A. ACCREDITATION CERTIFICATE TO BIOEQUIVALENCE (BE) TESTING CENTERS (INITIAL and RENEWAL)

This Accreditation Certificate in granted to Bioequivalence (BE) Testing Centers conducting the clinical and bioanalytical phases of a BE Study upon site inspection to confirm compliance with principles of Good Clinical (GCP) and Laboratory Practices (GLP).

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	Bioequivalence (BE) Testing Centers (Clinical & Bioanalytical facilities)
Fees to be Paid	:	Based on Administrative Order No. 2012-0024 - All fees with additional 1% Legal Research Fee (LRF) 1. Accreditation of BE testing center (3-year validity): Php 20,000.00 (per year) 2. Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) audit of BE testing centers A. Local 1. Within Metro Manila: Php 15,000 + Transportation Cost 2. Outside Metro Manila: Php 15,000 + Per Diem/Per inspector + Transportation Cost B. Overseas 1. ASEAN Countries: US$3,500 + UNDP Per Diem Rate* + Transportation Cost 2. Asia Pacific Countries (other than ASEAN): US$7,000 + UNDP Per Diem Rate + Transportation Cost 3. All Countries Outside of Asia Pacific: US$10,500 + UNDP Per Diem Rate + Transportation Cost

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Documents to be submitted based on FDA Circular No. 2021-006, Subject: Interim Guidelines on the Issuance of Accreditation and Inspection of Bioequivalence (BE) Testing Centers	
1. Letter of Request	Applicant
2. Proof of Payment, i.e. copy of Official Receipt (OR) or Oncoll payment slip	FDA Cashier
3. Organizational Chart	Applicant
4. Certificates of Accreditation and/or Licenses-to-Operate from relevant agencies	Relevant Agencies
5. Quality Manual	Applicant
6. Personnel Records including curricula vitae and training records demonstrating sufficient qualifications based	Applicant

on educational background, training and work experience	
7. Standard Operating Procedures (SOPs), Work Instructions, and forms of all the critical processes and activities	Applicant
8. Records/logbooks of instrument and equipment usage, maintenance, calibration and standardization	Applicant
9. Records of environmental monitoring and control (e.g. temperature, relative humidity, pests, microbes)	Applicant
10. Memoranda of Understanding/Contracts of Agreement between the Bioequivalence testing center and: a. Duly licensed/accredited 3rd party Screening Laboratory (for hematology, urinalysis, X-ray, ECG, drug testing, etc.) (where applicable) b. Duly licensed/accredited 3rd party Clinical or Bioanalytical Facility (where applicable) c. Other relevant parties involved in biological sample transport, waste disposal, instrument calibration, maintenance and standardization	Applicant
11. List of BE Studies Completed for the Past Accreditation Period and/or schedule of on-going and future studies	Applicant
12. Full Report of at least 2 Most-Recently Completed Bioequivalence Studies (for renewal applications)	Applicant
13. Other relevant documents in fulfillment of applicable principles of Good Clinical (GCP) and Good Laboratory Practices (GLP)	Applicant

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Manual Submission to FDAC Submit the letter of request and all other supporting documents (see table above) at the FDAC-PACD.	1. An acknowledgement receipt with a corresponding Document Tracking Number shall be issued to the applicant.	See Table Above	1 working day	FDAC *Personnel*
2. Pays the required fee through any of the following: • BANCNET • Landbank OnColl • Landbank Link.BizPortal				FDA Cashier/Landbank
	2. Endorses the received application to the Center	None	1 working day	FDAC *Personnel*
	3. Receives the application from FDAC and encodes /updates the database	None		Center for Drug Regulation and Research (CDRR)

				– Central Receiving and Releasing (CRR) Unit *Personnel*
	4. Decks/Assigns the application to the Bioequivalence (BE) Inspection Team Leader	None	1 working day	CDRR *Director*/Licensing and Registration Division (LRD) *Chief*
	5. Assigns co-inspectors and discusses the schedule of the desktop review	None	1 working day	BE Inspection *Team Leader* and *assigned members* of BE Inspection Team
	6. Conducts desktop review of the application based on the checklist of requirements	None	12 working days	*BE Inspection Team*
	7. Consolidates the evaluation findings of the Inspection Team	None	3 working days	*BE Inspection Team*
3. Submits any additional documents or clarifications requested by the BE Team	8. Sends the list of deficiencies to the applicant via email	None	20 working days	*BE Inspection Team*
	9. Evaluates the compliance documents submitted by the applicant	None	10 working days	*BE Inspection Team*
4. Confirms the schedule of virtual/remote inspection	10. Sends a proposed date of virtual/remote inspection to the applicant via email if necessary	None	1 working day	BE Inspection *Team Leader*
5. Participates in the opening and closing meetings at the BE Testing Center Provides overview of the BE Testing Center and conducts a brief tour at the site and its facilities	11. Inspection Proper at the BE Testing Center, including conduct of opening and closing meetings, examination of documents with direct access, interviews, and observation of activities, equipment, and conditions in the inspected areas	None	5 working days	*BE Inspection Team*

