observed using CLST
AUMCIFP	AUMC infinity determined by CLSTP
AUMCPEO	AUMC % extrapolated observed
AUMCPEP	AUMC % extrapolated predicted
MRTIVLST	mean residence time (MRT) to TLST, for intravascular administration
MRTIVIFO	mean residence time (MRT) infinity using CLST, for intravascular administra-

tion

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MRTIVIFP	mean residence time (MRT) infinity using CLSTP, for intravascular administration
MRTEVLST	mean residence time (MRT) to TLST, for extravascular administration
MRTEVIFO	mean residence time (MRT) infinity using CLST, for extravascular administration
MRTEVIFP	mean residence time (MRT) infinity using CLSTP, for extravascular administration $% \left(\frac{1}{2}\right) =\frac{1}{2}\left(\frac{1}{$
VZO	volume of distribution determined by LAMZ and AUCIFO, for intravascular administration
VZP	volume of distribution determined by LAMZ and AUCIFP, for intravascular administration
VZFO	VZO for extravascular administration, VZO/F, F is bioavailability
VZFP	VZP for extravascular administration, VZP/F, F is bioavailability
CLO	clearance using AUCIFO, for intravascular administration
CLP	clearance using AUCIFP, for intravascular administration
CLF0	CLO for extravascular administration, CLO/F, F is bioavailability
CLFP	CLP for extravascular administration, CLP/F, F is bioavailability
VSS0	volume of distribution at steady state using CLST, for intravascular administration only
VSSP	volume of distribution at stead state using CLSTP, for intravascular administration only

Author(s)

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References

- 1. Gabrielsson J, Weiner D. Pharmacokinetic and Pharmacodynamic Data Analysis Concepts and Applications. 5th ed. 2016.
- 2. Shargel L, Yu A. Applied Biopharmaceutics and Pharmacokinetics. 7th ed. 2015.
- 3. Rowland M, Tozer TN. Clinical Pharmacokinetics and Pharmacodynamics Concepts and Applications. 4th ed. 2011.
- 4. Gibaldi M, Perrier D. Pharmacokinetics. 2nd ed. revised and expanded. 1982.

See Also

AUC, BestSlope

8 IntAUC

IntAUC

Calculate interval AUC

Description

It calculates interval AUC

Usage

```
IntAUC(x, y, t1, t2, Res, Method = "Linear")
```

Arguments

X	vector values of independent variable, usually time
у	vector values of dependent variable, usually concentration
t1	start time for AUC
t2	end time for AUC
Res	result from IndiNCA function
Method	either of "Linear" or "Log" to indicate the way to calculate AUC

Details

This calculates an interval (partial) AUC (from t1 to t2) with the given series of x and y. If t1 and/or t2 cannot be found within x vector, it interpolates according to the Method.

Value

return interval AUC value (scalar)

Author(s)

Kyun-Seop Bae <k@acr.kr>

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References

- 1. Gabrielsson J, Weiner D. Pharmacokinetic and Pharmacodynamic Data Analysis Concepts and Applications. 5th ed. 2016.
- 2. Shargel L, Yu A. Applied Biopharmaceutics and Pharmacokinetics. 7th ed. 2015.
- 3. Rowland M, Tozer TN. Clinical Pharmacokinetics and Pharmacodynamics Concepts and Applications. 4th ed. 2011.
- 4. Gibaldi M, Perrier D. Pharmacokinetics. 2nd ed. revised and expanded. 1982.

See Also

```
AUC, Interpol
```

Examples

```
Res = IndiNCA(Theoph[Theoph$Subject==1, "Time"], Theoph[Theoph$Subject==1, "conc"], Dose=320)
IntAUC(Theoph[Theoph$Subject==1, "Time"], Theoph[Theoph$Subject==1, "conc"], t1=0.5, t2=11, Res)
```

Interpol

Interpolate y value

Description

It interpolates y value when a corresponding x value (xnew) does not exist within x vector

Usage

```
Interpol(x, y, xnew, Slope, b0, Method = "Linear")
```

Arguments

x vector values of x-axis, usually time

y vector values of y-axis, usually concentration

xnew new x point to be interpolated, usually new time point

Slope slope of regression $log(y) \sim x$ b0 y value of just left point of xnew

Method either of "Linear" or "Log" to indicate the way to interpolate

Details

This function interpolate y value, if xnew is not in x vector. If xnew is in x vector, it just returns the given x and y vector. This function usually is called by IntAUC function Returned vector is sorted in the order of increasing x values.

Value

new x and y vector containing xnew and ynew point

Author(s)

Kyun-Seop Bae <k@acr.kr>

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See Also

IntAUC

Examples

```
x = 10:1 + 0.1
y = -2*x + 40.2
Interpol(x, y, 1.5)
Interpol(x, y, 1.5, Method="Log")
```

LinAUC

Area Under the Curve(AUC) and Area Under the first Moment Curve(AUMC) by linear trapezoidal method

Description

It calculates AUC and AUMC using linear trapezoidal method

Usage

```
LinAUC(x, y)
```

Arguments

x vector values of independent variable, usually time

y vector values of dependent variable, usually concentration

Details

This function returns AUC and AUMC by linear trapezoidal method.

