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| **Bahagian Regulatori Farmasi Negara**  ***National Pharmaceutical Regulatory Agency (NPRA)***  Lot 36, Jalan Profesor Diraja Ungku Aziz (Jalan Universiti),  Description: Related image46200 Petaling Jaya,  Selangor.  No. Tel. *Tel. No.* : 03-78835400  No. Faks. *Fax No.* : 03-7956 2924  03-7956 7075  Laman Web *Website* : <http://www.npra.gov.my> | **Untuk Kegunaan Seksyen Kewangan, Akaun dan Hasil Sahaja**  *For Finance, Account and Revenue Section Use Only*  **Tarikh Diterima**  *Date Received* | **Untuk Kegunaan PKKK Sahaja**  **No. Rujukan Permohonan:**  *Application Reference No.:*  *For CCQC Use Only*  **Tarikh Diterima**  *Date Received* |
| **BORANG PERMOHONAN PENILAIAN PELAN SUSUN ATUR PREMIS PENGILANG**  *APPLICATION FOR THE EVALUATION OF MANUFACTURING PLANT LAYOUT* | | |
| **ARAHAN *INSTRUCTIONS*** | | |
| 1. Sila isikan borang permohonan ini dalam 2 salinan: salinan asal (kegunaan pejabat) dan salinan pemohon.   *Please fill in this application form in 2 copies: original copy and applicant copy.*   1. Sila tanda (✓) pada kotak yang berkenaan. *Please tick (✓) the appropriate boxes.* 2. Satu borang hendaklah diisi bagi setiap kawasan pengeluaran berasingan yang memerlukan kelulusan.   *One application needs to be filled for every separate manufacturing area which require approval.*  Contoh:  *For example:*  Permohonan berasingan untuk premis pengilangan Drug Substances dan Drug Product (Biologik).  *Separate application for Drug Substances and Drug Product manufacturing premises (Biologic).*  Permohonan berasingan untuk barisan pengilangan berbeza dengan akses personel dan bahan yang berasingan.  *Separate application for different manufacturing line with dedicated personel and material access.*   1. Borang permohonan lengkap (dilampirkan dengan dokumen sokongan) yang sahkan oleh pegawai PKKK hendaklah dikemukakan ke **Seksyen** **Kewangan, Akaun dan Hasil, Pusat Pentadbiran, NPRA** (seperti alamat yang dinyatakan di atas).   *The completed application form (attached with supporting documents) that verified by CCQC Officer should be submitted to* ***Finance, Account and Revenue Section, Centre for Administration, NPRA*** *(above-mentioned address).*   1. Fi pemprosesan (tidak dikembalikan) hendaklah dibuat dalam bentuk Wang Pos/Kiriman Wang/Draf Bank atas nama **BAHAGIAN REGULATORI FARMASI NEGARA.** Bagi bayaran secara kad kredit/debit perlu dibuat di kaunter bayaran Seksyen Kewangan, Akaun dan Hasil.   *Processing Fee (not refundable) should be submitted in the form of Postal Order/Money Order/Bank Draft made payable to* ***BAHAGIAN REGULATORI FARMASI NEGARA****. For payments by credit/debit card,it must to be made at the* ***Finance, Account and Revenue Section*** *payment counter.*  Fi Pemprosesan *Processing Fee*   |  |  |  | | --- | --- | --- | | **i) Swasta *Private*** | | | | **a** | Pelan Premis Baharu /*New Premises Layout* | **RM 1000.00** | | **b** | Pindaan Pelan /*Revision of Existing Premises Layout* | **RM 500.00** | | **ii) Kerajaan *Government*** | | | | **Di bawah Kementerian Kesihatan Malaysia *Ministry of Health (MOH)*** | | | | **a** | Pelan Premis Baharu /*New Premises Layout* | **Dikecualikan** *exempted* | | **b** | Pindaan Pelan /*Revision of Existing Premises Layout* | **Dikecualikan** *exempted* | | **Bukan di bawah Kementerian Kesihatan Malaysia *Non - MOH*** | | | | **a** | Pelan Premis Baharu /*New Premises Layout* | **RM 500.00** | | **b** | Pindaan Pelan /*Revision of Existing Premises Layout* | **RM 250.00** |   **Nota/ *Note*:**   1. Hanya borang permohonan yang lengkap diisi dan telah disahkan pembayaran akan diproses oleh **Pusat Komplians dan Kawalan Kualiti, NPRA.**   *Only completed application form with confirmed payment will be processed by* ***Centre for Compliance and Quality Control, NPRA.*** | | |

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| **Lampiran : SENARAI SEMAK PERMOHONAN *Attachment: Application Checklist*** | |
