CENTER FOR DRUG REGULATION AND RESEARCH
LIST OF REQUIREMENTS FOR REGISTRATION OF GENERIC PRESCRIPTION DRUG PRODUCTS

A. Initial Application

Part I: Administrative Data and Product Information
Sec. A Introduction
Sec. B Table of Contents
1. Integrated Application Form
2. Letter of Authorization (where applicable)
3. Certifications
4. Labeling
5. Product Information

Sec. C Guidance on the Administrative Data and Product Information
1. Application Form
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
   a. License of pharmaceutical industries
   b. GMP certificate (country specific)
   For imported products
   a. License of pharmaceutical industries/importer/wholesaler (country specific)
   b. Certificate of Pharmaceutical Product issued by the competent authority in the country of origin according to the current WHO format
4. Labeling
5. Product Information
   5.1. Package Insert

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 5.5. 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

Additional Requirements:

1) Representative Sample with corresponding Certificate of Analysis
2) For imported products:

(a) Foreign GMP Clearance

3) For single component Vitamin A products and drug products containing non-vitamin/non-mineral APIs combined with vitamins nad/or minerals (e.g. Isoniazid + Vitamin B6):
   (a) Proof of interchangeability
4) MR/E to Initial:
   (a) Risk Management Plan (RMP)
   (b) Periodic Safety Update Report (PSUR)

B. Regular Renewal Application

1) Integrated Application Form
2) Unit Dose and Batch Formulation
3) Technical Specifications of Finished Product
4) Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample)
5) Assay and Other Test Procedures including Assay with Data Analysis
6) Stability Studies
7) Labeling Materials (actual/commercial label)
8) Actual commercial sample

Additional Requirements:

1) Post-marketing commitments (if any)

C. Automatic Renewal Application

1) Integrated Application Form
2) Copy of Certifications issued as a result of post-approval change(s)
3) Labeling materials (actual/commercial labels)
4) Actual commercial sample

Additional Requirements:

1) Post-marketing commitments (if any)

Notes:

- All documentary requirements must be in PDF format to be submitted to PAIR
- Image files should be at least 150 dots per inch (dpi)
- A hard copy of the integrated application form is required
- Samples may be submitted at a later date, e.g. when the application has already been decked as indicated in the Document Tracking System
- ICH Common Technical Document format is acceptable provided that the products are approved in ICH member countries/ regions