



CENTER FOR DRUG REGULATION AND RESEARCH

INITIAL REGISTRATION OF MEDICAL GRADE OXYGEN

- Who May Avail** : All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Medical Grade Oxygen
- 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

1. Duly accomplished and notarized Integrated Application Form
2. Proof of payment (based on AO No. 50 s. 2001)
3. Valid agreements between the manufacturer, trader, importer, distributor, where applicable
4. Technical Specifications of Finished Product
5. Certificate of Analysis (CA) of Finished Product
6. Certificate of Analysis issued by CIGI for the product
7. Manufacturing Procedure, Production, Equipment, Sampling, In-process controls
8. Complete quality control procedures for the finished product.
9. Philippine Standard Quality Certification Mark issued by the Bureau of Product Standards, Department of Trade and Industry
10. Labeling Materials (facsimile)
11. For imported products: Foreign GMP Clearance
12. Valid LTO (Importer/Manufacturer/Distributor/Trader)

END

