

**PUSAT KOMPLIANS DAN KAWALAN KUALITI**

*CENTRE FOR COMPLIANCE AND QUALITY CONTROL*

**BAHAGIAN REGULATORI FARMASI NEGARA**

*NATIONAL PHARMACEUTICAL REGULATORY AGENCY* (NPRA)

**KEMENTERIAN KESIHATAN MALAYSIA**

*MINISTRY OF HEALTH MALAYSIA*

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

*APPLICATION FOR GOOD LABORATORY PRACTICE COMPLIANCE PROGRAMME*

**BAHAGIAN 1: TUJUAN PERMOHONAN**

*PART 1: REASON FOR APPLICATION*

**Sila tandakan (√) pada kotak berkenaan**

*Please tick (√) the relevant boxes*

|  |  |
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|  | **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*

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| **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*

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| **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 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*

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| **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*

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| **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)** |

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| **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*

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| **A. Fasiliti kajian di bawah Kementerian Kesihatan Malaysia (KKM)***KKM test facility***Percuma***Free* |
| **B. Fasiliti kajianmilik 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. Fasiliti kajianswasta** *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*

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| **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 (2) 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*

1. Semua pembayaran hendaklah dikemukakan dalam bentuk draf bank.

*All payment shall be made by using bank draft.*

1. 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.*

1. Bayaran fi perkhidmatan lain-lain hendaklah dibuat atas nama **Biro Pengawalan Farmaseutikal Kebangsaan selewat-lewatnya dua (2) minggu** sebelum pemeriksaan 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 two (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.*

1. Bayaran hendaklah dikemukakan kepada Seksyen Kewangan, Akaun dan Hasil, Pusat Pentadbiran, NPRA bagi mendapatkan resit atau bukti pembayaran. Salinan bukti pembayaran hendaklah dikemukakan bersama - sama borang permohonan kepada pegawai bertugas, Pusat Komplians dan Kawalan Kualiti, 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 Compliance and Quality Control*.

**BAHAGIAN 7: PERAKUAN PEMOHON**

*PART 7: 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. 1-21.***

*I have read, understood and will comply with GLP Principles as published in OECD series of Principles of GLP and Compliance Monitoring, Document No. 1-21.*

1. **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.*

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

*I hereby, declare that all information provided and contained in this form are true and accurate.*

1. **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;*

1. **Saya bersetuju membenarkan akses kepada pemeriksa 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 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 be listed in the NPRA GLP Compliance Programme.*

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| --- | --- |
| **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)* |  |

**Lampiran 1**

**Fi permohonan untuk Program Komplians GLP NPRA**

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| --- | --- |
| **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 Pengekalan | RM2,000 |
| Bayaran had maksimum bagi setiap pemeriksaan yang akan dijalankan adalah sebanyak **RM 10,000** termasuk yuran pemprosesan permohonan, penilaian dokumentasi dan sijil pengekalan. |
| ***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 Komplians dan Kawalan Kualiti, Bahagian Regulatori Farmasi Negara, Kementerian Kesihatan Malaysia, Lot 36, Jalan Profesor Diraja Ungku Aziz, 46200 Petaling Jaya, Malaysia.**

*Please submit the completed form to: Deputy Director, Centre for Compliance and Quality Control, National Pharmaceutical Regulatory Agency, Lot 36, Jalan Profesor Diraja Ungku Aziz, 46200 Petaling Jaya, Malaysia.*