Value

AUC area under the curve

AUMC area under the first moment curve

Author(s)

Kyun-Seop Bae <k@acr.kr>

References

- 1. Gabrielsson J, Weiner D. Pharmacokinetic and Pharmacodynamic Data Analysis Concepts and Applications. 5th ed. 2016.
- 2. Shargel L, Yu A. Applied Biopharmaceutics and Pharmacokinetics. 7th ed. 2015.
- 3. Rowland M, Tozer TN. Clinical Pharmacokinetics and Pharmacodynamics Concepts and Applications. 4th ed. 2011.
- 4. Gibaldi M, Perrier D. Pharmacokinetics. 2nd ed. revised and expanded. 1982.

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See Also

```
LogAUC,AUC
```

Examples

```
LinAUC(Theoph[Theoph$Subject==1, "Time"],Theoph[Theoph$Subject==1, "conc"])
AUC(Theoph[Theoph$Subject==1, "Time"],Theoph[Theoph$Subject==1, "conc"]) # compare the last line
```

LogAUC

Area Under the Curve(AUC) and Area Under the first Moment Curve(AUMC) by linear-up log-down method

Description

It calculates AUC and AUMC using linear-up log-down method

Usage

```
LogAUC(x, y)
```

Arguments

x vector values of independent variable, usually time

y vector values of dependent variable, usually concentration

Details

This function returns AUC and AUMC by linear-up log-down method.

Value

AUC area under the curve

AUMC area under the first moment curve

Author(s)

Kyun-Seop Bae <k@acr.kr>

References

- 1. Gabrielsson J, Weiner D. Pharmacokinetic and Pharmacodynamic Data Analysis Concepts and Applications. 5th ed. 2016.
- 2. Shargel L, Yu A. Applied Biopharmaceutics and Pharmacokinetics. 7th ed. 2015.
- 3. Rowland M, Tozer TN. Clinical Pharmacokinetics and Pharmacodynamics Concepts and Applications. 4th ed. 2011.
- 4. Gibaldi M, Perrier D. Pharmacokinetics. 2nd ed. revised and expanded. 1982.

See Also

LinAUC,AUC

NCA NCA

Examples

```
LogAUC(Theoph[Theoph$Subject==1, "Time"],Theoph[Theoph$Subject==1, "conc"])
# Compare the last line with the above
AUC(Theoph[Theoph$Subject==1, "Time"],Theoph[Theoph$Subject==1, "conc"], Method="Log")
```

NCA

Noncompartmental analysis for a dataset with multiple subjects

Description

conduct noncompartmental analysis for many subjects in a data table

Usage

Arguments

Data	name of data table containing time-concentration data of multiple subjects
colSubj	column name for subject ID
colTime	column name for the time
colConc	column name for the concentration
colTrt	column name for the treatment code. This is useful for crossover study like bioequivalence trial.
Method	one of "Linear" or "Log" to indicate the way to calculate AUC
Dose	administered dose. One should be careful for the unit. This can be a vector containing dose for each subject in order.
AdmMode	one of "Bolus" or "Infusion" or "Extravascular" to indicate drug administration mode $% \left(1\right) =\left(1\right) \left($
TimeInfusion	infusion duration for constant infusion, otherwise 0. This can be a vector containing values for each subject in order.
Report	either of "Table" or "Text" to specify the type of return value
iAUC	data.frame with three columns, "Name", "Start", "End" to specify partial interval $\ensuremath{\mathrm{AUC}}$

Details

This function calls IndiNCA repeatedly to do NCA for each subject. If you specify Report="Text", this function returns in free text format to be used in a report file.

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Value

CMAX maximum concentration, Cmax

CMAXD dose normalized Cmax, CMAX / Dose, Cmax / Dose

TMAX time of maximum concentration, Tmax

TLAG time to observe the first non-zero concentration, for extravascular administration

only

CLST last positive concentration observed, Clast

CLSTP last positive concentration predicted, Clast pred

TLST time of last positive concentration, Tlast

LAMZHL half-life by lambda z, ln(2)/LAMZ

LAMZ lambda_z negative of best fit terminal slope

LAMZLL earliest time for LAMZ
LAMZUL last time for LAMZ

LAMZNPT number of points for LAMZ

CORRXY correlation of log(concentration) and time

R2 R-squared

R2ADJ R-squared adjusted

C0 back extrapolated concentration at time 0, for bolus intravascular administration

only

AUCLST AUC from 0 to TLST

AUCALL AUC using all the given points, including trailing zero concentrations

AUCIFO AUC infinity observed

AUCIFOD AUCIFO / Dose

AUCIFP AUC infinity predicted using CLSTP instead of CLST

AUCIFPD AUCIFP / Dose

AUCPEO AUC % extrapolation observed AUCPEP AUC % extrapolated for AUCIFP

AUCPBEO AUC % back extrapolation observed, for bolus IV administration only

AUCPBEP AUC % back extrapolation predicted with AUCIFP, for bolus IV administration

