



## Summary of a Bioavailability or Bioequivalence Study

### Part 1 – Study Identification

Study Report Title:

Report / Protocol Identification Number:

Volume where the full trial report is located:  Pages:

### Part 2 – Study Type

Are you sure this is a bioavailability and/or bioequivalence study (and not a pharmacokinetic study)? YES  NO

*A pharmacokinetic study concerns the properties of the drug whereas a bioavailability study concerns the properties of specific formulations or of different routes of administration. A food study is considered to be a bioavailability study. You are encouraged to contact the TGA to discuss studies if this is not clear for a given submission.*

### Part 3 – Product Details

Drug Products Tested	Dosage Regimen

**For trials comparing a new product with that of a competitor (eg. comparison of a controlled release product with an immediate release brand already on the market in Australia, or comparison of a generic with an Australian market leader), state in what country and under what circumstances the competitor’s batch was obtained.**

The formulations and batch numbers of all products used in the trial

are located in Volume No:

Pages:

Were any of these formulations identical to the one which is the subject of this registration application?

NO

YES

If yes, detail which:



## Part 4 – Quality Control

Quality control data are provided for each batch of each product used in the trial, including:

- assay for the batch and, *where relevant*, dissolution rate results

These data are located in  
Volume No:

Pages:

- particle size distribution data for the API used to manufacture the batch, *where relevant*

These data are located in  
Volume No:

Pages:

The study report is signed by the principal investigator

In Volume No:

Pages:

## Part 5 – Assay Details

Details are provided of the assay method and its validation, including:

- description of the assay method (*in blood etc*)

These data are located in  
Volume No:

Pages:

- pre-study validation procedures

These data are located in  
Volume No:

Pages:

- within study validation (as performed by the trialist)

These data are located in  
Volume No:

Pages:

• decision criteria for acceptance of each analytical run

These data are located in  
Volume No:

Pages:

## Part 6 – Individual Subject

**Individual assay results for all sampling times for each subject and for each treatment**

are located in Volume No:

Pages:

(Reports presented without individual patient data will not normally be evaluable)

**Tabulations of the derived parameters for individual subjects**, such as  $C_{max}$ ,  $T_{max}$ ,  $AUC_{0-inf}$ ,  $t_{1/2}$  or  $k_{el}$ ; cumulative urinary excretion etc.

are located in Volume No:

Pages:

**Graphs of concentration-time data have been provided:**

• for each individual subject

in Volume No:

Pages:

• for the mean of each treatment

in Volume No:

Pages:

## Part 7 – Statistical Analysis

**The results of the statistical analysis**

are located in Volume No:

Pages:

If any of the data indicated previously are not provided, please explain why: