**ARAHAN:**

INSTRUCTIONS:

1. **Borang permohonan hendaklah ditaip dan dicetak atas kertas A4 putih depan dan belakang kecuali Lampiran A, B dan C yang dicetak berasingan (muka depan sahaja). Lampiran D hanya perlu dicetak bagi permohonan yang melibatkan kajian klinikal *First-In Human (FIH).***

The application form should be typed and printed on both sides of white A4 size paper except for Appendix A, B, and C which should be printed separately (single sided only). Appendix D should only be printed for applications involving First-In Human (FIH) clinical trials.

1. **Borang permohonan yang dikemukakan hendaklah dalam salinan asal.**

The submitted application form should be in original copy.

1. **Sila rujuk *Malaysian* *Guideline for the Application of Clinical Trial Import Licence and Clinical Trial Exemption* edisi terkini untuk maklumat lanjut.**

Please refer to latest edition of Malaysian Guideline for the Application of Clinical Trial Import Licence and Clinical Trial Exemption for more information.

**BAHAGIAN 1 BUTIRAN PENAJA**

PART 1 DETAILS OF THE SPONSOR

|  |  |  |
| --- | --- | --- |
| **1.1** | **Nama individu untuk dihubungi**  Name of contact person |  |
| **1.2** | **Nama organisasi**  Name of organisation |  |
| **1.3** | **Alamat organisasi**  Address of organisation |  |
| **1.4** | **Nombor telefon**  Telephone number |  |
| **1.5** | **Alamat emel**  Email address |  |

**BAHAGIAN 2 BUTIRAN PEMOHON**

PART 2 DETAILS OF THE APPLICANT

|  |  |  |
| --- | --- | --- |
| **2.1** | **Sila tanda pada kotak yang berkaitan:**  Please tick the appropriate box: | |
|  | **Penaja**  Sponsor |
|  | **Orang atau organisasi yang diberi kuasa oleh penaja untuk memohon**  Person or organisation authorised by the sponsor to make the application |

|  |  |  |
| --- | --- | --- |
| **2.2** | **Nama pemohon**  Name of applicant |  |
| **2.3** | **Nombor kad pengenalan**  Identity card number |  |
| **2.4** | **Nama organisasi**  Name of organisation |  |
| **2.5** | **Alamat organisasi**  Address of organisation |  |
| **2.6** | **Nombor telefon**  Telephone number |  |
| **2.7** | **Alamat emel**  Email address |  |

**Sila isikan butiran individu kedua untuk dihubungi, sekiranya ada.**

Please fill in the details of the second contact person, if necessary.

|  |  |  |
| --- | --- | --- |
| **2.8** | **Nama individu untuk dihubungi**  Name of contact person |  |
| **2.9** | **Nombor telefon**  Telephone number |  |
| **2.10** | **Alamat emel**  Email address |  |

**BAHAGIAN 3 BUTIRAN KAJIAN KLINIKAL**

PART 3 DETAILS OF THE CLINICAL TRIAL

|  |  |  |
| --- | --- | --- |
| **3.1** | **Nombor Pendaftaran National Medical Research Registry (NMRR)**  NMRR Registration Number | Pending  Given: **NMRR ID-**  This trial will not be conducted in Malaysia |
| **3.2** | **Tajuk penuh kajian**  Full title of the trial |  |
| **3.3** | **Tajuk singkatan kajian, jika ada**  Abbreviated title of the trial, where available |  |
| **3.4** | **Nombor protokol**  Protocol number |  |
| **3.5** | **Fasa**  Phase | Human Pharmacology (Phase I)  First-in Human  Bioequivalence study  Other, please specify:  Therapeutic exploratory (Phase II)  Therapeutic confirmatory (Phase III)  Therapeutic use (Phase IV) |
| **3.6** | **Kategori Subjek**  Category of subjects | Healthy Volunteers  Note: Both the trial and the participants must be registered with the Malaysian National Healthy Research Volunteer Register (NHRVR) if the trial is conducted in Malaysia (as per Directive NPRA.600-1/9/13 (27))  Patients |
| **3.7** | **Anggaran jangkamasa kajian**  Estimated duration of the trial |  |
| **3.8** | **Cadangan tarikh kajian bermula**  Proposed start date for recruitment |  |
| **3.9** | **Jumlah subjek di Malaysia**  Total number of subjects in Malaysia |  |
| **3.10** | **Jumlah Tapak Kajian di Malaysia**  Total number of trial sites in Malaysia |  |
| **3.11** | **Jumlah subjek keseluruhan (global)**  Total number of subjects globally |  |

