



CENTER FOR DRUG REGULATION AND RESEARCH

**CERTIFICATE OF PHARMACEUTICAL PRODUCTS (CPP),
CERTIFICATE OF FREE SALE (CFS), EXPORT CERTIFICATE (EC),
AND GENERIC LABELING EXEMPTION (GLE) APPLICATION**

Who May Avail : All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products

Fees to be Paid : **CPP:**
PHP 500.00 each/per product/per country + LRF
CFS:
PHP 500.00 each/per product/per country + LRF
EC:
PHP 500.00 each/per product/per country + LRF
GLE:
PHP 500.00 each/per product/per year for low volume of importation + LRF
PHP 500.00/product for special handling + LRF

CHECKLIST OF REQUIREMENTS

Certificate of Pharmaceutical Product:

1. Application Form
2. Valid Certificate of Product Registration with attachments, if applicable
3. Valid License to Operate (LTO) of manufacturer/exporter/importer/distributor/trader
4. Valid cGMP of manufacturer
5. Immediate and secondary labeling materials
6. Unit Dose Formulation
7. Payment of PHP 500.00 each/per product/per country

Certificate of Free Sale:

1. Application Form
2. Valid Certificate of Product Registration with attachments, if applicable
3. Valid License to Operate (LTO) of manufacturer/exporter/importer/distributor/trader
4. Payment of PHP 500.00 each/per product/per country

Export Certificate:

1. Application Form
2. Valid Certificate of Product Registration
3. Valid License to Operate (LTO)
4. Quantity, batch number, manufacturing and expiry dates of the drug product/s to be exported
5. Payment of PHP 500.00 each/per product/per country



Generic Labeling Exemption:

1. Completely filled and signed Integrated Application Form
2. Signed Letter of Request (stating the basis of exemption)
3. Valid Certificate of Product Registration with attachments, if applicable
4. License to Operate (LTO) as Drug Importer (for low volume of importation)
5. Facsimile of the labeling materials (primary and secondary packaging materials)
6. Copy of previously approved certificate of generic labeling exemption (for renewal applications)
7. Market forecast for the period applying for, in case of low volume of importation (must be specified monthly and separated with the letter of request)
8. Proof of Payment

END