



PUSAT KAJIAN PRODUK BARU
CENTRE FOR INVESTIGATIONAL NEW PRODUCT

AGENSI REGULATORI FARMASI NEGARA
NATIONAL PHARMACEUTICAL REGULATORY AGENCY

KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA

**PERMOHONAN PEMERIKSAAN UNTUK PROGRAM
PEMATUHAN AMALAN MAKMAL BAIK**

*APPLICATION FOR GOOD LABORATORY PRACTICE
COMPLIANCE MONITORING PROGRAMME*

BAHAGIAN 1: TUJUAN PERMOHONAN**PART 1: REASON FOR APPLICATION**

Sila tandakan (✓) pada kotak berkenaan

Please tick (✓) the relevant boxes

	Permohonan baru <i>New application</i>
	Permohonan berikutan keperluan oleh pihak berkuasa tempatan /antarabangsa <i>Application prompted by the request of national/international authorities</i>

BAHAGIAN 2: BUTIRAN ORGANISASI**PART 2: DETAILS OF ORGANISATION**

1.	Nama Syarikat Pemohon <i>Name of Company</i>	
2.	Alamat <i>Address</i>	
3.	Pegawai untuk Dihubungi <i>Contact Person</i>	
4.	Jawatan <i>Designation</i>	
5.	Nombor Telefon <i>Telephone Number</i>	
6.	Nombor Fax <i>Facsimile number</i>	
7.	Alamat Emel <i>Email address</i>	

BAHAGIAN 3: BUTIRAN TEST FACILITY
PART 3: DETAILS OF TEST FACILITY

A. Maklumat Test Facility* <i>Test Facility Information*</i>	
1.	Nama <i>Name</i>
2.	Alamat <i>Address</i>
3.	No. Telefon <i>Telephone number</i>
4.	No. Faks <i>Facsimile number</i>
5.	Pegawai untuk Dihubungi <i>Contact Person</i>
6.	Jawatan <i>Designation</i>
7.	Emel <i>Email</i>
8.	Nombor Pendaftaran <i>Registration Number</i> <i>(A copy of ROC to be attached – if applicable)</i>

*Maklumat ini akan dipapar dalam laman sesawang NPRA sekiranya *Test Facility* tersebut disenaraikan dalam program komplians.

The above information will be published in NPRA website once the Test Facility is listed in the compliance programme.

Sila tandakan (v) pada kotak berkenaan

Please tick (v) the relevant boxes

B. Kategori Test Item <i>Category of Test Item</i>	
1.	Produk farmaseutikal <i>Pharmaceuticals</i>
2.	Kosmetics <i>Cosmetics</i>
3.	Ubat Veterinar <i>Veterinary Drugs</i>
4.	Aditif Makanan <i>Food Additives</i>
5.	Lain – lain <i>Others (please specify)</i>

Sila tandakan (✓) pada kotak berkenaan*Please tick (✓) the relevant boxes*

C. Area of Studies/Expertise <i>Area of Studies/Expertise</i>		
1.	<i>Physical-Chemical Testing</i>	
2.	<i>Toxicity Studies</i>	
3.	<i>Mutagenicity Studies</i>	
4.	<i>Analytical and Clinical Chemistry Associated with Non-Clinical Studies</i>	
5.	Lain-lain: Sila Nyatakan <i>Others: Please Specify</i>	a) b) c)

D. Senarai Key Personnel <i>List of Key Personnel</i>		
Bilangan pegawai yang terlibat dengan kajian GLP <i>Number of staff involved in GLP studies</i>		
No.	Jawatan <i>Designation</i>	Nama <i>Name</i>
1.	<i>Test Facility Management(s) (TFM)</i>	
2.	<i>Quality Assurance Personnel (QA)</i>	
3.	<i>Study Director(s) (SD)</i>	
4.	<i>Archivist(s)</i>	
5.	<i>Principal Investigator(s) (if applicable)</i>	

BAHAGIAN 4: BAYARAN**PART 4: FEE**

Sila tandakan (v) pada kotak berkenaan

Please tick (v) the relevant boxes

<p>A. Test Facility di bawah Kementerian Kesihatan Malaysia (KKM) <i>KKM Test Facility</i></p> <p>Percuma <i>Free</i></p>	<input type="checkbox"/>
<p>B. Test Facility milik kerajaan selain dibawah KKM <i>Non-KKM government facility</i></p> <p>Fi Pemprosesan permohonan (RM 1,000) No. draf bank : _____ <i>Application processing fee (RM 1,000)</i> <i>Bank draft number: _____</i></p>	<input type="checkbox"/>
<p>C. Test Facility Swasta <i>Private Test Facility</i></p> <p>Fi Pemprosesan permohonan (RM 2,000) No. draf bank : _____ <i>Application processing fee (RM 2,000)</i> <i>Bank draft number: _____</i></p>	<input type="checkbox"/>

BAHAGIAN 5: DOKUMEN YANG PERLU DISERTAKAN**PART 5: SUBMISSION OF DOCUMENTS**

<p>Organogram Terbaru <i>Recent Organogram</i></p>	<input type="checkbox"/>
<p>Pelan Lantai dengan kawasan bertanda 'GLP' <i>Floor-plans with GLP marked-area</i></p>	<input type="checkbox"/>
<p>Senarai peralatan <i>List of instruments/ equipments involved in GLP studies</i></p>	<input type="checkbox"/>
<p>Senarai Induk SOP <i>Master List of Standard Operating Procedures (SOPs)</i></p>	<input type="checkbox"/>
<p>Jadual Induk <i>Master Schedule reflecting all on-going and completed studies as well as all studies completed within the last two years: GLP/non-GLP, study code/identification, type of study, test system, test item, study initiation/completion date, study director, status, sponsor.</i></p>	<input type="checkbox"/>

BAHAGIAN 6: MAKLUMAT MENGENAI PEMBAYARAN**PART 6: INFORMATION ON PAYMENT**

(a) Semua pembayaran hendaklah dikemukakan dalam bentuk draf bank.

