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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(3)]**  *Control of Drugs and Cosmetics Regulations 1984 [Regulation 12(3)]*  **PERMOHONAN SENARAI KELUARAN (TAMBAHAN) LESEN KELUARAN BERDAFTAR UNTUK AGENSI KERAJAAN**  *APPLICATION FOR (ADDITIONAL) PRODUCT LIST OF LICENCE FOR REGISTERED PRODUCT FOR GOVERMENT AGENCY* | | | | | | | | | |
| **BAHAGIAN I : ARAHAN *SECTION 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.* 2. Borang permohonan yang telah lengkap diisi hendaklah dikemukakan ke **Seksyen Pelesenan dan Pensijilan**, **Pusat Koordinasi dan Perancangan Strategik Regulatori, NPRA** (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).*  **Nota:** Hanya **borang permohonan yang lengkap** akan diproses oleh Seksyen Pelesenan dan Pensijilan, NPRA  *Note:* *Only* ***completed application form*** *will be processed by Licensing and Certification Section, NPRA.* | | | | | | | | | |
| **BAHAGIAN II : SENARAI SEMAK untuk DOKUMEN SOKONGAN *SECTION II: CHECKLIST for SUPPORTING DOCUMENTS*** | | | | | | | | | |
| 1. Senarai semak ini perlu diisi oleh pemohon. *This checklist is to be filled in by the applicant.* 2. 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.* | | | | | | | | | |
| **DOKUMEN SOKONGAN *SUPPORTING DOCUMENTS*** | | | | | | | | | |
| 1. 1 salinan Lesen Keluaran Berdaftar Mengimport/Pengilang   *A copy of Import/Manufacturing Licence for Registered Product* | | | | | | | | 🞎 | |
| 1. 1 salinan    1. Perakuan Pendaftaran Produk ; atau    2. Keputusan Mesyuarat PBKD; atau    3. Surat Kelulusan   *A copy of*   1. *Product’s Registration Certificate ; or* 2. *Decision of DCA Meeting; or* 3. *Approval Letter* | | | | | | | | 🞎 | |
| **BAHAGIAN III : BUTIR-BUTIR LESEN** ***SECTION III: DETAILS OF LICENCE*** | | | | | | | | | |
| **Jenis Lesen**  *Licence Type* | | | 🞎 Pengilang *Manufacturer’s* | | | | | | 🞎 Import *Import* |
| **Nombor Lesen**  *Licence Number* | | |  | | | | | | |
| **Tempoh Sah Lesen**  *Validity Period* | | |  | | | | | | |
| **Tarikh Lesen Dikeluarkan**  *Licence’s Issuance Date* | | |  | | | | | | |
| **Kaedah Kutipan**  **Senarai Keluaran Tambahan**  *Method of Collection for Aditional List* | | | 🞎 Pos 🞎 Kutip di kaunter  *Post Collect from Centre* | | | | | | |
| **BAHAGIAN IV : BUTIR-BUTIR AGENSI** ***SECTION IV: DETAILS OF AGENCY*** | | | | | | | | | |
| **Nama Syarikat**  *Agency Name* | |  | | | | | | | |
| **Alamat Premis yang Dilesenkan** *Address of Licenced Premise* | | | | | | | | | |
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| **Telefon**  *Telephone* |  | | | **Telefon Bimbit**  *Handphone* | | | |  | |
| **Faksimili**  *Fax* |  | | | **Emel**  *E-Mail* | | | |  | |
| **Alamat Surat Menyurat** *Correspondence Address* | | | | | | | | | |
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| **BAHAGIAN V : BUTIR-BUTIR PEMOHON (PEMEGANG LESEN)** ***SECTION V: DETAILS OF APPLICANT (LICENCE HOLDER)*** | | | | | | | | | |
| **Nota:** Pemohon mestilah Pemegang Lesen. ***Note:*** *Applicant must be the Licence Holder.* | | | | | | | | | |
| **Nama**  *Name* | |  | | | | | | | |
| **No. Kad Pengenalan**  *I.C. No.* | |  | | | | | | | |
| **Jantina**  *Gender* | | Lelaki *Male* | | | | Perempuan *Female* | | | |
| **Jawatan**  *Position* | |  | | | | | | | |
| **BAHAGIAN VI : PERAKUAN PEMOHON (PEMEGANG LESEN)** ***SECTION VI: DECLARATION OF APPLICANT (LICENCE HOLDER)*** | | | | | | | | | |
| **Saya mengaku bahawa *I confirm that***   1. Semua maklumat dan lampiran yang disertakan adalah benar dan tepat.   *All the information and attachment provided is true and complete.*   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.* | | | | | **Tandatangan Pemegang Lesen** *Signature of Licence Holder* | | | | |
| **Cop Jawatan & Gred** *Official stamp* | | | | |
| **Tarikh**  *Date* | | | | |
| **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. Semua maklumat yang diberikan adalah benar dan tepat.   *All the information provided is true and complete.*   1. Senarai keluaran (tambahan) lesen yang dipohon adalah untuk aktiviti di syarikat yang tersebut di atas sahaja.   *The licence (additional) product list applied is only for the purpose of activity of the above-mentioned company.* | | | | | **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 UNTUK DITAMBAH DALAM SENARAI KELUARAN**  ***SECTION VIII :*** ***DETAILS OF REGISTERED PRODUCTS TO BE ADDED TO THE PRODUCT LIST*** | | | | |
| **Nota *Notes***   1. Sila senaraikan keluaran berdaftar mengikut klasifikasi produk (A/X/T/N/HA/HX/HN).   *Please list the registered products according to product classification (A/X/T/N/HA/HX/HN).*   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.(only for manufacturing & import licence application)*   1. Sila sertakan lampiran lain jika ruang tidak mencukupi.   *Please attach additional pages if the space provided is insufficient.* | | | | |
| **Bil.**  *No.* | **Nama Keluaran**  *Product’s Name* | **Nombor Pendaftaran**  *Registration Number* | **Jangkamasa Pendaftaran** *Registration Period* | **Sistem QUEST**  *System QUEST* |
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