

ANNEX C

CENTER FOR DRUG REGULATION AND RESEARCH

LICENSE TO OPERATE (LTO)	Fees (in PhP) per Year*
1. Drug Manufacturer	
a. Low risk	27,500.00
b. Medium risk	47,500.00
c. High risk	56,000.00
2. Drug Trader	8,000.00
3. Drug Distributor (Importer/Exporter/Wholesaler)	8,000.00
4. Drugstore	3,000.00
5. Retail Outlet for Non-Prescription Drug	3,000.00
6. Sponsor/ Contract Research Organization	63,000.00
Variation	Fees (in PhP) per Variation*
1. Drug Manufacturer	
a. Major variation with inspection	56,000.00
b. Major variation without inspection	1,250.00
c. Minor variation	1,170.00
2. Drug Trader/ Drug Distributor	
a. Major variation with inspection	8,000.00
b. Minor variation	620.00
3. Drugstore / Retail Outlet for Non-prescription drug	
a. Major variation with inspection	3,000.00
b. Minor variation	620.00
4. Sponsor/ Contract Research Organization	
a. Major variation with inspection	63,000.00
b. Minor variation	620.00
Other Permit/ Certificate/Clearance (LTO/Pharmacist Verification request from private individual/law firm, etc.)	1000.00
Certificate of GMP Compliance	Fees (in PhP) per Year*
1. Foreign Manufacturer	Covered by a separate FC No. 2014-016
2. Local Manufacturer	
a. Low risk	27,500.00
b. Medium risk	47,500.00
c. High risk	56,000.00
Certificate of Accreditation of Bioequivalence Testing Center (local and foreign)	Fees shall follow AO No. 2012-0024

CERTIFICATE OF PRODUCT REGISTRATION	Fees (in PhP) per Year*
New Drug/ New Biological	43,000.00
Generic Drug Rx / Biosimilar	18,000.00
Non-prescription Drug (Pharmacy only & General Sales List)	17,000.00
Medical Gas	9,000.00
Traditional Medicine	14,500.00
Herbal Medicine	17,000.00
PCPR Conversion	1,000.00
CLIDP	16,700.00
Foreign Donation	2,000.00
Variation	Fees (in PhP) per Variation*
Major variation turned initial	18,000.00
Other Major variation	14,000.00
Minor variation	7,000.00
Notification	1,800.00
Reapplication (Initial/Renewal/Variation)	2,000.00
Reconsideration	18,000.00
Brand name	600.00
Certificate of Pharmaceutical Product, Certificate of Free Sale, Export Certificate, Generic Labeling Exemption	1,650.00
Clinical Trial (Phase I, II, III)	Fees (in PhP) per Year*
Clinical Trial Approval and Import License	69,000.00
Prior Approval CT Protocol Amendment	9,000.00
Other CT Protocol Amendment/Notification	3,000.00
Import License Amendment	3,500.00
Import License Notification	1,900.00
PMS (Phase IV) CT Approval	34,000.00
Prior Approval CT Protocol Amendment	9,000.00
Other CT Protocol Amendment/Notification	3,000.00
Compassionate Special Permit (CSP)	1,200.00

Import/Export Permit (e.g., samples for registration, one-time importation (drug shortage), BE/Biowaiver comparator/sample)	1,200.00
Product classification	6,500.00
Exhaustion of existing labeling materials/ Relabeling/ Repacking, etc.	1,700.00

* All fees are subject to an additional 1% for Legal Research Fee (LRF)

Other Services:

Batch Notification	6500
Lot Release Certification	5300

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