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Bahagian Regulatori Farmasi Negara (NPRA)
National Pharmaceutical Regulatory Agency (NPRA)
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CENTRE OF PRODUCT AND COSMETIC EVALUATION

BIOEQUIVALENCE STUDY REPORT SUBMISSION CHECKLIST

General Instructions

- Please submit this checklist together with the bioequivalence study report (including all appendices) in QUEST 3+ system under section P9 for product screening and evaluation.
- Provide/fill in as much detailed, accurate and final information as possible.
- All the appended documents should be clearly identifiable by their location and tagging of the file names. Kindly refer to the 'Guide on how to upload the BE study report and other relevant documents in QUEST 3+ system under section P9'.
- 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@npra.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.

Signed on behalf of:

_____ (Product registration holder)

_____ (Date)

_____ (Name & title)

A. Bioequivalence Study Information

(Please fill in the following information)

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

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	
		Name and full address of the test product manufacturing site *Please indicate whether the test product used has the same qualitative and quantitative composition as the product proposed for registration	
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 reference product manufacturing site *Please indicate whether the reference product is the same as Malaysia Comparator Product (MCP). If **NO**, please provide document no. 7 & 9 under section B. Documents to be submitted.	

10. Summary results of the study

Parameter **Logarithmic transformed data**	Test (Geometric mean)	Reference (Geometric mean)	% Ratio of geometric means	90% Confidence interval	Intra-subject coefficient of variation, ISCV (%)
AUC_{0-t}					
$AUC_{0-\infty}$					
C_{max}					

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 NPRA BE Centre Compliance Programme issued by NPRA OR (ii) Bioequivalence Desktop Evaluation (BEDE) letter for exemption of BE study inspection issued by NPRA OR (iii) Proof of acceptance of inspection application for NPRA BE Centre Compliance Programme	
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 **test product** 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 **active substance** 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) *The document should contain the information of the batch number, expiry date, name and address of manufacturer*	
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 *The dissolution study report should be dated and signed by analyst or relevant personnel.*	
9.	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) (i) Dissolution study report for comparative dissolution profile (CDP) conducted between BE 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 *The dissolution study report should be dated and signed by analyst or relevant personnel.*	
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 *The dissolution study report should be dated and signed by analyst or relevant personnel.*	
11.	Clinical study report	
12.	Pharmacokinetic and statistical analysis report	
13.	Bioanalytical method validation report and relevant addendum(s)	
14.	Bioanalytical study report	
15.	Quality assurance statement	
16.	Letter of approval of Institutional Review Board/ Independent Ethical Committee (IEC)	
17.	Study protocol approved by Independent Ethical Committee (IEC)	
18.	Informed consent form	
19.	Literature references (if applicable)	