FREQUENTLY ASKED QUESTIONS (FAQs) ABOUT GMP INSPECTION BY NATIONAL PHARMACEUTICAL REGULATORY AGENCY (NPRA)

Contents

Good Manufacturing Practice (GMP) Section
Centre of Compliance and Quality Control
Mac 2026

Q1: WHAT IS GOOD MANUFACTURING PRACTICE (GMP)?

A: Good Manufacturing Practice (GMP) is a standard that should be followed by manufacturers of registered pharmaceuticals/ veterinary products/ health supplements/ traditional products and/ or notified cosmetics to ensure that the product manufactured is safe, efficacious, and of quality.

Q2: WHAT IS THE DEFINITION OF 'MANUFACTURING'?

A: According to the Control of Drugs and Cosmetics Regulations 1984 (CDCR 1984), the term 'manufacturing' is defined as:

a) The making or assembling of the product.

b) The enclosing or packing of the product in any container in a form suitable for administration or application, the labelling of the container, and.

c) The carrying out of any process during any of the foregoing activities.

Q3: WHY IS THE GMP STATUS OF A MANUFACTURER REQUIRED?

A: GMP compliance is **one of the requirements for product registration and/ or notification of cosmetics**, as well as to apply for a Manufacturer's Licence with the Drug Control Authority (DCA).
Uncontrolled manufacturing operations may be detrimental to consumer health and safety. GMP status attained gives assurance that the product manufactured is safe, efficacious, and of quality and thus gaining the confidence of consumers.

Q4: HOW WILL MANUFACTURERS BE INSPECTED?

A: An inspection of a manufacturer of registered products or notified cosmetics is conducted based on the requirements of the following guidelines:

GMP / GDP Guidelines	Product Type / Category
PIC/S Guide to Good Manufacturing Practice for Medicinal Products. www.picscheme.org	Pharmaceuticals (Poison and Non-Poison) Veterinary Products
Guidelines on GMP for Traditional Medicines & Health Supplements, 1st Edition, 2008. www.npra.gov.my	Traditional Products Health Supplements
Annex 1, Part 11: Guidelines for Cosmetic Good Manufacturing Practice, Guidelines for Control of Cosmetic Products in Malaysia, 2nd Edition, August 2022. www.npra.gov.my	Cosmetics
Guidelines on GMP for Veterinary Premixes, 1st Edition, 2015. www.npra.gov.my	Veterinary Products (Premixes)
Guidelines on Good Distribution Practice (GDP), 3rd Edition, 2018. www.npra.gov.my	** For activities related to the storage and distribution by manufacturers, importers, and wholesalers (where applicable)

There are a few types of GMP inspection:

- Initial Inspection: An inspection conducted on new cosmetics manufacturers that have not notified any cosmetics.
- Pre-licensing: An inspection conducted on the new manufacturer as a prerequisite to register products and for applying for a Manufacturer's Licence.
- Pre-approval: An inspection conducted on the new production line(s) of licensed manufacturers.
- Pre-certification: An inspection conducted on premises that are not regulated by the Drug Control Authority.
- Verification: An inspection conducted following a punitive action. Depending on the conditions, a verification inspection can be combined with a routine inspection.

Please refer to User Manual Quest 3+ System Module: Compliance and Licensing on how to apply for an inspection via the Quest 3+ system at https://www.npra.gov.my/index.php/en/quest3-system-basic/user-manual-for-quest-module.html

Q5: IF I AM CURRENTLY MANUFACTURING PRODUCTS AT HOME, WILL AN OFFICER CONDUCT AN INSPECTION AT MY HOME?

A: As required by the CDCR 1984, all registered products and notified cosmetics are to be manufactured within GMP-compliant premises. The premises should be licensed by the local town council, Department of Environment, and/ or Fire and Rescue Department.

To encourage new entrepreneurs to produce registered products/ notified cosmetics within GMP-compliant premises, each entrepreneur is given the choice of building their factory or appointing a GMP-compliant contract manufacturer.

Q6: WHAT IF I WOULD LIKE TO BUILD NEW MANUFACTURING PREMISES?

A: Kindly refer to the diagram below as a guide before setting up a new manufacturing premise.

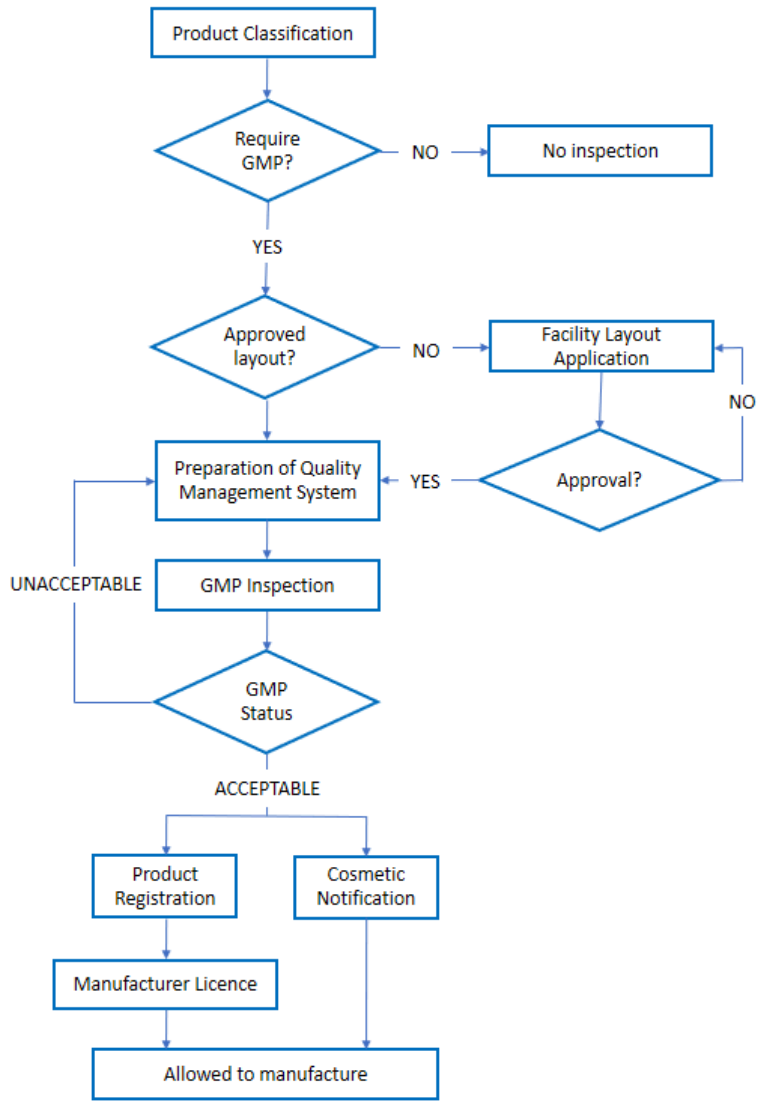

Figure 1: Setting up GMP Manufacturing Facility Process Flow

The manufacturer may apply to the Evaluation of Manufacturing Plant Layout (NPRA/431/12-3) to the Good Manufacturing Practice Section, Centre of Compliance and Quality Control for evaluation and approval. The form is accessible at: https://www.npra.gov.my/easyarticles/images/users/1133/2023%20Mar/230328/NPRA.431.12.3-Borang-Permohonan-Penilaian-Pelan-Susun-Atur-Premis-Pengilang.pdf

Q7: WHAT ARE THE LEVELS OF GMP COMPLIANCE?

A: GMP compliance is rated as Acceptable or Unacceptable. The level of compliance is determined by the weaknesses/ non-conformances found during an inspection.

Q8: IS AN INSPECTION CONDUCTED ONLY ONCE OR ROUTINELY?

A: In general, all manufacturers of registered products/ notified cosmetics will be inspected routinely. The frequency of inspection is determined according to the risk level of the product manufactured as well as the latest GMP compliance rating.

For pharmaceutical manufacturers, inspections will be scheduled via Risk Based Inspection Planning, which considers aspects such as site complexity, process complexity, product complexity, the number of deficiencies from the recent inspection, any changes to the site since the previous inspection, product complaints, and/ or regulatory actions received.

Q9: HOW MUCH DOES A GMP INSPECTION COST?

A: Please refer to the document (Caj Baru Bayaran Pemeriksaan Amalan Perkilangan Baik bagi Premis Tempatan dan Luar Negara) displayed under 'Circulars & Directives' on the NPRA website at https://www.npra.gov.my/images/Circulars_Directive/Regulatory_Information/page-16/Caj-Baru-Bayaran-Pemeriksaan-APB.pdf

Q10: HOW IS A GMP INSPECTION CONDUCTED?

