|  |  |
| --- | --- |
| **Bahagian Regulatori Farmasi Negara (NPRA)*****National Pharmaceutical Regulatory Division (NPRA)***Lot 36, Jalan Profesor Diraja Ungku Aziz (Jalan Universiti), 46200 Petaling Jaya, Selangor, Malaysia. 🕿 03-78835400[http://www.npra.gov.my](http://www.bpfk.gov.my) | **BORANG PERMOHONAN PEMERIKSAAN****AMALAN PERKILANGAN BAIK (APB)*****APPLICATION FORM FOR******GOOD MANUFACTURING PRACTICE (GMP) INSPECTION*** |
| **Untuk Kegunaan Seksyen Kewangan, Akaun dan Hasil Sahaja** *For Finance, Account and Revenue Section Use Only*Tarikh Diterima: | Untuk Kegunaan PKKK Sahaja *For CCQC Use Only***Tarikh Diterima:****Wang Pos/Kiriman Wang/Draf Bank***Postal Order/Money Order/Bank Draft*..................................................... |

Borang permohonan ini perlu dilengkapkan oleh syarikat pengilang yang memohon pemeriksaan APB bukan rutin bagi premis pengilang baru/line pengilangan baru/ pensijilan ke atas premis yang tidak dikawal oleh Pihak Berkuasa Kawalan Dadah (PBKD) dan fasiliti kesihatan yang tidak dilesenkan. Borang ini dikecualikan ke atas pengilang berlesen/pengilang kosmetik yang diperiksa secara rutin oleh Pusat Komplians dan Kawalan Kualiti (PKKK), NPRA. **NOTA:** **Borang permohonan yang tidak lengkap tidak akan diproses.**

*This is form should be completed in full by a manufacturing company that would like to request for a non-routine GMP Inspection for e.g., GMP inspection on a new manufacturing premise/ new manufacturing line certification of premises that are not controlled by the Drug Control Authority (DCA) and healthcare establishments. This form is not applicable for licensed manufacturers/ cosmetic manufacturers that are subjected to routine GMP inspection by the Center for Compliance & Quality Control (CCQC), NPRA.* ***NOTE: INCOMPLETE APPLICATION FORM WILL NOT BE PROCESSED.***

|  |
| --- |
|  **Bahagian I: Maklumat Pemohon*****Part I: Particulars of Applicant*** |
| Nama Pemohon*Name of Applicant* |  |
| No. Kad Pengenalan*National Registration Identity Card (NRIC) No.* |  |
| Nama Syarikat*Name of Company* |  |
| Alamat Syarikat*Address of Company* |  |

|  |
| --- |
| **Pengesahan Permohonan (kegunaan pejabat sahaja) *Application Verification (for office use only)***  |
| **Tarikh Pengesahan** *Verification Date*  |  |
| **Status Permohonan** *Application Status*  | **❑ Lengkap** *Completed* | **❑ Tidak Lengkap** *Not Completed*  |
| **Pegawai Bertugas** *Officer-on-duty*  |  |

|  |
| --- |
| **Bahagian II: Maklumat Pengilang / Premis Pemeriksaan*****Part II: Particulars of Manufacturer*** |
| Nama Pengilang*Name of Manufacturer* |  |
| Alamat PengilangAddress of Manufacturer |  |
| No. Telefon*Telephone No.* |  |
| E-mel*Email* |  |
| Laman Web *Website*  |  |

|  |
| --- |
| **Bahagian III: Entiti Pemohon (Sila tanda yang berkenaan)*****Part III: Applicant Entity (Please tick which is appropriate)*** |
| **Entiti Pemohon****\* Sila kepilkan bukti***Company Entity**\* Please attach evidence* | * Kerajaan *Government*
* Kementerian Kesihatan Malaysia
* Bukan di bawah Kementerian Kesihatan Malaysia
 | * Swasta *Private*
 |

|  |
| --- |
| **Bahagian IV: Maklumat Bentuk Dos Produk Yang Dikilangkan (Sila tanda yang berkenaan)*****Part IV: Particulars of Dosage Form of Product Manufactured*** ***(Please tick which is appropriate)*** |
| Farmaseutikal (Racun & Bukan Racun)*Pharmaceutical (Poison & Non-Poison)* |  * Tablet (*Tablet)*
* Serbuk/Granul (*Powder/Granule)*
* Persediaan Steril (LVP/SVP/Gel) (*Sterile Preparation)*
* Pil (Pill)
* Kapsul (*Capsule)*
 |  * Sachet (*Sachet)*
* Losyen (*Lotion)*
* Salap *(Ointment)*
* Gel (*Gel*)
* Krim *(Cream)*
* Cecair internal/Cecair eksternal (*Liquid internal/external*)
 | * Lain-lain. Sila nyatakan .....................................

