

ANNEX E
SCHEDULE OF FEES

1. Foreign

Type of application / Process	Category I	Category II
Application Fee (Initial, re-issuance, and major variation application) a. Application of GMP Evidence b. Desktop Evaluation	a. Php 5,000 (per distributor/importer) + LRF b. Php 5,000 (per manufacturing site and per distributor/importer) + LRF	Php 5,000 (per product line per manufacturing site and per distributor/importer) + LRF
Minor Variation	Php 620 (per manufacturing site and per distributor/importer) + LRF	N/A
Inspection Fee**	N/A	N/A
1. ASEAN Countries	N/A	USD 3 500 + (UNDP-DSA + Airfare)*
2. Asia Pacific Countries	N/A	USD 7 000 + (UNDP-DSA + Airfare)*
3. Other Countries	N/A	USD 10 500 + (UNDP-DSA + Airfare)*
<p>* Inspection expenses including UNDP-DSA, Airfare, and translator (if necessary) shall be paid by the Foreign Pharmaceutical Manufacturer through the appropriate FDA account.</p> <p>**Payment is exclusive of all bank charges.</p> <p>***No inspection fee in cases of minor variation.</p>		

2. **Local**

Type of application / Process	Category I	Category II	
Application Fee (Initial and Major Variation - Transfer of Location) a. Application of GMP Evidence b. Desktop Evaluation	Php 5,000 + LRF Php 5,000 + LRF	Low	Php 8,250 + LRF
		Medium	Php14,250 + LRF
		High	Php16,800 + LRF
Re-issuance Fee	Php 5,000 + LRF		
Other Major and Minor Variation	Payment fee shall be covered under the Licensing-Variation Application		
Payment is exclusive of all bank charges.			

3. The Inspection Fee shall cover the costs of GMP-related inspections, inspection services' capacitation, and other activities aligned with the FDA's mission and vision.
4. In cases of variation the fees exacted for LTO variation shall apply.