A: Before an inspection, an officer is appointed as the lead inspector and will determine the date of inspection, as well as a proposed inspection plan. Each inspection is led by a lead inspector, who may be joined by other inspectors. The number of inspectors required is based on the size of the facility, the type of product manufactured, and the scope of the inspection.

- An inspection is preceded by an Opening Meeting, during which the objective, related guidelines, scope, and inspection areas will be explained.
- After the Opening Meeting, the inspection of the manufacturing premises, store premises, laboratory, and documentation system shall commence.
- At the end of the inspection, the lead inspector (and other accompanying inspectors) will present inspection findings during a Closing Meeting. The GMP compliance status will be determined during the Premises Inspection Evaluation Committee Meeting.

Q11: WILL INSPECTION FINDINGS BE DISCUSSED OR REPORTED?

A: Generally, a Good Manufacturing Practice (GMP) Inspection Report will be issued after each inspection is conducted. The manufacturer is expected to provide feedback regarding Corrective And Preventive Actions (CAPA) taken toward each reported finding within a stipulated time frame. The format for CAPA feedback can be accessed via this link: https://www.npra.gov.my/index.php/en/component/content/article/2-uncategorised/988-capa?Itemid=437

Q12: WHAT HAPPENS IF A MANUFACTURER DOES NOT COMPLY WITH GMP REQUIREMENTS?

A: Punitive actions can be imposed on manufacturers and will be determined by the Premises Inspection Evaluation Committee Meeting.

Registered products manufacturers:

i) New product registration applications will be rejected.
ii) Product registration renewal will not be allowed.
iii) Currently registered products will be suspended.

Notified cosmetics manufacturers:

- New cosmetic notification applications will be rejected.
- Renewal of cosmetic notification will not be allowed.

The Manufacturer's License may be revoked by the Director of Pharmaceutical Services, according to Regulation 17(1) of the Control of Drugs and Cosmetics Regulations 1984.

Q13: DO NOTIFIED COSMETICS MANUFACTURERS REQUIRE A MANUFACTURER'S LICENCE?

A: Currently, no Manufacturer's Licence is required for cosmetics manufacturers. A cosmetics manufacturer is allowed to manufacture a cosmetic product once it is notified. However, the manufacturer is still required to comply with GMP requirements.

Q14: WHAT IS GMP CERTIFICATE?

A: A GMP Certificate is issued to endorse the compliance of the local manufacturer with the current GMP requirements. These certificates are required by overseas regulatory agencies for product registration in the respective countries.
The application for GMP certificates by local manufacturers shall be submitted online via the QUEST3+ system. Please refer to User Manual Quest 3+ System Module: Compliance and Licensing on how to apply for GMP Certificate via Quest 3+ system at
https://www.npra.gov.my/index.php/en/quest3-system-basic/user-manual-for-quest-module.html

Q15: AS A NEW PHARMACEUTICAL/BIOLOGICAL MANUFACTURER WHO INTENDS TO APPLY FOR A NON-ROUTINE GMP INSPECTION, SHOULD THE PROCESS VALIDATION FOR THE PRODUCTION SCALE BATCHES BE COMPLETED BEFORE AN INSPECTION?

A: The objective of a GMP inspection is to confirm that any manufacturer has a satisfactory pharmaceutical quality system in ensuring that manufacturing activities are adequately within control. The requirements to execute process validation on a production scale batch depend on the objective(s) of an inspection and categories(s) of a product. E.g.:

Inspection Objective	Product Category*	Inspection Type	PV Requirement
Confirmation of a new facility	A, X, B	Pre-licensing, Pre-approval, Pre-certification	• Prerequisites before the implementation of process validation for production scale batches have been completed based on cGMP understanding. • Process validation protocol for production scale batches.
Confirmation of a product	API**	Pre-certification	• Process validation for the production scale batches has been completed

*Reference: Drug Registration Guidance Document (DRGD) (Third Edition, Third Revision, July 2022)
**API = Active Pharmaceutical Ingredient

Depending on the risk of the product being manufactured, NPRA may request the manufacturer to execute process validation on the production scale batches before an inspection.

Q16: CAN THE BATCHES MANUFACTURED FOR THE PURPOSE OF PROCESS VALIDATION BE RELEASED FOR SALE?

