**National Pharmaceutical Regulatory Agency**
**Ministry of Health Malaysia**
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# GUIDANCE DOCUMENT FOR PREPARATION OF GOOD MANUFACTURING PRACTICE (GMP) INSPECTIONS ON TRADITIONAL MEDICINES, HEALTH SUPPLEMENTS AND COSMETICS MANUFACTURERS

**1st edition**
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## 1. INTRODUCTION

National Pharmaceutical Regulatory Agency (NPRA) is responsible to ensure that registered products / notified cosmetics that is available in the market are safe, efficacious and of quality. These registered products / notified cosmetics are required to be manufactured in a manufacturing facility that is compliant to the current Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) requirements. Therefore, to ensure compliance, GMP Section from Centre of Compliance and Quality Control (CCQC), NPRA will conduct various types of inspection onto these manufacturers.

A new local manufacturer for registered products / notified cosmetics is required to be inspected prior to product/ cosmetics registration or notification. Therefore, they are subjected to different types of inspection i.e. Pre-Licensing Inspection where GMP inspection conducted on local manufacturing facilities prior to being licensed, or Initial Inspection for new cosmetic local manufacturer, whereas for an existing local licensed manufacturer, a Pre-Approval Inspection will be conducted for a new production line.

## 2. PURPOSE & SCOPE

The document is intended as a guide to assist new local manufacturers in preparation for a **pre-licensing, initial inspection** or **pre-approval** inspection for existing manufacturer. It is not meant to be used as a replacement of the guidelines in which the inspections are based upon.

Depending on the category of the manufacturer, the extent of GMP guidance requirement may differ between pharmaceutical and non-pharmaceutical manufacturer. Therefore, the scope of this document is only applicable to the non-pharmaceutical manufacturer category such as **Traditional Medicine (TM), Health Supplement (HS) and Cosmetic manufacturers**. It is the responsibility of the manufacturer to have a complete understanding of GMP and GDP requirement before commencement of planning to manufacture TMHS products and cosmetics.

At the time of issue, this document reflects the current state of the requirements. It is also not intended to be a barrier to technical innovation or the pursuit of excellence for the manufacturers.

## 3. GUIDELINES USED

Below are the guidelines used for the inspection:

