PUSAT KOMPLIANS DAN KAWALAN KUALITI
CENTRE OF COMPLIANCE AND QUALITY CONTROL

BAHAGIAN REGULATORI FARMASI NEGARA
NATIONAL PHARMACEUTICAL REGULATORY AGENCY (NPRA)

KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA

PERMOHONAN PEMERIKSAAN UNTUK PROGRAM KOMPLIANS AMALAN MAKMAL BAIK

APPLICATION FOR GOOD LABORATORY PRACTICE (GLP) COMPLIANCE PROGRAMME

BAHAGIAN 1: TUJUAN PERMOHONAN
PART 1: REASON FOR APPLICATION

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

Permohonan pra-pemeriksaan *Application for pre-inspection*	
Permohonan pemeriksaan penuh *Application for full inspection*	
Permohonan pemeriksaan surveilans *Application for surveillance inspection*	

Permohonan pemeriksaan *Extra-ordinary* (sila tandakan pada perkara berkenaan): *Application for Extra-ordinary inspection (please indicate at the applicable item):*	
	Permohonan berikutan keperluan oleh pihak berkuasa tempatan/antarabangsa *Application prompted by the request of national/international authorities*
	Verifikasi pelaksanaan tindakan pembetulan *Verification of the implementation of the corrective actions*
	Penambahan skop/*area of expertise* *Extension of scope/area of expertise*
	Perubahan infrastruktur dan susun atur fasiliti kajian yang ketara *Significant changes in the test facility*
	Lain-lain (sila nyatakan): **_____** *Others (please specify): _____*

BAHAGIAN 2: MAKLUMAT PEMOHON
PART 2: DETAILS OF APPLICANT

1.	**Nama Syarikat / Fasiliti Kajian Pemohon** *Name of Company / Test Facility*	
2.	**Alamat** *Address*	
3.	**Pegawai untuk dihubungi** *Contact Person*	
4.	**Jawatan** *Designation*	
5.	**Nombor Telefon** *Telephone Number*	

6.	**Alamat Emel** *Email address*	

BAHAGIAN 3: PERINCIAN FASILITI KAJIAN DAN PERMOHONAN GLP
PART 3: DETAILS OF TEST FACILITY AND GLP APPLICATION

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

*Maklumat ini akan dipapar dalam laman sesawang NPRA sekiranya fasiliti kajian 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*	**Sedia ada** *Existing*	**Baru** *New*
1.	**Produk Farmaseutikal** *Pharmaceutical Products*		
2.	**Produk Kosmetik** *Cosmetics Products*		
3.	**Ubat Veterinar** *Veterinary Drugs*		
4.	**Aditif Makanan** *Food Additives*		
5.	**Peranti Perubatan** *Medical Devices*		

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

C.	***Bidang Kajian*/Kepakaran** *Area of Studies/Expertise*	**Sedia ada** *Existing*	**Baru** *New*
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: DOKUMEN YANG PERLU DISERTAKAN
PART 4: SUBMISSION OF DOCUMENTS

Sila tandakan (√) pada kotak untuk dokumen yang disertakan
Please tick (√) the respective box for each document that has been submitted

Organogram terkini *Recent organogram*	
Pelan lantai dengan kawasan bertanda '*GLP*' *Floor-plans with GLP marked-area*	
Senarai instrumen / peralatan yang terlibat dalam kajian GLP *List of instruments/ equipment involved in GLP studies*	
Senarai induk SOP *Master list of Standard Operating Procedures (SOPs)*	
Jadual induk kajian keselamatan bukan klinikal *Master Schedule reflecting all on-going and completed studies as well as all studies completed within the **last two (2) years**: GLP/non-GLP, study code/identification, type of study, test system, test item, study initiation/completion date, study director, status, sponsor.*	

BAHAGIAN 5: MAKLUMAT MENGENAI PEMBAYARAN
PART 5: INFORMATION ON PAYMENT

(a) Pemohon akan dikemukakan invois pembayaran sekiranya hasil penyaringan didapati memuaskan. Pengiraan fi adalah seperti Lampiran 1. Semua pembayaran hendaklah dikemukakan dalam bentuk draf bank/kiriman wang/wang pos.
The applicant will be issued a payment invoice if the screening is found satisfactory. The breakdown of the fee is as in Lampiran 1*. All payments shall be made using a bank draft/money order/postal order.*

(b) Bayaran fi hendaklah dibuat atas nama **Bahagian Regulatori Farmasi Negara** sebelum tarikh akhir yang dinyatakan di dalam invois.
Payment of the fees shall be made to **Bahagian Regulatori Farmasi Negara** *prior to the due date indicated on the invoice.*

(c) Bayaran hendaklah dikemukakan kepada Seksyen Kewangan, Akaun dan Hasil, Pusat Pentadbiran, NPRA bagi mendapatkan resit atau bukti pembayaran. Salinan bukti pembayaran hendaklah diemel kepada Seksyen Amalan Klinikal Baik dan Amalan Makmal Baik, NPRA (sgcpglp@npra.gov.my).
Payment shall be submitted to the Finance, Account and Revenue Section, Centre of Administration, NPRA for issuance of receipt. A copy of the proof of payment shall be emailed to the Good Clinical Practice and Good Laboratory Practice Section, NPRA (sgcpglp@npra.gov.my).

