TGA use only

This form, when completed, will be classified as '**For official use only**'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <http://www.tga.gov.au/about/tga-information-to.htm>.

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 (*e.g. 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? Yes No

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 relevan*t**

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}; $AUC_{0\text{-}inf;}$ $t_{1/2}$ 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: