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Ministry of Health Malaysia

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GUIDANCE DOCUMENT

GMP INSPECTION ON MEDICINAL GASES MANUFACTURERS IN MALAYSIA

2nd Edition

August 2026

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1.0 INTRODUCTION

1.1 OBJECTIVE

This guidance document describes the procedures and documentation requirements for submitting an application for Good Manufacturing Practice (GMP) inspection of medicinal/medical gases products in Malaysia.

The intention of publishing this guideline is to facilitate the manufacturers through understanding the procedures and requirements which will ensure an efficient regulatory GMP inspection process.

1.2 BACKGROUND

Any gas or mixture of gases intended for the administration to patients for medicinal purposes (e.g. anaesthetic, therapeutic, diagnostic or prophylactic) are referred to as medicinal gases.

According to the Sales of Drugs Act (SODA) 1952, a 'drug' includes any substance, product or article intended to be used or capable, or purported or claimed to be capable, of being used on humans or any animal, whether internally or externally, for a medicinal purpose. Under the Control of Drugs and Cosmetics Regulations (CDCR) 1984, Regulation 7(1), no person shall manufacture, sell, supply, import or possess or administer any product unless –

a. the product is a registered product; and
b. the person holds the appropriate licence required and issued under these Regulations.

Inspection of manufacturing premises or facilities of medicinal gases on the basis of compliance with Good Manufacturing Practice (GMP) as well as Good Distribution Practice (GDP) are vital elements of drug control. Compliance to GMP is a prerequisite for the application of the Manufacturer's Licence as well as product registration.

With reference to the *Direktif Bilangan 8 Tahun 2021 – Direktif Berkenaan Pengukuhan Pelaksanaan Kawalan Regulatori ke atas Produk-produk Gas Perubatan dan Penggunaan Guideline on Registration of Medicinal Gases*, starting 1st June 2021, GMP inspection on medicinal gases manufacturers (gas in cylinders) is implemented as part of the regulatory control requirements.

1.3 SCOPE

The scope of this guidance note is only for medicinal gases classified as a medicinal product/ drug and in cylinders intended for inhalation, which is manufactured in a filling plant from bulk liquid gas in Malaysia.

1.4 ABBREVIATION

GMP	: Good Manufacturing Practice
GDP	: Good Distribution Practice
CAPA	: Corrective and Preventive Action
CCQC	: Centre of Compliance and Quality Control
CPCE	: Centre of Product and Cosmetic Evaluation
CDCR	: Control of Drugs and Cosmetics Regulations
NPRA	: National Pharmaceutical Regulatory Agency
PIC/S	: Pharmaceutical Inspection Co-operation Scheme
PQS	: Pharmaceutical Quality System

2.0 REGULATORY PROCESS DESCRIPTION

The overall regulatory process involved is as per diagram below:

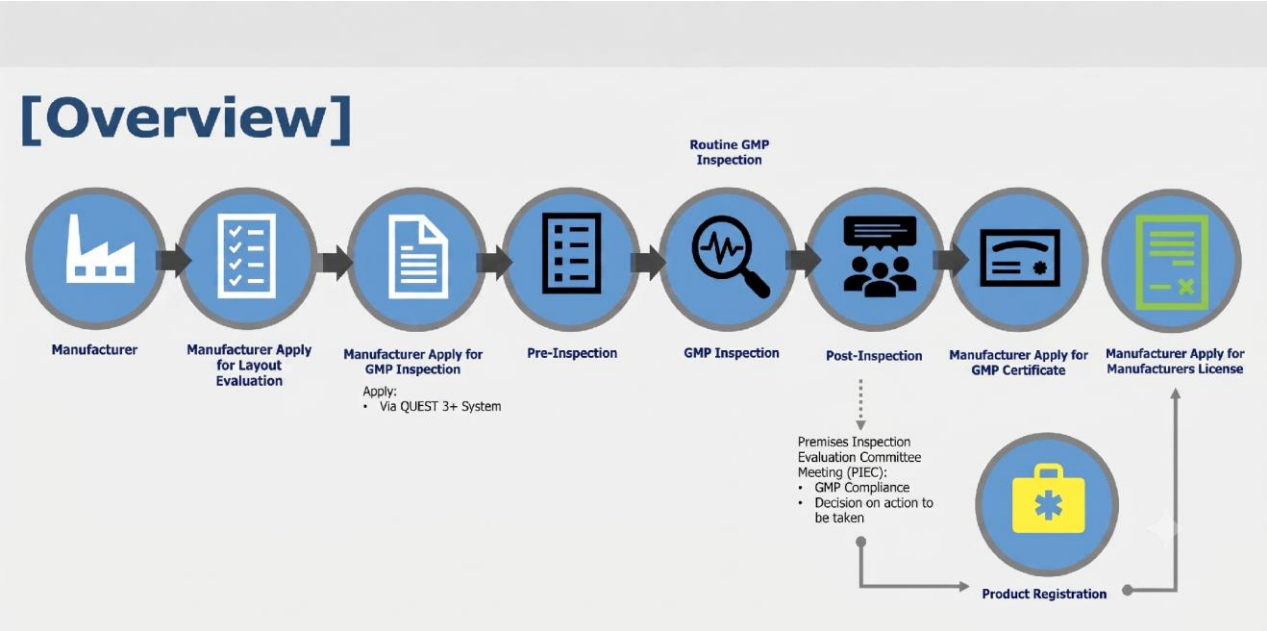


Diagram 1: Regulatory Process Overview. (Updated: 01/08/2026)

In general,

a) Prior to applying for a pre-licensing (for new manufacturing facility) or pre-approval (involving major changes to an existing manufacturing facility) inspection, manufacturers should ensure that the manufacturing facility layout complies with GMP principles. The proposed layout, together with

the **Application for the Evaluation of Manufacturing Plant Layout (N3-FR-12)** and supporting documents, may be submitted to the GMP Section, Centre of Compliance and Quality Control (CCQC) for evaluation. Upon satisfactory assessment, an approval letter will be issued.

b) The manufacturer is required to apply online through the QUEST system for GMP Inspection with upfront payment of RM 1,000. Applicants will receive an additional invoice of the total inspection fee based on the number of inspection day(s) and Inspector(s) involved. The inspection is charged at RM 1,000/day/Inspector (maximum RM 10,000) based on *Surat Kajian Semula Caj Bayaran Pemeriksaan GMP Bagi Premis Pengilang Tempatan dan Luar Negara (KK/BP09/441/239 Jld 3 [50])* dated 13 March 2007*.*

c) The GMP inspection application will be received by the GMP Section, CCQC, NPRA.

d) Once payment of inspection fee is confirmed, Inspector(s) will proceed with the necessary pre-inspection preparation.

e) Inspection will be conducted by the appointed GMP Inspector(s). The output of inspection will be issued out to the manufacturer in the format of GMP Inspection Report.

f) The inspection observation will be tabled in Premises Inspection & Clinical Trial Evaluation Committee Meeting.

g) The Generic Medicines Section/ New Drug Product Section, CPCE will refer to the manufacturer's recent GMP status for medicinal gases product registration.

h) The manufacturer is required to apply for Manufacturer's Licence once the manufacturer has medicinal gas products registered.

i) The manufacturer may apply for a GMP Certificate upon satisfactory GMP compliance status through the QUEST System for export purpose only.

j) The inspected manufacturer is then subjected to routine GMP inspection by NPRA to ensure the compliance towards GMP requirements are met and maintained.

3.0 APPLICATION OF QUEST USB TOKEN

The manufacturer is required to apply for USB token and QUEST membership. NPRA has provided the guidance on how to apply for USB token in the NPRA website (https://www.npra.gov.my/index.php/en/regulation-basic.html)

The Manufacturer may refer to the guidance provided including the USER MANUAL for QUEST Module via website (https://www.npra.gov.my/index.php/en/quest3-system-basic/user-manual-for-quest-module.html).

4.0 APPLICATION OF GMP INSPECTION

The manufacturer may refer to the USER MANUAL QUEST 3+ System Module: Compliance and Licensing via website (https://www.npra.gov.my/images/q3plus/manual/User_Manual_Module_GMP_GDP_Inspection_Licensing.pdf) for the step wise approach on the application.

5.0 TYPES OF GMP INSPECTION

The types of GMP inspection performed by GMP Section are as follows:

a) Pre-Licensing Inspection : An inspection conducted on new manufacturing facility as a pre-requisite to register products and for applying Manufacturer's Licence.

b) Pre-Approval Inspection : An inspection conducted on additional manufacturing line in an existing inspected/ licensed manufacturing facility.

c) Routine Inspection : A subsequent inspection conducted on existing inspected manufacturing facility according to a planned schedule by NPRA.

d) Verification Inspection : An inspection conducted following punitive action or due to an unacceptable GMP compliance status identified during a previous routine or investigational inspection.

e) Investigation Inspection : Investigation Inspection is an inspection conducted on premises based on complaint received and product recall activity.

6.0 REGULATIONS AND GUIDELINES FOR GMP INSPECTION

These are the related regulations and guidelines for reference:

REGULATIONS

a) Sales of Drugs Act 1952 (SODA 1952)
b) Control of Drugs and Cosmetics Regulations 1984 (CDCR 1984)
c) Directive and Guidelines issued under Regulations 29, CDCR 1984
d) *Arahan Pengarah Kanan Perkhidmatan Farmasi Bilangan 8 Tahun 2021: Direktif Berkenaan Pengukuhan Pelaksanaan Kawalan Regulatori ke atas Produk-produk Gas Perubatan dan Penggunaan* Guideline on Registration of Medicinal Gases, *11 Februari 2021*

GUIDELINES

a) PIC/S Guide to Good Manufacturing Practice for Medicinal Products and its related Annexes. The relevant PIC/S Annexes include Annex 6 Manufacture of Medicinal Gases etc.
b) PIC/S Aide-Memoire Inspection of Medicinal Gases
c) Drug Registration Guidance Document
d) Malaysia Good Distribution Practice Guideline
e) Guideline on Registration of Medicinal Gases

Note:

The list is non-exhaustive. Applicants are required to refer to the latest regulations and guidelines.

7.0 GMP INSPECTION PROCESS

The GMP inspection process includes the pre-inspection preparation, then performing the inspection and the post-inspection process. Generally, GMP inspection will be performed 'on-site'.

The pre-inspection, on-site inspection, and post-inspection activities performed include:

Pre-Inspection Preparation	Inspection Performed On-Site	Post Inspection Procedure
1. The application for a pre-licensing inspection is received and GMP Inspector(s) are appointed. 2. The inspection team reviews the manufacturer's profile, products, facilities, and inspection scope, including the relevant personnel and areas to be inspected. 3. The inspection schedule, agenda, and logistics are arranged with the manufacturer. 4. The manufacturer is notified of the inspection date and inspection plan via email or telephone.	1. The inspection commences with an opening meeting attended by the manufacturer's management and key personnel. 2. The Lead Inspector will introduce the inspection team and share the inspection agenda/plan. Further arrangements for the 2 days inspection will be make known to the attendees. 3. During the **opening meeting**, the manufacturer shall present its quality system, key personnel and facility overview. 4. A site tour (if required) and detailed inspection of the manufacturing facility, quality control, warehouses, utilities, and other supporting systems are conducted to verify compliance with GMP requirements. 5. Relevant documents, records, and Standard Operating Procedures (SOPs) are reviewed, and observations are	1. The output of the inspection will be tabled at the NPRA Committee Meeting. 2. The GMP Inspector(s) will prepare the inspection report, which will be posted to the manufacturer. 3. Once the inspection report is received, the manufacturer shall submit a Corrective and Preventive Action (CAPA) report for review by the GMP Inspector(s). 4. A satisfactory GMP compliance status enables the manufacturer to proceed with product registration, followed by application for a Manufacturer's Licence. The manufacturer may also apply for a GMP Certificate for export purposes. 5. An unsatisfactory GMP compliance status may result in withholding of product registration and the issuance or renewal of the Manufacturer's Licence. Manufacturing activities shall not commence or continue until satisfactory CAPA

Pre-Inspection Preparation	Inspection Performed On-Site	Post Inspection Procedure
	discussed with the responsible personnel. 6. All inspection findings are presented during the **exit/closing meeting**.	implementation has been verified through a verification inspection, applied by the manufacturer. 6. The inspection data will be recorded to generate the next date for routine inspection.

7.1 INSPECTION PLAN/AGENDA

The GMP inspection plan/agenda will be prepared by the GMP Inspector(s) and given to the manufacturer prior to the inspection or will be shared during the opening meeting. The inspection plan/agenda consists of:

a) Inspection Team members and roles
b) The time, date and place for the opening meeting
c) The time and duration for inspection
d) The organizational units to be inspected
e) A tentative time and date for the exit meeting

7.2 ELEMENTS INSPECTED DURING GMP INSPECTION

The GMP Inspector(s) will refer to the PIC/S Guide to Good Manufacturing Practice for Medicinal Products Part 1 and its related Annexes for the GMP requirement. The Annexes may include Annex 6 Manufacture of Medicinal Gases as well as other as deemed relevant such as Annex 11 Computerized Systems and Annex 20 Quality Risk Management.

The PIC/S GMP Guidelines can be downloaded from the PIC/S Website, **https://picscheme.org/en/publications.**

There are 9 chapters as stated in the PIC/S Guide to Good Manufacturing Practice for Medicinal Products Part 1. These 9 chapters will be the elements inspected during the inspection. The chapters are:

Chapter 1 - Pharmaceutical Quality System
Chapter 2 - Personnel
Chapter 3 - Premises and Equipment
Chapter 4 - Documentation
Chapter 5 - Production
Chapter 6 - Quality Control
Chapter 7 - Outsource Activities
Chapter 8 - Complaint and Product Recall
Chapter 9 - Self Inspection

Due to the differences in manufacturing process, Annex 6 which specifies the specific requirement of manufacturing process of medicinal gases applies simultaneously.

CHAPTER 1 – PHARMACEUTICAL QUALITY SYSTEM

The holder of a Manufacturing Authorisation must ensure medicinal products manufactured are fit for their intended use, comply with the requirements of the Marketing Authorisation, as appropriate, and do not place patients at risk due to inadequate safety, quality or efficacy.

The attainment of this quality objective is the responsibility of senior management and requires the participation and commitment by staff in many different departments and at all levels within the company, by the company's suppliers and by its distributors.

To achieve this quality objective reliably there must be a comprehensively designed and correctly implemented Pharmaceutical Quality System incorporating Good Manufacturing Practice and Quality Risk Management. It should be fully documented and its effectiveness monitored.

All parts of the Pharmaceutical Quality System should be adequately resourced with the competent personnel, and suitable and sufficient premises, equipment and facilities.

CHAPTER 2 – PERSONNEL

The correct manufacture of medicinal products relies upon people. For this reason there must be sufficient qualified personnel to carry out all the tasks which are the responsibility of the manufacturer. Individual responsibilities should be clearly understood by the individuals and recorded. All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training, including hygiene instructions, relevant to their needs.

CHAPTER 3 – PREMISES AND EQUIPMENT

Premises and equipment must be located, designed, constructed, adapted and maintained to suit the operations to be carried out. Their layout and design must aim to minimise the risk of errors and permit effective cleaning and maintenance in order to avoid cross-contamination, build-up of dust or dirt and, in general, any adverse effect on the quality of products.

CHAPTER 4 – DOCUMENTATION

Good documentation constitutes an essential part of the quality assurance system and is key to operating in compliance with GMP requirements. The various types of documents and media used should be fully defined in the manufacturer's Quality Management System. Documentation may exist in a variety of forms, including paper-based, electronic or photographic media. The main objective of the system of documentation utilised must be to establish, control, monitor and record all activities which directly or indirectly impact on all aspects of the quality of medicinal products. The Quality Management System should include sufficient instructional detail to facilitate a common understanding of the requirements, in addition to providing for sufficient recording of the various processes and evaluation of any observations, so that ongoing application of the requirements may be demonstrated.

There are two primary types of documentation used to manage and record GMP compliance: instructions (directions, requirements) and records/reports. Appropriate good documentation practice should be applied with respect to the type of document.

Suitable controls should be implemented to ensure the accuracy, integrity, availability and legibility of documents. Instruction documents should be free from errors and available in writing. The term 'written' means recorded or documented on media from which data may be rendered in a human readable form.

