**ARAHAN:**

INSTRUCTION:

1. **Borang permohonan hendaklah ditaip dan dicetak atas kertas A4 putih depan dan belakang**

Application form should be typed and printed on both sides using white A4 size paper

1. **Lampiran variasi yang berkaitan sahaja perlu dicetak.**

Only applicable appendix of variation should be printed.

1. **Setiap jenis permohonan variasi perlu dikemukakan secara berasingan.**

Each variation application should be submitted as a separate application.

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

The submitted application form should be in original copy.

1. **Bagi permohonan variasi yang melibatkan pengeluaran Lesen Import Percubaan Klinikal (LIPK), pemohon diminta membuat bayaran di kaunter Seksyen Kewangan, Akaun dan Hasil dengan menggunakan Borang Penyerahan Yuran Pemprosesan Lesen Import Percubaan Klinikal. Salinan resit bayaran perlu disertakan bersama borang permohonan variasi.**

For variation applications involving the issuance of Clinical Trial Import Licence variations (CTIL), applicants are requested to make the payment at Financial, Accounts, and Revenue Section counter using the Clinical Trial Import Licence Processing Fee Submission Form. A copy of the payment receipt must be enclosed with the variation application form.

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

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

**BAHAGIAN 1 BUTIRAN PEMOHON**

PART 1 DETAILS OF THE APPLICANT

|  |  |  |
| --- | --- | --- |
| **1.1** | **Nama pemohon**Name of applicant |  |
| **1.2** | **Nombor kad pengenalan**Identity card number |  |
| **1.3** | **Nama organisasi** Name of organisation  |  |
| **1.4** | **Alamat organisasi**Address of organisation |  |
| **1.5** | **Nombor telefon** Telephone number  |  |
| **1.6** | **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.

|  |  |  |
| --- | --- | --- |
| **1.7** | **Nama individu untuk dihubungi**Name of contact person |  |
| **1.8** | **Nombor telefon** Telephone number  |  |
| **1.9** | **Alamat emel**Email address |  |

**BAHAGIAN 2 BUTIRAN KAJIAN KLINIKAL**

PART 2 DETAILS OF THE CLINICAL TRIAL

|  |  |  |
| --- | --- | --- |
| **2.1** | **Nombor pendaftaran National Medical Research Registry (NMRR)**National Medical Research Registry (NMRR) Registration ID | **NMRR-** |
| **2.2** | **Tajuk penuh kajian** Full title of the trial |  |
| **2.3** | **Nombor protokol**Protocol number |  |
| **2.4** | **Senarai produk yang terlibat**List of products involved |  |  |
|  |  |
|  |  |
| **2.5** | **No. CTIL/CTX dan****tarikh luput (hh/bb/tttt)**CTIL/CTX no. andexpiry date (dd/mm/yyyy) |  | PBKD/LK- | hh/bb/tttt |
|  | PBKD/LK- | hh/bb/tttt |
|  | PBKD/LK- | hh/bb/tttt |

**BAHAGIAN 3 PERMOHOHAN VARIASI**

PART 3 VARIATION APPLICATION

**3.1 MAKLUMAT KELULUSAN VARIASI TERDAHULU**

 INFORMATION OF PREVIOUS VARIATION APPROVAL

**(Sila tambah ruang sekiranya diperlukan)**

(Please add additional lines as needed)

|  |  |  |  |
| --- | --- | --- | --- |
| **Bil.**No. | **Tarikh kelulusan**Approval date **(hh/bb/tttt)1 (dd/mm/yyyy) 1** | **Nombor rujukan dokumen kelulusan2**Approval document**2** reference number | **Jenis permohonan variasi**Type of variation application |
| 1. |  |  |  |
| 2. |  |  |  |
| 3. |  |  |  |
| 4. |  |  |  |
| 5. |  |  |  |

