

Dept. of Clinical Pharmacology and Therapeutics

## **Manual for Clinical Trial**

# **Noncompartmental Analysis**

**Implemented in NonCompart R package**

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## [1] Preparation

This is just for the preparation of data for the subsequent R scripts.

```
Adm = c("BOLUS", "INFUSION", "EXTRAVASCULAR")[3] # Drug Administration Method
Dose = 320 # mg
x = x0 = Theoph[Theoph$Subject==1, "Time"] # h
y = y0 = Theoph[Theoph$Subject==1, "conc"] # ug/L

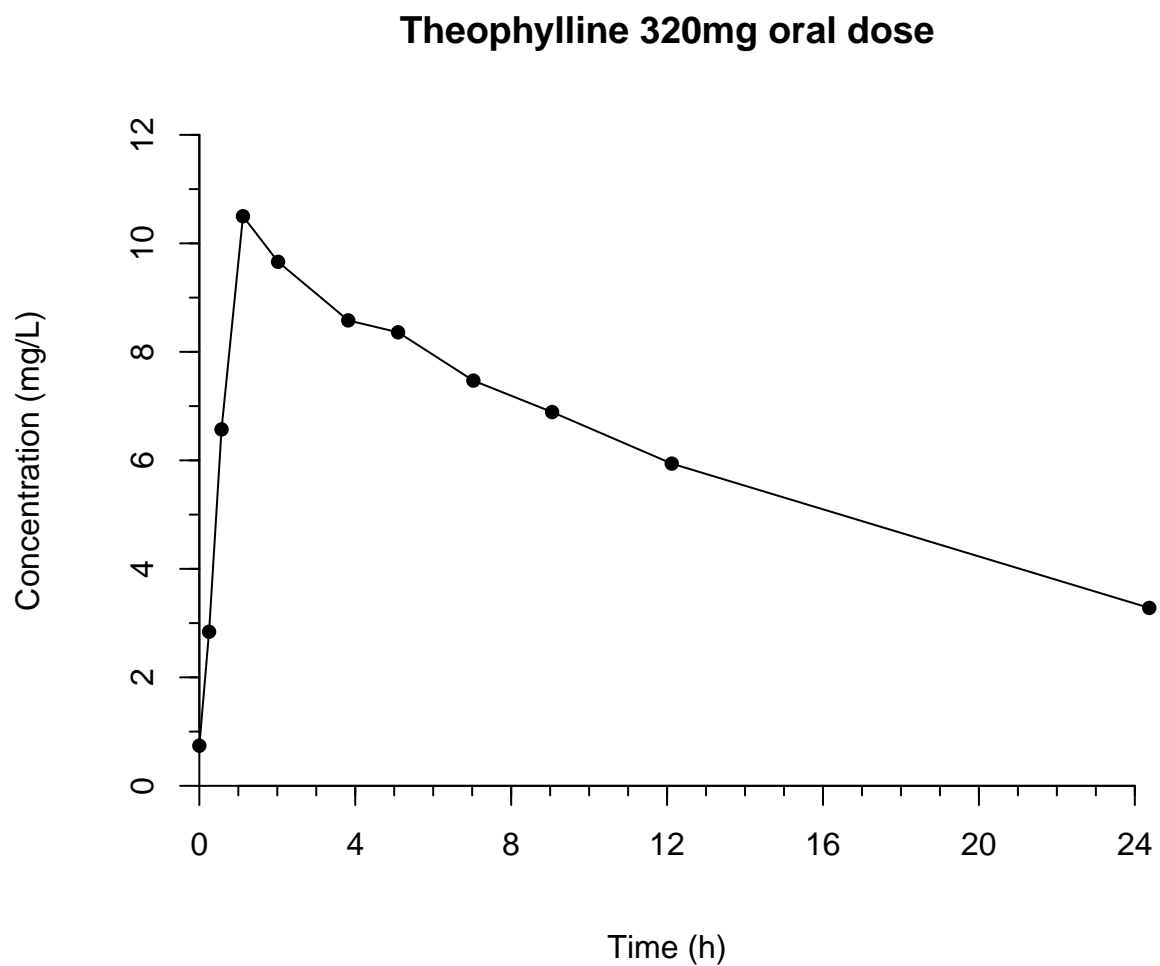
# For the calculation of AUClast
iLastNonZero = max(which(y > 0)) # index of last non-zero concentration
x1 = x0[1:iLastNonZero]
y1 = y0[1:iLastNonZero]

# For the log-concentration vs. time regression
x2 = x0[y0 > 0]
y2 = y0[y0 > 0]

# Print data
cbind(Time=x0, Conc=y0)
#      Time Conc
# [1,] 0.00 0.74
# [2,] 0.25 2.84
# [3,] 0.57 6.57
# [4,] 1.12 10.50
# [5,] 2.02 9.66
# [6,] 3.82 8.58
# [7,] 5.10 8.36
# [8,] 7.03 7.47
```

```
# [9,] 9.05 6.89
# [10,] 12.12 5.94
# [11,] 24.37 3.28
```

