**L1 MAKLUMAT UNTUK PENILAIAN PENENTUAN KEPERLUAN PEMERIKSAAN KAJIAN BE**

*L1 INFORMATION FOR EVALUATION ON THE NEED FOR BE STUDY INSPECTION*

**BAHAGIAN 1: MAKLUMAT PEMOHON**

*PART 1: DETAILS OF APPLICANT*

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| **1.** | **Nama Penuh (Huruf Besar)**  *Full Name (Block Letter)* |  |
| **2.** | **Nama dan Alamat Syarikat Pemohon**  *Name and Address of the Applicant’s Company* |  |
| **3.** | **E-mel**  *Email address* |  |
| **4.** | **No. Telefon**  *Contact Number* |  |

**BAHAGIAN 2: MAKLUMAT PRODUK**

*PART 2: DETAILS OF PRODUCT*

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| **1.** | **Nama, - Kekuatan Produk dan Bentuk Dosej untuk Didaftar**  *Name, - Strength and Dosage Form of Product to be Registered* | |  | |
| **2.** | **Bahan Aktif**  *Active Ingredient* | |  | |
| **3.** | **Jumlah Kajian BE yang diperlukan untuk menyokong pendaftaran produk di Malaysia**  *Total number of BE study(ies) required to support the product registration in Malaysia* | |  | |
| **4.** | **Status Pendaftaran di Negara Lain/** *Registration Status in Other Countries* | | | |
| 1. **Hanya Badan Regulatori dari Negara rujukan NPRA yang akan diberi keutamaan semasa penilaian**   *Only Regulatory Authorities from NPRA’s reference countries will be given priority during an assessment.*  **Negara Rujukan NPRA/** *NPRA’s Reference Countries***:**  **United Kingdom, Sweden, France, United States of America, Australia, Canada, Japan, Switzerland, WHO and EMA centralised registration pathway.** | | | |
| **Negara/** *Country* | **Status/** *Status* | | **Laporan Penilaian/** *Assessment Report* |
|  |  | | **[ ] Ada/** *Available*  **[ ] Tiada/** *None* |
|  |  | | **[ ] Ada/** *Available*  **[ ] Tiada/** *None* |
| **Lampiran yang diperlukan/** *Attachment(s) required:*   1. **Salinan dokumen ini (NPRA/434/12-1-L1)dalam format .doc/.docx (*Microsoft Word*): Lampiran 1 - L1**   *A copy of this document (NPRA/434/12-1-L1) in .doc/.docx (Microsoft Word) format: Appendix 1 - L1*   1. **Bukti produk berdaftar di negara yang disenaraikan diatas: Lampiran 2a - MA Letter**   *Proof of Product Registration/ Marketing Authorization Letter: Appendix 2a - MA Letter*   1. **Public Assessment Report (PAR) yang dikeluarkan oleh badan regulatori: Lampiran 2b - PAR**   *Full Public Assessment Report (PAR)/ assessment report issued by regulatory authority: Appendix 2b - PAR*  **[Nota: Laporan PAR penuh yang mengandungi maklumat kajian BE yang dinilai semasa pendaftaran produk serta status kepatuhan Amalan Klinikal Baik (GCP) untuk Kajian berkaitan adalah menjadi keutamaan semasa penilaian dibuat terhadap Laporan Penilaian yang disertakan**  *[Note: Full PAR provided shall include the details of BE study evaluated during product registration and statement on Good Clinical Practice (GCP) compliance for the relevant study(ies)]* | | | |

**BAHAGIAN 3: MAKLUMAT KAJIAN BE**

*PART 3: DETAILS BE STUDY (IES)*

**Jika terdapat lebih daripada satu kajian BE yang akan digunakan untuk menyokong pendaftaran produk tersebut, sila ulangi bahagian 3 untuk setiap kajian tersebut.**

*If there are more than one BE study to be used to support the registration of the same product, please repeat section 3 for each study.*

