

 <p><b>Bahagian Regulatori Farmasi Negara (NPRA)</b> <i>National Pharmaceutical Regulatory Division (NPRA)</i> Lot 36, Jalan Universiti 46200 Petaling Jaya, Selangor. No. Tel. <i>Tel. No.</i> : 03-78835400 (ext 8558) No. Faks. <i>Fax No.</i> : 03-79571200 Laman Web <i>Website</i> : <a href="http://www.bpfk.gov.my">http://www.bpfk.gov.my</a></p>	<p><b>BORANG PERMOHONAN PEMERIKSAAN AMALAN PERKILANGAN BAIK (APB)</b></p> <p><b>APPLICATION FORM FOR GOOD MANUFACTURING PRACTICE (GMP) INSPECTION</b></p>	
	<p>Untuk Kegunaan Unit Kewangan Sahaja <i>For Finance Unit Use Only</i></p> <p>Tarikh Diterima <i>Date Received</i></p>	<p>Untuk Kegunaan PKP Sahaja <i>For CCL Use Only</i></p> <p>Tarikh Diterima <i>Date Received</i></p> <p>Wang Pos/Kiriman Wang/Draf Bank <i>Postal Order/Money Order/Bank Draft</i></p> <p>.....</p>

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 Pelesenan (PKP),BPFK. **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 & Licensing (CCL), NPCB. **NOTE: INCOMPLETE APPLICATION FORM WILL NOT BE PROCESSED.***

Bahagian I: Maklumat Pemohon <i>Part I: Particulars of Applicant</i>			
Nama Pemohon <i>Name of Applicant</i>		No. Kad Pengenalan <i>I/C No.</i>	
Nama Syarikat <i>Name of Company</i>			
Alamat Syarikat <i>Address of Company</i>			
Bahagian II: Maklumat Pengilang / Premis Pemeriksaan <i>Part II: Particulars of Manufacturer</i>			
Nama Pengilang <i>Name of Manufacturer</i>			
Alamat Pengilang <i>Address of Manufacturer</i>			
No. Telefon <i>Telephone No.</i>		No. Faks <i>Fax No.</i>	
E-mel <i>Email</i>		Laman Web (jika ada) <i>Website (if any)</i>	

**Bahagian III: Entiti Pemohon (Sila tanda yang berkenaan)**  
**Part III: Applicant Entity (Please tick which is appropriate)**