## [2] Plot of raw data



## [3] Cmax (CMAX)

Maximum concentration.

```
CMAX = NA
CMAX = max(y, na.rm=TRUE) ; CMAX
# [1] 10.5
```

#### [4] Cmax\_D (CMaxD)

Dose normalized Cmax.

```
CMaxD = NA  
CMaxD = CMax/Dose ; CMaxD  
# [1] 0.0328125
```

#### [5] Tmax (TMax)

Time of maximum concentration.

```
TMax = NA  
if (CMax > 0) TMax = x[which.max(y)]  
TMax  
# [1] 1.12
```

#### [6] Tlag (TLAG)

Time until first non-zero concentration.

```
TLAG = NA  
if (CMax > 0) TLAG = x[max(1, min(which(y > 0)) - 1)]  
TLAG  
# [1] 0
```

#### [7] Clast (CLST)

Last non-zero concentration.

```
CLST = y[iLastNonZero] ; CLST  
# [1] 3.28
```

## [8] Tlast (TLST)

Time of last non-zero concentration.

```
TLST = x[iLastNonZero] ; TLST  
# [1] 24.37
```

## [9] Rsq (R2)

R-squared value from the log concentration and time regression.

## [10] Rsq\_adjusted (R2ADJ)

Adjusted R-squared value.