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| **1.** | **Tajuk Kajian BE**  *Title of BE Study* |  |
| **2.** | **Produk Kajian BE**  *BE study test product* |  |
| **3.** | **Produk Perbandingan**  *Comparator Product* |  |
| **4.** | **Nombor Protokol**  *Protocol Number* |  |
| **5.** | **Tarikh Kajian BE dijalankan**  **Contoh: 1 Januari 2022 - 10 Januari 2022**  *Date of BE Study conducted.*  *E.g.:* 1 January 2022 - 10 January 2022 | **Klinikal**/*Clinical*:  **Bioanalitikal**/*Bioanalytical*:  **Tarikh Laporan**/*Date of Report:* |
| **6.** | **Nama Tapak Klinikal**  *Name of Clinical Site* |  |
| **7.** | **Alamat Tapak Klinikal**  *Address of Clinical Site* |  |
| **8.** | **Nama Tapak Bioanalitikal**  *Name of Bioanalytical Site* |  |
| **9.** | **Alamat Tapak Bioanalitikal**  *Address of Bioanalytical Site* |  |
| **10.** | **Penaja BE Kajian**  *Sponsor of the BE Study* |  |
| **11.** | **Penyelidik Utama**  *Principal Investigator* |  |
| **12.** | **Kelulusan Menjalankan Kajian BE**  *Approval for the BE Study Conduct* | **Jawatankuasa Etika (EC)/** *Ethics Committee (EC):*  **Status Pendaftaran** **EC**/ *Registration status of* *EC:*  **Badan Regulatori/** *Regulatory Authority:* |
| **Lampiran yang diperlukan/** *Attachment(s) required:*   1. **Ringkasan laporan kajian BE: Lampiran 3 - Summary**   *Summary of Clinical Study Report: Appendix 3 - Summary*   1. **Kelulusan daripada badan regulatori tempatan untuk menjalankan kajian BE (BENOC & T-Import License): Lampiran 4 - RA Approval**   *Approval letter from local regulatory authority for BE study conduct (BENOC & T-Import License): Appendix 4 - RA Approval*   1. **Surat kelulusan daripada jawatankuasa etika untuk menjalankan Kajian BE: Lampiran 5a - EC Approval**   *Approval letter from ethics committee for BE study conduct: Appendix 5a - EC Approval*   1. **Bukti bahawa jawatankuasa etika berdaftar dengan badan regulatori tempatan semasa kelulusan (6) di atas diperoleh: Lampiran 5b - EC Registration**   *Evidence that the ethics committee is registered with the local regulatory authority during the approval (6) above was obtained: Appendix 5b - EC Registration*  **Nota: Sila pastikan maklumat di dalam kesemua dokumen kelulusan adalah konsisten dengan kajian yang berkaitan.**  *Note: Please ensure that the information in the approval documents is consistent with the relevant study(ies).* | |
| **13.** | **Status kepatuhan Kajian BE terhadap garis panduan**  **Nota: Sila nyatakan garis panduan yang digunakan**  *Compliance status of the BE study to Guidelines*  *Note: Please state the guidance referred to in the study* | **\*United States Food and Drug Administration (USFDA), European Medicines Agency (EMA), Association of Southeast Asian Nations (ASEAN) atau lain-lain.**  *USFDA, EMA, ASEAN or others.* |
| **14.** | **Status pemeriksaan ke atas Kajian BE yang sama (Jika ada)**  *Inspection status of the same BE study (If any)* | **[ ] Ada/** *Available.* **Sila isi maklumat di bawah/** *Please include the details below.*  **[ ] Tiada/** *None*  **Badan Regulatori /** *Regulatory Authority:*  **Tarikh Pemeriksaan/** *Inspection Date:*  **Status Pemeriksaan/***Inspection Status:* |
| **Status penerimaan Kajian BE yang sama (Jika ada)**  *Acceptance status of the same BE study (If any)* | **[ ] Diterima/** *Accepted.* **Sila isi maklumat di bawah/** *Please include the details below.*  **[ ] Tidak diterima/** *Not accepted*  **[ ] Tidak berkaitan/** *Not applicable*  **Badan Regulatori /** *Regulatory Authority:*  **Tarikh Penerimaan/** *Submission Date:*  **Status Penerimaan/***Submission Status:* |
| **Lampiran yang diperlukan/** *Attachment(s) required:*   1. **Laporan pemeriksaan/ penilaian yang dijalankan oleh badan regulatori ke atas kajian BE yang sama: Lampiran 6 - BE Study Inspection/ Evaluation Report**   *Inspection/ evaluation report conducted by the regulatory authority on the same BE study: Appendix 6 - BE Study Inspection/ Evaluation Report*  **\*Sila pastikan maklumat di dalam dokumen yang disertakan adalah konsisten dengan kajian yang berkaitan.**  *Please ensure that the information provided in the attached documents is consistent with the relevant study(ies).* | |
