

# Assignment 1 solutions for m2209259

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This document is not designed to be a perfect example of what you should have done in the assignment, it simply provides some example text alongside tables and figures.

In this study, 50 mg of drug ND42 was given to 12 participants. Table 1 summarises the characteristics of the study participants. The median weight was 69.95kg (range 44.7 to 83.5kg). 14 samples were taken from each participant over a 24 hour period. Figures 2 & 1 show the time concentration profile for individuals and a mean profile respectively.

Tables 2 and 3 show a summary of the non-compartmental analysis of these data. Mean oral  $AUC_{0-\infty}$  was 10.7 mg.h/L. Mean IV  $AUC_{0-\infty}$  was 16.7 mg.h/L Oral  $C_{max}$  was 0.997 mg/L , which was reached in a median time of 4 hours (median) with a range of 1.5 to 6 hours. The bioavailability was 0.65 (+/- 0.005)

Table 1: Summary of participant characteristics

Characteristic	N = 12
Weight (kg)	70.0 (62.5, 75.0)
Height (m)	1.71 (1.66, 1.78)
Female participants	9 (75%)

<sup>1</sup> Median (IQR); n (%)

Table 2: Non-compartmental data analysis

Route	$AUC_{0-\tau}$ (h.mg/L)	$C_{max}$ (mg/L)	T max (hours)	Elimination half life (hours)	$AUC_{0-\infty}$ (h.mg/L)
IV	16.2 [17.2]	2.54 [8.74]	0.000 [0.000, 0.000]	4.64 [0.753]	16.7 [18.5]
Oral	10.3 [17.3]	0.997 [16.6]	4.00 [1.50, 6.00]	4.70 [0.727]	10.7 [18.6]
Ratios	NA	0.39 [ 0.05 ]	NA	NA	0.65 [ 0.005 ]

Tmax: median [range], half-life and ratios: arithmetic mean [standard deviation]. Other parameters are presented as geometric mean [coefficient of variation]

Table 3:  $k_e$ , Cl and Vd estimates using a non-compartmental approach (IV data only)

Elimination rate constant ( $k_e$ )	Clearance (L/hr)	Volume of distribution (L)
0.169 [11.0]	3.00 [18.5]	19.8 [9.35]

Parameters are presented as geometric mean [coefficient of variation]

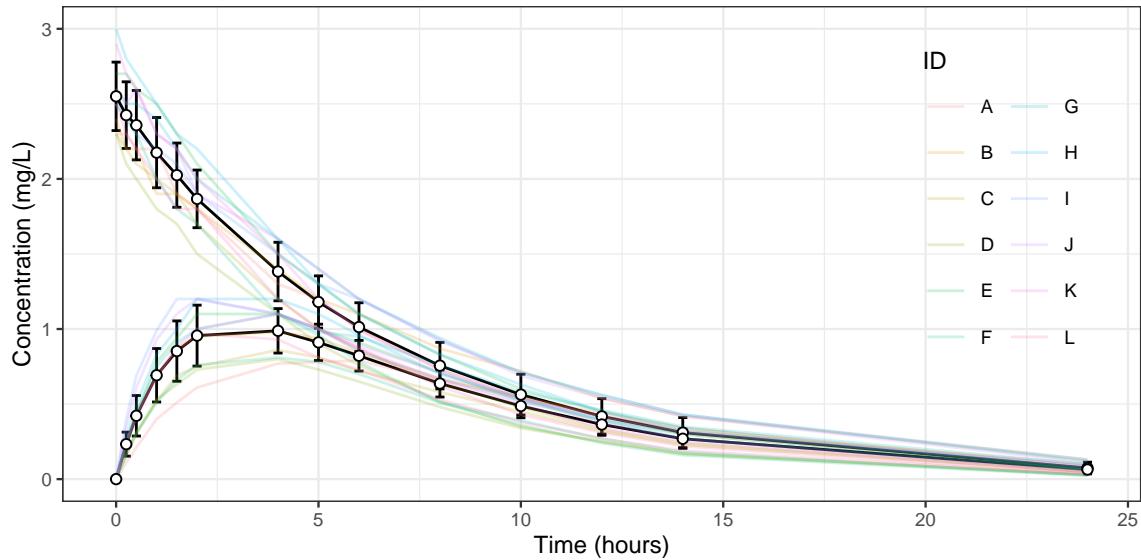


Figure 1: Concentration-time plot for drug ND42 via oral and IV route, showing individual plots in colour and mean concentration with standard deviation superimposed (black line)

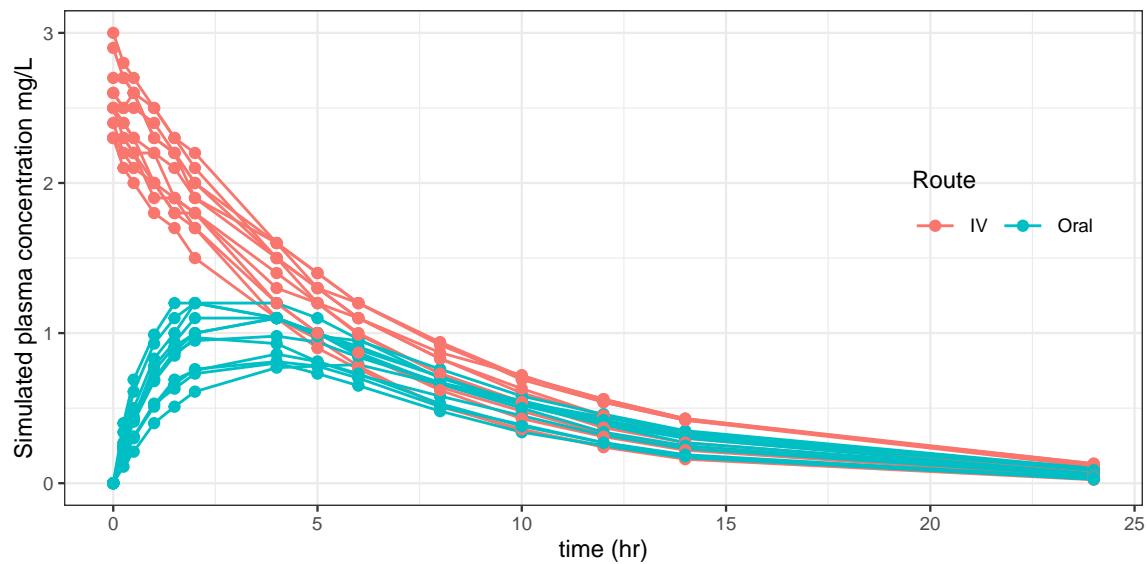


Figure 2: Concentration-time plot for drug ND42