$$R_{\text{adj}}^2 = 1 - (1 - R^2) \frac{n - 1}{n - 2}$$

## [11] Corr\_XY (CORRXY)

Correlation value of the regression

## [12] b0

Intercept of the simple linear regression of log(y) vs x

## [13] Lambda\_z (LAMZ)

Terminal slope as a positive value

## [14] No\_points\_Lambda\_z (LAMZNPT)

Number of points used for the regression

## [15] Lambda\_z\_lower (LAMZLL)

First time point used for the regression

## [16] Lambda\_z\_upper (LAMZUL)

Last time point used for the regression

## [17] R2, R2ADJ, CORRXY, b0, LAMZ, LAMZNPT, LAMZLL, LAMZUL

Only positive concentrations are used. In case of oral administration, the first possible point is next to Tmax point. In case of intravascular administration, the first point can be Tmax point. If the difference of R2ADJ (R2-squared adjusted) is less than 1e-4, the longer slope is chosen. Regression points should be at least 3.

```
x = x2 ; y = y2

if (toupper(Adm) == "EXTRAVASCULAR") {
  iFirst = which.max(y) + 1 # for oral administration
} else {
  iFirst = which.max(y)      # for intravenous administration
}
iLast = iLastNonZero

ColNames = c("R2", "R2ADJ", "CORRXY", "b0", "LAMZ", "LAMZNPT", "LAMZLL", "LAMZUL")
mRes = matrix(nrow = iLast - iFirst + 1 - 2, ncol=length(ColNames))
colnames(mRes) = ColNames
for (i in iFirst:(iLast - 2)) {
  Res = lm(log(y[i:iLast]) ~ x[i:iLast])
  mRes[i - iFirst + 1, "R2"]      = summary(Res)$r.squared
  mRes[i - iFirst + 1, "R2ADJ"]  = summary(Res)$adj.r.squared
  mRes[i - iFirst + 1, "CORRXY"] = cor(log(y[i:iLast]), x[i:iLast])
  mRes[i - iFirst + 1, "b0"]     = Res$coefficients[1]
  mRes[i - iFirst + 1, "LAMZ"]   = -Res$coefficients[2]
  mRes[i - iFirst + 1, "LAMZNPT"] = iLast - i + 1
  mRes[i - iFirst + 1, "LAMZLL"] = x[i]
  mRes[i - iFirst + 1, "LAMZUL"] = x[iLast]
} ; mRes
```



```
#           R2      R2ADJ      CORRXY      b0      LAMZ LAMZNPT LAMZLL LAMZUL
# [1,] 0.9988013 0.9985615 -0.9994005 2.355187 0.04778625      7  2.02  24.37
# [2,] 0.9987305 0.9984131 -0.9993650 2.350845 0.04751440      6  3.82  24.37
# [3,] 0.9995671 0.9994229 -0.9997836 2.362429 0.04817356      5  5.10  24.37
# [4,] 0.9996109 0.9994164 -0.9998054 2.356834 0.04787556      4  7.03  24.37
# [5,] 0.9999997 0.9999995 -0.9999999 2.368785 0.04845700      3  9.05  24.37

OKs = abs(max(mRes[, "R2ADJ"]) - mRes[, "R2ADJ"]) < 1e-4
resNCA = as.data.frame(mRes[which(OKs)[1],,drop=FALSE]) ; resNCA
#           R2      R2ADJ      CORRXY      b0      LAMZ LAMZNPT LAMZLL LAMZUL
# 1 0.9999997 0.9999995 -0.9999999 2.368785 0.048457      3  9.05  24.37
attach(resNCA, warn.conflicts=FALSE)
```

If you want to manually omit some points, use an R package for convenience.

## [18] HL\_Lambda\_z (LAMZHL)

Terminal half-life calculated by  $\ln(2)/\lambda_Z$

```
LAMZHL = NA
if (LAMZ > 0) LAMZHL = log(2)/LAMZ
LAMZHL
# [1] 14.30438
```

## [19] Clast\_pred (CLSTP)

Predicted Clast, predicted concentration at Tlast.

$$C_{\text{last,pred}} = \exp(\beta_0 - \lambda \cdot T_{\text{last}})$$

```
CLSTP = NA
if (LAMZ > 0) CLSTP = exp(b0 - LAMZ*x[iLast])
CLSTP
# [1] 3.280146
```

## [20] C0 (C0)

Concentration at time 0, initial concentration. This is calculated only for BOLUS administration.

$$C_0 = \exp \left( \log(C_1) - t_1 \frac{\log(C_2) - \log(C_1)}{t_2 - t_1} \right)$$

```
x = x0 ; y = y0
if (toupper(Adm) == "BOLUS") {
  if (y[1] > y[2] & y[2] > 0) {
    C0 = exp(log(y[1]) - x[1]*(log(y[2]) - log(y[1]))/(x[2] - x[1]))
  } else {
    C0 = y[x==min(x[y > 0])]
  }
} else {
  C0 = NA
}
```

## [21] AUClast (AUCLAST)

Area under the time-concentration curve from dosing to the last positive concentration.