| **15.** | **Pemantauan ke atas pelaksanaan Kajian BE oleh Sponsor, Contract Research Organisation (CRO) atau lain-lain**  *Monitoring of the BE study conducted by Sponsor, CRO or others* | **[ ] Ada/** *Available*  **[ ] Tiada/** *None*  **Syarikat Pemantau/** *Monitoring Company***:**  **Kekerapan pemantauan/** *Monitoring frequency:* |
| **Lampiran yang diperlukan/** *Attachment(s) required:*   1. **Laporan-laporan pemantauan yang dijalankan oleh penaja ke atas kajian BE: Lampiran 7 - Monitoring Report**   *Monitoring report conducted by sponsor during BE study conduct: Appendix 7 - Monitoring Report*  **\*Sila pastikan maklumat di dalam dokumen yang disertakan adalah konsisten dengan kajian yang berkaitan.**  *Please ensure that the information provided in the attached documents is consistent with the relevant study(ies).* | |
| **16.** | **Ringkasan Kajian BE/** *Summary of the BE Study* | |
| ***Design* Kajian/** *Study Design:*  **Jumlah Subjek/** *Subject No.:*  **Deviasi dari Protokol/** *Protocol Deviation:* **[ ] Ada/** *Available* **[ ] Tiada/** *None* | |
| **Validasi Tatacara Analisa*/*** *Method Validation:*   1. **Tarikh Mula & Akhir Validasi Tatacara Analisa/** *Method Validation Start & End*   **(\*Termasuk P*artial Validation/*** *Include partial validation***)**  *Date: (e.g dd/mm/yyyy - dd/mm/yyyy)* | |
| **Analisis Sampel Subjek/** *Subject Sample Analysis:*   1. **Deviasi dari *Method* Analisis@SOP/** *Method@SOP Deviation:*   **[ ] Ada/** *Available* **[ ] Tiada/** *None*   1. **Analisis Semula@*Reinjection* Sampel/** *Sample Reanalysis@Reinjection:*   **[ ] Ada/** *Available* **[ ] Tiada/** *None*   1. **Integrasi Semula@ Integrasi Secara Manual/** *Reintegration@Manual Integration:*   **[ ] Ada/** *Available* **[ ] Tiada/** *None* | |
| **Analisis farmakokinetik dan Statistik/** *Pharmacokientics and Statistical Analysis:*   1. **Tarikh Analisis/** *Date of Analysis:* 2. **Pengecualian Subjek/** *Subject Exclusion:*   **[ ] Ada/** *Available* **[ ] Tiada/** *None* | |
| **Audit oleh Quality Assurance/** *Quality Assurance Audit:*  **[ ] Ada/** *Available* **[ ] Tiada/** *None* | |
| **Lampiran yang diperlukan/** *Attachment(s) required:*   1. **Perician *protocol deviation* seperti yang dilaporkan di dalam laporan kajian BE: Lampiran 8 - PD**   *Details of protocol deviation as reported in the Clinical Study Report: Appendix 8 - PD*   1. **Perician *method deviation* seperti yang dilaporkan di dalam laporan kajian BE: Lampiran 9 - Method Deviation**   *Details of method deviation as reported in the Clinical Study Report: Appendix 9 - Method Deviation*   1. **Perician *repeat analysis* dan *reinjection* seperti yang dilaporkan di dalam laporan bioanalitikal: Lampiran 10 - Reanalysis & Reinjection**   *Details of repeat analysis and reinjection as reported in the Bioanalytical Report: Appendix 10 - Reanalysis & Reinjection*   1. **Perician *reintegration* seperti yang dilaporkan di dalam laporan bioanalitikal: Lampiran 11 - Reintegration**   *Details of reintegration as reported in the Bioanalytical Report: Appendix 11 - Reintegration*   1. **Perician pengecualian subjek seperti yang dilaporkan di dalam laporan kajian BE: Lampiran 12 - Subject Exclusion**   *Details of subject exclusion as reported in the Clinical Study Report: Appendix 12 - Subject Exclusion*   1. ***Quality Assurance Statement* bagi kajian klinikal dan bioanalitikal: Lampiran 13 - QA Statement**   *Quality Assurance Statement conducted on clinical and bioanalytical study: Appendix 13 - QA Statement*   1. **Laporan Bioanalitikal penuh: Lampiran 14 - BA Report**   *Complete Bioanalytical Report: Appendix 14 - BA Report*  **\*Sila pastikan maklumat yang di atas adalah konsisten dengan maklumat di dalam lampiran yang disertakan.**  *Please ensure that the information above is consistent with the attached document provided.* | |

