

 <p>Bahagian Regulatori Farmasi Negara (NPRA)</p> <p>National Pharmaceutical Regulatory Agency (NPRA) Lot 36, Jalan Universiti (Jalan Profesor Diraja Ungku Aziz), 46200 Petaling Jaya, Selangor, Malaysia.</p> <p>☎ 03-78835400</p> <p>http://www.npra.gov.my</p>	<p>BORANG PERMOHONAN PEMERIKSAANAMALAN PERKILANGAN BAIK (APB)</p> <p>APPLICATION FORM FOR GOOD MANUFACTURING PRACTICE (GMP) INSPECTION</p>	
	<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>			
Bahagian II: Maklumat Pengilang / Premis Pemeriksaan Part II: Particulars of Manufacturer			
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) Part III: Applicant Entity (Please tick which is appropriate)		
Entiti Pemohon * Sila kekilkan bukti <i>Company Entity</i> * Please attach evidence	<input type="checkbox"/> Kerajaan <i>Government</i> <input type="checkbox"/> Kementerian Kesihatan Malaysia <input type="checkbox"/> Bukan di bawah Kementerian Kesihatan Malaysia	<input type="checkbox"/> Swasta <i>Private</i>

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 & 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)</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>) 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"/> Racun (<i>Poison</i>) <input type="checkbox"/> Bukan Racun (<i>Non-poison</i>) <small>*Rujuk Pengawalan 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)</i>

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 <i>Pre-licensing</i> <input type="checkbox"/> Verifikasi <i>Verification</i> <input type="checkbox"/> Pra-kelulusan <i>Pre-approval</i>	<input type="checkbox"/> Pemeriksaan awal (Premis kosmetik sahaja) <i>Initial inspection</i> (Cosmetic premises only) <input type="checkbox"/> Pra-pensijilan <i>Pre-certification</i>	<input type="checkbox"/> Pra-kualifikasi (untuk fasiliti kesihatan sahaja) <i>Pre-qualification</i> (for healthcare establishment only)
Definisi /Definition: Pra-pelesenan (<i>Pre-licensing</i>): pemeriksaan yang dijalankan ke atas premis pengilang yang baru dan belum pernah dilesenkan (<i>inspection conducted on new premises that have never been licensed</i>). Verifikasi (<i>Verification</i>): pemeriksaan yang dijalankan susulan daripada tindakan punitif yang telah dikenakan (<i>inspection conducted following a punitive action</i>). Pemeriksaan awal (<i>Initial Inspection</i>): pemeriksaan yang dijalankan ke atas premis pengilang kosmetik yang baru, yang mana tidak termasuk di dalam jadual pemeriksaan rutin (<i>inspection conducted only on new cosmetic premises which is not in the Routine Inspection Schedule</i>). Pra-pensijilan (<i>Pre-certification</i>): pemeriksaan yang dijalankan ke atas premis pengilang bagi produk yang belum dikawal oleh Pihak Berkuasa Kawalan Dadah [PBKD] (<i>inspection conducted on premises that manufacture products that are not regulated by Drug Control Authority, DCA</i>). Pra-kelulusan (<i>Pre-approval</i>): pemeriksaan yang dijalankan ke atas 'line' pengeluaran pengilang yang berlesen (<i>inspection conducted on a new production line of licensed manufacturer</i>). Pra-kualifikasi (<i>Pre-qualification</i>): Berkait dengan Amalan Penyediaan Baik (GPP) dan dijalankan ke atas fasiliti hospital farmasi dan Jabatan Perubatan Nuklear yang baru dibina atau diubahsuai (<i>related to Good Preparation Practice (GPP) and the inspection is conducted on new/renovated pharmacy hospital and nuclear medicine facility</i>).		

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 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)</p> <p><i>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.</i></p> <p><i>** Note: Inspection fee for premises other than stated below shall be paid upon completion of inspection (post-paid)</i></p>	
<input type="checkbox"/> Swasta Private Fi Pemeriksaan bagi premis Tradisional/Suplemen Kesihatan/Kosmetik RM 1000.00 <i>Inspection Fee for Traditional/Health Supplement/Cosmetics premise</i>	
<input type="checkbox"/> Kerajaan Government <input type="checkbox"/> Di bawah Kementerian Kesihatan Malaysia <i>Ministry of Health</i> Fi Pemeriksaan Dikecualikan <i>Inspection Fee exempted</i>	
<input type="checkbox"/> Bukan di bawah Kementerian Kesihatan Malaysia <i>Non – Ministry of Health</i> Fi Pemeriksaan RM 500.00 <i>Inspection Fee</i>	
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 VI / <i>Mode of payment to NPRA has been attached (refer Part VI;</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>