For linear trapezoidal method,

$$AUC_{\text{last}} = \sum_{i=2} \frac{(t_i - t_{i-1}) \times (C_i - C_{i-1})}{2}$$

```
n = length(x1)
AUCLAST = sum((y1[-1] + y1[-n]) * (x1[-1] - x1[-n]))/2 ; AUCLAST
# [1] 148.923
```

For 'linear-up log-down' method,

```
AUCLAST = 0
for (i in 2:n) {
  if (y1[i] < y1[i-1] & y1[i] > 0) {
    k = (log(y1[i - 1]) - log(y1[i]))/(x1[i] - x1[i - 1]) # slope in log
    AUCLAST = AUCLAST + (y1[i - 1] - y1[i])/k
  } else {
    AUCLAST = AUCLAST + (x1[i] - x1[i - 1])*(y1[i] + y1[i - 1])/2
  }
} ; AUCLAST
```

## [22] AUCall (AUCALL)

AUC values including all zero concentrations.

For linear trapezoidal method,

```
AUCALL = sum((y0[-1] + y0[-n]) * (x0[-1] - x0[-n]))/2 ; AUCALL  
# [1] 148.923
```

For 'linear-up log-down' method,

```
AUCALL = 0  
for (i in 2:n) {  
  if (y0[i] < y0[i-1] & y0[i] > 0) {  
    k = (log(y0[i - 1]) - log(y0[i]))/(x0[i] - x0[i - 1]) # slope in log  
    AUCALL = AUCALL + (y0[i - 1] - y0[i])/k  
  } else {  
    AUCALL = AUCALL + (x0[i] - x0[i - 1])*(y0[i] + y0[i - 1])/2  
  }  
} ; AUCALL
```

Zero concentrations to be log-transformed need not be removed, because R can handle infinity value.

## [23] AUCinf\_obs (AUCIFO)

AUCinf observed.

$$AUC_{\text{inf,obs}} = AUC_{\text{last}} + \frac{C_{\text{last}}}{\lambda_z}$$

## [24] AUC\_%Extrap\_obs (AUCPEO)

AUC percent extrapolated observed.

$$AUC_{\% \text{Extrap,obs}} = \left( 1 - \frac{AUC_{\text{last}}}{AUC_{\text{inf,obs}}} \right) \times 100$$

#### [25] AUCinf\_D\_obs (AUCIFOD)

Dose normalized AUCinf observed.

$$AUC_{\text{dose,inf,obs}} = \frac{AUC_{\text{inf,obs}}}{\text{Dose}}$$

#### [26] AUCinf\_pred (AUCIFP)

AUCinf predicted.

$$AUC_{\text{inf,pred}} = AUC_{\text{last}} + \frac{C_{\text{last,pred}}}{\lambda_z}$$

#### [27] AUC\_%Extrap\_pred (AUCPEP)

AUC percent extrapolated predicted.

$$AUC_{\% \text{Extrap,pred}} = \left( 1 - \frac{AUC_{\text{last}}}{AUC_{\text{inf,pred}}} \right) \times 100$$

#### [28] AUCinf\_D\_pred (AUCIFPD)

Dose normalized AUCinf predicted.

$$AUC_{\text{dose,inf,pred}} = \frac{AUC_{\text{inf,pred}}}{\text{Dose}}$$

#### [29] AUMClast (AUMCLST)

$$AUMC_{\text{last}} = \int_0^{t_{\text{last}}} t C(t) dt$$

For linear trapezoidal method;

$$AUMC_{\text{last}} \approx \sum_{i=2} \frac{(t_i - t_{i-1}) \times (t_i C_i + t_{i-1} C_{i-1})}{2}$$

```
AUMCLST = sum((x1[-1] - x1[-n])*(x1[-1]*y1[-1] + x1[-n]*y1[-n]))/2
```