| **Sila lengkapkan senarai semak permohonan.**  *Please complete the application checklist* | **Sila tanda (√)**  *Please Tick (√)* |
| **1) Bahagian I, II dan III telah lengkap diisikan dengan sewajarnya.**  *Part I, II and III were filled in properly* |  |
| **2) Dokumen-dokumen yang perlu dilampirkan adalah seperti yang berikut:**  *Documents to be attached are as below:* |  |
| **a) Ringkasan Proses Pengilangan bagi bentuk dos yang dikilangkan**  *The Summary of Manufacturing Processes for each dosage form manufactured* |  |
| **b) Aliran Personel, Bahan Mentah, Bahan Pembungkusan dan Produk Siap**  *Personnel, Raw Material, Packaging Materials and Finished Product Flow* |  |
| **c) Nama dan saiz (dengan ukuran) Bilik/Kawasan Pengeluaran dan Makmal**  *Name and size (with measurement) of Production Rooms/Area and Laboratory* |  |
| **d) Aliran Bahan Buangan (^bagi kategori A/B/C/E/I/J)**  *Waste Flow (^For Category A/B/C/E/I/J)* |  |
| **e) Aliran Perbezaan Tekanan Udara (^bagi kategori A/B/C/E/I/J)**  *Pressure Differential Flow (^For Category A/B/C/E/I/J)* |  |
| **f) Penggredan Bilik Bersih (untuk premis pengilangan steril sahaja)**  *Cleanroom Classification (only for sterile manufacturing premises)* |  |
| **g) Sila nyatakan maklumat/butiran utiliti yang digunakan seperti berikut dan sertakan**  **diagram bagi sistem utiliti yang berkenaan**  **a) Sistem Pengudaraan: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **b) Sistem Air Terawat : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  *Please specify the details of utilities used as below and attach the diagram for the utilities:*  *a) Heating, Ventilation and Air-Conditioning System : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*  *b) Water System : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* |  |
| **h) Sila nyatakan peralatan yang disediakan di Bilik Pengeluaran dan Makmal serta labelkan**  **kedudukan peralatan-peralatan tersebut.**  *Please specify the location and equipment prepared in all Production Room and Laboratory.* |  |
| **i) Bagi permohonan pindaan pelan, sila lampirkan pelan susun atur yang sedia ada dan ringkasan berkenaan cadangan pindaan berkenaan.**  *For application to revise the existing layout, please attach a copy of existing layout and briefing of the*  *proposed changes.* |  |

**^ Sila rujuk Bahagian II untuk kategori produk.** *^Please refer to Part II for product categories.*

**\*Permohonan tidak dipertimbangkan sebagai permohonan lengkap sekiranya lampiran-lampiran yang berkaitan tidak dilampirkan dengan sewajarnya.** *\* Application will not be considered as completed application if the relevant attachments are not submitted properly.*

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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 I : BUTIR-BUTIR PEMOHON & SYARIKAT *PART I : DETAILS OF APPLICANT & COMPANY*** | | | | | | | | | | |
| **Nama Pemohon**  *Applicant Name* | | | |  | | | | | | |
| **No. Kad Pengenalan**  *I.C. No.* | | | |  | | | | | | |
| **Jantina**  *Gender* | | | | Lelaki *Male* | | | | Perempuan *Female* | | |
| **Jawatan**  *Position* | | | |  | | | | | | |
| **Nama syarikat**  *Company’s Name* | | | |  | | | | | | |
| **Telefon (Pejabat)**  *Telephone (Office)* | |  | | | | **Telefon bimbit**  *Handphone* | | | |  |
| **Faksimili**  *Fax* | |  | | | | **Emel**  *Email* | | | |  |
| **Alamat premis perniagaan/premis pengilangan** *Address of business premise/manufacturing premise* | | | | | | | | | | |
| **Jenis kawasan premis kilang:**  Industri *Industry*  Perdagangan *Commercial*  Pertanian *Agriculture*  *Type of Manufacturing Premises:*  Lain-lain *Others* (sila nyatakan/*please specify*: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) | | | | | | | | | | |
| **Jenis bangunan kilang:**  Bungalow *Bungalow*   Bangunan berkembar *Detached building*  *Type of Building***:** Teres bertingkat *Storey Terrace*  Lain-lain (*Others* sila nyatakan/*please specify*: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) | | | | | | | | | | |