**BAHAGIAN 4 BUTIRAN TAPAK KAJIAN KLINIKAL**

PART 4 DETAILS OF THE CLINICAL TRIAL SITE

**Sekiranya kajian klinikal melibatkan lebih daripada tiga (3) tapak kajian, sila ulang dengan melengkapkan Bahagian 4 untuk setiap tapak kajian dan beri nombor turutan seperti T4, T5, T6 dan seterusnya.**

If the clinical trial is conducted across more than three (3) trial sites, please replicate and complete Part 4 for each trial site, assigning a sequential numbers such as T4, T5, T6, and so forth.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **4.1** | **Nombor rujukan tapak kajian**  Reference number of trial site | T1 | T2 | T3 | |
| **4.2** | **Nama tapak kajian**  Name of trial site |  |  |  | |
| **4.3** | **Alamat tapak kajian**  Address of trial site |  |  |  | |
| **4.4** | **Nama Jawatankuasa Etika**  Name of the Ethics Committee |  |  |  | |
| **4.5** | **Status Kelulusan Jawatankuasa Etika**  Ethics Committee Approval Status | Pending  Given | Pending  Given | Pending  Given | |
| **4.6** | **Status Akreditasi bagi Unit Fasa Satu*1***  Phase 1 Unit Accreditation Status1 | Not listed  Provisionally Listed  Listed  Not Applicable | Not listed  Provisionally Listed  Listed  Not Applicable | | Not listed  Provisionally Listed  Listed  Not Applicable |
| **4.7** | **Nama dan alamat tapak bioanalitikal2**  Name and address of bioanalytical site2 | Bioequivalence Study:  Not Bioequivalence Study | | | |
| **Maklumat PI**  Details of PI | | | | | |
| **4.8** | **Nama penyelidik utama (PI)**  Name of principal investigator (PI) |  |  | |  |
| **4.9** | **Nombor kad pengenalan/ passport3**  Identity card/ passport number3 |  |  | |  |
| **4.10** | **Profil PI3**  Profile of PI3 | Declaration of PI  Curriculum vitae  GCP Certificate | Declaration of PI  Curriculum vitae  GCP Certificate | | Declaration of PI  Curriculum vitae  GCP Certificate |
| **4.11** | **Nombor telefon**  Telephone number |  |  | |  |
| **4.12** | **Alamat Emel**  E-mail address |  |  | |  |

**1Untuk kajian klinikal *First-in Human* sahaja**

1 For First-in Human clinical trial only

**2Untuk kajian bioekuivalens sahaja**

2For bioequivalence study only

**3Untuk kajian yang dijalankan di Malaysia sahaja.**

3For trial conducted in Malaysia only.

**BAHAGIAN 5 BUTIRAN STATUS KAJIAN KLINKAL DI NEGARA LAIN**

PART 5 DETAILS OF THE CLINICAL TRIAL STATUS IN OTHER COUNTRIES

|  |  |  |
| --- | --- | --- |
| **5.1** | **Status permohonan kajian di negara-negara lain**  Trial application status in the other countries | |
| **Belum dikemukakan**  Pending submission |  |
| **Dikemukakan**  Submitted |  |
| **Lulus**  Approved |  |
| **Ditolak**  Refused |  |

**BAHAGIAN 6 BUTIRAN PRODUK KAJIAN (IP)**

PART 6 DETAILS OF THE INVESTIGATIONAL PRODUCT (IP)

**Maklumat bagi setiap IP yang memerlukan Kebenaran Mengilang Produk-produk Tidak Berdaftar Untuk Tujuan Percubaan Klinikal (CTX) termasuk setiap *comparator* dan setiap plasebo perlu diisi di bawah Bahagian 6.**

**Sekiranya kajian klinikal melibatkan lebih daripada satu IP, sila ulang dan lengkapkan 6.1 hingga 6.24 untuk setiap IP serta beri nombor turutan seperti A1, A2, A3 dan seterusnya. Maklumat berkenaan plasebo hendaklah diisi di bawah “D) Butiran Placebo” sekiranya ada. Maklumat berkenaan ubat-ubat lain/ produk *Auxiliary* hendaklah diisi di bawah “E) Ubat-ubat lain/ Produk *Auxiliary* yang memerlukan Kebenaran Mengilang Produk-produk Tidak Berdaftar Untuk Tujuan Percubaan Klinikal”**

Information on all IP requiring Clinical Trial Exemption (CTX), including each comparator and each placebo should be provided in Part 6.

If the clinical trial involves multiple IPs that require CTX, please replicate and complete Part 6.1 to 6.24 for each IP, assigning sequential numbers such as A1, A2, A3, and so forth. Information regarding placebo must be filled out in part “D) Details on placebo”, if applicable. Information regarding other medications/ Auxiliary Products must be filled out in part “E) Other medications/ auxiliary product that require CTX”, if applicable.

**A) Pengenalan IP**

A) Identification of IP

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **6.1** | **Nombor rujukan IP**  Reference number of IP | | | | A1 | | |
| **6.2** | **Kegunaan IP**  Use of IP | | | | | | |
|  | | | **IP yang diuji**  IP being tested | | | |
|  | | | **IP yang digunakan sebagai comparator**  IP used as a comparator | | | |
| **6.3** | | **Jenis IP**  Type of IP | | | | | | |
|  | **Bahan kimia**  Chemical origin | | |  | **Generik**  Generic | |
|  | **Biologik/ bioteknologi**  Biological / biotechnological origin | | |  | **Biosimilar**  Biosimilar | |
|  | **Vaksin**  Vaccine | | |  | **Suplemen Kesihatan**  Health Supplement | |
|  | **Produk Terapi Sel & Gen**  Cell & Gene Therapy Products (CGTPs) | | |  | **Produk Herba**  Herbal Products | |
|  | |  | **Lain-lain, sila nyatakan:**  Others, please specify: | | | | | |

**B) Deskripsi IP**

B) Description of IP

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **6.4** | | **Nama Produk**  Product name |  | |
| **6.5** | | **Kod Produk, jika berkenaan4**  Product code, where applicable4 |  | |
| **6.6** | | **Nama produk dicetak pada CTX**  **(termasuk nama, bentuk dos dan kekuatan)**  Product name to be printed on CTX  (includes name, dosage form and strength) |  | |
| **6.7** | | **Kod ATC, sekiranya telah berdaftar**  ATC code, if officially registered |  | |
| **6.8** | | **Nama bahan aktif (INN atau INN dicadangkan sekiranya ada)**  Name of active substance (INN or proposed INN, if available) |  | |
| **6.9** | | **Kekuatan dan unit kepekatan**  Strength and concentration unit |  | | |
| **6.10** | | **Bentuk dosej (guna terma piawai)**  Dosage form (use standard terms) |  | | |
| **6.11** | | **Adakah bentuk dos dan bahan aktif yang digunakan mengandungi sumber yang dianggap *culturally unacceptable*?**  Does the dosage form or active ingredient contain a source or origin that may be culturally unacceptable? | Yes. Please specify the source:  No | | |
| **6.12** | | **Laluan pemberian**  Route of administration |  | | |
| **6.13** | | **Data Stabiliti bagi wakil kelompok bagi *Drug Product* (Kondisi & Tempoh)**  Drug Product’s stability Data of the Representative Batch (Condition & Duration) | Real Time Data  \_\_\_\_\_\_ °C  \_\_\_\_\_\_ %RH  \_\_\_\_\_\_\_ months | Accelerated Data  \_\_\_\_\_\_ °C  \_\_\_\_\_\_ %RH  \_\_\_\_\_\_\_ months | |
| **6.14** | | **Cadangan tempoh penyimpanan bagi *drug product***  Proposed shelf life of the drug product |  | | |
| **6.15** | | **Keadaan Penyimpanan *drug product***  Storage condition of the drug product |  | | |
| **6.16** | | **Ringkasan cara tindakan**  Brief description of mode of action |  | | |
| **6.17** | **Maklumat pengilang**  Information of manufacturer | Name and address:  Certificate issuance authority:  Date of inspection/validity (dd/mm/yyyy):  Note: Please repeat this information for all manufacturers | | |
| **6.18** | **Dokumen dikemukakan**  Submitted documents | Pharmaceutical Data of Drug Substance and Drug Product  Certificate of Analysis of Drug Substance and Drug Product  Stability Data  IP Label | | |