All payment shall be made by using bank draft.

(b) Bayaran fi permohonan perlu dibuat kepada **Biro Pengawalan Farmaseutikal Kebangsaan** sewaktu permohonan dibuat. Fi permohonan tidak akan dikembalikan.

*The application fee payment shall be made to **Biro Pengawalan Farmaseutikal Kebangsaan** during the submission of application. The application fee is not refundable.*

(c) Bayaran fi perkhidmatan lain-lain hendaklah dibuat atas nama **Biro Pengawalan Farmaseutikal Kebangsaan** **selewat-lewatnya dua minggu** sebelum pemeriksaan *Test Facility* dijalankan. Pengiraan fi perkhidmatan adalah seperti Lampiran 1. Maklumat jumlah bayaran akan dinyatakan di dalam invois selepas permohonan yang lengkap diterima.

*The other applicable fee payment shall be made to **Biro Pengawalan Farmaseutikal Kebangsaan** at least **2 weeks** before the inspection. The breakdown of the fee is as in Lampiran 1. Details of payment will be stated in the invoice after the complete application is received.*

(d) Bayaran hendaklah dikemukakan kepada Unit Kewangan, Pusat Pentadbiran, NPRA bagi mendapatkan resit atau bukti pembayaran. Salinan bukti pembayaran hendaklah dikemukakan bersama - sama borang permohonan kepada pegawai bertugas, Pusat Kajian Produk Baru, NPRA.

Payment shall be submitted to Finance Unit, Centre of Administration, NPRA for issuance of receipt. Copy of proof of payment shall be submitted together with the application form to officer at Centre for Investigational New Product.

BAHAGIAN 7: PERAKUAN PEMOHON
PART 7: APPLICANT'S DECLARATION

1. *I have read, understood and will comply with GLP Principles as published in OECD series of Principles of GLP and Compliance Monitoring, Document No. 1-18.*
2. *I hereby, give my consent on behalf of the test facility to abide by the National Pharmaceutical Regulatory Agency (NPRA) GLP Compliance Program requirements.*
3. *I hereby, declare that the information furnished above is correct.*
4. *I will provide access to those documents that provide insight into the level of independence and impartiality of the test facility from its related bodies, where applicable; and;*
5. *I agree to allow NPRA inspector/s access to the test facility specify area, resources, operations, procedures, records and staff so that the inspector/s can effectively inspect the GLP system and activities of my test facility. I understand that the failure to allow the above access will lead to my test facility not be included in the NPRA GLP Compliance Program.*

Tandatangan Pemohon*Signature of Applicant* _____**Nama Penuh (Huruf Besar)***Full Name (Block Letter)* _____**No. Kad Pengenalan***Identity Card No.* _____**Jawatan Dalam Syarikat/Organisasi***Position in the Company/Organisation* _____**Cop Rasmi Syarikat:***Official Stamp of the Company:***Tarikh (HH/BB/TT):***Date (DD/MM/YY):*

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Lampiran 1**Fi permohonan untuk program komplians GLP NPRA**

Aktiviti	Kadar Caj#
Pemprosesan Permohonan	RM2,000 setiap pemprosesan permohonan
Penilaian Dokumentasi*	RM2,000 bagi penilaian dokumentasi setiap pemeriksaan
Pra-Pemeriksaan	RM2,000 / pemeriksa / hari bekerja
Pemeriksaan Penuh termasuk pemeriksaan surveilan	RM2,000 / pemeriksa / hari bekerja
Pemeriksaan Verifikasi	RM2,000 / pemeriksa / hari bekerja
Pemeriksaan Pakar Teknikal	RM2,000 / pemeriksa / hari bekerja
Sijil Tahunan	RM2,000
Bayaran had maksimum bagi setiap pemeriksaan yang akan dijalankan adalah sebanyak RM 10,000 termasuk yuran pemprosesan permohonan dan penilaian dokumentasi.	
<i>Nota:</i>	
<i>*Penilaian dokumentasi meliputi penilaian dokumen bagi semua jenis pemeriksaan yang dinilai sebelum pemeriksaan dijalankan dan dokumen tindakan pembetulan dan pencegahan yang dikemukakan selepas pemeriksaan.</i>	
<i># Pengurangan yuran pemprosesan dan yuran pemeriksaan sebanyak 50% bagi pemeriksaan GLP di fasiliti milik kerajaan, dan percuma bagi fasiliti milik KKM.</i>	

Borang yang telah lengkap hendaklah dihantar kepada Timbalan Pengarah, Pusat Kajian Produk Baru, Agensi Regulatori Farmasi Negara, Kementerian Kesihatan Malaysia, Lot 36, Jalan Universiti, 46200 Petaling Jaya, Malaysia.

Please submit the completed form to: Deputy Director, Centre For Investigational New Product, National Pharmaceutical Regulatory Agency, Lot 36, Jalan Universiti, 46200 Petaling Jaya, Malaysia.