

 Biro Pengawasan Farmaseutikal Kebangsaan (BPFK) National Pharmaceutical Control Bureau (NPCB) Lot 36, Jalan Universiti 46200 Petaling Jaya, Selangor. No. Tel. <i>Tel. No.</i> : 03-78835400 (ext 5565) No. Faks. <i>Fax No.</i> : 03-79571200 Laman Web <i>Website</i> : http://www.bpfk.gov.my	BORANG PERMOHONAN PEMERIKSAAN AMALAN PERKILANGAN BAIK (APB) APPLICATION FORM FOR GOOD MANUFACTURING PRACTICE (GMP) INSPECTION	
	Untuk Kegunaan Unit Kewangan Sahaja <i>For Finance Unit Use Only</i> Tarikh Diterima <i>Date Received</i>	Untuk Kegunaan PKP Sahaja <i>For CCL Use Only</i> Tarikh Diterima <i>Date Received</i> Wang Pos/Kiriman Wang/Draf Bank <i>Postal Order/Money Order/Bank Draft</i>

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: Maklumat Bentuk Dos Produk Yang Dikilangkan (Sila tanda yang berkenaan)
Part III: Particulars of Dosage Form of Product Manufactured (Please tick which is appropriate)

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 Steril (LVP/SVP/Gel) (<i>Sterile Preparation</i>) <input type="checkbox"/> Pili (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>) Pili (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. 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 Makan Haiwan/Feed Additive Termasuk Product Suplemen Kesihatan/Dietary Supplemens dan Produk Herbal/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 IV: Jenis Pemeriksaan Amalan Perkilangan Baik (APB) (Tandakan 1 jenis sahaja)
Part IV: Types of Good Manufacturing Practice (GMP) Inspection (Tick 1 only)

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

Part V: Supporting Documents Required

- | | |
|--|--|
| <input type="checkbox"/> Fail Induk Pengilang
<i>Site Master File</i> | <input type="checkbox"/> Sebarang Urusan surat-menyurat bersama PKP
<i>Any correspondence letter with CCL previously.</i> |
| <input type="checkbox"/> Sijil Pendaftaran Suruhanjaya Syarikat Malaysia (SSM)
<i>Registration of Company Certificate</i> | <input type="checkbox"/> Surat Kelulusan Pelan Aliran Kilang dari BPFK (Jika ada)
<i>Layout plan approval letter from NPCB (If any)</i> |

Bahagian VI: Fi Pemeriksaan APB (Untuk Pengilang Tradisional/ Suplemen Kesihatan/ Kosmetik Sahaja)
Part VI: GMP Inspection Fee (Only for Traditional/Health Supplement/Cosmetic Manufacturer)

Fi Pemeriksaan
Inspection Fee

RM1,000

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

****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 cash or credit card, please contact Finance Unit, Centre for Administration, NPCB.*

****Note:** Payment of inspection for other categories as stated above will be after inspection is conducted (post-paid)

Bahagian VII: 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 BPFK telah disertakan (Rujuk Bahagian VI / *Mode of payment to NPCB has been attached (refer Part VI;*
- Saya akan sentiasa memberi kerjasama untuk mengemukakan dokumen tambahan jika diperlukan oleh BPFK / *I will always cooperate and provide any additional documents if needed by NPCB.*

Tandatangan & Cop Syarikat (jika ada)
Signature & Company Stamp (if any)

Tarikh:
Date