**4Hendaklah diisi sekiranya IP tersebut tiada nama produk. Ini merujuk kepada nama yang digunakan oleh pihak penaja untuk mengenalpasti IP dalam dokumen kajian (contohnya, protokol, brosur penyelidik dan sebagainya)**

4To be provided only when there is no product name. This is the code designated by the sponsor to represent the name routinely used by the sponsor to identify the IP in the trial documentation (e.g. protocol, investigator’s brochure etc.).

**C) Status Pendaftaran Produk**

C) Product Registration status

|  |  |  |
| --- | --- | --- |
| **6.19** | **Adakah IP ini produk berdaftar dengan PBKD?**  Is this IP a registered product with DCA? | Yes  No |
| **Sekiranya ada, sila nyatakan nama dagangan dan Nombor Pendaftaran Produk**  If yes, please specify the trade name and Product Registration number | MAL |
| **6.20** | **Adakah IP ini akan didaftarkan di Malaysia?**  Will this IP be registered in Malaysia? | Yes  No |
| **6.21** | **Adakah IP ini berdaftar di luar negara?**  Is the IP registered overseas? | Yes  No |
| **Sekiranya ada, sila nyatakan nama negara dan nama dagangan produk**  If yes, please specify the country name and product’s trade name |  |
| **6.22** | **Adakah IP ini berbeza daripada yang telah berdaftar?**  Has the IP been modified compared to the registered form? | Yes  No  Not Applicable |
| **Jika ya, sila nyatakan:**  If yes, please specify: |  |
| **6.23** | **Adakah IP mempunyai/ pernah mempunyai CTX?**  Does this IP have/ used to have CTX?  **Jika ya, sila lengkapkan maklumat di bawah:**  If yes, please complete the following details: | Yes  No |
| **Nama Produk (seperti di dalam CTX)**  Product Name (as per CTX) |  |
| **Nombor CTX**  CTX Number | CTX- \_\_ \_\_ \_\_ |
| **Tarikh Luput CTX (hh/bb/tttt)**  CTX Expiry Date(dd/mm/yyyy) | \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_ |
| **6.24** | **Adakah IP ini mempunyai laporan saintifik dari agensi regulatori negara lain?**  Has this IP received scientific advice from other regulatory agencies? | Yes  No |

**D) Butiran *Plasebo***

D) Details on Placebo

**Sekiranya kajian klinikal melibatkan lebih daripada satu plasebo, sila beri nombor turutan seperti D1, D2, D3 dan seterusnya, serta lengkapkan 6.25 hingga 6.33 untuk setiap plasebo. Sekiranya tiada placebo yang digunakan di dalam kajian klinikal, 6.26 hingga 6.33 tidak perlu diisi.**

If the clinical trial involves multiple placebos that require CTX, please assign sequential numbers to each placebo such as D1, D2, D3, and so forth and complete 6.25 to 6.33 for each placebo. If no placebo is used in the clinical trial, 6.26 to 6.33 do not need to be filled.