**1 Tarikh yang dinyatakan pada dokumen kelulusan permohonan variasi yang berkaitan.**

**1** Date as stated in the relevant variation application approval document.

**2 Contoh** **dokumen kelulusan: surat kelulusan dan/atau Lampiran A**

2 Examples of approval document: approval letter and/or Lampiran A

**3.2 MAKLUMAT PERMOHONAN VARIASI TERKINI**

 INFORMATION OF CURRENT VARIATION APPLICATION

**ARAHAN:**

INSTRUCTION:

**Sila isi dan cetak lampiran bagi permohonan variasi yang berkenaan sahaja.**

Please fill in and print the appendix for the applicable variation application only.

|  |  |  |  |
| --- | --- | --- | --- |
| **Bil.**No. | **Lampiran**Appendix | **Permohonan Variasi**Variation Application | **Sila tandakan (√) pada kotak yang berkenaan**Please tick (√) the relevant box |
| **1.** | **Lampiran V1** | **Penambahan kuantiti produk kajian**Additional quantity of investigational product |  |
| **2.** | **Lampiran V2** | **Penambahan/Penukaran tapak kajian**Additional/Change of trial site |  |
| **3.** | **Lampiran V3** | **i) Penukaran pemegang Lesen Import Percubaan Klinikal (LIPK)/Kebenaran Mengilang dalam syarikat yang sama**Change of Clinical Trial Import Licence (CTIL)/Clinical Trial Exemption (CTX) holder within the same company |  |
| **ii) Penukaran pemegang Lesen Import Percubaan Klinikal (LIPK)/Kebenaran Mengilang kepada syarikat yang berlainan**Change of Clinical Trial Import Licence (CTIL)/Clinical Trial Exemption (CTX) holder to a different company  |  |
| **4.** | **Lampiran V4** | **i) Penambahan produk kajian untuk produk kajian yang** **diuji/ produk kajian yang digunakan sebagai *comparator***Additional product for IP being tested/ IP used as a comparator  |  |
| **ii) Penambahan produk untuk plasebo** Additional product for placebo  |  |
| **iii) Penambahan produk untuk ubat-ubat lain yang memerlukan LIPK**Additional product for other medications that require CTIL |  |
| **5.** | **Lampiran V5** | **i) Penambahan tapak pengilang**Additional manufacturer |  |
| **ii) Penukaran tapak pengilang**Change of manufacturer |  |
| **6.** | **Lampiran V6** | **Pembaharuan Lesen Import Percubaan Klinikal (LIPK)/ Kebenaran Mengilang**Clinical Trial Import Licence (CTIL)/Clinical Trial Exemption (CTX) Renewal |  |
| **7.** | **Lampiran V7** | 1. **Penukaran nama syarikat pemohon**

Change of applicant’s company name  |  |
| **ii) Penukaran alamat syarikat pemohon**Change of applicant’s company address |  |
| **8.** | **Lampiran V8** | **Penukaran penyelidik/penyelidik utama**Change of investigator/principal investigator |  |
| **9.** | **Lampiran V9** | **Lain-lain (cth: perubahan saiz pek/jenis bungkusan)**Others (e.g. change in pack size/type of packaging) |  |

**PERAKUAN PEMOHON**

APPLICANT DECLARATION

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

I, the undersigned, on behalf of the company hereby confirm 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 documents provided 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 (Disemak 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, together with other regulatory requirements/ 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 V1**

**Sekiranya permohonan penambahan kuantiti produk melibatkan lebih daripada satu produk, sila ulang dan lengkapkan Lampiran V1 bagi setiap produk.**

If there is more than one product for additional quantity, please replicate and complete Lampiran V1 for each product.

|  |
| --- |
| **Penambahan kuantiti produk kajian**Additional quantity of investigational product |
| **Nama produk** Product name  |  |
| **Tambahan kuantiti yang diperlukan** Additional quantity required  |  |
| **Jumlah kumulatif kuantiti untuk diimport (CTIL)/dikilangkan (CTX)**Total cumulative quantity to be imported (CTIL)/manufactured (CTX) |  |
| **Dokumen disertakan**Documents included | [ ]  **Salinan semua LIPK/ Kebenaran Mengilang bagi protokol ini**Copy of all CTIL/CTX for this protocol[ ]  **Salinan Lampiran A yang terkini untuk protokol ini**Copy of the latest *Lampiran A* for this protocol[ ]  **Justifikasi penambahan kuantiti**Justification of additional quantity[ ]  **Pengiraan kuantiti** Calculation of quantity[ ]  **Lampiran I** *Lampiran I* |

**Lampiran V2**

**Sekiranya permohonan penambahan tapak kajian melibatkan lebih daripada satu tapak kajian, sila ulang dan lengkapkan Lampiran V2 bagi setiap tapak kajian.**

If there is more than one additional trial site, please replicate and complete Lampiran V2 for each trial site.

|  |
| --- |
| **Penambahan/Penukaran tapak kajian**Additional/Change of trial site |
| **Nama tapak kajian baru**Name of new trial site |  |
| **Alamat tapak kajian baru**Address of new trial site |  |
| **Nama tapak kajian asal1**Name of initial trial site1  |  |
| **Alamat tapak kajian asal1**Address of initial trial site1 |  |
| **Nama penyelidik utama (PI)**Name of principal investigator (PI) |  |
| **Nombor kad pengenalan/pasport2 PI**Identity card/passport number2 of PI |  |
| **Profil penyelidik utama**Profile of PI  | ☐ Declaration of PI: ☐ Curriculum vitae☐ Good Clinical Practice (GCP) Certificate |
| **Nombor telefon PI**Telephone number of PI |  |
| **Alamat emel PI**E-mail address of PI |  |
| **Jumlah subjek yang dijangka**Total number of subjects planned |  |
| **Nama jawatankuasa etika**Name of ethics committee |  |
| **Status kelulusan daripada jawatankuasa etika**  Ethics committee approval status | [ ] ☐ To be requested☐ Pending☐ Given. If given, please specifiy:Date of authorisation/opinion (dd/mm/yyyy):\_ \_/\_ \_/\_ \_ \_ \_☐ Authorisation accepted/ favourable opinion☐ Not accepted/ not favourable The reasons:­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Adakah penambahan kuantiti produk diperlukan?**Is an additional quantity of product needed? | ☐ No☐ Yes. If yes, please apply for an additional quantity in a separate application. |
| **Dokumen disertakan**Document included | ☐ **Salinan semua LIPK/ Kebenaran Mengilang bagi protokol ini**Copy of all CTIL/CTX for this protocol☐ **Salinan Lampiran A yang terkini untuk protokol ini**Copy of the latest *Lampiran A* for this protocol☐ **Pengakuan asal daripada penyelidik utama bagi setiap tapak kajian**Originaldeclaration by PI for each trial site☐ **Sijil GCP bagi penyelidik utama**GCP certificate for PI☐ ***Vitae* kurikulumbagi penyelidik utama** *Curriculum Vitae* (CV) for PI☐ **Surat kelulusan/pendapat jawatankuasa etika** Letter of approval/opinion of ethics committee☐ **Lampiran I, jika berkenaan** *Lampiran I*, if applicable |

**1Untuk penukaran tapak kajian sahaja**

**1**For change of site only

2**Untuk kajian klinikal yang dijalankan di Malaysia sahaja**

2For clinical trial conducted in Malaysia only

 **Lampiran V3**

|  |
| --- |
| **i) Penukaran pemegang LIPK/ Kebenaran Mengilang dalam syarikat yang sama**Change of CTIL/CTX holder within the same company |
| **Nama pemegang LIPK/ Kebenaran Mengilang yang asal**Name of current CTIL/CTX holder |  |
| **Nama pemegang LIPK/ Kebenaran Mengilang yang baru** Name of new CTIL/CTX holder |  |
| **Nombor kad pengenalan**Identity card number |  |
| **Nombor telefon** Telephone number  |  |
| **Alamat emel**Email address |  |
| **Dokumen disertakan**Document included | [ ]  **Salinan semua LIPK/ Kebenaran Mengilang bagi protokol ini**Copy of all CTIL/CTX for this protocol[ ]  **Salinan Lampiran A yang terkini untuk protokol ini**Copy of the latest *Lampiran A* for this protocol[ ]  **Alasan bagi penukaran pemegang LIPK/ Kebenaran Mengilang** Reason for the change of CTIL/CTX holder[ ]  **Lesen Racun Jenis A/Perakuan Pengekalan Tahunan**  Type A Poison Licence/Annual Retention Certificate (ARC) |
| **ii) Penukaran pemegang LIPK/ Kebenaran Mengilang kepada syarikat yang berlainan**Change of CTIL/CTX holder to a different company  |
| **Nama pemegang LIPK/ Kebenaran Mengilang yang asal**Name of current CTIL/CTX holder |  |
| **Nama syarikat pemegang LIPK/ Kebenaran Mengilang yang asal**Company name of current CTIL/CTX holder |  |
| **Alamat syarikat pemegang LIPK/ Kebenaran Mengilang yang asal**Company address of current CTIL/CTX holder |  |
| **Nama pemegang LIPK/ Kebenaran Mengilang yang baru** Name of new CTIL/CTX holder |  |
| **Nombor kad pengenalan**Identity card number |  |
| **Nama syarikat pemegang LIPK/ Kebenaran Mengilang yang baru**Company name of new CTIL/CTX holder |  |
| **Alamat syarikat pemegang LIPK/ Kebenaran Mengilang yang baru**Company address of new CTIL/CTX holder |  |
| **Nombor telefon** Telephone number  |  |
| **Alamat emel**Email address |  |
| **Dokumen disertakan**Document included | [ ]  **Salinan semua LIPK/ Kebenaran Mengilang bagi protokol ini**Copy of all CTIL/CTX for this protocol[ ]  **Salinan Lampiran A yang terkini untuk protokol ini**Copy of the latest *Lampiran A* for this protocol[ ]  **Alasan bagi penukaran pemegang LIPK/ Kebenaran Mengilang** Reason for the change of CTIL/CTX holder[ ]  **Lesen Racun Jenis A/Perakuan Pengekalan Tahunan**Type A Poison Licence/Annual Retention Certificate (ARC)[ ]  **Sijil pendaftaran syarikat bagi pemegang LIPK/ Kebenaran Mengilang yang baru**Company registration certificate of the new CTIL/CTX holder[ ]  **Surat kebenaran penukaran pemegang LIPK/ Kebenaran Mengilang** Letter of authorisation for the transfer of CTIL/CTX holder[ ]  **Kenyataan penerimaan**  Statement of acceptance |

**Lampiran V4**

**Sekiranya permohonan penambahan produk melibatkan lebih daripada satu produk, sila ulang dan lengkapkan Lampiran V4 bagi setiap produk.**

If there is more than one additional product, please replicate and complete Lampiran V4 for each IP.

|  |
| --- |
| **Penambahan produk kajian**Additional investigational product  |
| 1. **Produk kajian yang diuji/Produk kajian yang digunakan sebagai *comparator***

IP being tested/IP used as a comparator |
| **Kegunaan produk kajian**Use of IP | [ ]  **Produk kajian yang diuji** IP being tested[ ]  **Produk kajian yang digunakan sebagai *comparator*** IP used as a comparator |
| **Nama produk** Name of product |  |
| **Nama produk dicetak pada LIPK/Kebenaran Mengilang (termasuk nama, bentuk dos dan kekuatan)**Product name to be printed on CTIL/CTX (include name, dosage form and strength) |  |
| **Nama bahan aktif (INN atau INN dicadangkan sekiranya ada)**Name of active substance (INN or proposed INN, if available) |  |
| **Kekuatan dan unit kepekatan** Strength and concentration unit  |  |
| **Bentuk dosej (guna terma piawai)**Dosage form (use standardterms) |  |
| **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  |
| **Laluan pemberian** Route of administration |  |
| **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 |
| **Cadangan tempoh penyimpanan bagi *drug product***Proposed shelf life of the drug product |  |
| **Keadaan penyimpanan *drug product***Storage condition of the drug product |  |
| **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 |
| **Status pendaftaran produk**Product registration status |
| **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 |
| **Adakah IP ini akan didaftarkan di Malaysia?**Will this IP be registered in Malaysia? | [ ]  Yes [ ]  No  |
| **Adakah IP ini produk berdaftar di luar negara?** Is the IP registered overseas? | [ ]  Yes [ ]  No  |
| **Sekiranya ada, sila nyatakan nama negara serta nama dagangan produk**If yes, please specify the country name and product’s trade name |  |
| **Adakah produk kajian berbeza daripada yang telah berdaftar?**Has the IP been modified compared to the registered form? | [ ]  Yes [ ]  No  |
| **Jika ya, sila nyatakan**If yes, please specify |  |
| **Dokumen disertakan**Document included | [ ]  **Salinan semua LIPK/ Kebenaran Mengilang bagi protokol ini**Copy of all CTIL/CTX for this protocol[ ]  **Salinan Lampiran A yang terkini untuk protokol ini**Copy of the latest *Lampiran A* for this protocol[ ]  **Justifikasi penambahan produk kajian**Justification for additional IP[ ]  **Pengiraan kuantiti**Calculation of quantity[ ]  **Data farmaseutikal** Pharmaceutical data[ ]  **Sijil analisa**Certificate of analysis[ ]  **Label produk kajian**IP label[ ]  **Bukti Komplians Amalan Perkilangan Baik (APB)**  Evidence of Good Manufacturing Practice (GMP) compliance[ ]  **Salinan resit rasmi** **yuran pemprosesan** Copy of official receipt of payment[ ]  **Lampiran I, jika berkenaan** *Lampiran I,* if applicable |
| **ii) *Plasebo*** Placebo |
| **Nama produk dicetak pada LIPK/Kebenaran Mengilang (termasuk nama, bentuk dos, dan kekuatan)**Product name to be printed on CTIL/CTX (include name, dosage form, and strength) |  |
| **Bentuk dosej (guna terma piawai)**Dosage form (use standard terms) |  |
| **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  |
| **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 |  |
| **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. |
| **Dokumen disertakan**Documents included | [ ]  **Salinan semua LIPK/ Kebenaran Mengilang bagi protokol ini**Copy of all CTIL/CTX for this protocol[ ]  **Salinan Lampiran A yang terkini untuk protokol ini**Copy of the latest *Lampiran A* for this protocol[ ]  **Justifikasi penambahan produk** Justification for additional product[ ]  **Pengiraan kuantiti**Calculation of quantity[ ]  **Data farmaseutikal** Pharmaceutical data[ ]  **Sijil analisa**Certificate of analysis[ ]  **Label produk** Product label[ ]  **Bukti Komplians Amalan Perkilangan Baik (APB)**  Evidence of Good Manufacturing Practice (GMP) compliance[ ]  **Salinan resit rasmi** **yuran pemprosesan** Copy of official receipt of payment[ ]  **Lampiran I, jika berkenaan** *Lampiran I,* if applicable |
| **iii) Ubat-ubat lain yang/Produk *Auxiliary* yang memerlukan LIPK** Other medications/Auxiliary Products that require CTIL  |
| **Nama produk** Name of product |  |
| **Kegunaan produk** Use of product | [ ]  Standard of care[ ]  Rescue medication [ ]  Concomitant medication[ ]  Others. Please specify: |
| **Nama produk dicetak pada LIPK/Kebenaran Mengilang (termasuk nama, bentuk dos dan kekuatan)**Product name to be printed on CTIL/CTX (includes name, dosage form and strength) |  |
| **Bahan aktif**Active ingredient |  |
| **Kekuatan dan unit kepekatan** Strength and concentration unit |  |
| **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 |
| **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** |
| **Adakah produk ini produk berdaftar di luar negara?** Is this product a registered product 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. |  |
| **Adakah produk ini berbeza daripada yang telah berdaftar?**Has this product been modified compared to the registered form? | [ ]  Yes [ ]  No  |
| **Jika ya, sila nyatakan:**If yes, please specify: |  |
| **Dokumen disertakan**Documents included | [ ]  **Salinan semua LIPK/ Kebenaran Mengilang bagi protokol ini**Copy of all CTIL/CTX for this protocol[ ]  **Salinan Lampiran A yang terkini untuk protokol ini**Copy of the latest *Lampiran A* for this protocol[ ]  **Justifikasi penambahan produk** Justification for additional product[ ]  **Pengiraan kuantiti**Calculation of quantity[ ]  **Approved package insert or other equivalent document**Sisipan bungkusan atau dokumen lain yang setaraf[ ]  **Label product**Product label[ ]  **Bukti Komplians Amalan Perkilangan Baik (APB)**  Evidence of Good Manufacturing Practice (GMP) compliance[ ]  **Salinan resit rasmi** **yuran pemprosesan** Copy of official receipt of payment[ ]  **Lampiran I, jika berkenaan** *Lampiran I,* if applicable |

**Lampiran V5**

|  |
| --- |
| **i) Penambahan tapak pengilang** Additional manufacturer |
| **Nama produk**Product name |  |
| **Nama pengilang baru**Name of the new manufacturer |  |
| **Alamat pengilang baru**Address of the new manufacturer |  |
| **Maklumat pengilang baru**Information of the new manufacturer | Certificate issuance authority:Date of inspection/validity (dd/mm/yyyy):Note: Please repeat this information for all manufacturers |
| **Dokumen disertakan**Documents included | [ ]  **Salinan semua LIPK/Kebenaran Mengilang bagi protokol ini**Copy of all CTIL/CTX for this protocol[ ]  **Salinan Lampiran A yang terkini untuk protokol ini**Copy of the latest *Lampiran A* for this protocol[ ]  **Bukti komplians Amalan Perkilangan Baik (APB)** Evidence of Good Manufacturing Practice (GMP) compliance |
| **ii) Penukaran tapak pengilang**Change of manufacturer  |
| **Nama produk** Product name |  |
| **Nama pengilang asal**Name of initial manufacturer |  |
| **Alamat pengilang asal**Address of initial manufacturer |  |
| **Nama pengilang baru**Name of new manufacturer |  |
| **Alamat pengilang baru**Address of new manufacturer |  |
| **Maklumat pengilang baru**Information of the new manufacturer | Certificate issuance authority:Date of inspection/validity (dd/mm/yyyy):Note: Please repeat this information for all manufacturers |
| **Dokumen disertakan**Documents included | [ ]  **Salinan semua LIPK/ Kebenaran Mengilang bagi protokol ini**Copy of all CTIL/CTX for this protocol[ ]  **Salinan Lampiran A yang terkini untuk protokol ini**Copy of the latest *Lampiran A* for this protocol[ ]  **Bukti komplians Amalan Perkilangan Baik (APB)** Evidence of Good Manufacturing Practice (GMP) compliance |

**Lampiran V6**

**Sekiranya permohonan Pembaharuan LIPK/Kebenaran Mengilang melibatkan lebih daripada satu produk, sila ulang dan lengkapkan Lampiran V6 bagi setiap produk untuk pembaharuan.**

If CTIL/CTX renewal involves more than one product, please replicate and complete Lampiran V6 for each product to be renewed.

|  |
| --- |
| **Pembaharuan LIPK/Kebenaran Mengilang**CTIL/CTX renewal  |
| **Nama produk untuk pembaharuan (seperti di dalam LIPK/Kebenaran Mengilang)**Product name for renewal (as per CTIL/CTX) |  |
| **Nombor LIPK/Kebenaran Mengilang**CTIL/CTX number | PBKD/LK- \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_/ CTX\_\_ \_\_ \_\_ \_\_ \_\_ \_\_ |
| **Tarikh luput CTIL/Kebenaran Mengilang**CTIL/CTX expiry date**(dd/mm/yyyy)** | \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_ |
| **Senarai protokol yang menggunakan LIPK/Kebenaran Mengilang yang sama**List of protocol(s) using the same CTIL/CTX | 1.2.3. |
| **1Nama dan alamat pengilang dan *final releaser* produk sahaja**1Name and address of the manufacturer(s) and finalreleaser for the product only |  |
| **Adakah penambahan kuantiti produk diperlukan?**Is additional quantity of product required? | [ ]  No[ ]  Yes If yes, please apply for additional quantity in a separate application |
| **Dokumen disertakan**Documents included | [ ]  **Salinan semua LIPK/Kebenaran Mengilang bagi protokol ini**Copy of all CTIL/CTX for this protocol[ ]  **Salinan Lampiran A yang terkini untuk protokol ini**Copy of the latest *Lampiran A* for this protocol[ ]  **Lampiran I, jika berkenaan** *Lampiran I*, if applicable[ ]  **Salinan resit rasmi** **yuran pemprosesan, if applicable** Copy of official receipt of payment, if applicable  |

**1Sila pastikan nama dan alamat pengilang dan *final releaser* produkadalah berdasarkan LIPK/ Kebenaran Mengilang dan variasi yang telah diluluskan.**

1Please ensure the name and address of manufacturer and final releaser for the product are based on the approved CTIL/CTX and variation.

**Lampiran V7**

|  |
| --- |
| **i) Penukaran nama syarikat pemohon** Change of applicant’s company name  |
| **Nama asal syarikat** Current name of the company |  |
| **Alamat asal syarikat**Current address of the company |  |
| **Nama baru syarikat** New name of the company |  |
| **Alamat emel**Email address |  |
| **Dokumen disertakan**Documents included | [ ]  **Salinan semua LIPK/ Kebenaran Mengilang bagi protokol ini**Copy of all CTIL/CTX for this protocol[ ]  **Salinan Lampiran A yang terkini untuk protokol ini**Copy of the latest *Lampiran A* for this protocol[ ]  **Sijil pendaftaran syarikat yang terkini** Latestcompany registration certificate [ ]  **Lesen Racun Jenis A/Perakuan Pengekalan Tahunan yang terkini** Latest Type A Poison Licence/Annual Retention Certificate (ARC) |
| **ii) Penukaran alamat syarikat pemohon** Change of applicant’s company address |
| **Nama asal syarikat** Current name of the company |  |
| **Alamat asal syarikat**Current address of the company |  |
| **Alamat baru syarikat**New address of the company |  |
| **Alamat emel**Email address |  |
| **Dokumen disertakan**Documents included | [ ]  **Salinan semua LIPK/ Kebenaran Mengilang bagi protokol ini**Copy of all CTIL/CTX for this protocol[ ]  **Salinan Lampiran A yang terkini untuk protokol ini**Copy of the latest *Lampiran A* for this protocol[ ]  **Sijil pendaftaran syarikat yang terkini** Latestcompany registration certificate [ ]  **Lesen Racun Jenis A/Perakuan Pengekalan Tahunan yang terkini** Latest Type A Poison Licence/Annual Retention Certificate (ARC) |