A: Process Validation is a means of ensuring that manufacturing processes are capable of consistently producing a finished product of the required quality. However, any decision to release process validation batches for sale shall be in line with the legislative provisions and current regulatory requirements.

Q17: WHAT ARE INVESTIGATIONAL MEDICINAL PRODUCTS (IMP)?

A: Investigational Medicinal Products (IMP) is a pharmaceutical form of an active ingredient including herbal/natural, animal medicinal products or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication (off-label use), or when used to gain further information about the approved use.

[Reference: Malaysian Guideline for Application of CTIL and CTX (7.1th edition, 2020)]

Q18: IF I MANUFACTURE IMP, ARE MY MANUFACTURING PREMISES SUBJECTED TO GOOD MANUFACTURING PRACTICE (GMP) INSPECTION BY NPRA?

A: All manufacturers of IMP are subjected to comply with the PIC/S GMP requirements which are detailed in PIC/S Guide to Good Manufacturing Practice for Medicinal Products (Annex 13), PIC/S Guide to Good Manufacturing Practice for Medicinal Products (Part I) and other related Annexes. The requirements of IMP were also stated in other relevant guidance such as the Malaysian Guideline for Application of CTIL and CTX, Drug Registration Guidance Document (DRGD), ASEAN Guideline for the Conduct of Bioequivalence Studies, and Frequently Asked Questions - Bioequivalence.

Starting in 2022, NPRA will extend the scope of GMP inspection by including IMP production, especially those involved in BE and Phase III clinical trials during a routine inspection of pharmaceutical manufacturers. New and existing pharmaceutical manufacturers will be inspected towards the scope of IMP production after the manufacturer confirmed the intention/direction of IMP production. For high-claim herbal/natural products and health supplements which are manufactured locally, products should be manufactured in the premises/facilities which comply with the requirements of the PIC/S Guide to Good Manufacturing Practice for Medicinal Products.

Q19: CURRENTLY I MANUFACTURE IMP FOR USE IN BIOEQUIVALENCE STUDIES (BE) AND CLINICAL TRIALS. DOES NPRA INSPECT ALL THE IMP THAT IS PRODUCED DURING ROUTINE INSPECTION?

Inspection of IMP production will be conducted in stages, which consist of stages I, II, and III.

For stage I, which started in 2022-2026, NPRA will inspect the IMP which complies with the criteria below:
a) sharing the same line as registered/commercial products.
b) granted valid CTX approval.
c) used for BE and Phase III clinical trials.

For stage II, NPRA will expand the scope to IMP used in BE and clinical trials (except phase I). The implementation date will be announced later.

For stage III, NPRA will expand the scope to IMP used in BE and all clinical trials. The implementation date will be announced later.

Q20: DO I NEED TO APPLY FOR INSPECTION OF IMP PRODUCTION VIA QUEST 3+?

For new manufacturers, an application for pre-licensing GMP inspection via the QUEST 3+ online system is required. The scope of IMP production will be included during the inspection after the manufacturer confirms their direction/intention of IMP production.

For existing local pharmaceutical manufacturers, the scope of IMP [which has been granted with valid Clinical Trial Exemption (CTX) approval] production will be covered during scheduled routine GMP inspection.

(Note: The manufacturer is not required to apply for routine GMP inspection as NPRA will schedule routine inspection based on NPRA's internal procedure.)

Q21: WILL NPRA INSPECT THE IMP PRODUCTION AS PER OUR CTX APPLICATION SUBMITTED TO NPRA?

Yes, the inspection will be performed using a risk-based approach and the sampling process of the IMP will be based on the list of CTX approval that is granted to the manufacturer.

Q22: DOES NPRA PERFORM GMP INSPECTION TOWARDS OVERSEA MANUFACTURERS WHO PRODUCE IMP?

Yes. We will perform GMP inspection of manufacturing premises that produced registered products and IMP. Companies can apply for foreign GMP inspection for the scope of IMP based on our current process and procedure if they intend to apply for a Clinical Trial Import License (CTIL) if valid GMP evidence is not available and is subject to requirements set by NPRA.

Q23: IS THE INSPECTION OF IMP PRODUCTION APPLICABLE TO LOCAL CELL AND GENE THERAPY PRODUCT (CGTPS) MANUFACTURERS?