|  |  |  |
| --- | --- | --- |
| **6.25** | **Adakah kajian ini melibatkan plasebo**?  Is there a placebo involved in this trial? | Yes  No |
| **6.26** | **Nombor rujukan Plasebo**  Reference number of placebo | D1 |
| **6.27** | **Sila nyatakan plasebo ini adalah untuk nombor produk kajian yang berkaitan (contohnya, A1, A2, A3, dan seterusnya)**  Please specify the IP Number (e.g. A1, A2, A3, etc) for this placebo |  |
| **6.28** | **Nama produk dicetak pada Kebenaran Mengilang**  **(termasuk nama, bentuk dos dan kekuatan)**  Product name to be printed on CTX  (includes name, dosage form and strength) |  |
| **6.29** | **Bentuk dosej (guna terma piawai)**  Dosage form (use standard terms) |  |
| **6.30** | **Adakah bentuk dos dan bahan aktif yang digunakan mengandungi sumber yang dianggap *culturally unacceptable*?**  Does the dosage form or active ingredient contain source/ origin that may be culturally unacceptable? | Yes. Please specify the source:  No |
| **6.31** | **Komposisi, selain daripada bahan aktif, adalah sama dengan produk kajian**  Composition, apart from the active substance(s), is otherwise identical to the IP | Yes  No |
| **Sekiranya tidak, nyatakan bahan utama**  If not, specify major ingredients |  |
| **6.32** | **Maklumat pengilang**  Information of manufacturer | Name and address:  Certificate issuance authority:  Date of inspection/validity (dd/mm/yyyy):  Note: Please repeat this information for all manufacturers |
| **6.33** | **Dokumen dikemukakan**  Submitted documents | Pharmaceutical Data  Certificate of Analysis  IP Label |

**E) Butiran Ubat-ubat lain / Produk *Auxiliary* yang memerlukan Kebenaran Mengilang Produk-produk Tidak Berdaftar Untuk Tujuan Percubaan Klinikal.**

E) Details of Other medications / Auxiliary Products that require CTX.

**Sekiranya kajian klinikal melibatkan lebih daripada satu ubat-ubat lain atau produk *Auxiliary*, sila lengkapkan 6.34 hingga 6.44 untuk setiap produk. Sekiranya tiada ubat-ubat lain atau produk *Auxiliary* yang digunakan di dalam kajian klinikal, 6.35 hingga 6.44 tidak perlu diisi.**

If the clinical trial involves multiple other medications or Auxiliary Products that require CTX, please complete 6.34 to 6.44 for each product. If no other medications or Auxiliary Products are used in the clinical trial, 6.35 to 6.44 do not need to be filled.

|  |  |  |  |
| --- | --- | --- | --- |
| **6.34** | **Adakah kajian ini melibatkan Ubat-ubat lain / Produk *Auxiliary*?**  Is there any Other medications / Auxiliary Products involved in this trial? | | Yes  No |
| **6.35** | **Nama, bentuk dosej dan kekuatan**  Name, dosage form and strength | |  |
| **6.36** | **Kegunaan produk**  Use of product | | Standard of care  Rescue medication  Concomitant medication  Others. Please specify:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **6.37** | **Nama produk dicetak pada Kebenaran Mengilang (termasuk nama, bentuk dos dan kekuatan)**  Product name to be printed on CTX (includes name, dosage form and strength) | |  |
| **6.38** | **Bahan aktif**  Active ingredient | |  |
| **6.39** | **Maklumat pengilang**  Information of manufacturer | | Name and address of manufacturer:  Certificate issuance authority:  Date of inspection/validity (dd/mm/yyyy):  Note: Please repeat this information for all manufacturers |
| **6.40** | **Dokumen dikemukakan**  Submitted documents | Approved package insert or other equivalent document  Product Label | |
| **6.41** | **Adakah produk ini produk berdaftar dengan PBKD?**  Is this product registered with DCA? | Yes  No | |
| **Sekiranya ada, sila nyatakan nama dagangan dan Nombor Pendaftaran Produk**  If yes, please specify the trade name and Product Registration number | **MAL** | |
| **6.42** | **Adakah produk ini produk berdaftar di luar negara?**  Is this product registered overseas? | Yes  No | |
| **Sekiranya ada, sila nyatakan nama negara dan nama dagangan produk**  If yes, please specify the country name and product’s trade name |  | |
| **6.43** | **Adakah produk kajian berbeza daripada yang telah berdaftar?**  Has the IP been modified compared to the registered form? | Yes  No  Not applicable | |
| **Jika ya, sila nyatakan:**  If yes, please specify: |  | |
| **6.44** | **Adakah produk ini mempunyai/ pernah**  **mempunyai Kebenaran Mengilang?**  Does this product have/ used to have CTX?  **Jika ya, sila lengkapkan maklumat di bawah:**  If yes, please complete the following details: | Yes  No | |
| **Nama Produk (seperti di dalam CTX)**  Product Name (as per CTX) |  | |
| **Nombor CTX**  CTX Number | CTX- \_\_ \_\_ \_\_ | |
| **Tarikh Luput CTX (hh/bb/tttt)**  CTX Expiry Date(dd/mm/yyyy) | \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_ | |