| **Alamat surat menyurat** [Jika berlainan daripada alamat di atas] *Correspondence address* [*If different from the address above*] | | | | | | | | | | |
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| **BAHAGIAN II : BUTIR-BUTIR PERMOHONAN *PART II: DETAILS OF APPLICATION*** | | | | | | | | | | |
| **Entiti Syarikat**  *Company Entity* | | | Kerajaan *Government*  Kementerian Kesihatan Malaysia *Ministry of Health*  Bukan di bawah Kementerian Kesihatan Malaysia *Non - Ministry of Health* | | | | | | Swasta  *Private* | |
| **Jenis Permohonan**  *Application type*  **# Sila rujuk Drug Registration Guidance Document (DRGD), Appendiks 27, Para 2: Managing Changes of Manufacturers Facility untuk penjelasan yang selanjutnya.**  *# Please refer to DRGD, Appendix 27: Para 2: Managing Changes of Manufacturers Facility**for any further explanation.* | | | Pelan Premis Baharu (sila terus ke bahagian Kategori Produk)  *New Premises Layout (please proceed to Product Categories Section)* | | | | | | 🞎 Pindaan Pelan  *Revision of Existing Premises Layout*  Immediate notification #  *Immediate notification*  Periodical notification #  *Periodical Notification* | |
| **Kategori Produk**  *Product Categories*  \*Sila potong yang tidak berkenaan  *\*Please strike through those that are not relevant* | | | **A) Farmaseutikal (Racun, A)**  ***A) Pharmaceutical (Poison, A)***  Dos Pepejal (\*tablet/ serbuk/ granul/ kapsul/ pil)  *Solid Dosage (*\**tablet/ powder/ granules/ capsules/ pills)*  Separa-pepejal (\*krim/ losyen/ gel)  *Semi-solid (\*cream/ lotion/ gel)*  Cecair untuk kegunaan (\*internal/ eksternal)  *Liquids for (\*internal/ external) use*  Persediaan Steril (\*LVP/ SVP/ Gel)  *Sterile Preparation (\*LVP/ SVP/ Gel)*  Lain-lain/ *Others*  (sila nyatakan/*please specify*: \_\_\_\_\_\_\_\_\_\_\_\_)  Sila nyatakan nama bahan aktif bagi premis radiofarmaseutikal/ *please specify active ingredient for radiopharmaceutical premis: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* | | | | | **B) Farmaseutikal (Bukan Racun, X)**  ***B) Pharmaceutical (Non-poison, X)***  Dos Pepejal (\*tablet/ serbuk/ granul/ kapsul/ pil)  *Solid Dosage (*\**tablet/ powder/ granules/ capsules/ pills)*  Separa-pepejal (\*krim/ losyen/ gel)  *Semi-solid (\*cream/ lotion/ gel)*  Cecair untuk kegunaan (\*internal/ eksternal)  *Liquids for (\*internal/ external) use*  Persediaan Steril (\*LVP/ SVP/ Gel)  *Sterile Preparation (\*LVP/ SVP/ Gel)*  Lain-lain/ *Others*  (sila nyatakan/*please specify*: \_\_\_\_\_\_\_\_\_\_\_\_) | | |
| **C) Bioteknologi (A)**  ***C) Biotechnology (A)***  Persediaan Steril (\*LVP/ SVP/ Gel)  *Sterile Preparation (\*LVP/ SVP/ Gel)*  Lain-lain / *Others*  (sila nyatakan/*please specify*: \_\_\_\_\_\_\_\_\_\_\_\_)  Sila nyatakan nama bahan aktif/ *please specify active ingredient: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* | | | | | **D) Penubuhan Biologikal**  ***D) Biological Establishment***  Sila rujuk/ *Please refer to:*  *Guidance Note for Cell and Gene Therapy (CGTPs) Manufacturing Facility in Malaysia at* [*http://npra.moh.gov.my*](http://npra.moh.gov.my)(jika berkenaan*/ if applicable)*  Sila nyatakan nama bahan aktif/ *please specify active ingredient: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* | | |
| **E) Veterinar (\*Racun/ Bukan Racun/ Suplemen kesihatan, H)**  ***E) Verterinary (\*Poison/ Non-poison/ health supplement, H)***  Dos Pepejal (\*tablet/ serbuk/ granul/ kapsul/ pil)  *Solid Dosage (*\**tablet/ powder/ granules/ capsules/ pills)*  Separa-pepejal (\*krim/ losyen/ gel)  *Semi-solid (including cream, lotion and gel)*  Cecair untuk kegunaan (\*internal/ eksternal)  *Liquids for (\*internal/ external) use*  Persediaan Steril (\*LVP/ SVP/ Gel)  *Sterile Preparation (\*LVP/ SVP/ Gel)*  Lain-lain/ *Others*  (sila nyatakan/*please specify*: \_\_\_\_\_\_\_\_\_\_\_\_) | | | | | **F) Suplemen Kesihatan (N)**  ***F) Health Supplement (N)***  Dos Pepejal (\*tablet/ serbuk/ granul/ kapsul/ pil)  *Solid Dosage (*\**tablet/ powder/ granules/ capsules/ pills)*  Cecair untuk kegunaan (\*internal/ eksternal)  *Liquids for (\*internal/ external) use*  Lain-lain/ *Others*  (sila nyatakan/ *please specify*: \_\_\_\_\_\_\_\_\_\_\_\_) | | |
