

Assignment 1 solutions for m2202444

Dagan Lonsdale

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 64.75kg (range 51.9 to 86.9kg). 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 11.6 mg.h/L. Mean IV $AUC_{0-\infty}$ was 18 mg.h/L Oral C_{\max} was 1.07 mg/L, which was reached in a median time of 4 hours (median) with a range of 1.5 to 4 hours. The bioavailability was 0.64 (+/- 0.006)

Table 1: Summary of participant characteristics

| Characteristic | N = 12 |
|---------------------|-------------------|
| Weight (kg) | 64.8 (61.2, 73.3) |
| Height (m) | 1.70 (1.67, 1.73) |
| Female participants | 8 (67%) |

¹ 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 | 17.4 [19.4] | 2.69 [12.5] | 0.000 [0.000, 0.000] | 4.72 [1.03] | 18.0 [21.2] |
| Oral | 11.1 [19.2] | 1.07 [17.7] | 4.00 [1.50, 4.00] | 4.77 [1.03] | 11.6 [21.4] |
| Ratios | NA | 0.4 [0.05] | NA | NA | 0.64 [0.006] |

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) |
|-------------------------------------|------------------|----------------------------|
| 0.170 [17.0] | 2.77 [21.2] | 18.5 [12.7] |

Parameters are presented as geometric mean [coefficient of variation]

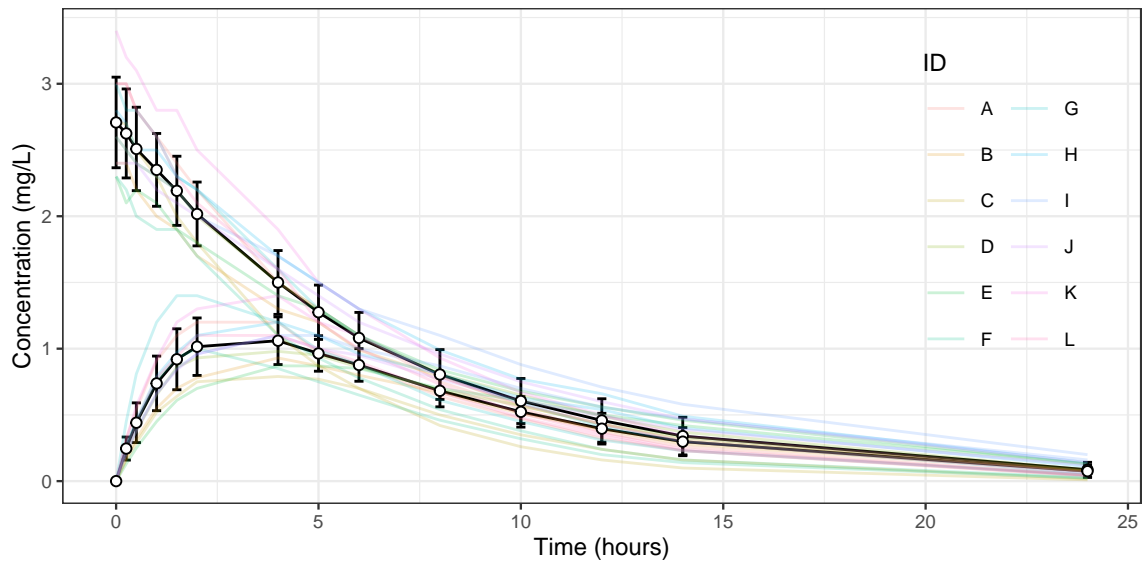


Figure 1: Concentration-time plot for drug ND42 via oral and IV route, showing individual plots in colour and mean concentration with standard deviation superimposed (black line)

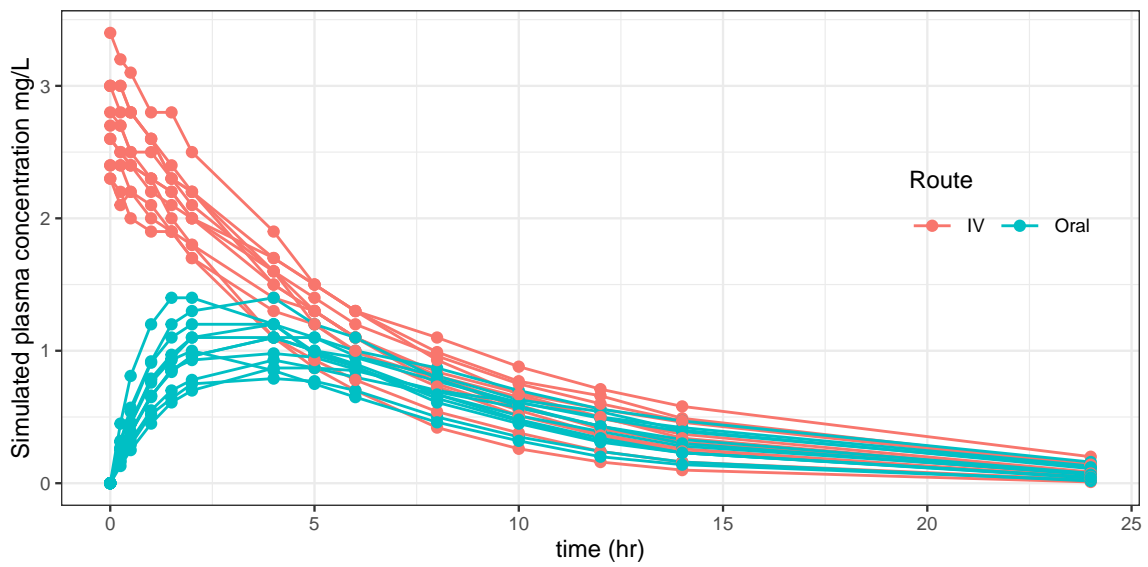


Figure 2: Concentration-time plot for drug ND42