Yes, if the manufacturer was granted CTX approval.

Q24: AS A LICENSED PHARMACEUTICAL MANUFACTURER, CAN I MANUFACTURE OTHER CATEGORIES OF PRODUCTS BESIDES PHARMACEUTICALS?

Generally, all pharmaceutical manufacturers had established and implemented the Pharmaceutical Quality System (PQS) based on the requirements specified in PIC/S Guide to Good Manufacturing Practice for Medicinal Products with the objective of ensuring that medicinal products manufactured are of quality, safety and efficacy.

Hence, if the pharmaceutical manufacturer intends to manufacture other categories of registered products such as traditional medicines, health supplements and notified cosmetics, they are required to implement equal PQS for other categories of products to ensure the manufacturing activities of other categories of products will not jeopardize the quality of existing pharmaceutical products and introduce any risk of contamination to all the products manufactured.

Please refer to Q28 on management of cross-contamination risk in multi-product manufacturing facilities.

Note: In this context, the term "medicinal product" refers to the term "product" as stipulated in Regulation 2, the Control of Drugs and Cosmetics Regulations (CDCR) 1984 which is applicable to pharmaceuticals (generics, biologics, veterinary products), health supplements and natural products.

Q25: AS A LICENSED TRADITIONAL MANUFACTURER, CAN I MANUFACTURE HEALTH SUPPLEMENTS IN SHARING FACILITIES?

Generally, traditional medicines (natural products) are sourced from 2 types of raw materials, namely crude herbs and extract-based herbs. For crude herbs, the source of origin is variable and improper handling will introduce contamination risk to the traditional medicines manufactured. Hence, considering the risk of cross-contamination, the traditional medicines manufacturer that manufactures products made up of crude herbs are not allowed to manufacture health supplements in a shared facility. However, the traditional medicines manufacturer that manufactures products made up of extract-based herbs can be considered to manufacture health supplements in a shared facility with the condition that precautionary measures are established to ensure the quality of both categories of products.

Please refer to Q28 on management of cross-contamination risk in multi-product manufacturing facilities.

To manufacture health supplement products, a traditional medicines manufacturer should notify NPRA of such intention through Immediate Notification (Appendix 27, DRGD) before proceeding manufacturing. The manufacturer is obliged to make available the relevant documents during NPRA inspection for NPRA review. NPRA will verify the effectiveness of the contamination control strategy implemented during the inspection.

Q26: AS A NOTIFIED COSMETIC MANUFACTURER, CAN I MANUFACTURE OTHER PRODUCTS (FOR EXAMPLE HOUSEHOLD PRODUCTS) IN SHARING FACILITIES?

A cosmetic product shall mean "any substance or preparation intended to be placed in contact with various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with teeth and the mucous membranes of the oral cavity, with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition".

Cosmetic manufacturers are responsible to implement a Quality Management System appropriate for the manufacture of cosmetics to ensure that they are fit for the intended use, comply with the regulations and requirements of the Cosmetic Notification, as appropriate, and do not place consumers at risk due to inadequate safety or quality.

If the manufacturer intends to produce other products such as household products, insect repellent or veterinary cosmetic, then the production of such products should be avoided in areas and with equipment destined for the production of cosmetic products but, where justified (e.g., if containing non-hazardous materials/ingredients) could be allowed provided that due care should be exercised to prevent cross-contamination and risk of mix-up.

Please also refer to Figure 2 of Q28.

However, due to the concern of risk of contamination, cosmetic manufacturers should obtain permission to manufacture non-cosmetic products such as veterinary cosmetics or household products before proceeding with manufacturing by notifying NPRA of such intention through Immediate Notification (Appendix 27, DRGD). Aspects that will be assessed are the content of the non-cosmetic products, the capabilities of the existing manufacturing facilities, the effectiveness of cleaning activities, the prevention of the risk of cross-contamination and mix-ups, etc. Cosmetic manufacturers are obliged to make available the relevant documents during NPRA inspection for NPRA review. NPRA will verify the effectiveness of the contamination control strategy implemented during the inspection.

Q27: CAN MEDICAL DEVICES BE MANUFACTURED IN THE LICENSED PHARMACEUTICAL MANUFACTURING PREMISES?

