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| **Bahagian Regulatori Farmasi Negara (NPRA)**  ***National Pharmaceutical Regulatory Division (NPRA)***  Lot 36, Jalan Universiti  46200 Petaling Jaya,  Selangor.  No. Tel. *Tel. No.* : 03-78835400  No. Faks. *Fax No.* : 03-79571200  Laman Web *Website* : [npra.moh.gov.my](http://www.npra.gov.my) | | | | | | | | | | | | **Untuk Kegunaan SPP Sahaja**  *For LCS Use Only*  **Tarikh Diterima**  *Date Received* | | | | |
| **Peraturan-Peraturan Kawalan Dadah Dan Kosmetik 1984 [Peraturan 12(1)]**  *Control of Drugs and Cosmetics Regulations 1984 [Regulation 12(1)]*  **PERMOHONAN LESEN KELUARAN BERDAFTAR**  **UNTUK AGENSI KERAJAAN**  **(Lesen Pengilang, Lesen Mengimport, Lesen Pemborong)**  *APPLICATION FOR LICENCE FOR REGISTERED PRODUCT FOR GOVERMENT AGENCIES*  *(Manufacturer’s Licence, Import Licence, Wholesaler’s Licence)* | | | | | | | | | | | | | | | | |
| **BAHAGIAN I : ARAHAN *PART I: INSTRUCTIONS*** | | | | | | | | | | | | | | | | |
| 1. Sila isikan borang permohonan ini dengan HURUF BESAR dalam 1 salinan asal.   *Please fill in this application form in CAPITAL LETTERS in 1 original copy.*   1. Sila tanda (✓) pada kotak yang berkenaan.   *Please tick (✓) the appropriate boxes.*   1. Borang permohonan yang telah lengkap diisi hendaklah dikemukakan ke **Seksyen Pelesenan dan Pensijilan**, **Pusat Koordinasi dan Perancangan Strategik Regulatori, NPRA** (seperti alamat yang dinyatakan di atas).   *The completed application form should be submitted to* ***Licensing and Certification Section,******Centre of Regulatory Coordination & Strategic Planning, NPRA*** *(above-mentioned address).*   1. Tiada fi pemprosesan permohonan lesen untuk agensi kerajaan (KKM dan Bukan KKM)   *No processing fee for goverment agency application (MOH & non-MOH)*  **Nota:** a. Hanya **borang permohonan yang** **lengkap** akan diproses oleh Seksyen Pelesenan dan Pensijilan, NPRA.  ***Note:***  a. *Only****completed application form*** *will be processed by Licensing and Certification Section, NPRA* | | | | | | | | | | | | | | | | |
| **BAHAGIAN II : SENARAI SEMAK UNTUK DOKUMEN SOKONGAN *PART II: CHECKLIST FOR SUPPORTING DOCUMENTS*** | | | | | | | | | | | | | | | | |
| 1. Senarai semak ini perlu diisi oleh pemohon.   *This checklist is to be filled in by the applicant.*   1. Borang permohonan perlu disertakan dengan dokumen-dokumen berikut. Sila tanda (✓) sekiranya dokumen ada disertakan.   *The application form should be submitted with the following documents. Please tick (*✓*) the appropriate boxes if the documents are attached.*   1. Bagi permohonan **baru,** sila ke **Bahagian** **II(A)** manakala bagi permohonan **pembaharuan**, sila ke **Bahagian** **II(B)**.   *For* ***new*** *application, please proceed to* ***Part******II(A)*** *whereas for* ***renewal*** *application, please proceed to* ***Part******II(B)****.*   1. 🟋Dokumen sokongan ini diperlukan sekiranya keluaran yang dikilang/diimport/diborong adalah keluaran jenis Racun Berjadual A dan keluaran-keluaran lain yang memerlukan seorang Ahli Farmasi.   🟋*This document is necessary if products manufactured/imported/wholesale are scheduled poison A products or any other products that require a Pharmacist.* | | | | | | | | | | | | | | | | |
| **SENARAI DOKUMEN SOKONGAN *LIST OF SUPPORTING DOCUMENTS*** | | | | | | | | | | | | | | | | |
| 1. **Permohonan Baru *New Application*** | | | | | | | | | | | | | | | | |
| 1. Salinan Kad Pengenalan Pemohon / Pemegang Lesen   *A copy of Applicant’s / Licence Holder’s Identity Card* | | | | | | | | | | | | | | | 🞎 | |