*(Others..........................)* |
| Bioteknologi / Biologikal*Biotechnology/Biological* | * Persediaan Steril (LVP/SVP/Gel) (*Sterile Preparation)*
 | * Lain-lain. Sila nyatakan .................................

*(Others. Please specify ................................)* |
| Tradisional*Traditional* |  * Tablet (*Tablet)*
* Serbuk/Granul (*Powder/Granule)*
* Kapsul (*Capsule)*
* Gel (*Gel*) Pil (Pill)
* Krim (Cream)
 | * Sachet (*Sachet)*
* Losyen (*Lotion)*
* Salap *(Ointment)*
* Cecair internal/Cecair eksternal (*Liquid internal/external*)
 | * Lain-lain. Sila nyatakan .....................................

*(Others..........................)* |
| Suplemen Kesihatan*Health Supplement* | * Tablet (*Tablet)*
* Serbuk/Granul (*Powder/Granule)*
* Kapsul (*Capsule)*
 | * Sachet (*Sachet)*
* Cecair internal/Cecair eksternal (*Liquid internal/external*)
 | * Lain-lain. Sila nyatakan ......................................

*(Others..........................)* |
| Veterinar\**Veterinary** Racun *(Poison)*
* Bukan Racun *(Non-poison)*

\*Rujuk Pengawalan Bahan Tambahan Makan Haiwan/Feed Additive Termasuk Produck Suplemen Kesihatan/Dietary Supplemens dan Produk Herbal/Natural | * Tablet (*Tablet)*
* Serbuk/Granul (*Powder/Granule)*
* Persediaan Steril (LVP/SVP/Gel,dll) (*Sterile Preparation)*
 | * Kapsul (*Capsule)*
* Sachet (*Sachet)*
* Cecair internal/eksternal (*Liquid internal/external*)
 | * Lain-lain. Sila nyatakan .......................................

*(Others..........................)* |

|  |  |  |  |
| --- | --- | --- | --- |
| Bahan Aktif Farmaseutikal*(Active Pharmaceutical Ingredient)* | * Serbuk/Granul (*Powder/Granule)*
* Persediaan Steril (LVP/SVP/Gel,dll) (*Sterile Preparation)*
 |  * Sachet (*Sachet)*
* Cecair internal/eksternal (*Liquid internal/external*)
 | * Lain-lain. Sila nyatakan .......................................

*(Others...........................)* |
| Kosmetik*Cosmetic* | * Serbuk/Granul (*Powder/Granule)*
* Cecair eksternal *(Liquid external)*
 | * Losyen (*Lotion)*
* Gel (*Gel*)
* Krim *(Cream)*
* *Gincu (Lipstick)*
* Aerosol
 | * Lain-lain. Sila nyatakan .......................................

(Others...........................) |
| Fasiliti Kesihatan*Healthcare Establishment* | * CDR
* Non-CDR : TPN/IV Admixture / Eye Drop
 |  * Radiopharmaceutical :

Kit based/ Radioiodine/ Blood Radiolabelled |
| Lain-lain*Others* | Sila nyatakan...............................................................................................................Please specify..............................................................................................................  |

|  |
| --- |
| **Bahagian V: Jenis Pemeriksaan Amalan Perkilangan Baik (APB)** **(Tandakan 1 jenis sahaja)*****Part V: Types of Good Manufacturing Practice (GMP) Inspection (Tick 1 only)*** |
| * Pra-pelesenan

*Pre-licensing** Verifikasi

*Verification** Pra-kelulusan

*Pre-approval* | * Pemeriksaan awal

(Premis kosmetik sahaja)*Initial inspection* *(Cosmetic premises only)** Pra-pensijilan

