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| **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.***

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| **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* |  |

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| **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* |  | |

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

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| **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* |

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| **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..........................)* |

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| 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.............................................................................................................. | | |

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| **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).* | |

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| **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* |