BAHAGIAN 6: PERAKUAN PEMOHON
PART 6: APPLICANT'S DECLARATION

1. **Saya mengaku, telah membaca, memahami dan akan mematuhi Prinsip-prinsip GLP seperti yang terdapat dalam *OECD series of Principles of GLP and Compliance Monitoring, Document No. 1-25.***

I have read, understood and will comply with the GLP Principles as published in the OECD series of Principles of GLP and Compliance Monitoring, Document No. 1-25.

2. Saya dengan ini memberi kebenaran bagi pihak fasiliti kajian untuk akur kepada keperluan *NPRA GLP Compliance Programme*.

I hereby give my consent on behalf of the test facility to abide by the National Pharmaceutical Regulatory Agency (NPRA) GLP Compliance Programme requirements.

3. Saya dengan ini mengaku bahawa semua kenyataan di atas adalah benar.

I hereby declare that all information provided and contained in this form is true and accurate.

4. Saya bersetuju memberi akses kepada dokumen yang memberi gambaran berkaitan tahap kebebasan dan kesaksamaan fasiliti kajian dari badan berkaitan, sekiranya perlu; dan;

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. Saya bersetuju membenarkan akses kepada inspektor NPRA ke bahagian fasiliti kajian berkaitan, sumber, operasi, prosedur, rekod dan staf, supaya pemeriksaan secara efektif dapat dilakukan ke atas sistem GLP dan aktiviti yang dijalankan di fasiliti kajian saya. Saya memahami bahawa kegagalan untuk memberi akses tersebut boleh menyebabkan fasiliti kajian saya tidak disenaraikan di dalam *NPRA GLP Compliance Programme*.

I agree to allow NPRA inspectors to access the test facility's specific area, resources, operations, procedures, records and staff so that the inspectors 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 being listed in the NPRA GLP Compliance Programme.

Tandatangan Pemohon *Signature of Applicant*	
Nama Penuh *Full Name*	
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)*	

Sila emel borang yang telah lengkap diisi dan dokumen seperti yang dinyatakan di *Bahagian 4* kepada Seksyen Amalan Klinikal Baik dan Amalan Makmal Baik, Bahagian Regulatori Farmasi Negara (sgcpglp@npra.gov.my).

Please email the completed form, along with the required documents as stated in Part 4, to the Good Clinical Practice and Good Laboratory Practice Section at the National Pharmaceutical Regulatory Agency (sgcpglp@npra.gov.my).

Lampiran 1

Fi permohonan untuk Program Komplians GLP NPRA

Aktiviti	Kadar Caj#
Permohonan *Application*	RM 2,000 setiap permohonan *RM 2,000 every application*
Penilaian Dokumentasi* *Document Assessment*	RM 2,000 setiap penilaian dokumentasi *RM 2,000 every document evaluation*
Pra-Pemeriksaan / Pemeriksaan Penuh / Pemeriksaan *Extra-ordinary* / Pemeriksaan Surveilan *Pre-inspection / Full Inspection / Extra-ordinary Inspection / Surveillance Inspection*	RM 2,000/hari bekerja/inspektor RM 2,000/working day/inspector
Yuran Pakar Teknikal *Technical Expert Fee*	RM2,000/hari bekerja/inspektor RM 2,000/working day/inspector
Sijil GLP *GLP Certificate*	RM 2,000
Bayaran had maksimum bagi setiap pemeriksaan yang akan dijalankan adalah sebanyak **RM 10,000** termasuk fi permohonan, penilaian dokumentasi dan sijil GLP. *The maximum chargeable fees for each inspection to be conducted is **RM 10,000**, which includes the application fee, documentation assessment, and GLP certificate.*	
Nota: ***Notes:*** *Penilaian dokumentasi meliputi penilaian dokumen bagi semua jenis pemeriksaan yang dinilai sebelum pemeriksaan dijalankan dan dokumen tindakan pembetulan dan pencegahan yang dikemukakan selepas pemeriksaan. **The assessment of documentation includes the evaluation of documents for all types of inspections that are assessed before the inspection is conducted, as well as the documents for corrective and preventive actions submitted after the inspection.*	

[#]Pengurangan fi sebanyak 50% bagi pemeriksaan GLP di fasiliti milik agensi/institusi kerajaan (selain daripada Kementerian Kesihatan Malaysia, KKM), dan percuma bagi fasiliti kajian bukan klinikal bagi semua fasiliti di bawah KKM.

[#]A 50% reduction in fees for GLP inspections at facilities owned by government agencies/institutions (other than the Ministry of Health, MOH), and free of charge for non-clinical testing facilities under the MOH.