**BAHAGIAN 7 KUANTITI UNTUK DIKILANG**

PART 7 QUANTITY TO BE MANUFACTURED

* 1. **Jumlah kuantiti untuk dikilang dan kuantiti yang diperlukan untuk kajian klinikal**

Total quantity to be manufactured and quantity required for clinical trial purpose

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Bil.**  No. | **Nama Produk\***  Product Name\* | **Saiz Kelompok:**  Batch Size: | **Bilangan Kelompok:** Number of batches | **Jumlah Kuantiti yang Diperlukan untuk Kajian**  Total Quantity Required for Trial Purpose |
|  |  |  |  |  |
|  |  |  |  |  |

**\*Mengikut unit pembungkusan primer yang akan dikilang sebagai contoh: vial, botol, blister, ampul, syringe.**

\*According to primary packaging to be manufactured for example: vial, bottle, blister, ampoule, and syringe.

**7.2 Butiran Pengiraan Kuantiti dengan Justifikasi untuk Jumlah Kuantiti yang Diperlukan untuk Kajian**

Detailed Calculation with Justification for Total Quantity Required for Trial Purpose

|  |
| --- |
|  |

**PERAKUAN PEMOHON**

APPLICANT’S DECLARATION

**Saya, yang bernama dan beralamat di bawah sebagai wakil syarikat yang memohon, mengaku bahawa:**

I, the undersigned, hereby confirm on behalf of the company that:

1. **Segala maklumat yang dibekalkan adalah lengkap**.

The information provided is complete.

1. **Segala maklumat dalam borang permohonan ini dan dokumen-dokumen dibekalkan adalah benar dan tepat.**

All information provided in this form and attached documents are true and accurate.

1. **Saya akan bertanggungjawab sepenuhnya terhadap kualiti, efikasi dan keselamatan produk-produk dalam permohonan ini.**

I will be fully responsible towards the quality, efficacy and safety of the product(s) in this application.

1. **Saya akan mematuhi semua peruntukan dalam Akta Jualan Dadah 1952 (Semakan 1989), Peraturan-Peraturan Kawalan Dadah dan Kosmetik 1984 serta lain-lain keperluan regulatori/ garispanduan.**

I will comply with all provisions under the Sale of Drugs Act 1952 (Revised 1989), Control of Drugs and Cosmetics Regulations 1984 along with other regulatory requirements and guidelines.

|  |  |  |  |
| --- | --- | --- | --- |
| **Nama Penuh**  Full Name |  | **Jawatan**  Position |  |
| **No. Kad Pengenalan**  Identity Card No. |  | **Cop Rasmi Syarikat**  Official Stamp of the Company  *Note: The stamp must be wet-inked.* |  |
| **Tandatangan Pemohon**  Signature of applicant |  |
| **Tarikh (HH/BB/TTTT):**  Date (DD/MM/YYYY): |  |