**BAHAGIAN 4: MAKLUMAT PUSAT KAJIAN**

*PART 4: DETAILS OF STUDY CENTRE*

**Jika Tapak Klinikal dan Bioanalitkal merupakan entiti yang berbeza, sila ulangi bahagian 4 untuk setiap tapak.**

*If the Clinical and Bioanalytical sites are different entities, please repeat section 4 for each site.*

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| **[ ] Tapak Klinikal/**  *Clinical Site*  **[ ] Tapak Bioanalitikal/** *Bioanalytical Site* | | | | | | | |
| **1.** | **Nama Tapak**  *Facility Name* | |  | | | | |
| **2.** | **Alamat Tapak**  *Facility Address* | |  | | | | |
| **3.** | **Senarai Pemeriksaan ke atas Tapak Kajian oleh Badan Regulatori**  *List of Inspection on Facility by Regulatory Authority* | | | | | | |
| **Arahan/** *Instruction:*   1. **Hanya senaraikan pemeriksaan yang dilalui dalam tempoh 5 tahun sebelum dan selepas kajian BE dijalankan.**   *Only list down the inspection conducted at the site within 5 years before and after the BE study was conducted.*   1. **Maklumat pemeriksaan hendaklah dimasukkan di dalam jadual dibawah.** *Inspection history has to be filled in according to the format below.* 2. **Semua maklumat di dalam laporan pemeriksaan tidak boleh ditapis. Dalam keadaan di mana maklumat tidak boleh didedahkan kepada pemohon, laporan tersebut boleh dilindungi dengan kata laluan sebelum dimuatnaik ke pautan yang dikongsikan semasa proses penyaringan/ penilaian. Kata laluan tersebut boleh dikongsikan kepada NPRA secara terus.**   *All information in the BE centre inspection report must not be redacted. In case confidentiality considerations prevent the disclosure of certain information to the applicant, the inspection report can be protected with a password before the same document is uploaded to the link shared during the screening/ evaluation process. The password can be shared directly with NPRA.*   1. **Semua dokumen hanya perlu dihantar di dalam format *softcopy (OCR pdf).***   *All documents need to be submitted in softcopy format (OCR pdf).*   1. **Hanya laporan pemeriksaan dari badan regulatori rujukan NPRA untuk pemeriksaan BE yang akan diberi keutamaan semasa penilaian.**   *Only inspection reports from NPRA’s reference regulatory authorities for BE inspection will be given priority during the assessment.*  **Badan Regulatori Rujukan NPRA untuk pemeriksaan BE***/ NPRA’s Reference Regulatory Authorities for BE Inspection***:**   * **United States Food and Drug Administration (USFDA),** * **Medicines and Healthcare products Regulatory Agency (MHRA) United Kingdom** * **European Medicines Agency (EMA) atau beberapa badan regulatori di bawahnya seperti:**   + **National Agency for the Safety of Medicine and Health Products (ANSM), France**   + **Federal Institute for Drugs and Medical Devices (BfArM)**   + **Austrian Agency for Health and Food Safety (AGES) dan lain-lain** * **World Health Organization (WHO) Inspection Report** | | | | | | |
| **No./** *No.* | **Badan Regulatori/** *Regulatory Authority* | | **Skop/** *Scope (e.g. Clinical/ Bioanalytical)* | **Tarikh/** *Date* | **Status/** *Status* | **Laporan/** *Report* |
|  |  | |  |  |  | **[ ] Ada/** *Available*  **[ ] Tiada/** *None* |
|  |  | |  |  |  | **[ ] Ada/** *Available*  **[ ] Tiada/** *None* |
|  |  | |  |  |  | **[ ] Ada/** *Available*  **[ ] Tiada/** *None* |
|  |  | |  |  |  | **[ ] Ada/** *Available*  **[ ] Tiada/** *None* |
|  |  | |  |  |  | **[ ] Ada/** *Available*  **[ ] Tiada/** *None* |
|  |  | |  |  |  | **[ ] Ada/** *Available*  **[ ] Tiada/** *None* |
| |  |  | | --- | --- | |  | **Saya dengan ini mengisytiharkan bahawa sejarah pemeriksaan yang disenaraikan diatas adalah LENGKAP bagi kedua-dua tapak CL dan BA dari 5 tahun sebelum dan 5 tahun selepas kajian BE dijalankan.**  *I hereby declare that this is the COMPLETE inspection history for both the CL and BA sites from 5 years before and 5 years after the BE study was conducted.* |   **Lampiran yang diperlukan/** *Attachment(s) required:*   1. **Laporan penuh pemeriksaan, surat penutupan pemeriksaan serta laporan CAPA bagi pemeriksaan berikut:**   *Full inspection report, closure letter and CAPA report for the following inspection:*  *Appendix 15a -*  *Appendix 15b -*  *Appendix 15c -*  *Appendix 15d -* | | | | | | |

