



**Bahagian Regulatori Farmasi Negara (NPRA)**  
**National Pharmaceutical Regulatory Division (NPRA)**  
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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 GOVERNMENT 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.*
2. Sila tanda (✓) pada kotak yang berkenaan. *Please tick (✓) the appropriate boxes.*
3. 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<br><i>A copy of Import/Manufacturing Licence for Registered Product</i>                                                                                                                              | <input type="checkbox"/> |
| 2) 1 salinan<br>a. Perakuan Pendaftaran Produk ; atau<br>b. Keputusan Mesyuarat PBKD; atau<br>c. Surat Kelulusan<br><i>A copy of</i><br>a. <i>Product's Registration Certificate ; or</i><br>b. <i>Decision of DCA Meeting; or</i><br>c. <i>Approval Letter</i> | <input type="checkbox"/> |

**BAHAGIAN III : BUTIR-BUTIR LESEN | SECTION III : DETAILS OF LICENCE**

|                                                                                               |                                                                                                               |                                               |
|-----------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| Jenis Lesen<br><i>Licence Type</i>                                                            | <input type="checkbox"/> Pengilang <i>Manufacturer's</i>                                                      | <input type="checkbox"/> Import <i>Import</i> |
| Nombor Lesen<br><i>Licence Number</i>                                                         |                                                                                                               |                                               |
| Tempoh Sah Lesen<br><i>Validity Period</i>                                                    |                                                                                                               |                                               |
| Tarikh Lesen Dikeluarkan<br><i>Licence's Issuance Date</i>                                    |                                                                                                               |                                               |
| Kaedah Kutipan<br>Senarai Keluaran Tambahan<br><i>Method of Collection for Aditional List</i> | <input type="checkbox"/> Pos <i>Post</i> <input type="checkbox"/> Kutip di kaunter <i>Collect from Centre</i> |                                               |

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| BAHAGIAN IV : BUTIR-BUTIR AGENSI   SECTION IV : DETAILS OF AGENCY                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                      |                                                                                   |                                           |
| Nama Syarikat<br>Agency Name                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                      |                                                                                   |                                           |
| Alamat Premis yang Dilesenkan Address of Licenced Premise                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                      |                                                                                   |                                           |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                      |                                                                                   |                                           |
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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                      |                                                                                   |                                           |
| Telefon<br>Telephone                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                      | Telefon Bimbit<br>Handphone                                                       |                                           |
| Faksimili<br>Fax                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                      | Emel<br>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<br>Name                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                      |                                                                                   |                                           |
| No. Kad Pengenalan<br>I.C. No.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                      |                                                                                   |                                           |
| Jantina<br>Gender                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <input type="checkbox"/> Lelaki Male |                                                                                   | <input type="checkbox"/> Perempuan Female |
| Jawatan<br>Position                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                      |                                                                                   |                                           |
| BAHAGIAN VI : PERAKUAN PEMOHON (PEMEGANG LESEN)   SECTION VI : DECLARATION OF APPLICANT (LICENCE HOLDER)                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                      |                                                                                   |                                           |
| <p>Saya mengaku bahawa I confirm that</p> <p>i) Semua maklumat dan lampiran yang disertakan adalah benar dan tepat.<br/>All the information and attachment provided is true and complete.</p> <p>ii) Saya akan mematuhi semua peruntukan di bawah Akta Jualan Dadah 1952 dan Peraturan-Peraturan Kawalan Dadah dan Kosmetik 1984.<br/>I will comply with all the provisions of Sale of Drugs Act 1952 and Control of Drugs and Cosmetics Regulations 1984.</p>                                                                                                                      |                                      | Tandatangan Pemegang Lesen Signature of Licence Holder                            |                                           |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                      | Cop Jawatan & Gred Official stamp                                                 |                                           |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                      | Tarikh<br>Date                                                                    |                                           |
| BAHAGIAN VII : PENGESAHAN AGENSI   SECTION VII : CERTIFICATION OF AGENCY                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                      |                                                                                   |                                           |
| <p>Saya mengesahkan bahawa I confirm that</p> <p>i) Pemohon adalah seorang *kakitangan/pemilik di agensi yang tersebut di atas.<br/>The applicant is an *employee/owner of the above-mentioned agensi.</p> <p>ii) Semua maklumat yang diberikan adalah benar dan tepat.<br/>All the information provided is true and complete.</p> <p>iii) Senarai keluaran (tambahan) lesen yang dipohon adalah untuk aktiviti di syarikat yang tersebut di atas sahaja.<br/>The licence (additional) product list applied is only for the purpose of activity of the above-mentioned company.</p> |                                      | Tandatangan Ketua Jabatan/Pegawai Yang Menjaga<br>Signature of Head of Department |                                           |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                      | Nama dan Cop Jawatan<br>Name & Official stamp                                     |                                           |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                      | Tarikh<br>Date                                                                    |                                           |

**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).*
- 2) 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)*
- 3) Sila sertakan lampiran lain jika ruang tidak mencukupi.  
*Please attach additional pages if the space provided is insufficient.*

| Bil.<br>No. | Nama Keluaran<br>Product's Name | Nombor Pendaftaran<br>Registration Number | Jangkamasa Pendaftaran<br>Registration Period | Sistem QUEST<br>System QUEST |
|-------------|---------------------------------|-------------------------------------------|-----------------------------------------------|------------------------------|
|             |                                 |                                           |                                               |                              |