**Lampiran A (Appendix A)**

**Senarai Semak Saringan Permohonan Kebenaran Mengilang Produk-produk Tidak Berdaftar Untuk Tujuan Percubaan Klinikal**

|  |  |
| --- | --- |
| Nombor Protokol |  |
| Nama Produk Kajian | 1. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| No. | Perkara | Pemohon | Untuk Kegunaan Pejabat | |
|  | Jadual kandungan |  | Sila pilih. |  |
|  | Surat pengiring |  | Tiada |  |
|  | *Letter of Authorisation*, jika berkaitan |  | Sila pilih. |  |
|  | Borang Permohonan yang lengkap dan telah ditandatangani dan cop oleh pemohon |  | Sila pilih. |  |
|  | Lesen Racun Jenis A/ Sijil Pengekalan Tahunan (ARC) bagi pegawai farmasi kerajaan, jika berkaitan |  | Sila pilih. |  |
|  | Sijil Pendaftaran Syarikat |  | Sila pilih. |  |
|  | Protokol untuk kajian klinikal |  | Sila pilih. |  |
|  | *Overall risk and benefit assessment* |  | Sila pilih. |  |
|  | Borang persetujuan termaklum (versi asal sahaja untuk salah satu tapak kajian) |  | Sila pilih. |  |
|  | *Declaration by Principal Investigator/ Investigator* |  | Sila pilih. |  |
|  | Sijil *Good Clinical Practice* bagi penyelidik untuk setiap tapak kajian |  | Sila pilih. |  |
|  | *Curriculum Vitae* bagi penyelidik untuk setiap tapak kajian |  | Sila pilih. |  |
|  | Surat Keputusan Jawatankuasa Etika |  | Sila pilih. |  |
|  | Data Farmaseutikal untuk bahan aktif dan produk |  | Sila pilih. |  |
|  | Bukti komplians Amalan Perkilangan Baik *(APB)* bagi setiap pengilang |  | Sila pilih. |  |
|  | Sijil Analisa/ *Batch Analysis* untuk bahan aktif dan produk |  | Sila pilih. |  |
|  | Label kajian untuk produk kajian |  | Sila pilih. |  |
|  | Brosur Penyelidik |  | Sila pilih. |  |
|  | Salinan laporan saintifik dari agensi regulatori negara lain, jika ada |  | Sila pilih. |  |
|  | Dokumen tambahan yang dibekalkan, jika ada |  | Sila pilih. |  |
| Permohonan untuk kajian klinikal *First-in Human* (FIH) sahaja: | | | | |
|  | Sijil Akreditasi Unit Fasa I yang dikeluarkan oleh NPRA |  | Sila pilih. |  |
|  | Sijil/Polisi insurans bagi kajian klinikal *First-in Human* |  | Sila pilih. |  |
|  | *Declaration by Sponsor for CTIL/CTX Application Involving First-in Human Clinical Trial* (salinan asal) |  | Sila pilih. |  |

Kesimpulan: Hasil saringan mendapati permohonan adalah **sila pilih.**.

|  |
| --- |
| T.T. & Cop  Pegawai Saringan |
| Tarikh: Click or tap to enter a date. |

**Peringatan Penting!**

Selepas saringan didapati memuaskan, pemohon perlu mengemukakan dokumen *hardcopy* bagi permohonan di atas di Kaunter Pusat Penilaian Produk & Kosmetik bersama dokumen asal (Item no. 4, no. 10 dan/atau no. 23) dan dokumen tambahan seperti yang disenaraikan berikut:

* Item no. 4:Borang Permohonan yang lengkap dan telah ditandatangani dan cop oleh pemohon
* Item no. 10: *Declaration by Principal Investigator/ Investigator*
* Item No. 23: *Declaration by Sponsor for CTIL/CTX Application Involving First-in Human Clinical Trial* (jika berkenaan)
* CD/DVD-ROM yang mengandungi semua dokumen-dokumen elektronik dalam permohonan anda.