| 1. 🟋 Salinan Sijil Pengekalan Tahunan Ahli Farmasi   🟋 *A copy of Annual Retention Certificate* | | | | | | | | | | | | | | | 🞎 | |
| 1. **Permohonan Pembaharuan *Renewal Application*** | | | | | | | | | | | | | | | | |
| 1. Salinan lesen terdahulu   *A copy of previous licence* | | | | | | | | | | | | | | | 🞎 | |
| 1. Salinan Kad Pengenalan Pemohon / Pemegang Lesen   *A copy of Applicant’s / Licence Holder’s Identity Card* | | | | | | | | | | | | | | | 🞎 | |
| 3. 🟋 Salinan Sijil Pengekalan Tahunan Ahli Farmasi  🟋 *A copy of Annual Retention Certificate* | | | | | | | | | | | | | | | 🞎 | |
| **BAHAGIAN III : BUTIR-BUTIR PERMOHONAN** ***PART III: DETAILS OF APPLICATION*** | | | | | | | | | | | | | | | | |
| **Jenis lesen**  *Licence type* | | | | | 🞎 Pengilang *Manufacturer’s* | | | | | | 🞎 Import *Import* | | | | | 🞎 Pemborong *Wholesaler’s* |
| **Permohonan bagi tahun**  *Application for year* | | | | | Tahun *Year* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | | |
| **Butir-butir lesen terdahulu (Jika pembaharuan)**  *Details of previous licence (If renewal)* | | | | | No. Lesen *Licence No*. ­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Tempoh Sah Lesen *Validity Period* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | | |
| **Kaedah kutipan lesen**  *Method of collection* | | | | | 🞎 Pos 🞎 Kutip di kaunter  *Post Collect from Counter* | | | | | | | | | | | |
| **BAHAGIAN IV : BUTIR-BUTIR AGENSI** ***PART IV: DETAILS OF AGENCY*** | | | | | | | | | | | | | | | | |
| **Nama agensi**  *Agency Name* | | |  | | | | | | | | | | | | | |
| **Alamat premis /premis pengilangan** *Address of premise/manufacturing premise* | | | | | | | | | | | | | | | | |
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| **Telefon (Pejabat)**  *Telephone (Office)* |  | | | | | | **Telefon bimbit**  *Handphone* | | | | | | |  | | |
| **Faksimili**  *Faximile* |  | | | | | | **Emel**  *E-Mail* | | | | | | |  | | |
| **Alamat stor** [Jika berlainan daripada alamat di atas]*Store address*[*If different from the above address*] | | | | | | | | | | | | | | | | |
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| **Alamat surat menyurat** *Correspondence address* | | | | | | | | | | | | | | | | |
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| **Maklumat dua individu yang bertanggungjawab (Boleh dihubungi 24 jam)**  *Details of two responsible persons**(Contactable 24 hours)* | | | | | | | | | | | | | | | | |
| Nama  *Name* | | | | | | | | Nama  *Name* | | | | | | | | |
| No. Kad Pengenalan  *I.C. No.* | | | | | | | | No. Kad Pengenalan  *I.C. No.* | | | | | | | | |
| Jawatan & Gred  *Position & Grade* | | | | | | | | Jawatan & Gred  *Position & Grade* | | | | | | | | |
| Telefon (Pejabat)  *Telephone (Office)* | | | | | | | | Telefon (Pejabat)  *Telephone (Office)* | | | | | | | | |
| Telefon Bimbit  *Handphone* | | | | | | | | Telefon Bimbit  *Handphone* | | | | | | | | |
| **Klasifikasi Keluaran** *Product Classification* | | | | | | | | | | | | | | | | |
| Racun  *Poison* (A) | | | | Bukan Racun  *Non Poison* (X) | | | | | Tradisional  *Traditional* (T) | | | | | | | Suplemen Kesihatan  *Health supplement* (N) |
| Veterinar Racun  *Poison Veterinary* (HA) | | | | Veterinar Bukan Racun  *Non Poison Veterinary* (HX) | | | | |
| **BAHAGIAN V : BUTIR-BUTIR PEMOHON *PART V: DETAILS OF APPLICANT*** | | | | | | | | | | | | | | | | |
| **Nama**  *Name* | |  | | | | | | | | | | | | | | |
| **No. Kad Pengenalan**  *I.C. No.* | |  | | | | | | | | | | | | | | |
| **Jantina**  *Gender* | | Lelaki *Male* | | | | | | | | | | | Perempuan *Female* | | | |
| **Jawatan**  *Position* | |  | | | | | | | | | | | | | | |