<b>Entiti Pemohon</b> * Sila kekilkan bukti <i>Company Entity</i> * Please attach evidence	<input type="checkbox"/> Kerajaan Government <input type="checkbox"/> Kementerian Kesihatan Malaysia <i>Ministry of Health</i> <input type="checkbox"/> Bukan di bawah Kementerian Kesihatan Malaysia <i>Non-Ministry of Health</i>	<input type="checkbox"/> Swasta <i>Private</i>
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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) <i>Pharmaceutical (Poison &amp; Non-Poison)</i>	<input type="checkbox"/> Tablet ( <i>Tablet</i> ) <input type="checkbox"/> Serbuk/Granul ( <i>Powder/Granule</i> ) <input type="checkbox"/> Persediaan Steril (LVP/SVP/Gel) ( <i>Sterile Preparation</i> ) <input type="checkbox"/> Pil (Pill) <input type="checkbox"/> Kapsul ( <i>Capsule</i> )	<input type="checkbox"/> Sachet ( <i>Sachet</i> ) <input type="checkbox"/> Losyen ( <i>Lotion</i> ) <input type="checkbox"/> Salap ( <i>Ointment</i> ) <input type="checkbox"/> Gel ( <i>Gel</i> ) <input type="checkbox"/> Krim ( <i>Cream</i> ) <input type="checkbox"/> Cecair internal/Cecair eksternal ( <i>Liquid internal/external</i> )	<input type="checkbox"/> Lain-lain. Sila nyatakan ..... <i>(Others. Please specify .....)</i>
Bioteknologi / Biologiikal <i>Biotechnology/Biological</i>	<input type="checkbox"/> Persediaan Steril (LVP/SVP/Gel) ( <i>Sterile Preparation</i> )	<input type="checkbox"/> Lain-lain. Sila nyatakan ..... <i>(Others. Please specify .....)</i>	
Tradisional <i>Traditional</i>	<input type="checkbox"/> Tablet ( <i>Tablet</i> ) <input type="checkbox"/> Serbuk/Granul ( <i>Powder/Granule</i> ) <input type="checkbox"/> Kapsul ( <i>Capsule</i> ) <input type="checkbox"/> Gel ( <i>Gel</i> ) <input type="checkbox"/> Pili (Pill) <input type="checkbox"/> Krim (Cream)	<input type="checkbox"/> Sachet ( <i>Sachet</i> ) <input type="checkbox"/> Losyen ( <i>Lotion</i> ) <input type="checkbox"/> Salap ( <i>Ointment</i> ) <input type="checkbox"/> Cecair internal/Cecair eksternal ( <i>Liquid internal/external</i> )	<input type="checkbox"/> Lain-lain. Sila nyatakan ..... <i>(Others. Please specify .....)</i>
Suplemen Kesihatan <i>Health Supplement</i>	<input type="checkbox"/> Tablet ( <i>Tablet</i> ) <input type="checkbox"/> Serbuk/Granul ( <i>Powder/Granule</i> ) <input type="checkbox"/> Kapsul ( <i>Capsule</i> )	<input type="checkbox"/> Sachet ( <i>Sachet</i> ) <input type="checkbox"/> Cecair internal/Cecair eksternal ( <i>Liquid internal/external</i> )	<input type="checkbox"/> Lain-lain. Sila nyatakan ..... <i>(Others. Please specify .....)</i>
Veterinar* <i>Veterinary</i> <input type="checkbox"/> Racun ( <i>Poison</i> ) <input type="checkbox"/> Bukan Racun ( <i>Non-poison</i> )  <small>*Rujuk Pengawasan Bahan Tambahan Makanan Haiwan/Feed Additive Termasuk Produk Suplemen Kesihatan/Dietary Supplemens dan Produk Herba/Natural</small>	<input type="checkbox"/> Tablet ( <i>Tablet</i> ) <input type="checkbox"/> Serbuk/Granul ( <i>Powder/Granule</i> ) <input type="checkbox"/> Persediaan Steril (LVP/SVP/Gel,dll) ( <i>Sterile Preparation</i> )	<input type="checkbox"/> Kapsul ( <i>Capsule</i> ) <input type="checkbox"/> Sachet ( <i>Sachet</i> ) <input type="checkbox"/> Cecair internal/eksternal ( <i>Liquid internal/external</i> )	<input type="checkbox"/> Lain-lain. Sila nyatakan ..... <i>(Others. Please specify .....)</i>
Bahan Aktif Farmaseutikal <i>(Active Pharmaceutical Ingredient)</i>	<input type="checkbox"/> Serbuk/Granul ( <i>Powder/Granule</i> ) <input type="checkbox"/> Persediaan Steril (LVP/SVP/Gel,dll) ( <i>Sterile Preparation</i> )	<input type="checkbox"/> Sachet ( <i>Sachet</i> ) <input type="checkbox"/> Cecair internal/eksternal ( <i>Liquid internal/external</i> )	<input type="checkbox"/> Lain-lain. Sila nyatakan ..... <i>(Others. Please specify .....)</i>
Kosmetik <i>Cosmetic</i>	<input type="checkbox"/> Serbuk/Granul ( <i>Powder/Granule</i> ) <input type="checkbox"/> Cecair eksternal ( <i>Liquid external</i> )	<input type="checkbox"/> Losyen ( <i>Lotion</i> ) <input type="checkbox"/> Gel ( <i>Gel</i> ) <input type="checkbox"/> Krim ( <i>Cream</i> ) <input type="checkbox"/> Gincu ( <i>Lipstick</i> ) <input type="checkbox"/> Aerosol	<input type="checkbox"/> Lain-lain. Sila nyatakan ..... <i>(Others. Please specify .....)</i>