CHAPTER 5 – PRODUCTION

Production operations must follow clearly defined procedures; they must comply with the principles of Good Manufacturing Practice in order to obtain products of the requisite quality and be in accordance with the relevant manufacturing and marketing authorisations.

CHAPTER 6 – QUALITY CONTROL

Quality Control is concerned with sampling, specifications and testing as well as the organisation, documentation and release procedures which ensure that the necessary and relevant tests are carried out, and that materials are not released for use, nor products released for sale or supply, until their quality has been judged satisfactory. Quality Control is not confined to laboratory operations, but must be involved in all decisions which may concern the quality of the product. The independence of Quality Control from Production is considered fundamental to the satisfactory operation of Quality Control.

CHAPTER 7 – OUTSOURCED ACTIVITIES

Any activity covered by the GMP Guide that is outsourced should be appropriately defined, agreed and controlled in order to avoid misunderstandings which could result in a product or operation of unsatisfactory quality. There must be a written contract between the Contract Giver and the Contract Acceptor which clearly establishes the roles and responsibilities of each party.

CHAPTER 8 – COMPLAINTS AND PRODUCT RECALL

In order to protect public health, a system and appropriate procedures should be in place to record, assess, investigate and review complaints including potential quality defects, and if necessary, to effectively and promptly recall medicinal products for human or veterinary use and investigational medicinal products from the distribution network. Quality Risk Management principles should be applied to the investigation and assessment of quality defects and to the decision-making process in relation to product recalls corrective and preventative actions and other risk-reducing actions.