*Pre-certification* | * Pra-kualifikasi

(untuk fasiliti kesihatan sahaja)Pre-qualification *(for healthcare establishment only)* |
| **Definisi /Definition:**Pra-pelesenan *(Pre-licensing)* :  | pemeriksaan yang dijalankan ke atas premis pengilang yang baru dan belum pernah dilesenkan *(inspection conducted on new premises that have never been licensed).* |
| Verifikasi *(Verfication)* :  | pemeriksaan yang dijalankan susulan daripada tindakan punitif yang telah dikenakan *(inspection conducted following a punitive action).* |
| Pemeriksaan awal *(Intial Inspection)* :  | pemeriksaan yang dijalankan ke atas premis pengilang kosmetik yang baru, yang mana tidak termasuk di dalam jadual pemerikaan rutin *(inspection conducted only on new cosmetic premises which is not in the Routine Inspection Schedule).* |
| Pra-pensijilan *(Pre-certification)* :  | pemeriksaan yang dijalankan ke atas premis pengilang bagi produk yang belum dikawal oleh Pihak Berkuasa Kawalan Dadah [PBKD] *(inspection conducted on premises that manufacture products that are not regulated by Drug Control Authority, DCA).* |
| Pra-kelulusan *(Pre-approval)* :  | pemeriksaan yang dijalankan ke atas ‘line’ pengeluaran pengilang yang berlesen *(inspection conducted on a new production line of licensed manufacturer).* |
| Pra-kualifikasi *(Pre-qualification)* :  | Berkait dengan Amalan Penyediaan Baik (GPP) dan dijalankan ke atas fasiliti hospital farmasi dan Jabatan Perubatan Nuklear yang baru dibina atau diubahsuai *(related to Good Preparation Practice (GPP) and the inspection is conducted on new/renovated pharmacy hospital and nuclear medicine facility).* |

|  |
| --- |
| **Bahagian VI: Dokumen Sokongan Yang Diperlukan** ***Part VI: Supporting Documents Required*** |
| * Fail Induk Pengilang

 *Site Master File* * Sijil Pendaftaran Suruhanjaya Syarikat Malaysia (SSM)

*Registration of Company Certificate* | * Sebarang Urusan surat-menyurat bersama PKKK

*Any correspondence letter with CCQC previously.** Surat Kelulusan Pelan Aliran Kilang dari NPRA (Jika ada)

*Layout plan approval letter from NPRA (If any)* |
| **Bahagian VII: Fi Pemeriksaan APB *Part VII: GMP Inspection Fee*** |
| Pembayaran (tidak dikembalikan) hendaklah dalam bentuk Wang Pos/Kiriman Wang/Draf Bank atas nama **BAHAGIAN REGULATORI FARMASI NEGARA**. Pembayaran juga boleh dilakukan melalui kad kredit atau kad debit di kaunter Seksyen Kewangan, Akaun dan Hasil (SKAH).\*\*Nota: Pembayaran pemeriksaan bagi premis pengilang selain daripada yang dinyatakan perlu di bayar selepas pemeriksaan dijalankan (pasca-bayar)*Fee (non-refundable) should be submitted in the form of Postal Order/Money Order/Bank Draft made payable to* **BAHAGIAN REGULATORI FARMASI NEGARA**. *Alternatively, payment can also be made directly at the Seksyen Kewangan, Akaun dan Hasil (SKAH) counter, NPRA via credit or debit cards.*\*\* Note: Inspection fee for premises other than stated below shall be paid upon completion of inspection (post-paid)

|  |
| --- |
| * **Swasta *Private***
 |
|  | Fi Pemeriksaan bagi premis Tradisional/Suplemen Kesihatan/Kosmetik *Inspection Fee for Traditional/Health Supplement/Cosmetics premise* | **RM 1000.00** |
|  |
| * **Kerajaan *Government***
 |
| * **Di bawah Kementerian Kesihatan Malaysia *Ministry of Health***
 |
|  | Fi Pemeriksaan *Inspection Fee* | **Dikecualikan** *exempted* |
|  |
| * **Bukan di bawah Kementerian Kesihatan Malaysia *Non – Ministry of Health***
 |
|  | Fi Pemeriksaan *Inspection Fee* | **RM 500.00** |
|  |  |  |

 |
| **Bahagian VIII: Perakuan Pemohon*****Part VII: Applicant’s Declaration*** |
| Saya mengakui dan bersetuju bahawa / *I hereby declare and agree that* * Maklumat yang diberikan adalah benar dan lengkap /*Information provided are true and complete;*
* Tujuan permohonan pemeriksaan ini telah difahami /*Understand the purpose of this application;*
* Kaedah pembayaran kepada NPRA telah disertakan (Rujuk Bahagian VII / Mode of payment to NPRA has been attached (refer Part VII);
* Saya akan sentiasa memberi kerjasama untuk mengemukakan dokumen tambahan jika diperlukan oleh NPRA / *I will always cooperate and provide any additional documents if needed by NPRA.*
 | Tandatangan & Cop Syarikat: *Signature & Company Stamp* Tarikh:*Date*  |