Fasiliti Kesihatan <i>Healthcare Establishment</i>	<input type="checkbox"/> CDR <input type="checkbox"/> Non-CDR : TPN/IV Admixture/ Eye Drop	<input type="checkbox"/> Radiopharmaceutical : Kit based/ Radioiodine/ Blood Radiolabelled
Lain-lain <i>Others</i>	Sila nyatakan ..... Please specify .....	

**Bahagian V: Jenis Pemeriksaan Amalan Perkilangan Baik (APB) (Tandakan 1 jenis sahaja)**  
**Part V: Types of Good Manufacturing Practice (GMP) Inspection (Tick 1 only)**

- |   |   |  |
|---|---|--|
| <input type="checkbox"/> Pra-pelesenan<br><i>Pre-licensing</i><br><input type="checkbox"/> Verifikasi<br><i>Verification</i><br><input type="checkbox"/> Pra-kelulusan<br><i>Pre-approval</i> | <input type="checkbox"/> Pemeriksaan awal (Premis kosmetik sahaja)<br><i>Initial inspection (Cosmetic premises only)</i><br><input type="checkbox"/> Pra-pensijilan<br><i>Pre-certification</i> | <input type="checkbox"/> Pra-kualifikasi (untuk fasiliti kesihatan sahaja)<br><i>Pre-qualification (for healthcare establishment only)</i> |
|---|---|--|

**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 (Verification) :	pemeriksaan yang dijalankan susulan daripada tindakan punitif yang telah dikenakan (inspection conducted following a punitive action).
Pemeriksaan awal (Initial Inspection) :	pemeriksaan yang dijalankan ke atas premis pengilang kosmetik yang baru, yang mana tidak termasuk di dalam jadual pemeriksaan 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).

**Bahagian VI: Dokumen Sokongan Yang Diperlukan**  
**Part VI: Supporting Documents Required**

- |  |  |
|--|--|
| <input type="checkbox"/> Fail Induk Pengilang<br><i>Site Master File</i><br><input type="checkbox"/> Sijil Pendaftaran Suruhanjaya Syarikat Malaysia (SSM)<br><i>Registration of Company Certificate</i> | <input type="checkbox"/> Sebarang Urusan surat-menyurat bersama PKP<br><i>Any correspondence letter with CCL previously.</i><br><input type="checkbox"/> Surat Kelulusan Pelan Aliran Kilang dari NPRA (Jika ada)<br><i>Layout plan approval letter from NPRA (If any)</i> |
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**Bahagian VII: Fi Pemeriksaan APB**  
**Part VII: GMP Inspection Fee**

Pembayaran (tidak dikembalikan) hendaklah dibuat dalam bentuk Wang Pos/Kiriman Wang/Draf Bank atas nama **BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN**. Bagi bayaran dalam bentuk kad kredit/kad debit, sila berhubung dengan Unit Kewangan, Pusat Pentadbiran, NPRA.

\*\*Nota: Pembayaran pemeriksaan bagi premis pengilang selain daripada yang dinyatakan perlu di bayar selepas pemeriksaan dijalankan (pasca-bayar)

*Fee (not refundable) should be submitted in the form of Postal Order/Money Order/Bank Draft made payable to **BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN**. For payment in the form of credit card/debit card, please contact Finance Unit, Centre for Administration, NPRA.*

\*\* 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 **Dikecualikan**  
*Inspection Fee* *exempted*

**Bukan di bawah Kementerian Kesihatan Malaysia Non – Ministry of Health**  
Fi Pemeriksaan **RM 500.00**  
*Inspection Fee*

**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 VI / *Mode of payment to NPRA has been attached (refer Part VI;*
- 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 (jika ada)  
*Signature & Company Stamp (if any)*

Tarikh:  
*Date*