In principle, the PIC/S Guide to Good Manufacturing Practice for Medicinal Products had stipulates that the production of non-medicinal products should be avoided in areas and with equipment destined for the production of medicinal products but, where justified, could be allowed if the measures to prevent cross-contamination with medicinal products described in Chapter 3 and Chapter 5 had been applied. However, the production and/or storage of technical poisons, such as pesticides (except where these are used for manufacture of medicinal products) and herbicides, should not be allowed in areas used for the manufacture and/or storage of medicinal products.

In addition, manufacturer is responsible to implement a Pharmaceutical Quality System (PQS) appropriate for the manufacture of medicinal products as to ensure that they are fit for their intended use, comply with the regulations and requirements of the Marketing Authorisation or Clinical Trial Authorisation, as appropriate, and do not place patients at risk due to inadequate safety, quality or efficacy.

For manufacturing of medical devices, it is controlled by separate regulations and requirements. Hence, if the manufacturer intends to manufacture medical devices in the sharing facility with pharmaceutical products, they are required to comply with requirements stipulated in regulations and requirements for both medicinal products and medical devices. Manufacturers also required to ensure the activities of other categories of products/devices will not jeopardize the quality of existing pharmaceutical products and introduce the risk of contamination to the existing activities.

Besides, manufacturers should notify NPRA of such intention through Periodical Notification (Appendix 27, DRGD) and make available the relevant documents during NPRA inspection for NPRA review. NPRA will verify the effectiveness of the contamination control strategy implemented during the inspection.

Q28: HOW TO MANAGE CROSS-CONTAMINATION RISK IN MULTI-PRODUCT MANUFACTURING FACILITIES?

Cross-contamination associated with multi-product manufacturing should be prevented by giving appropriate attention to the design of the premises and equipment, as described in Chapter 3 of the PIC/S GMP Guide, as well as Chapter 3 of the TMHS GMP Guide. This should be supported by attention to process design and implementation of any relevant technical or organizational measures, including effective and reproducible cleaning processes to control risk of cross-contamination.

A Quality Risk Management (QRM) process which includes a potency and toxicological evaluation, as well as factors including facility/equipment design and use, personnel and material flow, microbiological controls, physico-chemical characteristics of the active substance, process characteristics, cleaning processes and analytical capabilities relative to the relevant limits established from the evaluation of the products should also be taken into account to assess and control the cross-contamination risks presented by the products manufactured. The outcome of the QRM process should be the basis for determining the necessity for and extent to which premises and equipment should be dedicated to a particular product or product family. This may include dedicating specific product contact parts or dedication of the entire manufacturing facility. It may be acceptable to confine manufacturing activities to a segregated, self-contained production area within a multi-product facility, where justified. Hence, if the issue of cross-contamination can be adequately addressed, sharing of manufacturing facilities may be considered provided the regulations and requirements stipulated are complied accordingly by manufacturer.

The decision tree in Figure 2 is intended to assist in the assessment of current state before any new 'product' being introduced to the existing multi-product manufacturing facilities. This decision tree should be read in conjunction with all other relevant regulations and directives/circulars in force, and all relevant guidelines and other documents as published on the NPRA website (www.npra.gov.my).

It is the manufacturer's responsibility to implement an appropriate Pharmaceutical Quality System (PQS) for the manufacture of medicinal products as to ensure that they are fit for their intended use, comply with the requirements of the Marketing Authorisation or Clinical Trial Authorisation, as appropriate, and do not place patients at risk due to inadequate safety, quality or efficacy.

