

 <p>Bahagian Regulatori Farmasi Negara (NPRA)</p> <p>National Pharmaceutical Regulatory Division (NPRA) Lot 36, Jalan Profesor Diraja Ungku Aziz (Jalan Universiti), 46200 Petaling Jaya, Selangor, Malaysia.</p> <p>☎ 03-78835400</p> <p>http://www.npra.gov.my</p>	BORANG PERMOHONAN PEMERIKSAAN AMALAN PERKILANGAN BAIK (APB)	
	APPLICATION FORM FOR GOOD MANUFACTURING PRACTICE (GMP) INSPECTION	
<p>Untuk Kegunaan Seksyen Kewangan, Akaun dan Hasil Sahaja <i>For Finance, Account and Revenue Section Use Only</i></p> <p>Tarikh Diterima:</p>	<p>Untuk Kegunaan PKKK Sahaja <i>For CCQC Use Only</i></p> <p>Tarikh Diterima:</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 Kawalan Kualiti (PKKK), NPRA. **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 & Quality Control (CCQC), NPRA. **NOTE: INCOMPLETE APPLICATION FORM WILL NOT BE PROCESSED.***

Bahagian I: Maklumat Pemohon Part I: Particulars of Applicant	
Nama Pemohon <i>Name of Applicant</i>	
No. Kad Pengenalan <i>National Registration Identity Card (NRIC) No.</i>	
Nama Syarikat <i>Name of Company</i>	
Alamat Syarikat <i>Address of Company</i>	

Pengesahan Permohonan (kegunaan pejabat sahaja) Application Verification (for office use only)		
Tarikh Pengesahan <i>Verification Date</i>		
Status Permohonan <i>Application Status</i>	<input type="checkbox"/> Lengkap <i>Completed</i>	<input type="checkbox"/> Tidak Lengkap <i>Not Completed</i>
Pegawai Bertugas <i>Officer-on-duty</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>	
E-mel <i>Email</i>	
Laman Web <i>Website</i>	
Bahagian III: Entiti Pemohon (Sila tanda yang berkenaan) <i>Part III: Applicant Entity (Please tick which is appropriate)</i>	
Entiti Pemohon * Sila kepilkan bukti <i>Company Entity</i> * Please attach evidence	<input type="checkbox"/> Kerajaan Government <input type="checkbox"/> Kementerian Kesihatan Malaysia <input type="checkbox"/> Bukan di bawah Kementerian Kesihatan Malaysia
	<input type="checkbox"/> Swasta Private

Bahagian IV: Maklumat Bentuk Dos Produk Yang Dikilangkan (Sila tanda yang berkenaan) <i>Part IV: Particulars of Dosage Form of Product Manufactured</i> <i>(Please tick which is appropriate)</i>	
Farmaseutikal (Racun & Bukan Racun) <i>Pharmaceutical (Poison & Non-Poison)</i>	<input type="checkbox"/> Tablet (<i>Tablet</i>) <input type="checkbox"/> Serbuk/Granul (<i>Powder/Granule</i>) <input type="checkbox"/> Persediaan (LVP/SVP/Gel) (<i>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.....</i>)
Bioteknologi / Biologiikal <i>Biotechnology/Biological</i>	<input type="checkbox"/> Persediaan (LVP/SVP/Gel) (<i>Preparation</i>)
	<input type="checkbox"/> Steril (<i>Sterile</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>) Pil (Pill) <input type="checkbox"/> Krim (<i>Cream</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"/> Cecair internal/Cecair eksternal (<i>Liquid internal/external</i>)
	<input type="checkbox"/> Lain-lain. Sila nyatakan (<i>Others.....</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.....</i>)
Veterinar* <i>Veterinary</i>	<input type="checkbox"/> Tablet (<i>Tablet</i>) <input type="checkbox"/> Serbuk/Granul (<i>Powder/Granule</i>) <input type="checkbox"/> Persediaan (LVP/SVP/Gel,dll) (<i>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.....</i>)
<input type="checkbox"/> Racun (<i>Poison</i>) <input type="checkbox"/> Bukan Racun (<i>Non-poison</i>)	
<small>*Rujuk Pengawalan Bahan Tambahan Makanan Haiwan/Feed Additive Termasuk Produk Suplemen Kesihatan/Dietary Supplements dan Produk Herbal/Natural</small>	