For ‘linear-up log-down’ method;

```
AUMCLST = 0
for (i in 2:n) {
  if (y1[i] < y1[i-1] & y1[i] > 0) {
    k = (log(y1[i-1]) - log(y1[i]))/(x1[i] - x1[i-1]) # slope in log
    AUMCLST = AUMCLST + (x1[i-1]*y1[i-1] - x1[i]*y1[i])/k + (y1[i-1] - y1[i])/k/k
  } else {
    AUMCLST = AUMCLST + (x1[i] - x1[i-1])*(x1[i]*y1[i] + x1[i-1]*y1[i-1])/2
  }
}
```

### [30] AUMCinf\_obs (AUMCIFO)

AUMC infinity observed.

$$AUMC_{inf,obs} = AUMC_{last} + \frac{C_{last} T_{last}}{\lambda_z} + \frac{C_{last}}{\lambda_z^2}$$

### [31] AUCinf\_D\_obs (AUCIFOD)

Dose normalized AUCinf observed.

$$AUC_{dose,inf,obs} = \frac{AUC_{inf,obs}}{Dose}$$

### [32] AUMC\_%Extrap\_obs (AUMCPEO)

AUMC percent extrapolated observed.

$$AUMC_{\%Extrap,obs} = \left(1 - \frac{AUMC_{last}}{AUMC_{inf,obs}}\right) \times 100$$

### [33] AUMCinf\_pred (AUMCIFP)

AUMC infinity predicted.

$$AUMC_{inf,pred} = AUMC_{last} + \frac{C_{last,pred} T_{last}}{\lambda_z} + \frac{C_{last,pred}}{\lambda_z^2}$$

### [34] AUCinf\_D\_pred (AUCIFPD)

Dose normalized AUCinf predicted.

$$AUC_{dose,inf,pred} = \frac{AUC_{inf,pred}}{Dose}$$

### [35] AUMC\_%Extrap\_pred (AUMCPEP)

AUMC percent extrapolated predicted.

$$AUMC_{\%Extrap,pred} = \left( 1 - \frac{AUMC_{last}}{AUMC_{inf,pred}} \right) \times 100$$

### [36] AUC\_Back\_Ext\_obs (AUCBEO)

AUC back extrapolated observed. This is only for BOLUS administration.

For trapezoidal method;

$$AUC_{backextrap} = \frac{t_1 \times (C_0 + C_1)}{2}$$

For log-down method;

$$AUC_{backextrap} = \frac{t_1 \times (C_0 + C_1)}{\log(C_0) - \log(C_1)}$$

### [37] AUC\_%Back\_Ext\_obs (AUCPBEO)

AUC percent back extrapolated observed. This is only for BOLUS administration.

$$AUC_{\%backextrap,obs} = \frac{AUC_{backextrap}}{AUC_{inf,obs}} \times 100$$

### [38] AUC\_%Back\_Ext\_pred (AUCPBEP)

AUC percent back extrapolated predicted. This is only for BOLUS administration.

$$AUC_{\%backextrap,pred} = \frac{AUC_{backextrap}}{AUC_{inf,pred}} \times 100$$

### [39] MRTlast (MRTEVLST, MRTIVLST)

Mean Residence Time (MRT) from 0 to Tlast.

$$MRT_{EV,last} = \frac{AUMC_{last}}{AUC_{last}}$$

$$MRT_{IV,last} = \frac{AUMC_{last}}{AUC_{last}} - \frac{Dur}{2}$$

EV: extravascular

IV: intravascular

Dur: duration of infusion

### [40] MRTinf\_obs (MRTEVIFO, MRTIVIFO)

MRT infinity observed.

$$MRT_{EV,inf,obs} = \frac{AUMC_{inf,obs}}{AUC_{inf,obs}}$$

$$MRT_{IV,inf,obs} = \frac{AUMC_{inf,obs}}{AUC_{inf,obs}} - \frac{Dur}{2}$$

#### [41] MRTinf\_pred (MRTEVIFP, MRTIVIFP)

MRT infinity predicted.

