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

BAHAGIAN 2: BUTIRAN ORGANISASI
PART 2: DETAILS OF ORGANISATION

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

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

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

*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 (√) pada kotak berkenaan
Please tick (√) the relevant boxes

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

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

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

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

BAHAGIAN 4: BAYARAN
PART 4: FEE

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

A. *Test Facility* di bawah Kementerian Kesihatan Malaysia (KKM) ☐
KKM Test Facility

Percuma
Free

B. *Test Facility* milik kerajaan selain dibawah KKM ☐
Non-KKM government facility

Fi Pemprosesan permohonan (RM 1,000)
No. draf bank :_____
Application processing fee (RM 1,000)
Bank draft number:_____

C. *Test Facility* Swasta ☐
Private Test Facility

Fi Pemprosesan permohonan (RM 2,000)
No. draf bank :_____
Application processing fee (RM 2,000)
Bank draft number:_____

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

Organogram Terbaru ☐
Recent Organogram

Pelan Lantai dengan kawasan bertanda '*GLP*' ☐
Floor-plans with GLP marked-area

Senarai peralatan ☐
List of instruments/ equipments involved in GLP studies

Senarai Induk SOP ☐
Master List of Standard Operating Procedures (SOPs)

Jadual Induk ☐
*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.*

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.*

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):

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.	
Nota: **Penilaian dokumentasi meliputi penilaian dokumen bagi semua jenis pemeriksaan yang dinilai sebelum pemeriksaan dijalankan dan dokumen tindakan pembetulan dan pencegahan yang dikemukakan selepas pemeriksaan.*	
# Pengurangan yuran pemprosesan dan yuran pemeriksaan sebanyak 50% bagi pemeriksaan GLP di fasiliti milik kerajaan, dan percuma bagi fasiliti milik KKM.	

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.