**Lampiran V8**

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| **Penukaran penyelidik/penyelidik utama** Change of investigator/principal investigator (PI) |
| **Nama tapak kajian**Name of trial site |  |
| **Nama penyelidik/penyelidik utama asal**Name of current investigator/PI |  |
| **Nama penyelidik/penyelidik utama yang baru**Name of new investigator/PI |  |
| **Nombor kad pengenalan/pasport1**Identity card/passport number1 |  |
| **Profil penyelidik utama**Profile of PI  | [ ]  Declaration of PI[ ]  Curriculum vitae[ ]  Good Clinical Practice (GCP) Certificate |
| **Nombor telefon**Telephone number |  |
| **Alamat emel**E-mail address |  |
| **Dokumen disertakan**Documents included | [ ]  **Salinan semua LIPK/ Kebenaran Mengilang bagi protokol ini**Copy of all CTIL/CTX for this protocol[ ]  **Salinan Lampiran A yang terkini untuk protokol ini**Copy of the latest *Lampiran A* for this protocol[ ]  **Borang pengakuan asal penyelidik/penyelidik utama yang baru**  Original declaration form of the new investigator/PI[ ]  **Sijil GCP penyelidik/penyelidik utama yang baru**GCP certificate of the new investigator/PI [ ]  **Vitae kurikulum penyelidik/penyelidik utama yang baru**CV of the new investigator/PI[ ]  **Surat kelulusan Jawatankuasa Etika, jika ada**Ethics committee approval letter, if available |

1**Untuk kajian klinikal yang dijalankan di Malaysia sahaja**

1For clinical trial conducted in Malaysia only

**Lampiran V9**

|  |
| --- |
| **Lain-lain (cth. perubahan saiz pek, jenis bungkusan)**Others (e.g. change in pack size, type of packaging) |
| **Dokumen disertakan**Documents included | [ ]  **Salinan semua LIPK/Kebenaran Mengilang bagi protokol ini**Copy of all CTIL/CTX for this protocol[ ]  **Salinan Lampiran A yang terkini untuk protokol ini**Copy of the latest *Lampiran A* for this protocol[ ]  **Justifikasi variasi**Justification of variation[ ]  **Dokumen sokongan**Supporting document(s) **Sila senaraikan dokumen sokongan:** Please list all supporting document(s): |

**Lampiran I**

**MAKLUMAT KUANTITI PRODUK YANG DILULUSKAN TERDAHULU**

INFORMATION OF PREVIOUSLY APPROVED QUANTITY OF THE PRODUCT

**(Satu lampiran untuk setiap produk berdasarkan dokumen kelulusan2)**

(One attachment for each product based on approval document2)

**i) Kuantiti yang diluluskan pada kelulusan asal**

 Quantity approved in the initial application

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Bil.**No. | **Tarikh kelulusan**Approval date**(dd/mm/yyyy)1** | **Nombor rujukan dokumen kelulusan2**Approval document reference number2 | **Tapak kajian**Trial site | **Jumlah produk kajian yang diluluskan3** Quantity approved3 |
| 1. |  |  |  |  |

**1Tarikh yang dinyatakan pada dokumen kelulusan yang berkaitan.**

**1**Date as stated in the relevant approval document.

**2 Dokumen kelulusan: surat kelulusan dan/atau Lampiran A**

2 Approval document: approval letter and/or Lampiran A

3**Jumlah produk yang dinyatakan pada dokumen kelulusan yang berkaitan.**

3Quantity of product stated on relevant approval document.

**ii) Kuantiti yang diluluskan bagi permohonan variasi yang melibatkan pertambahan kuantiti**

Quantity approved in variation application that involves additional quantity of product (eg. Additional quantity, Additional quantity for new protocol, Additional IP with quantity, Additional trial site with quantiy etc.)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Bil.**No. | **Tarikh kelulusan**Approval date**(dd/mm/yyyy)1** | **Nombor rujukan dokumen kelulusan2**Approval document2 reference number | **Tapak kajian**Trial site | **Jumlah produk yang diluluskan3** Quantity approved3 |
| 1. |  |  |  |  |
| 2. |  |  |  |  |

**1Tarikh yang dinyatakan pada dokumen kelulusan yang berkaitan.**

**1**Date as stated in the relevant approval document.

**2 Contoh dokumen kelulusan: surat kelulusan dan/atau Lampiran A**

2 Example of approval document: approval letter and/or Lampiran A

3**Jumlah produk yang dinyatakan pada dokumen kelulusan yang berkaitan.**

3Quantity of product stated on relevant approval document.