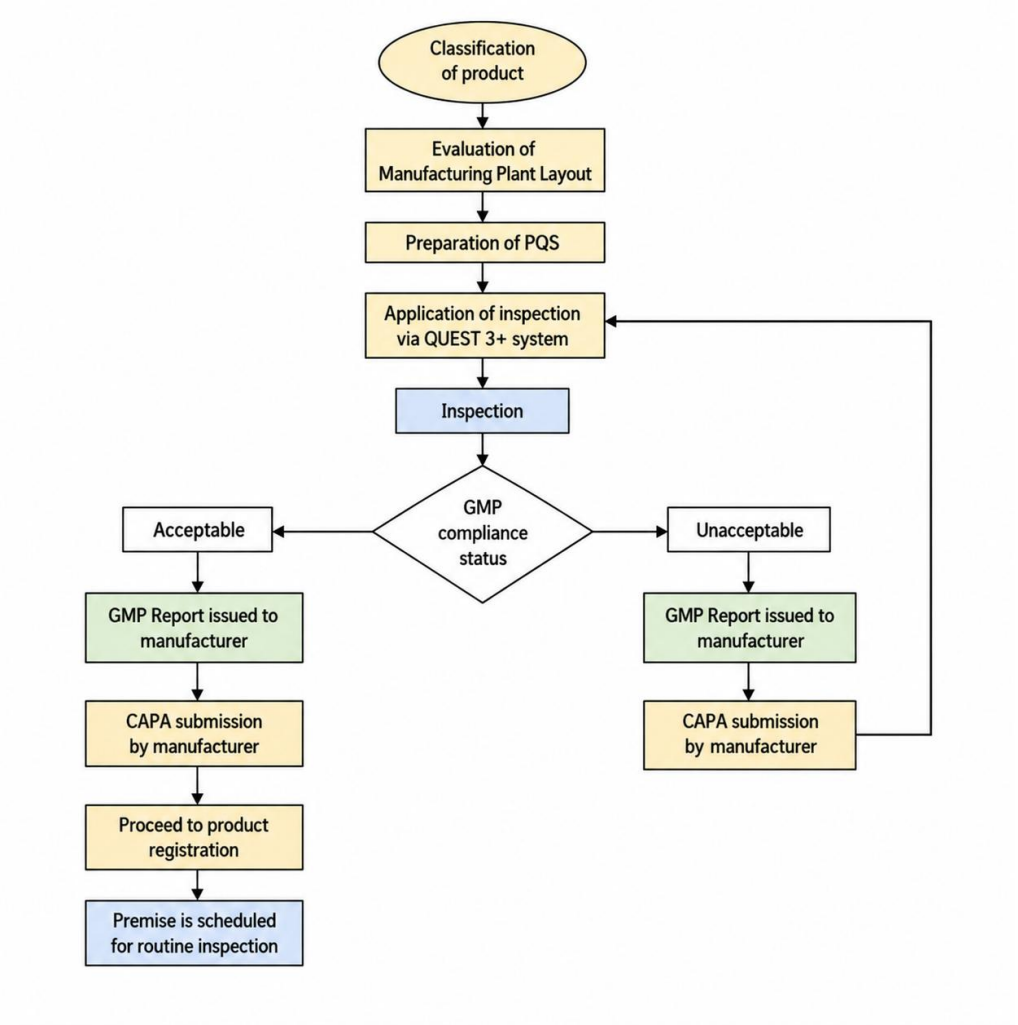
CHAPTER 9 – SELF INSPECTION

Self- inspections should be conducted in order to monitor the implementation and compliance with Good Manufacturing Practice principles and to propose necessary corrective measures.

7.3 INSPECTION REPORTING AND CAPA

The GMP Inspector(s) will prepare the GMP inspection report once the GMP inspection is completed. The report together with a cover letter and a template for CAPA report will be posted to the manufacturer. The manufacturer is required to submit the CAPA report to the Inspection team for CAPA evaluation.

7.4 FLOW CHART – GMP INSPECTION ON MEDICINAL GASES MANUFACTURER



8.0 APPLICATION FOR GMP CERTIFICATE AFTER RECEIVING SATISFACTORY GMP COMPLIANCE STATUS

The manufacturer may refer to the USER MANUAL QUEST System Module: Compliance and Licensing via website (https://www.npra.gov.my/images/q3plus/manual/User_Manual_Module_GMP_GDP_Inspection_Licensing.pdf) for the step wise approach on the GMP certificate application.

9.0 FAQs

1. Does NPRA issue a Manufacturer's Licence after the inspection?

Manufacturer's Licence will be issued to the manufacturer upon inspection with Acceptable GMP compliance status and upon valid registration of medicinal gases product via QUEST system. The Manufacturer's Licence is to be applied separately via the QUEST system and renewed every year.

2. Does the manufacturing facility require an annual inspection?

Routine inspection will be scheduled for manufacturing facility previously undergone pre-licensing inspection with acceptable GMP compliance status.

3. What happens if a manufacturer does not comply with GMP requirements during the pre-licensing inspection?

The manufacturer is required to conduct a complete Corrective Action and Preventive Action (CAPA) report before submitting a new inspection application via QUEST system.

A new pre-licensing inspection will be performed once the manufacturer is ready for the inspection.

4. Who should apply for the GMP Certificate?

GMP Certificate endorses that the local manufacturer complies with the current GMP requirements. The certificate is required by the overseas regulatory agencies for the purpose of product registration in the respective countries. This GMP Certificate shall be applied through QUEST system with processing fee of RM 50/certificate.

5. Who should I contact if I have further questions about medicinal gases?

In relation to specific queries pertaining to medicinal gases, you can contact the following department;

- Setting up of manufacturing facility/ GMP related enquiry: GMP Section, Centre of Compliance and Quality Control, NPRA.
- Registration related enquiry: Generic Medicines Section/ New Drug Product Section, Centre of Product and Cosmetic Evaluation, NPRA.

6. **What should a manufacturer do if they plan to construct a new manufacturing premise or make changes to the existing premise layout?**

   The manufacturer may submit an Application for the Evaluation of Manufacturing Plant Layout to the Good Manufacturing Practice (GMP) Section, Centre of Compliance and Quality Control for evaluation and approval. The form is accessible at www.npra.gov.my.

10.0 DEPARTMENT IN CHARGE

For any queries pertaining to this guidance, applicants may contact:

GMP Section
Centre of Compliance and Quality Control
National Pharmaceutical Regulatory Agency
Ministry of Health Malaysia
Lot 36, Jalan Profesor Diraja Ungku Aziz (Jalan Universiti),
46200 Petaling Jaya, Selangor.
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11.0 ATTACHMENT

11.1 ATTACHMENT 1: *DIREKTIF BILANGAN 8 TAHUN 2021 – DIREKTIF BERKENAAN PENGUKUHAN PELAKSANAAN KAWALAN REGULATORI KE ATAS PRODUK-PRODUK GAS PERUBATAN DAN PENGGUNAAN* GUIDELINE ON REGISTRATION OF MEDICINAL GASES.

