



**Bahagian Regulatori Farmasi Negara (NPRA)**  
**National Pharmaceutical Regulatory Agency (NPRA)**

Lot 36, Jalan Universiti, 46200 Petaling Jaya, Selangor.

No. Tel. *Tel. No.* : 03-78835400

No. Faks. *Fax No.* : 03-79571200

Laman Sesawang *Website* : <http://nptra.moh.gov.my>

**CENTRE FOR PRODUCT REGISTRATION**

**BIOEQUIVALENCE STUDY REPORT SUBMISSION CHECKLIST**

**General Instructions**

- Please submit this checklist together with the hardcopy of the bioequivalence study report (including all appendices) upon product screening approval.
- Provide/fill in as much detailed, accurate and final information as possible.
- All the appended documents (hardcopy and electronic format) should be clearly identifiable by their location and tagging of the file names, which should include the section name where the file is located, annex number and document version.
- Evaluation will be based on hardcopy of BE study report submitted. Submission in electronic format is allowable for case report form (CRF) of study subjects and 20% of chromatogram in analytical run due to the large file size.
- Kindly check that you have signed on the checklist, provided all requested information and enclosed all requested documents.
- Should you have any queries regarding this procedure or the checklist, kindly contact Generic Medicine Section (Bioequivalence Report Evaluation) via e-mail : [be\\_sug@nptra.gov.my](mailto:be_sug@nptra.gov.my)

**\*Reminder :**

- i. Please be informed that all data submitted to support the registration application for this product will be subjected to further evaluation
- ii. Please refrain from changing/removing all submitted data unless requested by NPRA or the data has been updated as per latest registration requirements.
- iii. Kindly be reminded that decision whether the dossier is allowed for registration will be subjected to full evaluation and the final decision by the Drug Control Authority (DCA).
- iv. Kindly also note that satisfactory and complete documentation must be submitted within 180 working days, after first evaluation remark is received to avoid rejection.

I, the undersigned, certify, that the information provided in this application and the attached documents is correct and true.

This declaration is prepared & submitted by:

Signatory: \_\_\_\_\_

(Name: )

(Designation/Job Title: )

(Name of company: )

(Date: )

**A. Bioequivalence Study Information**

(Please fill in the following information)

1.	Study number/ study protocol number			
2.	Study title			
3.	Start and end dates for each period of the clinical study	Study period	Start date	End date
		Period 1		
		Period 2		
4.	Start and end date for bio-analytical study			
5.	Clinical Study facility (Name and full address of clinical study site)			
6.	Bio-analytical facility (Name and full address of bioanalytical study site)			
7.	Institutional Review Board/ Independent Ethical Committee	Name & address of the ethics committee		
		Approval date of study protocol (together with study protocol number and version)		
		Approval date of informed consent form		

8.	Relevant information on the test product used in the BE study	Product name				
		Strength *Please indicate whether the test product used has the same strength as product proposed for registration				
		Dosage form				
		Batch number				
		Batch size				
		Manufacture date				
		Expiry date				
		Name and full address of the drug substance manufacturing site				
9.	Relevant information on the reference product used in the BE study	Product name				
		Strength				
		Dosage form				
		Batch number				
		Expiry date				
		Country where the product is sourced from				
		Name and full address of the drug product manufacturing site together with product label (e.g. outer carton, package insert/patient information leaflet) *Please indicate whether the reference product is the same listed Malaysia Comparator Product (MCP). If <b>NO</b> , please provide comparative dissolution profile (CDP) between reference product and MCP				
10.	Summary results of the study					
	Parameter <b>Logarithmic transformed data</b>	Test (Geometric mean)	Reference (Geometric mean)	% Ratio of geometric means	90% Confidence interval	Intra-subject coefficient of variation, ISCV (%)
	AUC <sub>0-t</sub>					
	AUC <sub>0-∞</sub>					
	C <sub>max</sub>					

## B. Documents to be submitted

(Please tag/state the name and location of the documents in the dossier)

No.	Documents	Name of document and location
1.	(i) Certificate of BE Centre Compliance Programme issued by NPRA OR (ii) Bioequivalence Inspection Report (BEIR) verification letter issued by NPRA	
2.	Formulation page and manufacturing process flow chart in the batch manufacturing record (BMR) of test product	
3.	Letter with a signed statement from the sponsor/manufacturer/product owner confirming that the <b>test product</b> is the same formulation, manufactured by the same process and using same equipment as the one that is submitted for marketing authorization	
4.	Certificate of analysis (COA) of BE test product	
5.	Certificate of analysis (COA) of reference product	
6.	Letter with a signed statement from the sponsor/manufacturer/product owner confirming that the <b>active substance</b> used in manufacturing of test product is the same as the one that is submitted for marketing authorization.	
7.	Outer packaging and/ or prescribing information sheet of BE reference product and Malaysia comparator product (if applicable)  <i>The document should contain the information of the batch number, expiry date, name and address of manufacturer</i>	
8.	(i) Dissolution study report for comparative dissolution profile (CDP) conducted between test product and reference product in pH 1.2, 4.5, 6.8 and quality control media (if applicable) (ii) Dissolution study protocol  <i>The dissolution study report should be dated and signed by analyst or relevant personnel.</i>	
9.	(i) Dissolution study report for comparative dissolution profile (CDP) conducted between reference product and Malaysia comparator product (MCP) in pH 1.2, 4.5, 6.8 and quality control media (if applicable) (ii) Dissolution study protocol  <i>The dissolution study report should be dated and signed by analyst or relevant personnel.</i>	
10.	Application form for a biowaiver of additional strength (if applicable), together with justification and documents for biowaiver request (i) All strengths are manufactured by the same manufacturing process (ii) Qualitative and quantitative composition of the different strengths (all) (iii) Dissolution study report for comparative dissolution profile (CDP) conducted between test product and other proposed additional strengths in pH 1.2, 4.5, 6.8 and quality control media (if applicable) (iv) Dissolution study protocol <i>The dissolution study report should be dated and signed by analyst or relevant personnel.</i>	
11.	Justifications and bridging data if BE reference product is not the same as MCP (i.e. same strength and manufacturing site as registered in Malaysia)	
12.	Clinical study report	
13.	Pharmacokinetic and statistical analysis report	
14.	Bioanalytical method validation report and relevant addendum(s)	
15.	Bioanalytical study report	
16.	Quality assurance statement	
17.	Letter of approval of Institutional Review Board/ Independent Ethical Committee (IEC)	
18.	Study protocol approved by Independent Ethical Committee (IEC)	
19.	Informed consent form	
20.	Literature references (if applicable)	