CENTER FOR DRUG REGULATION AND RESEARCH
LIST OF REQUIREMENTS FOR REGISTRATION OF MEDICAL GAS (OXYGEN)

A. Initial Application

1) Integrated Application Form
2) Valid agreements between the manufacturer, trader, importer, distributor, where applicable
3) Technical Specifications of Finished Product
4) Certificate of Analysis (CA) of Finished Product
5) Manufacturing Procedure, Production Equipment, Sampling, In-process controls
6) Philippine Standard Quality Certification Mark issued by the Bureau of Product Standards, Department of Trade and Industry
7) Labeling Materials (facsimile)

B. Regular Renewal Application

1) Integrated Application Form
2) Valid agreements between the manufacturer, trader, importer, distributor, where applicable
3) CA of Finished Product (from the same batch of representative sample)
4) Manufacturing Procedure, Production Equipment, Sampling, In-process controls
5) Labeling materials (actual/commercial labels, triplicate)

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, triplicate)

Additional Requirements:

1) Post-marketing commitments (if any)

Notes:

- All documentary requirements must be in PDF format to be submitted to PAIR
- Existing image file format shall be followed
- A hard copy of the integrated application form is required
- Samples may be submitted when the application has already been decked, as indicated in the Document Tracking System