Provides inspection-related documents and information as requested by the BE Inspection Team through observation and interview	Provides the provisional list of inspection findings on the last day of inspection			
	12. Prepares the Official Inspection Repor		Within 20 working days after the inspection	BE Inspection Team
	13. Reviews the Official Inspection Report, affixes initial on the draft document, and forwards it to the Section Supervisor		1 working day	BE Inspection Team
	14. Reviews and signs the Official Inspection Report, and forwards it to the Licensing and Registration (LRD) Chief			*FDRO IV (Supervisor)*
	15. Checks and endorses the recommendation of the inspectors and supervisor by affixing signature			LRD *Chief*
	16. Signs the Official Inspection Report		1 working day	CDRR *Director*
	17. Encodes/Updates the Database and Endorses the final output document to CDRR-Records	None	1 working day	CDRR-CRR Unit *Personnel*
	18. Scans and endorses the Inspection Report to the FDAC Releasing Sectior	None	1 working day (per batch of applications)	CDRR-Records *Personnel*
	19. Releases the Inspection Report to the client	None	1 working day	AFS Releasing Section *Personnel*
6. Submits the Corrective and Preventive Action (CAPA) Plan	20. Upon compliance by the BE testing center, receives the Corrective and Preventive Action (CAPA) Plan and	None	Client: Within 20 working days upon	FDAC *Personnel*

	forwards it to the Center for Drug Regulation and Research (CDRR)		receipt of inspection report by the client. FDAC: 1 working day	
	21. Receives the Corrective and Preventive Action (CAPA) Plan from FDAC and encodes/updates the database and forwards it to the BE Inspection Team Leader	None	1 working day	CDRR-CRR Unit *Personnel*
	22. Evaluates the Corrective and Preventive Action (CAPA) Plan	None	Within 20 working days upon receipt of CAPA Plan	*BE Inspection Team*
7. Submits responses and documents requested by the BE Inspection Team, if applicable	23. Prepares the Accreditation Certificate and Final Inspection Report if approva of the application is recommended Prepares and sends the Notice of Deficiencies (NOD) through email if information in the CAPA Plan or accompanying documents submitted are insufficient to make a final decision, then reviews the requested documents upon compliance by the BE Testing Center Prepares the Letter of Disapproval (LOD) and Final Inspection Report if approval of the application is not recommended	None	Client: Within 20 working days upon receipt of NOD BE Inspection Team: 1 working day (for approval or disapproval); Within 20 working days upon receipt of 2nd compliance from the BE Testing Center, (for NOD)	*BE Inspection Team*
	24. Reviews the final output document (Accreditation Certificate or LOD), affixes initial on the draft document, and forwards it to the Section	None		*BE Inspection Team*

	Supervisor			
	25. Reviews and signs the final output document, and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day	*FDRO IV (Supervisor)*
	26. Checks and endorses the recommendation of the inspectors and supervisor by affixing signature	None		LRD *Chief*
	27. Signs and approves the final decision	None	1 working day	CDRR *Director*
	28. Encodes/Updates the Database and Endorses the final output document to the CDRR-Records Section (for Accreditation Certificate) or Releasing Section (for LOD)	None	1 working day	CDRR-CRR Unit *Personnel*
	29. Scans the Accreditation Certificate, updates the database, and endorses the Accreditation Certificate to the FDAC Releasing Section	None	1 working day (per batch of applications)	CDRR-Records *Personnel*
8. Receives the Accreditation Certificate or LOD	30. Releases the Accreditation Certificate or LOD to the client	None	1 working day	FDAC Releasing Section *Personnel*
Service is covered under the ASEAN Mutual Recognition Arrangement for Bioequivalence Study Reports of Generic Medicinal Products		**TOTAL:**	**112 working days**	