CENTER FOR DRUG REGULATION AND RESEARCH
LIST OF REQUIREMENTS FOR REGISTRATION OF NEW DRUG PRODUCTS UNDER MONITORED RELEASE

Part I: Administrative Data and Product Information
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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
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5.2. Summary of Product Characteristics (Product Data Sheet)

Part II: Quality
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- S 1.2. Structural Formula
- S 1.3. General Properties

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- 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)

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- P 2.2. Components of the Drug Product
  - P 2.2.1. Active Ingredients
  - P 2.2.2. Excipients
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  - 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
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- P 5.2. Analytical Procedures

P 5.3. Validation of Analytical Procedures
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   1.1. Bioavailability (BA) Study Reports
   1.2. Comparative BA or Bioequivalence (BE) Study Reports
   1.3. *In vitro-In vivo* Correlation Study Reports
   1.4. Reports of Bioanalytical and Analytical Methods for Human Studies
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   2.1. Plasma Protein Binding Study Reports
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   5.4. Other Clinical Study Reports
6. Reports of Post-Marketing Experience
7. Case Report Forms and Individual Patient Listing

Sec. F List of Key Literature References

Additional Requirements:

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

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