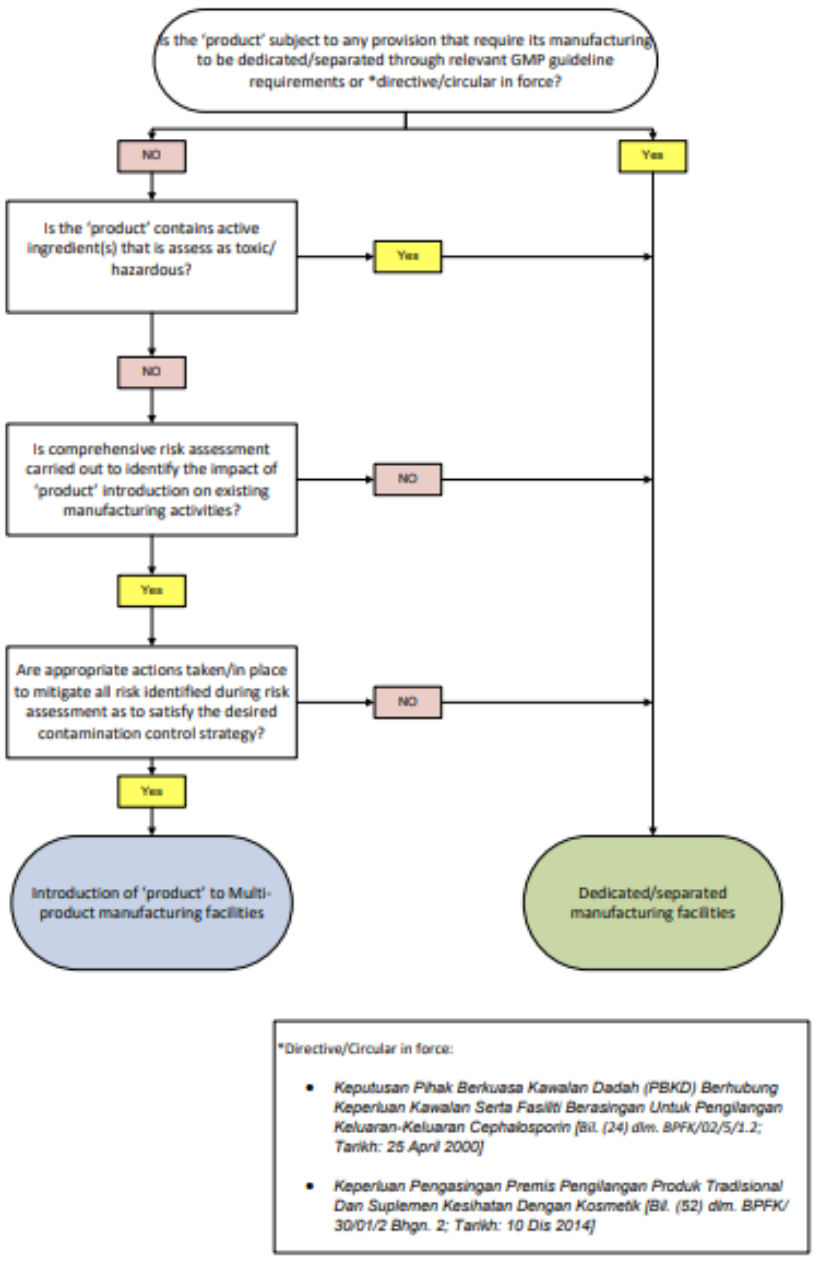

Figure 2: Decision Tree / Dedicated/Separated vs. Multi-Product Manufacturing Facilities

Q29: WHAT ARE THE REQUIREMENTS FOR WATER USED AS AN INGREDIENT OR FOR FINAL RINSING OF PRODUCTION EQUIPMENT IN THE MANUFACTURE OF TRADITIONAL MEDICINES AND/OR HEALTH SUPPLEMENTS, AND WHAT TYPE OF WATER TREATMENT SYSTEM IS REQUIRED?

Water used as an ingredient or for the final rinsing of production equipment in the manufacture of Traditional Medicines and/or Health Supplements shall comply with the specification for Purified Water as defined in a recognised pharmacopoeia monograph, such as the British Pharmacopoeia (BP), United States Pharmacopeia (USP), or other equivalent internationally recognised pharmacopoeias.

The water shall meet the relevant chemical and microbiological specifications of the selected monograph, including, but not limited to:

- Total Aerobic Microbial Count (TAMC)
- Total Organic Carbon (TOC)
- Conductivity

Manufacturers shall establish a comprehensive water quality monitoring program to ensure continued compliance with the Purified Water specification. The frequency of monitoring should be determined based on risk assessment and shall include sampling and testing at the point of use, and at appropriate points within the generation and distribution system.

There is no mandatory requirement for a specific type of water treatment system, provided that the system is capable of consistently producing water that meets the Purified Water specification.

Acceptable water treatment systems may include, but are not limited to:

- Reverse Osmosis (RO)
- Deionisation (DI)
- Distillation
- Appropriate system(s)

The water treatment system, including both generation and distribution systems, shall undergo verification in accordance with latest applicable guidelines and guidance documents.

For further clarifications, please email gmp@npra.gov.my and call 03-78835400
or visit https://www.npra.gov.my/index.php/en/public-enquiry.html

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