| **G) Tradisional (T)**  ***G) Traditional (T)***  Dos Pepejal (\*tablet/ serbuk/ granul/ ‘hard gel’ kapsul/ ‘soft gel’ kapsul/ pil)  *Solid Dosage (\*tablet/ powder/ granules/ hard shell capsules/ soft shell capsules/ pills)*  Separa-pepejal (\*krim/ losyen/ gel)  *Semi-solid (\*cream/ lotion/ gel)*  Cecair untuk kegunaan (\*internal/ eksternal)  *Liquids for (\*internal/ external) use*  Lain-lain/ *Others*  (sila nyatakan/*please specify*: \_\_\_\_\_\_\_\_\_\_\_\_) | | | | | **H) Kosmetik (NOT)**  ***H) Cosmetic (NOT)***  Dos Pepejal (\*serbuk/ granul)  *Solid Dosage (\*powder/ granules)*  Separa-pepejal (\*krim/ losyen/ gel)  *Semi-solid (\*cream/ lotion/ gel)*  Cecair untuk kegunaan eksternal  *Liquids for external use*  Lain-lain/ *Others*  (sila nyatakan/ *please specify*:\_\_\_\_\_\_\_\_\_\_\_\_) | | |
| **I) Bahan Aktif Farmaseutikal (V)**  ***I) Active Pharmaceutical Ingredients (V)***  Dos Pepejal (\*serbuk/ granul)  *Solid Dosage (\*powder/ granules)*  Cecair untuk kegunaan (\*internal/ eksternal)  *Liquid for (\*internal/ external) use*  Persediaan Steril (\*LVP/ SVP/ Gel)  *Sterile Preparation (\*LVP/ SVP/ Gel)*  Lain-lain/ *Others*  (sila nyatakan/*please specify*: \_\_\_\_\_\_\_\_\_\_\_\_)  Sila nyatakan nama bahan aktif/ *please specify active ingredient: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* | | | | | **J) Hospital**  ***j) Hospital***  CDR  Non-CDR  Radiofarmaseutikal  *Radiopharmaceutical* | | |
| **K) Lain-lain**  ***k) Others***  Sila nyatakan:\_\_\_\_\_\_\_\_\_\_\_\_  *Please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_* | | |
| **BAHAGIAN III : PENGESAHAN (SYARIKAT/PERTUBUHAN)*SECTION III: CERTIFICATION (COMPANY/ESTABLISHMENT)*** | | | | | | | | | | |
| **Saya mengesahkan dan bersetuju bahawa**  ***I confirmed and agreed that***   1. Pemohon adalah seorang **🟋**kakitangan/ pemilik di syarikat yang tersebut di atas.   *The applicant is an* ***🟋****employee/ owner of the above-mentioned company.*   1. Pihak syarikat hendaklah sentiasa bersedia untuk memberi kerjasama dalam mengemukakan maklumat tambahan yang diperlukan dari semasa ke semasa bagi tujuan penilaian. Sekiranya tiada sebarang maklum balas diterima daripada pihak syarikat dalam tempoh masa yang ditetapkan, permohonan akan dicadangkan untuk ditolak dan fi pemprosesan tidak akan dikembalikan.   *The company should be co-operative in providing any additional information required from time to time for the purposes of evaluation. If the company did not provide any feedback to the officer within the specified time frame, this application will be proposed to be rejected and the processing fee is not refundable.*   1. Premis pengilang yang dipohon \*BELUM/ SEDANG/ SIAP dibina di tapak semasa permohonan ini dikemukakan.   *The applied manufacturing premises \*has not been built/ is being builT/ is already built when the application is submitted.*   1. Pihak syarikat memahami bahawa cadangan pelan susun atur premis hanya digunapakai oleh keluaran berdaftar/ kosmetik bernotifikasi yang dikawalselia oleh pihak NPRA.   *The company is understand that the proposed layout is only applicable to the registered product/ notified cosmetic that regulated by NPRA.*   1. Pihak syarikat telah merujuk kepada keperluan yang dinyatakan di dalam Garis Panduan Amalan Perkilangan Baik (APB) yang bersesuaian dengan kategori produk.   *The company has referred to the current Good Manufacturing Practice (GMP) Guidelines in accordance with product categories.*   1. Semua maklumat dan lampiran yang diberikan adalah benar dan tepat.   *All the information and attachment provided are true and accurate.* | | | | | | | **Tandatangan \*Pemilik/ Pengurus/ Pengarah Syarikat & Cop Syarikat**  *Signature of \*Company’s Owner/ Manager/ Director & Company Stamp* | | | |
| **Nama**  *Name* | | | |
| **Tarikh**  *Date* | | | |

\*Sila potong yang tidak berkenaan

*\*Please strike through those that are not relevant*