only

AUMCLST AUMC to the TLST

AUMCIFO AUMC infinity observed using CLST

AUMCIFP AUMC infinity determined by CLSTP

AUMCPEO AUMC % extrapolated observed

AUMCPEP AUMC % extrapolated predicted

MRTIVLST mean residence time (MRT) to TLST, for intravascular administration

MRTIVIFO mean residence time (MRT) infinity using CLST, for intravascular administra-

tion

MRTIVIFP mean residence time (MRT) infinity using CLSTP, for intravascular administra-

tion

MRTEVLST mean residence time (MRT) to TLST, for extravascular administration

NCA NCA

MRTEVIFO	mean residence time (MRT) infinity using CLST, for extravascular administration
MRTEVIFP	mean residence time (MRT) infinity using CLSTP, for extravascular administration
VZO	volume of distribution determined by LAMZ and AUCIFO, for intravascular administration
VZP	volume of distribution determined by LAMZ and AUCIFP, for intravascular administration
VZFO	VZO for extravascular administration, VZO/F, F is bioavailability
VZFP	VZP for extravascular administration, VZP/F, F is bioavailability
CLO	clearance using AUCIFO, for intravascular administration
CLP	clearance using AUCIFP, for intravascular administration
CLF0	CLO for extravascular administration, CLO/F, F is bioavailability
CLFP	CLP for extravascular administration, CLP/F, F is bioavailability
VSS0	volume of distribution at steady state using CLST, for intravascular administration only
VSSP	volume of distribution at stead state using CLSTP, for intravascular administration only

Author(s)

Kyun-Seop Bae <k@acr.kr>

References

- 1. Gabrielsson J, Weiner D. Pharmacokinetic and Pharmacodynamic Data Analysis Concepts and Applications. 5th ed. 2016.
- 2. Shargel L, Yu A. Applied Biopharmaceutics and Pharmacokinetics. 7th ed. 2015.
- 3. Rowland M, Tozer TN. Clinical Pharmacokinetics and Pharmacodynamics Concepts and Applications. 4th ed. 2011.
- 4. Gibaldi M, Perrier D. Pharmacokinetics. 2nd ed. revised and expanded. 1982.

See Also

IndiNCA

Round 15

Round

Round Half Away from Zero

Description

This is an ordinary rounding function, so called round half away from zero

Usage

```
Round(x, n = 0)
```

Arguments

x numeric to be roundedn indicating decimal digits

Details

The function round in R base rounds to the even number, i.e. round(0.5) is 0 not 1. If you want rounding 0.5 be 1, you can use this Round function. This function is for the consistency with other software like MS-Excel, SAS.

Value

ordinarily rounded value

Author(s)

Kyun-Seop Bae <k@acr.kr>

References

See wikipedia subject "Rounding"

```
(x = 1:10 - 0.5)
Round(x)
round(x) # compare with the above
```

Slope

RptCfg

NCA Report Configuation Table

Description

Contains the names and order of colum of return table/text by IndiNCA and NCA functions

Usage

RptCfg

Format

A data frame with 48 observations on the following 10 variables.

PPTESTCD a character vector of CDISC SDTM PPTESTCD

SYNONYM a character vector of CDISC SDTM PPTESTCD Synonym

NCI a character vector of NCI peferred terms

WNL a character vector of WinNonlin(R) software variables

ExtravascularDefault a numeric vector of ordering in report for extravascular administration, Zero means exclusion in the report.

ExtravascularWNL a numeric vector of WinNonlin(R) style ordering in report for extravascular administration, Zero means exclusion in the report.

BolusDefault a numeric vector of ordering in report for extravascular administration, Zero means exclusion in the report.

BolusWNL a numeric vector of WinNonlin(R) style ordering in report for extravascular administration, Zero means exclusion in the report.

InfusionDefault a numeric vector of ordering in report for extravascular administration, Zero means exclusion in the report.

InfusionWNL a numeric vector of WinNonlin(R) style ordering in report for extravascular administration, Zero means exclusion in the report.

Details

This table should exist in NonCompart package. User can edit this table for shaping the report in one's own style.

Slope

Get the Slope of regression $log(y) \sim x$

Description

It calculates the slope with linear regression of $log(y) \sim x$

Usage

Slope(x, y)

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Arguments

x vector values of independent variable, usually time

y vector values of dependent variable, usually concentration

Details

With time-concentration curve, you frequently need to estimate slope in $log(concentration) \sim time$. This function is usually called by BestSlope function and you seldom need to call this function directly.

Value

R2 R-squared

R2ADJ adjusted R-squared

LAMZNPT number of points used for slope
LAMZ negative of slope, lambda_z
b0 intercept of regression line
CORRXY correlation of log(y) and x
LAMZLL earliest x for lambda_z
LAMZUL last x for lambda_z

CLSTP predicted y value at last point, predicted concentration for the last time point

Author(s)

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See Also

BestSlope

Examples

Slope(Indometh[Indometh\$Subject==1, "time"],Indometh[Indometh\$Subject==1, "conc"])

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