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| Untuk Kegunaan Pejabat:  Saringan ini telah direkodkan dalam pangkalan data. |

**Lampiran B (Appendix B)**

(Salinan Pemohon)

**Pengesahan Penerimaan Permohonan Kebenaran Mengilang Produk-produk Tidak Berdaftar Untuk Tujuan Percubaan Klinikal**

Permohonan Kebenaran Mengilang Produk-produk Tidak Berdaftar Untuk Tujuan Percubaan Klinikal seperti butiran di bawah telah diterima.

|  |  |
| --- | --- |
| Nombor Protokol |  |
| Nama Produk | **1.**  **2.** |

|  |  |  |
| --- | --- | --- |
| Tandatangan & cop pegawai | Cop tarikh penerimaan | Penyerahan dokumen oleh:  Nama:  Syarikat/CRO: |

**Lampiran C (Appendix C)**

**Pengesahan Penolakan Permohonan Kebenaran Mengilang Produk-produk Tidak Berdaftar Untuk Tujuan Percubaan Klinikal Semasa Penyemakan Dokumen *Hardcopy* Permohonan**

Arahan:

1. Lampiran ini hendaklah disimpan bersama-sama permohonan ini.
2. Sila cetak lampiran baru bagi setiap penyaringan.

|  |  |
| --- | --- |
| Nombor Protokol |  |
| Nama Produk | **1.**  **2.** |

Bagi penyaringan yang dibuat terhadap permohonan ini, berikut adalah dokumen-dokumen yang perlu dibekalkan oleh pemohon dalam penyaringan yang seterusnya:

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|  |
| --- |
| Tandatangan & cop pegawai  Tarikh |

**Lampiran D (Appendix D)**

**Maklumat Tambahan Bagi Kajian Klinikal *First-In Human***

Additional Information For First-In Human Clinical Trial

**Sila lengkapkan Lampiran D bagi IP di dalam kajian klinikal FIH. Sekiranya kajian klinikal FIH ini melibatkan lebih daripada satu IP, sila ulang dan lengkapkan Lampiran D untuk setiap IP yang terlibat serta beri nombor turutan seperti Appendix D1, Appendix D2, Appendix D3 dan seterusnya.**

Please complete Appendix D for IP being tested in FIH clinical trial. If the FIH clinical trial involves multiple IPs, please replicate and complete Appendix D for each IP, assigning sequential numbers such as Appendix D1, Appendix D2, Appendix D3, and so forth.

|  |  |
| --- | --- |
| **Nama IP**  IP Name | **1.** |

**Part 1 Pre-clinical Data**

|  |  |  |
| --- | --- | --- |
|  | Evidence of previous exposure of humans to compounds with related modes of action. | Yes    No  If Yes, provide details |
|  | Evidence from animal models for potential risk of serious toxicity.  Please provide details for:   1. Single and Repeat dose toxicity 2. Genotoxicity in vitro and in vivo 3. Phototoxicity   Other relevant toxicity study | Yes    No |
|  | Evidence of a risk analysis of the preclinical data for the IPs, including:   1. Identification of on-target and off-target areas of the IPs 2. The adverse events associated with on-target and off-target areas 3. Relevance of the animal model 4. Justification of safe starting dose 5. Justification of maximum administered dose/exposure 6. Justification of multiple dose (if applicable) |  |
|  | Preclinical toxicities that will be actively monitored in the First-in Human Clinical Trial and the intensity of monitoring |  |

**PART 2 Description of IP Administration**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Route of administration |  | |
|  | Rate of administration (for intravenous route only) |  | |
|  | Estimation of first dose in human |  | |
|  | Expected total exposure of the associated drug and the anticipated plasma concentrations in human |  | |
|  | Comparison of above value in **(D)** against the exposure and achieved concentrations in the non-clinical studies |  | |
|  | The dose escalation strategy with justification (if applicable) |  | |
|  | Application of sentinel dosing in trial design  Period of observation of the first subject prior to the subsequent doses with justification | | Yes    No |
|  | Period of observation between first subject administration of IP to subsequent subjects within the cohort | |  |
|  | Stopping Rules | |  |