LABELLING STANDARD

ETHYLENE OXIDE GASEOUS STERILANTS

I) **Description:**

This labelling standard applies to ethylene oxide products labelled for use as gaseous sterilants for medical instruments/devices.

This labelling standard does not apply to any other liquid and gaseous drug products to be used as sterilants for medical instruments/devices.

II) **Pharmaceutical Quality:**

a) All ingredients (medicinal and nonmedicinal) and finished product, should, as a minimum, meet the specifications described in the publications referred to in Schedule B to the *Food and Drugs Act* or equivalent standards. In the absence of a Schedule B standard, testing must be adequate to demonstrate the product's identity, potency, purity and quality.

b) **Special Notes:**

i) Validation of sterilization and sterility assurance should be conducted according to the specifications in *The United States Pharmacopoeia, USP 23, NF 18*, Chapter <1211>.

ii) The validation process should involve biological indicators prepared as detailed in *The United States Pharmacopoeia*, *USP 23, NF 18,* pages 202-204 and Chapter <1035>.

III) **Ingredients:**

a) **Single medicinal ingredient:**

Ethylene oxide 10-100%

b) **Nonmedicinal Ingredients:**

Nonmedicinal ingredients must be restricted to those substances, necessary for the formulation. Their concentration must not exceed the minimum required to provide their intended effect. Their presence must not adversely affect the efficacy or safety of the ethylene oxide and they must not interfere with assays and tests for the medicinal ingredients.

IV) **Labelling:**

a) This labelling standard describes those requirements that are specific for this type of product. Other requirements described in the *Regulations to the Food and Drugs Act* and in the *Drugs Directorate Guideline for Disinfectant Drugs* must also be met.

b) **Unacceptable claims:**

Statements such as non-toxic, safe, non-caustic, harmless, etc. are not considered appropriate for this type of product.

c) **Indications**:

For all products the labelling must indicate:

i) For use as a sterilant for medical instruments/devices in a health care facility (e.g, hospitals, dental clinic, etc.) in a sterilizer (model and type must be indicated).

d) **Directions for Use**

i) For all products complete directions for use as a gaseous sterilant including:

- types of instruments (e.g, implants, surgical instruments,laparoscopes, burs, needles, etc.);
- adequate wrapping procedures;
- adequate load procedures;
- specific precleaning procedures;
- specific instructions for the safe and effective use of the product including specific cycle times, temperature, humidity, pressure of the ethylene oxide in the exposure chamber, adequate ventilation/aeration procedures, etc.
- adequate in process validation procedure (i.e., use of biological indicators) as indicated in Section II) b) ii).

ii) A reference to an operator manual is considered acceptable provided that all the information listed in Section IV) d) i) is adequately addressed in the manual.

iii) **Warnings**

For all products, the label must indicate:

- the warning statement DANGER associated with the appropriate symbol;
- the hazard symbol, signal word and hazard statements for pressurized containers as prescribed in Sections A.01.060.1 to A.01.062 of the *Food and Drugs Regulations*;
- ETHYLENE OXIDE VAPOUR IS HARMFUL
- Avoid breathing vapours
- Keep container closed
- May cause burns
- Avoid contact with skin or eyes;
- This product is limited to use by medical professionals or appropriately trained personnel for ethylene oxide sterilization in medical use areas.

iv) **First aid and toxicological information**

- In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes;
- For eyes, call a physician;
- Remove and wash contaminated clothing before reuse;
- If ethylene oxide was swallowed, drink egg whites, gelatin solution or, if these are not available, drink large quantities of water. Call a physician.

V) **References:**

a) **Drugs Directorate Guideline, Disinfectant Drugs**, June 1994.
b) **The United States Pharmacopoeia, USP 23, NF 18**, 1995.