GUIDE ON HOW TO UPLOAD THE BE STUDY REPORT AND OTHER RELEVANT DOCUMENTS IN QUEST 3+ SYSTEM UNDER SECTION P9

1. Kindly ensure that the document is in searchable or optical character recognition (OCR) format and the text is legible.

2. All documents submitted for product registration shall be in English or Bahasa Malaysia.

3. Kindly ensure that the COMPLETE BE study report, including all the appendices are submitted for evaluation.

4. Please do not rearrange the BE study report.

5. Please note that the maximum single file size in QUEST 3+ system is 5MB. Kindly upload the BE study report under section P9 as multiple files.

6. Please label the files (BE study report) accordingly as in the example 1 or example 2 below:

Example 1	**Example 2** (as per ICH E3)
Report 1 Report 2 Report 3 Report 4 Report 5 Report 6 Report 7 Report 8 Report 9 Report 10	Clinical study report Appendix 16.0 – 16.1.5 Appendix 16.1.6 – 16.1.12 Appendix 16.2 – 16.2.5 Appendix 16.2.6 – 16.2.8 Appendix 16.3 – 16.4 Appendix 16.5 Part 1 Appendix 16.5 Part 2 Appendix 16.5 Part 3 Appendix 16.5 Part 4 Appendix 16.5 Part 5

7. Kindly label the additional documents requested in the Bioequivalence Study Report Submission Checklist accordingly as in the examples below:

Example 2
Certificate of BE Centre Compliance Program BMR of test product Test product declaration letter Active substance source of test product declaration letter Outer carton of reference product CDP between test product and reference product CDP between reference product and MCP Application for a biowaiver: additional strength checklist Justification for biowaiver of additional strength

8. Kindly state the file's name and page number (if applicable) in Bioequivalence Study Report Submission Checklist (part B) as in the example 1 or example 2 below:

Example 1

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) acceptance letter issued by NPRA OR (iii) Proof of acceptance of inspection application for NPRA BE Centre Compliance Programme	Certificate of BE Centre Compliance Programme
2.	Formulation page and manufacturing process flow chart in the batch manufacturing record (BMR) of test product	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	Test product declaration letter
4.	Certificate of analysis (COA) of BE test product	Report 5 page 1
5.	Certificate of analysis (COA) of reference product	Report 5 page 3
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.	Active substance source of test product declaration letter
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*	Outer carton of reference product
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.*	CDP between test product and reference product
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.*	CDP between reference product and MCP
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.*	Application for a biowaiver: additional strength checklist Justification for biowaiver of additional strength
11.	Clinical study report	Report 1 page 1
12.	Pharmacokinetic and statistical analysis report	Report 2 page 30
13.	Bioanalytical method validation report and relevant addendum(s)	Report 6 page 1
14.	Bioanalytical study report	Report 5 page 1
15.	Quality assurance statement	Report 4 page 20
16.	Letter of approval of Institutional Review Board/ Independent Ethical Committee (IEC)	Report 2 page 1
17.	Study protocol approved by Independent Ethical Committee (IEC)	Report 2 page 5
18.	Informed consent form	Report 2 page 65
19.	Literature references (if applicable)	Report 4 page 70

Example 2

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) acceptance letter issued by NPRA OR (iii) Proof of acceptance of inspection application for NPRA BE Centre Compliance Programme	Certificate of BE Centre Compliance Programme
2.	Formulation page and manufacturing process flow chart in the batch manufacturing record (BMR) of test product	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	Test product declaration letter
4.	Certificate of analysis (COA) of BE test product	Appendix 16.1.6 – 16.1.12 page 1
5.	Certificate of analysis (COA) of reference product	Appendix 16.1.6 – 16.1.12 page 3
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.	Active substance source of test product declaration letter
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*	Outer carton of reference product
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.*	CDP between test product and reference product
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.*	CDP between reference product and MCP
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.*	Application for a biowaiver: additional strength checklist Justification for biowaiver of additional strength
11.	Clinical study report	Clinical study report page 1
12.	Pharmacokinetic and statistical analysis report	Clinical study report page 30, Appendix 16.2 – 16.2.5 page 150, Appendix 16.2.6 – 16.2.8 page 1
13.	Bioanalytical method validation report and relevant addendum(s)	Appendix 15.5 Part 2 page 1
14.	Bioanalytical study report	Appendix 15.5 Part 1 page 1
15.	Quality assurance statement	Appendix 16.1.6 – 16.1.12 page 10
16.	Letter of approval of Institutional Review Board/ Independent Ethical Committee (IEC)	Appendix 16.0 – 16.1.5 page 70

17.	Study protocol approved by Independent Ethical Committee (IEC)	Appendix 16.0 – 16.1.5 page 3
18.	Informed consent form	Appendix 16.0 – 16.1.5 page 50
19.	Literature references (if applicable)	Appendix 16.1.6 – 16.1.12 page 50

9. Kindly fill in as 'Not applicable' if the document is not relevant to your product as in the example below [Bioequivalence Study Report Submission Checklist (part B) no. 9 & 10]:

No.	Documents	Name of document and location
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.*	Not applicable
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.*	Not applicable

10. Please note that starting from 1 MARCH 2022, the generic product registration application will be REJECTED during screening stage if the files uploaded in QUEST 3+ system under section P9 are not uploaded/labelled according to this guide.