**BAHAGIAN 5: PENILAIAN OLEH PEGAWAI PENYARING**

*PART 5: ASSESSMENT BY THE SCREENING OFFICER*

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| **1.** | **Pegawai Penyaring**  *Screening Officer* |  |
| **2.** | **Tarikh Permohonan Lengkap**  *Date of Completed Application* |  |
| **3.** | **Tarikh Penerimaan Semua Dokumen yang Diminta**  *Acceptance Date of All Requested Documents* |  |
| **4.** | **Pegawai Penilai yang dilantik**  *Appointed Evaluator* |  |
| **5.** | **Tarikh Lantikan Pegawai Penilai**  *Appointment Date of Evaluator* |  |

**BAHAGIAN 6: PENILAIAN OLEH PEGAWAI PENILAI**

*PART 6: ASSESSMENT BY EVALUATOR*

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| **1.** | **Pegawai Penilai Pertama**  *First Evaluator* |  |
| **2.** | **Cadangan/** *Recommendation* | |
| **[ ]** **Pemeriksaan Dikecualikan/** *Exempted from Inspection*  *via*  **[ ]**  *Auto-Exemption*  **[ ]**  *Expedited Evaluation*  **[ ]**  *Full Evaluation*  **[ ]** **Pemeriksaan Diperlukan/** *Inspection is Required*  Tapak kajian yang perlu diperiksa:  *Site that need to be inspected*:  Isu yang perlu diberi keutamaan dan disahkan semasa pemeriksaan:  *Issue that need to be prioritised and verified during inspection*:  **Sebab/** *Reasons:*  *Product Risk:*  *BE Study Risk:*  *BE Centre Risk:* | |
| **3.** | **Pegawai Penilai Kedua**  *Second Evaluator* |  |
| **4.** | **Komen**  *Comment* |  |
| **5.** | **Semakan Ketua Seksyen**  *Review by Head of Section* |  |
| **6.** | **Keputusan**  *Decision* |  |