|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No.** | **Question** | **Yes** | **No** | **Remarks** |
| 1. | Sila sahkan sama ada produk tersebut layak untuk diberi penilaian keutamaan di bawah Pusat Penilaian Produk dan Kosmetik, NPRA.  *Kindly confirm whether the product qualifies for priority review under Centre for Product and Cosmetic Evaluation, NPRA.*  Nota: Sila sertakan bukti bertulis daripada Pusat Penilaian Produk dan Kosmetik, NPRA.  *Note: Kindly provide written evidence from Centre for Product and Cosmetic Evaluation, NPRA.* |  |  |  |
| 2.  a) | Adakah produk ini layak didaftarkan dibawah FRP?  Adakah produk yang tersebut WHO Prequalified?  *The same product is WHO Prequalified?*  Untuk maklumat lanjut, sila layari pautan di bawah:  *For information, please visit the link below:*  [Direktif Berkenaan Pengemaskinian dan Pelaksanaan Guideline for Facilitated Registration Pathway (FRP), Revision 1, 2023 (npra.gov.my)](https://www.npra.gov.my/index.php/en/directive-general/1527544-direktif-berkenaan-pengemaskinian-dan-pelaksanaan-guideline-for-facilitated-registration-pathway-frp-revision-1-2023.html) |  |  | Jika ya, sila nyatakan tarikh *prequalification:*  *If yes, kindly state the date of product prequalification:*  ………………………………… |
| b) | Adakah produk yang sama didaftarkan oleh EMA dan/ atau Health Canada dan/ atau PMDA, Jepun dan/ atau Swissmedic, Switzerland dan/ atau TGA, Australia dan/ atau UKMHRA, dan/ atau USFDA?  *The same product is approved by the EMA and/ or Health Canada and/or PMDA, Japan and/ or Swissmedic, Switzerland and/ or TGA, Australia and/ or UKMHRA, and/ or USFDA?*  Untuk maklumat lanjut, sila layari pautan di bawah:  *For information, please visit the link below:*  [Direktif Berkenaan Pengemaskinian dan Pelaksanaan Guideline for Facilitated Registration Pathway (FRP), Revision 1, 2023 (npra.gov.my)](https://www.npra.gov.my/index.php/en/directive-general/1527544-direktif-berkenaan-pengemaskinian-dan-pelaksanaan-guideline-for-facilitated-registration-pathway-frp-revision-1-2023.html) |  |  |  |
| c) | Adakah produk yang sama didaftarkan melalui prosedur Penilaian Bersama ASEAN (JA)?  *The same product is registered through ASEAN Joint Assessment (JA) procedure?*  Untuk maklumat lanjut, sila layari pautan di bawah:  *For information, please visit the link below:*  [Direktif Berkenaan Pengemaskinian dan Pelaksanaan Guideline for Facilitated Registration Pathway (FRP), Revision 1, 2023 (npra.gov.my)](https://www.npra.gov.my/index.php/en/directive-general/1527544-direktif-berkenaan-pengemaskinian-dan-pelaksanaan-guideline-for-facilitated-registration-pathway-frp-revision-1-2023.html) |  |  |  |
| 3. | Adakah kajian BE tersebut telah diperiksa oleh NPRA?  *The BE study(ies) has been inspected by NPRA?* |  |  | Jika ya, sila nyatakan tarikh pemeriksaan:  *If yes, kindly state the inspection date:*  …………….. |
| 4. | Adakah kajian BE tersebut telah dikemukakan kepada NPRA untuk penilaian BEDE?  *The BE study(ies) has been submitted to NPRA for BEDE evaluation?* |  |  | Jika ya, sila nyatakan nombor rujukan BEDE:  *If yes, kindly state the BEDE reference number:* ………………………. |
| 5. | Adakah kajian BE yang dikemukakan dijalankan di Pusat BE yang pernah disenaraikan/ masih tersenarai dalam Program Komplians Pusat BE NPRA?  *The BE study(ies) submitted is conducted at BE Centres that were previously listed/ currently listed in the NPRA BE Centre Compliance Programme?*  Untuk maklumat lanjut, sila layari pautan di bawah:  *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> |  |  | Jika satu atau lebih tapak tidak tersenarai dalam Program Pematuhan Pusat BE NPRA, sila nyatakan tapak tersebut:  *If one or more sites are not listed in the NPRA BE Centre Compliance Programme, kindly state which site:*  .……………………………… |
| 6. | Fasa klinikal kajian BE dijalankan di tapak kajian yang disenaraikan dalam Program Komplians Pusat BE NPRA. **Walau bagaimanapun,** **kajian BE tersebut tidak dijalankan semasa tempoh penyenaraian yang sah.**  *For clinical phase of the BE study, it is conducted at the site that have been listed in the NPRA BE Centre Compliance Programme.* ***However, the BE study is not conducted during the valid listing.*** |  |  |  |
| 7. | Fasa bioanalitikal kajian BE dijalankan di tapak kajian yang disenaraikan dalam Program Komplians Pusat BE NPRA. **Walau bagaimanapun,** **kajian BE tersebut tidak dijalankan semasa tempoh penyenaraian yang sah.**  *For bioanalytical phase of the BE study, it is conducted at the site that have been listed in the NPRA BE Centre Compliance Programme.* ***However, the BE study is not conducted during the valid listing.*** |  |  |  |

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No.** | **Document** | **Appendices** | **Yes** | **No** |
| 1. | N3-FR-51 L1 Maklumat Penilaian Penentuan Keperluan Pemeriksaan Kajian BE (L1 form) in Microsoft Word format | Appendix 1 - L1 |  |  |
| 2a. | Proof of product registration/ submission in NPRA’s reference countries | Appendix 2a - MA Letter |  |  |
| 2b. | Public Assessment Report and/or evidence that the same BE study submitted to NPRA’s reference countries | 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) |  |  |

Reason(s) for Rejection: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_