Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

CENTER FOR DRUG REGULATION AND RESEARCH

INITIAL REGISTRATION OF PRESCRIPTION GENERIC PHARMACEUTICAL PRODUCTS

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

Fees to be Paid : **Initial**
Branded**:** PHP 3,000.00/year + PHP 500.00 (Brand Name Clearance) + 1% LRF
Unbranded: PHP 2,000.00/year + 1% LRF
The applicant may apply for 2 or 5-year CPR validity (Based on Bureau Circular No. 5 s. 1997).
2-year validity:
Branded: PHP 6,000.00 + PHP 500.00 (for Brand Name Clearance) = PHP 6,500.00 + 1% LRF
Unbranded: PHP 4,000.00 + 1% LRF
5-year validity:
Branded: PHP 15,000.00 + PHP 500.00 (for Brand Name Clearance) = PHP 15,500.00 + 1% LRF
Unbranded: PHP 10,000.00 + 1% LRF

CHECKLIST OF REQUIREMENTS

ASEAN Common Technical Dossier

Part I: Administrative Data and Product Information
Sec. A: Introduction
Sec. B: Overall ASEAN Common Technical Dossier Table of Contents
Sec. C: Guidance on the Administrative Data and Product Information

1. Duly accomplished and notarized Integrated Application Form (with proof of payment)
2. Letter of Authorization (where applicable)
3. Certifications

For contract manufacturing:
   a. License of pharmaceutical industries and contract manufacturer
   b. Contract manufacturing agreement
   c. GMP certificate of contract manufacturer

For manufacturing “under-license”:
   a. License of pharmaceutical industries
   b. GMP certificate of the manufacturer
   c. Copy of “under-license” agreement

For locally manufactured products:
   a. Valid License to Operate (LTO) (Manufacturer/Packer/Repacker/Trader/Distributor/ Wholesaler)
   b. Valid GMP certificate

c. Valid agreement between the manufacturer, trader, distributor (where applicable)

For imported products:

a. Valid License to Operate (LTO) (Packer/Repacker/Trader/Importer/Distributor/ Wholesaler)
b. Valid Foreign GMP Clearance
c. Valid Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format
d. Valid agreement between the manufacturer, trader, importer, distributor (where applicable)

For Dangerous Drugs (as per RA 9165 and Dangerous Drugs Board):

- License to Handle Dangerous Drugs

4. Site Master File
5. Labeling
6. Representative Sample with corresponding Certificate of Analysis (upon request of the evaluator)
7. Product Information
   a. Package Insert
   b. Summary of Product Characteristics (Product Data Sheet)

Part II: Quality

Sec. A: Table of Contents
Sec. B: Quality Overall Summary
Sec. C: Body of Data

Drug Substance (S)

S 1 General Information
- S 1.1. Nomenclature
- S 1.2. Structural Formula
- S 1.3. General Properties

S 2 Manufacture
- S 2.1. Manufacturer(s)

S 3 Characterization
- S 3.1. Elucidation of Structure and Characteristics
- S 3.2. Impurities

S 4 Control of Drug Substance
- S 4.1. Specifications
- S 4.2. Analytical Procedures
- S 4.3. Validation of Analytical Procedures

S 5 Reference Standards or Materials
S 7 Stability

Drug Product (P)

P 1 Description and Composition
P 2 Pharmaceutical Development
- P 2.2. Components of the Drug Product
  - P 2.2.1. Active Ingredients
  - P 2.2.2. Excipients

P 2.3. Finished Product
P 2.3.1. Formulation Development
P 2.3.2. Overages
P 2.3.3. Physicochemical and Biological Properties
P 2.5. Container Closure System
P 2.6. Microbiological Attributes
P 2.7. Compatibility
P 3 Manufacture
P 3.1. Batch Formula
P 3.2. Manufacturing Process and Process Control
P 3.3. Controls of Critical Steps and Intermediates
P 3.4. Process Validation and/or Evaluation
P 4 Control of Excipients
P 4.1. Specifications
P 4.2. Analytical Procedures
P 4.3. Excipients of Human and Animal Origin
P 5 Control of Finished Product
P 5.1. Specifications
P 5.2. Analytical Procedures
P 5.3. Validation of Analytical Procedures
P 5.4. Batch Analyses
P 5.5. Characterization of Impurities
P 5.6. Justification of Specifications
P 6 Reference Standards or Materials
P 7 Container Closure System
P 8 Product Stability
P 9 Product Interchangeability/Equivalence Evidence (if applicable)

Note:

- For *Part II: Quality - Drug Substance (S)*, the following may be submitted:
  Option 1: Full submission (S1-S7)
  Option 2: Certificate of Suitability (CEP) –with sections/sub-sections: S1, S2.1, S4.4 and S7 (if retest period is not stated) only. Copy of the latest version of the CEP shall be provided.
  Option 3: Active Pharmaceutical Ingredient Master File (APIMF)
- ICH Common Technical Document format is acceptable provided that the products are approved in ICH member countries / regions.

END