
Guidance Notes on Registration of Medical Gases

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Pharmacy and Poisons Board of Hong Kong

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1. Introduction

1.1 According to the Pharmacy and Poisons Regulations, all pharmaceutical products must satisfy the criteria of safety, quality, and efficacy before they can be registered with the Pharmacy and Poisons Board and be sold in Hong Kong.

1.2 The aim of this document is to provide guidance on making application for registration of pharmaceutical products containing medical gases. When applying for registration of medical gases, applicants should read this Guidance Notes in conjunction with the <Guidance Notes on Registration of Pharmaceutical Products/Substances>, where applicable.

2. Scope

2.1. The scope of this document is confined to any gases or mixtures of gases in cylinders that fulfil definition of pharmaceutical products. This may cover medical gases including oxygen, nitrogen, nitrous oxide, nitric oxide, carbon dioxide, helium, medical air and mixture of some of the above gases. The medical gas product covers the gas/gas mixtures and its primary packing including the container and the valve.

2.2. This Guidance Notes is generally not applicable to the following:

- (i) Gases that do not achieve their mode of action by pharmacological, immunological or metabolic action in human beings or animals;
- (ii) Gases that are produced *in situ* in healthcare facilities, i.e. manufactured, mixed and handled in hospitals or day procedure centres for their patients' own use;
- (iii) Bulk liquefied gases in tankers/vessels (e.g. Vacuum Insulated Evaporator) (Note: manufacturing and supply of bulk medical gases are subjected to the requirements of Pharmaceutical Inspection Co-operation Scheme (PIC/S) Good Manufacturing Practice.);
- (iv) The equipment attached later to the gas container at the time of use (e.g. pressure regulator and pipe network);
- (v) Gases specified for non-medicinal use such as in laboratories (e.g. for calibration), oxygen mixtures for smoke-helmeted firemen, and oxygen mixtures for divers during normal diving and ascent etc.; and

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- (vi) Oxygen that is produced via generator / concentrator to be used at patient's bedside.

3. General requirements

3.1 Generic product application

3.1.1 For generic product applications, the reference product must have been registered in Hong Kong for over 8 years.

3.1.2 For certain medical gases or gas mixtures, reference to a registered reference product can be exempted from the 3.1.1 requirement if:

- (i) the gas or components of the gas mixtures is/are specified in particular monograph in designated pharmacopoeia (Pharmacopoeia of the People's Republic of China, British Pharmacopoeia, European Pharmacopoeia, International Pharmacopoeia, Japanese Pharmacopoeia and/or United States Pharmacopoeia) unless otherwise justified; and
- (ii) the approved package insert (with evidence of approval) from the drug regulatory authority of one of the countries set out in paragraph 6.2.16 of the <Guidance Notes on Registration of Pharmaceutical Products/Substances> is provided to support the proposed indication.

3.2 For new medical gas which no previously registered reference products could be identified in Hong Kong, and exemption under paragraph 3.1.2 is not applicable, applicants should also refer to the <Guidance Notes on Registration of Pharmaceutical Products Containing a New Chemical or Biological Entity> for more requirements.

4. Specific requirements

4.1 The specification of the finished product should be demonstrated to comply with one or more of the following pharmacopoeias unless otherwise justified: Pharmacopoeia of the People's Republic of China, British Pharmacopoeia, European Pharmacopoeia, International Pharmacopoeia, Japanese Pharmacopoeia and/or United States Pharmacopoeia.

4.2 Stability of the finished product

4.2.1 Specific storage conditions for the medical gas product are proposed by the applicant. Stability data should be provided in determining appropriate storage conditions and any expiration date specified on the label;

4.2.2 For those very stable gases, bibliographic data can be provided to establish the shelf-life if they have long history of use and have been packed and used in the concerned containers for a long time.

4.3 Container closure system

4.3.1 Specification of the primary container should be provided;

4.3.2 In case of reusable container, procedures for maintenance and testing, for emptying, cleaning and filling of the primary container should be described.

4.4 Labelling requirements

4.4.1 General Labelling Requirements in respect of pharmaceutical products for the purpose of registration are stipulated in the < Guidelines on the Labelling of Pharmaceutical Products>;

4.4.2 Additional labelling requirements are required for medical gases:

(i) Safety aspects of medical gases as stipulated under other applicable legislations or guidelines;

(ii) Traceability measures for medical gases contained in cylinders; and

(iii) Designation label stating “For medical use only 只供醫療用途”.

4.5 For additional specific requirements on medical gases registration, applicants may take reference to relevant guidelines promulgated by regulatory authority of the countries list out in paragraph 6.2.16 of the <Guidance Notes on Registration of Pharmaceutical Products/Substances>.

5. Others

5.1 Medical gas or mixture of gases are also regulated under other legislations in Hong Kong. The registration of medical gases under the Pharmacy and Poisons Ordinance will not exempt the product for complying with other statutory regulations and relevant guidelines. Applicants should observe and

follow all the relevant statutory requirements stipulated under the related ordinances, which include but not limited to:

- 5.1.1 Boilers and Pressure Vessels Ordinance (Cap. 56);
- 5.1.2 Factories and Industrial Undertakings Ordinance (Cap. 59);
- 5.1.3 Fire Services Ordinance (Cap. 95);
- 5.1.4 Dangerous Goods Ordinance (Cap. 295);
- 5.1.5 Electricity Ordinance (Cap. 406); and
- 5.1.6 Occupational Safety and Health Ordinance (Cap. 509).

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