| **🟋 No. Sijil Pengekalan Tahunan (Pemegang lesen)**  *Annual Retention Certificate’s No. (Licence holder)* | | | | | |  | | | | | | | | | | |
| [🟋Untuk keluaran jenis Racun Berjadual A/HA dan keluaran-keluaran lain yang memerlukan seorang Ahli Farmasi, pemohon mestilah seorang Ahli Farmasi Berdaftar. *For Scheduled Poison products A/HA or any other products that require a Pharmacist, the applicant must be a Registered Pharmacist.*] | | | | | | | | | | | | | | | | |
| **BAHAGIAN VI : PERAKUAN PEMOHON (PEMEGANG LESEN)** ***PART VI: DECLARATION OF APPLICANT (LICENCE HOLDER)*** | | | | | | | | | | | | | | | | |
| **Saya mengaku bahawa *I confirm that***   1. Saya akan mematuhi semua peruntukan di bawah Akta Jualan Dadah 1952 dan Peraturan–Peraturan Kawalan Dadah dan Kosmetik 1984.   *I* *will comply with all the provisions of Sale of Drugs Act 1952 and Control of Drugs and Cosmetics Regulations 1984.*   1. Saya akan mematuhi semua keperluan Amalan Perkilangan Baik dan/atau Amalan Pengedaran Baik semasa.   *I will comply with the principles of the current Good Manufacturing Practice and/or Good Distribution Practice.*   1. Semua maklumat dan lampiran yang disertakan adalah benar dan tepat.   *All the information and attachment provided is true and complete.*   1. Tiada perubahan ke atas maklumat dan lampiran yang dikemukakan sebelum ini (Melainkan dinyatakan secara bertulis kepada Seksyen Pelesenan dan Pensijilan, NPRA).   *There are no changes on the information and attachment provided previously (Unless otherwise specified through a declaration letter to Licensing and Certification, NPRA).* | | | | | | | | | | **Tandatangan Pemegang Lesen** *Signature of Licence Holder* | | | | | | |
| **Tarikh** *Date* | | | | | | |
| **Cop Jawatan & Gred** *Official stamp* | | | | | | |
| **BAHAGIAN VII : PENGESAHAN AGENSI *SECTION VII: CERTIFICATION OF AGENCY*** | | | | | | | | | | | | | | | | |
| **Saya mengesahkan bahawa *I confirm that***   1. Pemohon adalah seorang **🟋**kakitangan/pemilik di agensi yang tersebut di atas.   *The applicant is an* ***🟋****employee/owner of the above-mentioned agensi.*   1. Lesen yang dipohon adalah untuk aktiviti di agensi yang tersebut di atas sahaja.   *The licence applied is only for the purpose of activity of the above-mentioned agency.*   1. Semua maklumat yang diberikan adalah benar dan tepat.   *All the information provided is true and complete.* | | | | | | | | | | **Tandatangan Ketua Jabatan/Pegawai Yang Menjaga**  *Signature of Head of Department* | | | | | | |
| **Nama dan Cop Jawatan**  *Name & Official stamp* | | | | | | |
| **Tarikh**  *Date* | | | | | | |

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| **BAHAGIAN VIII : BUTIR-BUTIR KELUARAN BERDAFTAR YANG DIKILANG / DIIMPORT**  ***SECTION VIII :*** ***DETAILS OF REGISTERED PRODUCTS MANUFACTURED / IMPORTED*** | | | | |
| 1. Sila senaraikan keluaran berdaftar mengikut klasifikasi produk (A/X/T/N/HA/HX).   *Please list the registered products according to product classification (A/X/T/N/HA/HX).*   1. Sila nyatakan sama ada keluaran didaftar menggunakan sistem QUEST (hanya untuk permohonan lesen pengilang & mengimport).   *Please specify whether the product was registered using the QUEST system.(only for manufacturing & import licence application)*   1. Sila sertakan lampiran lain jika ruang tidak mencukupi.   *Please attach additional page(s) if the space provided is insufficient.* | | | | |
| **Bil.**  *No.* | **Nama Keluaran**  *Product’s Name* | **Nombor Pendaftaran**  *Registration Number* | **Jangkamasa Pendaftaran** *Registration Period* | **Sistem QUEST**  *QUEST System* |
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