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POS BERDAFTAR

Ruj. Kami : NPRA.600-1/9/13 (18)
Tarikh : 11 Februari 2021

SEMUA PEMEGANG PENDAFTARAN PRODUK

SEMUA PERSATUAN BERKENAAN
(SEPERTI DI SENARAI EDARAN)

Tuan / Puan,

PERATURAN-PERATURAN KAWALAN DADAH DAN KOSMETIK 1984
ARAHAN PENGARAH PERKHIDMATAN FARMASI BILANGAN 8 TAHUN 2021: DIREKTIF BERKENAAN PENGUKUHAN PELAKSANAAN KAWALAN REGULATORI KE ATAS PRODUK - PRODUK GAS PERUBATAN DAN PENGGUNAAN *GUIDELINE ON REGISTRATION OF MEDICINAL GASES*

Adalah saya merujuk kepada perkara di atas.

2. Dikemukakan Arahan Pengarah Perkhidmatan Farmasi Bilangan 8 Tahun 2021: Direktif berkenaan pengukuhan pelaksanaan kawalan regulatori ke atas produk - produk gas perubatan dan penggunaan *Guideline on Registration of Medicinal Gases* untuk makluman dan perhatian pihak tuan / puan.

3. Sekiranya tuan / puan ingin mendapatkan maklumat lanjut, sila hubungi Seksyen Ubat Generik, Pusat Penilaian Produk dan Kosmetik (PPPK), NPRA.

4. Tuan / puan adalah diarahkan untuk mengambil maklum dan mematuhi Arahan tersebut di atas serta membuat perancangan yang sewajarnya selaras dengan pengukuhan pelaksanaan kawalan regulatori tersebut.

Sekian, terima kasih.

"PRIHATIN RAKYAT: DARURAT MEMERANGI COVID-19"

"BERKHIDMAT UNTUK NEGARA"

Saya yang menjalankan amanah,

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NPRA.600-1/9/13 (18)

ARAHAN DI BAWAH PERATURAN 29 PERATURAN – PERATURAN KAWALAN DADAH DAN KOSMETIK 1984

BILANGAN 8 TAHUN 2021

DIREKTIF BERKENAAN PENGUKUHAN PELAKSANAAN KAWALAN REGULATORI KE ATAS PRODUK - PRODUK GAS PERUBATAN DAN PENGGUNAAN *GUIDELINE ON REGISTRATION OF MEDICINAL GASES*

TUJUAN

1.1 Di bawah peruntukan Peraturan 8, Peraturan-peraturan Kawalan Dadah dan Kosmetik 1984 (PKDK 1984), Pihak Berkuasa Kawalan Dadah (PBKD) dalam mesyuarat kali ke - **353** pada **5 Februari 2021** telah bersetuju dengan pengukuhan pelaksanaan kawalan regulatori ke atas produk-produk gas perubatan.

1.2 Sehubungan dengan itu, arahan ini dikeluarkan oleh Pengarah Perkhidmatan Farmasi di bawah peruntukan Peraturan 29, PKDK 1984 untuk memaklumkan pemegang pendaftaran berhubung pengukuhan pelaksanaan kawalan regulatori ke atas produk-produk gas perubatan dan penggunaan *Guideline on Registration of Medicinal Gases.*

LATAR BELAKANG

2.1 Gas perubatan adalah gas-gas yang digunakan untuk tujuan perubatan kepada pesakit iaitu untuk kegunaan anestetik, rawatan (*therapeutic*), pencegahan (*prophylactic*) dan diagnostik.

2.2 Berdasarkan *Drug Registration Guidance Document 3rd Edition, January 2021, Table I: Medical Device-Drug-Cosmetic Interphase (MDDCI) and Combination Products Classification Decision*, gas perubatan dikelaskan kepada dua (2) kategori seperti berikut :

2.2.1 Gas perubatan yang dikelaskan sebagai **ubat** dan dikawal oleh PBKD

- Gas atau campuran gas dengan mekanisma tindakan utama berdasarkan kesan farmakologi, immunologi atau metabolik ke atas badan.