Bahan Aktif Farmaseutikal (Active Pharmaceutical Ingredient)	<input type="checkbox"/> Serbuk/Granul (Powder/Granule) <input type="checkbox"/> Persediaan Steril (LVP/SVP/Gel,dll) (Sterile Preparation)	<input type="checkbox"/> Sachet (Sachet) <input type="checkbox"/> Cecair internal/eksternal (Liquid internal/external)	<input type="checkbox"/> Lain-lain. Sila nyatakan (Others.....)
Kosmetik Cosmetic	<input type="checkbox"/> Serbuk/Granul (Powder/Granule) <input type="checkbox"/> Cecair eksternal (Liquid external)	<input type="checkbox"/> Losyen (Lotion) <input type="checkbox"/> Gel (Gel) <input type="checkbox"/> Krim (Cream) <input type="checkbox"/> Gincu (Lipstick) <input type="checkbox"/> Aerosol	<input type="checkbox"/> Lain-lain. Sila nyatakan (Others.....)
Fasiliti Kesihatan Healthcare Establishment	<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 Others	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
Pre-licensing | <input type="checkbox"/> Pemeriksaan awal
(Premis kosmetik sahaja)
Initial inspection
(Cosmetic premises only) | <input type="checkbox"/> Pra-kualifikasi
(untuk fasiliti kesihatan sahaja)
Pre-qualification
(for healthcare establishment only) |
| <input type="checkbox"/> Verifikasi
Verification | <input type="checkbox"/> Pra-pensijilan
Pre-certification | |
| <input type="checkbox"/> Pra-kelulusan
Pre-approval | | |

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 <i>Site Master File</i> <input type="checkbox"/> Sijil Pendaftaran Suruhanjaya Syarikat Malaysia (SSM) <i>Registration of Company Certificate</i>	<input type="checkbox"/> Sebarang Urusan surat-menyurat bersama PKKK <i>Any correspondence letter with CCQC previously.</i> <input type="checkbox"/> Surat Kelulusan Pelan Aliran Kilang dari NPRA (Jika ada) <i>Layout plan approval letter from NPRA (If any)</i>
Bahagian VII: Fi Pemeriksaan APB Part VII: GMP Inspection Fee	
<p>Pembayaran (tidak dikembalikan) hendaklah dalam bentuk Wang Pos/Kiriman Wang/Draf Bank atas nama BAHAGIAN REGULATORI FARMASI NEGARA. Pembayaran juga boleh dilakukan melalui kad kredit atau kad debit di kaunter Seksyen Kewangan, Akaun dan Hasil (SKAH).</p> <p>**Nota: Pembayaran pemeriksaan bagi premis pengilang selain daripada yang dinyatakan perlu di bayar selepas pemeriksaan dijalankan (pasca-bayar)</p> <p><i>Fee (non-refundable) should be submitted in the form of Postal Order/Money Order/Bank Draft made payable to BAHAGIAN REGULATORI FARMASI NEGARA. Alternatively, payment can also be made directly at the Seksyen Kewangan, Akaun dan Hasil (SKAH) counter, NPRA via credit or debit cards.</i></p> <p>** Note: Inspection fee for premises other than stated below shall be paid upon completion of inspection (post-paid)</p>	
<input type="checkbox"/> Swasta Private Fi Pemeriksaan bagi premis Tradisional/Suplemen Kesihatan/Kosmetik <i>Inspection Fee for Traditional/Health Supplement/Cosmetics premise</i>	
RM 1000.00	
<input type="checkbox"/> Kerajaan Government <input type="checkbox"/> Di bawah Kementerian Kesihatan Malaysia Ministry of Health Fi Pemeriksaan <i>Inspection Fee</i>	
Dikecualikan <i>exempted</i>	
<input type="checkbox"/> Bukan di bawah Kementerian Kesihatan Malaysia Non – Ministry of Health Fi Pemeriksaan <i>Inspection Fee</i>	
RM 500.00	
Bahagian VIII: Perakuan Pemohon Part VII: Applicant's Declaration	
Saya mengakui dan bersetuju bahawa / <i>I hereby declare and agree that</i> <input type="checkbox"/> Maklumat yang diberikan adalah benar dan lengkap / <i>Information provided are true and complete;</i> <input type="checkbox"/> Tujuan permohonan pemeriksaan ini telah difahami / <i>Understand the purpose of this application;</i> <input type="checkbox"/> Kaedah pembayaran kepada NPRA telah disertakan (Rujuk Bahagian VII / <i>Mode of payment to NPRA has been attached (refer Part VII);</i> <input type="checkbox"/> Saya akan sentiasa memberi kerjasama untuk mengemukakan dokumen tambahan jika diperlukan oleh NPRA / <i>I will always cooperate and provide any additional documents if needed by NPRA.</i>	Tandatangan & Cop Syarikat: <i>Signature & Company Stamp</i> Tarikh: <i>Date</i>