$$\text{MRT}_{\text{EV,inf,pred}} = \frac{\text{AUMC}_{\text{inf,pred}}}{\text{AUC}_{\text{inf,pred}}}$$

$$\text{MRT}_{\text{IV,inf,pred}} = \frac{\text{AUMC}_{\text{inf,pred}}}{\text{AUC}_{\text{inf,pred}}} - \frac{\text{Dur}}{2}$$

#### [42] Vz\_obs (VZO) or Vz\_F\_obs (VZFO)

Volume of distribution by AUCIFO. VZO is for intravascular administration and VZFO for extravascular administration.

$$V_{z,\text{obs}} = \frac{\text{Dose}}{\text{AUC}_{\text{inf,obs}} \times \lambda_z}$$

#### [43] Vz\_pred (VZP) or Vz\_F\_pred (VZFP)

Volume of distribution by AUCIFP. VZP is for intravascular administration and VZFP for extravascular administration.

$$V_{z,\text{pred}} = \frac{\text{Dose}}{\text{AUC}_{\text{inf,pred}} \times \lambda_z}$$

#### [44] CL\_obs (CLO) or CL\_F\_obs (CLFO)

Clearance observed. CLO is for intravascular administration and CLFO for extravascular administration.

$$\text{CL}_{\text{obs}} = \frac{\text{Dose}}{\text{AUC}_{\text{inf,obs}}}$$



#### [45] CL\_pred (CLP) or CL\_F\_pred (CLFP)

Clearance predicted. CLP is for intravascular administration and CLFP for extravascular administration.

$$CL_{pred} = \frac{\text{Dose}}{AUC_{inf,pred}}$$

#### [46] Vss\_obs (VSSO)

Volume of distribution at steady state, observed. This is for intravascular administration only.

$$V_{ss,obs} = MRT_{IV,inf,obs} \times CL_{obs}$$

#### [47] Vss\_pred (VSSP)

Volume of distribution at steady state, predicted. This is for intravascular administration only.

$$V_{ss,pred} = MRT_{IV,inf,pred} \times CL_{pred}$$

#### [48] AmtRecLast (RCAMLST)

Amount recovered in urine.

$$Ae_{last} = \sum_{i=1} Vol_i Conc_i$$

#### [49] CLrenal (RENALCL)

Renal clearance.

$$CL_R = \frac{Ae_{last}}{AUC_{last}}$$

## [50] fe (FE)

Fraction excreted unchanged.

$$fe = \frac{CL_R}{CL_{obs}} = \frac{Ae_{last}/AUC_{last}}{Dose/AUC_{inf,obs}} = \frac{Ae_{last}}{Dose} \times \frac{AUC_{inf,obs}}{AUC_{last}}$$

## [51] AI (ARCMAX, ARAUC, ARCMIN)

Accumulation index, accumulation ratio.

$$R_{ac} = \frac{C_{max,ss}}{C_{max,1}} = \frac{AUC_{tau,ss}}{AUC_{tau,1}} = \frac{AUC_{inf,ss}}{AUC_{inf,1}} = \frac{C_{min,ss}}{C_{min,1}}$$

## Example using NonCompart::sNCA

```
require(NonCompart)
x = Theoph[Theoph$Subject==1, "Time"]
y = Theoph[Theoph$Subject==1, "conc"]
r1 = sNCA(x, y, dose=320, concUnit="mg/L") ; r1
```