2.2.2 Gas perubatan yang dikelaskan sebagai **peranti perubatan** dan dikawal oleh Pihak Berkuasa Peranti Perubatan (PBPP) :

- Gas atau campuran gas dengan mekanisma tindakan utama berdasarkan kesan fizikal.

PELAKSANAAN

3.1 Untuk memastikan produk - produk gas perubatan berkaitan adalah selamat, berkualiti dan berkesan, pengukuhan pelaksanaan kawalan regulatori ke atas produk gas perubatan yang dikelaskan sebagai **ubat** adalah seperti berikut :

3.1.1 Pemeriksaan Amalan Perkilangan Baik (APB), pelesenan dan pendaftaran produk yang melibatkan **gas perubatan dalam silinder (*gas in cylinder*)**.

3.1.2 Skop kawalan gas perubatan adalah merangkumi **enam (6)** jenis gas berikut :

a) *Oxygen, O_2 (not less than 99%v/v oxygen)*
b) *Carbon dioxide, CO_2 (not less than 99%v/v carbon dioxide)*
c) *Nitrous oxide, N_2O (not less than 98%v/v nitrous oxide)*
d) **Nitric oxide, NO (not less than 99%v/v nitric oxide)*
e) *Nitrous oxide/oxygen mixture (50:50%)*
f) *Medical air (oxygen/nitrogen mixture; 19.5 - 23.5%v/v of oxygen (O_2))*

**Nitric oxide, NO (Group B Scheduled Poison)*

3.1.3 Gas-gas berikut adalah di luar skop pelaksanaan ini :

a) *Gases classified as medical devices*
b) *Gases that are manufactured, mixed and handled (including extemporaneous preparation) in hospitals for own patients use*
c) *Gases for animal use (veterinary)*
d) *Gases use for cosmetic/aesthetic purpose*
e) *Gases use in laboratory (e.g., gases for freezing of tissue samples, calibration gases)*
f) *Recreational gases (e.g., oxygen gases for diving, mountain climbing)*
g) *Industrial gases*

3.1.4 Secara umumnya, prosedur dan keperluan pendaftaran produk gas perubatan adalah sama dengan produk farmaseutikal yang lain. Keperluan pendaftaran yang khusus untuk gas perubatan diperincikan dalam ***Guideline on Registration of Medicinal Gases*** (rujuk Lampiran A).

TARIKH KUAT KUASA

4.1 Tarikh kuat kuasa pengukuhan pelaksanaan kawalan regulatori **gas perubatan dalam silinder** adalah seperti berikut :

Pemeriksaan APB: bermula **1 Jun 2021**
Pelesenan dan pendaftaran produk *(voluntary)*: bermula **1 Januari 2022**
Pelesenan dan pendaftaran produk *(mandatory)*: bermula **1 Januari 2023**

"PRIHATIN RAKYAT : DARURAT MEMERANGI COVID-19"

"BERKHIDMAT UNTUK NEGARA"

Saya yang menjalankan amanah,

(DATIN DR. FARIDAH ARYANI BINTI MD YUSOF) RPh. 1197
Pengarah Perkhidmatan Farmasi
Kementerian Kesihatan Malaysia

12.0 REVIEW HISTORY

Edition	Effective Date	Description of Amendment
1st	August 2021	Initial Publication.
2nd	August 2026	- Renamed from Guidance Note: Good Manufacturing Practice (GMP) Inspection on Medicinal Gases Manufacturers to Guidance Document: GMP Inspection on Medicinal Gases Manufacturers in Malaysia. - Added the requirement for Evaluation of Manufacturing Plant Layout prior to application of Pre-Licensing or Pre-Approval GMP inspection (Section 2.0). - Removed the definition of Pre-Certification Inspection (Section 5.0). - Simplified the GMP inspection process table (Section 7.0). - Removed examples for all GMP chapters (Section 7.2). - Removed Attachment 11.2 (Medical Gases Manufacturers GMP Inspection Report Template) and Attachment 11.3 (CAPA Report Template). - Added FAQ No. 6 (Section 9.0).

13.0 END OF DOCUMENT