**BEDE Submission Checklist**

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| --- | --- | --- | --- | --- |
| **No.** | **Question** | **Yes** | **No** | **Remarks** |
| 1. | The same product is WHO Prequalified? |  |  | If yes, kindly state the date of product prequalification: ………………………. |
| 2. | The BE study(ies) has been inspected by NPRA? |  |  | If yes, kindly state the inspection details: …………….. |
| 3. | The BE study(ies) has been submitted to NPRA for BEDE evaluation? |  |  | If yes, kindly state the BEDE number: ………………………. |
| 4. | The BE study(ies) submitted is conducted at BE Centres listed in the NPRA BE Centre Compliance Programme?For information, please visit the link below: <https://www.npra.gov.my/index.php/en/be-studies-centres/foreign-bioequivalence-centre.html><https://www.npra.gov.my/index.php/en/component/sppagebuilder/942-be-centres-sites-which-certificate-has-expired.html?Itemid=0>  |  |  | If one or more sites are not listed in the NPRA BE Centre Compliance Programme, kindly state which site:.………………………………….. |
| 5. | For clinical phase of the BE study of interest, it is conducted at facilities have been listed in the NPRA BE Centre Compliance Programme. **However, the BE study(ies) is not conducted during the valid listing.** |  |  |  |
| 6. | For bioanalytical phase of the BE study of interest, it is conducted at facilities have been listed in the NPRA BE Centre Compliance Programme. **However, the BE study(ies) is not conducted during the valid listing.** |  |  |  |

**The following documents are ready to be submitted for screening:**

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| **No.** | **Document** | **Appendices** | **Yes** | **No** |
| 1. | NPRA/434/12-1-L1 Maklumat Penilaian Penentuan Keperluan Pemeriksaan Kajian BE (L1 form) in Microsoft Word format  | Appendix 1 - L1  |  |  |
| 2a. | Proof of product registration in NPRA’s reference countries  | Appendix 2a - MA Letter  |  |  |
| 2b. | Full Public Assessment Report issued during product registration   | Appendix 2b - PAR  |  |  |
| 3. | Summary of BE Study of interest  | Appendix 3 - Summary  |  |  |
| 4. | Evidence of RA Approval for the BE Study. Eg: BENOC and/or T-import licence (India) | Appendix 4 - RA  |  |  |
| 5a. | Evidence of EC Approval for the BE Study  | Appendix 5a - EC Approval  |  |  |
| 5b. | Proof that EC approving the BE study is registered with CDSCO or relevant regulatory body during the BE study conduct (if applicable) | Appendix 5b - EC Registration  |  |  |
| 6. | Inspection/ Evaluation Report conducted by any RA on the same BE Study  | Appendix 6 – BE Study Inspection/ Evaluation Report  |  |  |
| 7. | Monitoring report conducted during the BE Study   | Appendix 7 - Monitoring Report  |  |  |
| 8. | Details of Protocol Deviation for the BE Study  | Appendix 8 - PD  |  |  |
| 9. | Details of Method Analysis Deviation in Bioanalytical Report for the BE Study  | Appendix 9 - Method Deviation  |  |  |
| 10. | Details of Reanalysis & Reinjection in Bioanalytical Report for the BE Study   | Appendix 10 - Reanalysis & Reinjection   |  |  |
| 11. | Details of Reintegration/ Manual integration in Bioanalytical Report for the BE Study  | Appendix 11 - Reintegration  |  |  |
| 12. | Details of Subject Exclusion for the BE Study as reported in BE Study Report  | Appendix 12 - Subject Exclusion  |  |  |
| 13. | QA Statement for both Clinical & Bioanalytical Part  | Appendix 13 - QA Statement  |  |  |
| 14. | Complete Bioanalytical Report   | Appendix 14 - BA Report  |  |  |
| 15. | Inspection Report, CAPA, Closure Letter and/or USFDA Form 483   |
|  | Clinical Site Address:  |
| a. | At least one inspection report before the BE study conduct (Preferably from NPRA reference agency) | Appendix 15a - (Name of Authority & Date of Inspection) |  |  |
| b. | At least one inspection report after the BE study conduct (Preferably from NPRA reference agency) | Appendix 15b - (Name of Authority & Date of Inspection) |  |  |
|  | Bioanalytical Site Address:  |
| c. | At least one inspection report before the BE study conduct (Preferably from NPRA reference agency) | Appendix 15c - (Name of Authority & Date of Inspection) |  |  |
| d. | At least one inspection report after the BE study conduct (Preferably from NPRA reference agency) | Appendix 15d - (Name of Authority & Date of Inspection) |  |  |
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