#	b0	CMAX	CMAXD	TMAX	TLAG	CLST
#	2.3687851	10.5000000	0.0328125	1.1200000	0.0000000	3.2800000
#	CLSTP	TLST	LAMZHL	LAMZ	LAMZLL	LAMZUL
#	3.2801465	24.3700000	14.3043776	0.0484570	9.0500000	24.3700000
#	LAMZNPT	CORRXY	R2	R2ADJ	AUCLST	AUCALL
#	3.0000000	-0.9999999	0.9999997	0.9999995	148.9230500	148.9230500
#	AUCIFO	AUCIFOD	AUCIFP	AUCIFPD	AUCPEO	AUCPEP
#	216.6119330	0.6769123	216.6149558	0.6769217	31.2489169	31.2498763
#	AUMCLST	AUMCIFO	AUMCIFP	AUMCPEO	AUMCPEP	VZF0
#	1459.0711035	4505.5348194	4505.6708646	67.6160287	67.6170065	30.4867482
#	VZFP	CLF0	CLFP	MRTEVLST	MRTEVIF0	MRTEVIFP
#	30.4863228	1.4772963	1.4772757	9.7974834	20.8000305	20.8003683

```
# attr("units")
# [1] "" "mg/L" "mg/L/mg" "h" "h" "mg/L" "mg/L"
# [8] "h" "h" "/h" "h" "h" "" ""
# [15] "" "" "h*mg/L" "h*mg/L" "h*mg/L" "h*mg/L/mg" "h*mg/L"
# [22] "h*mg/L/mg" "%" "%" "h2*mg/L" "h2*mg/L" "h2*mg/L" "%"
# [29] "%" "L" "L" "L/h" "L/h" "h" "h"
# [36] "h"
# attr("UsedPoints")
# [1] 9 10 11
```

```
r2 = data.frame(VALUE=r1, UNIT=attr(r1, "units")) ; r2
```

#	VALUE	UNIT
# b0	2.3687851	
# CMAX	10.5000000	mg/L
# CMAXD	0.0328125	mg/L/mg
# TMAX	1.1200000	h
# TLAG	0.0000000	h
# CLST	3.2800000	mg/L
# CLSTP	3.2801465	mg/L
# TLST	24.3700000	h
# LAMZHL	14.3043776	h
# LAMZ	0.0484570	/h
# LAMZLL	9.0500000	h
# LAMZUL	24.3700000	h
# LAMZNPT	3.0000000	
# CORRX	-0.9999999	
# R2	0.9999997	
# R2ADJ	0.9999995	
# AUCLST	148.9230500	h*mg/L
# AUCALL	148.9230500	h*mg/L
# AUCIFO	216.6119330	h*mg/L
# AUCIFOD	0.6769123	h*mg/L/mg
# AUCIFP	216.6149558	h*mg/L
# AUCIFPD	0.6769217	h*mg/L/mg
# AUCPEO	31.2489169	%
# AUCPEP	31.2498763	%
# AUMCLST	1459.0711035	h2*mg/L
# AUMCIFO	4505.5348194	h2*mg/L
# AUMCIFP	4505.6708646	h2*mg/L
# AUMCPEO	67.6160287	%
# AUMCPEP	67.6170065	%
# VZFO	30.4867482	L
# VZFP	30.4863228	L
# CLFO	1.4772963	L/h
# CLFP	1.4772757	L/h
# MRTEVLST	9.7974834	h
# MRTEVIFO	20.8000305	h
# MRTEVIFP	20.8003683	h

## Session Information

### Compile Time

```
# [1] "2025-05-02 15:24:55 KST"
```

### Session Information

```
# R version 4.5.0 (2025-04-11 ucrt)
# Platform: x86_64-w64-mingw32/x64
# Running under: Windows 10 x64 (build 19044)
#
# Matrix products: default
#   LAPACK version 3.12.1
#
# locale:
# [1] LC_COLLATE=Korean_Korea.utf8 LC_CTYPE=Korean_Korea.utf8
# [3] LC_MONETARY=Korean_Korea.utf8 LC_NUMERIC=C
# [5] LC_TIME=Korean_Korea.utf8
#
# time zone: Asia/Seoul
# tzcode source: internal
#
# attached base packages:
# [1] stats      graphics  grDevices  utils      datasets  methods   base
#
# other attached packages:
# [1] NonCompart_0.7.0 knitr_1.50      rmarkdown_2.29
```