A. **Initial Application**

**Part I: Administrative Data and Product Information**

**Sec. A** Introduction

**Sec. B** Overall Table of Contents

**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
   5.2. 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 2.2. Description of Manufacturing Process and Process Controls
S 2.3. Control of Materials
S 2.4. Control of Critical Steps and Intermediates
S 2.5. Process Validation and/or Evaluation
S 2.6. Manufacturing Process Development

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 4.4. Batch Analyses
S 4.5. Justification of Specifications

S 5 Reference Standards or Materials
S 6 Container Closure System
S 7 Stability

Drug Product (P)
P 1 Description and Composition

P 2 Pharmaceutical Development
P 2.1. Information on Development Studies
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 2.4. Manufacturing Process Development
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 4.4. Novel Excipients

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
Part III: Nonclinical Document
Sec. A Table of Contents
Sec. B Nonclinical Overview
  1. General Consideration
  2. Special Consideration
     2.1. In Vitro Studies
     2.2. In Vivo Studies

Part IV: Clinical Document
Sec. A Table of Contents
Sec. B Clinical Overview
  1. Pharmacokinetic Studies
  2. Pharmacodynamic Studies
  3. Confirmatory Pharmacokinetic/Pharmacodynamic Studies
  4. Efficacy Studies
  5. Safety Studies
  6. Immunogenicity
  7. Extrapolation of Efficacy and Safety Data

Additional Requirements:
  1) Representative Sample with corresponding Certificate of Analysis
  2) Risk Management Plan
  3) For imported products:
     (a) Foreign GMP Clearance

B. Renewal Application
  1) Integrated Application Form
  2) Periodic Safety Update Report (PSUR) and Risk Management Plan (RMP)
  3) Certification that there were no changes during the 5-year period. If there were any, the summary changes made by the manufacturer for the 5-year period shall be incorporated
  4) Labeling Materials (actual/commercial)
  5) Actual commercial sample
Additional Requirements:
1) Post-marketing commitments (if any)
2) For products qualifying for Generic Labeling Exemption (GLE):
   (a) Request for GLE

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