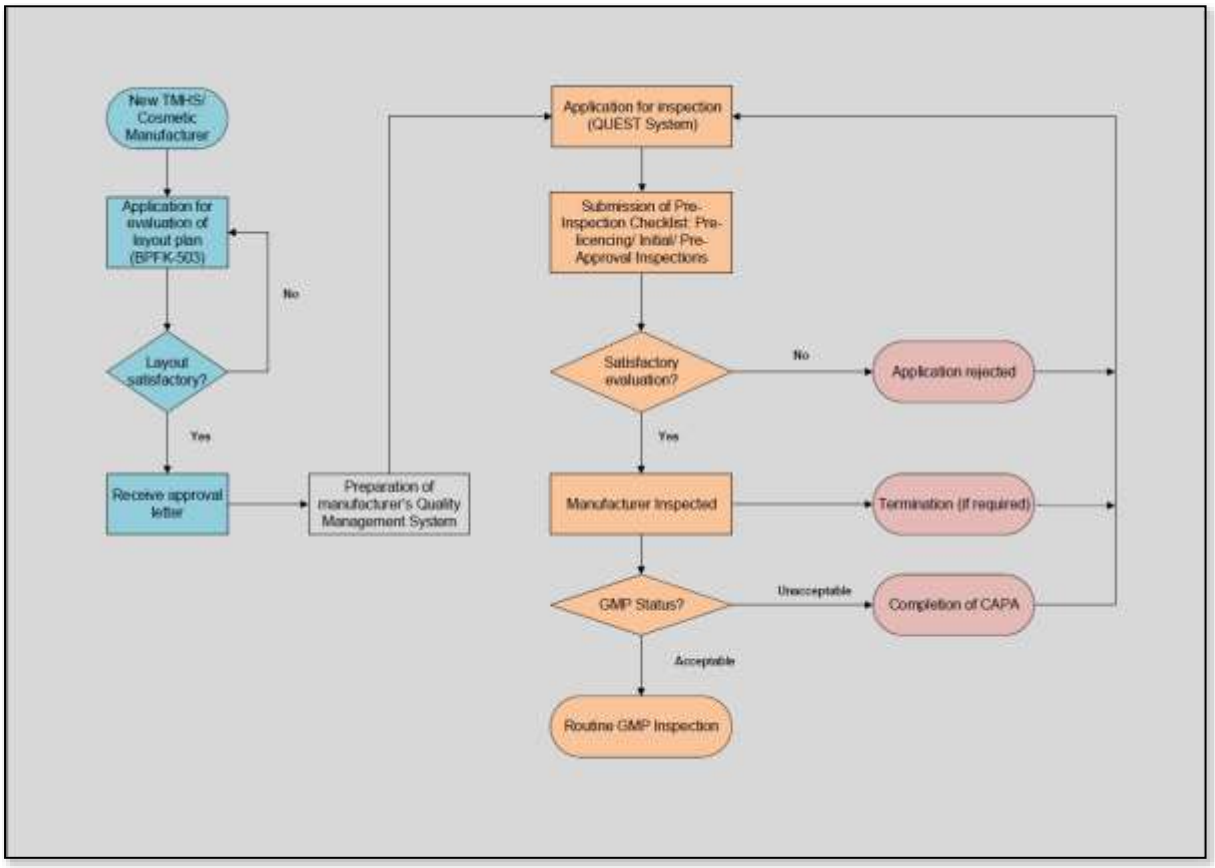
| Category of Manufacturer | GMP Guideline | GDP Guideline |
|---|---|---|
| Traditional Medicine and Health Supplements (TMHS) | Guidelines on Good Manufacturing Practice for Traditional Medicines & Health Supplements, 1st Edition, 2008 | Good Distribution Practice, 3rd Edition, 2018. |
| Cosmetics | Annex 1, Part 10; Guideline for Cosmetic Good Manufacturing Practice, Guideline for Control of Cosmetic Products in Malaysia, February 2017 Rev.01 | |
| All the guidelines stated above can be downloaded from the NPRA website at https://npra.gov.my | | |

## 4. OBJECTIVE OF PRE- LICENSING / INITIAL INSPECTION / PRE-APPROVAL INSPECTION

The main objective of a pre-licensing / initial inspection / pre-approval inspection is to assess the manufacturer's readiness for commercial manufacturing or new manufacturing line of an existing manufacturer.

## 5. REGULATORY PROCESS DESCRIPTION

Below is the brief regulatory flow description. Please read para 5.1 - 5.4 for further details.




### 5.1 Evaluation on workflow of manufacturing process and premises layout

Prior to applying for pre-licensing / initial inspection, the manufacturer needs to ensure that the layout of the manufacturing facility is designed and planned according to GMP principles. The proposed layout along with the Application for The Evaluation of Manufacturing Plant Layout (BPFK-503) and supporting documents may be submitted to GMP Section, CCQC for evaluation. An approval letter of the proposed layout will then be issued when it is deemed satisfactory and this is the prerequisite of every request for pre-licensing / initial inspection. This may also be applicable for pre-approval inspection application, especially if the existing manufacturer undergoes major changes to its facility (may refer to Managing Changes of Manufacturers Facility from Drug Registration Guidance Document, DRGD)

The approval letter is required during the submission of inspection request via QUEST System. Therefore, the evaluation of manufacturing layout is compulsory for TMHS and cosmetic manufacturer.

## 5.2 Preparation of Quality Management System (QMS)

Upon the approval of the facility layout plan and approval from other relevant authorities' such as the local authority and fire brigade department (BOMBA), the manufacturer may begin the setup of the QMS for the facility according to the requirements of current GMP and GDP. QMS is an overall system; consists of the quality system, documentation and records, facilities and equipment system, production system, packaging and labelling system, laboratory control system and material system. Thus, it is advisable for the manufacturer to self-assess its own quality system as part of the preparation before inspection conducted by NPRA.

In general, a manufacturer for TMHS / cosmetics products is required to:

a. Ensure the built of the manufacturing areas are done in accordance to the approved layout and in accordance to GMP principles.

b. Ensure the equipment (for both manufacturing and laboratory) and utilities are properly installed and functioning.

c. Maintain the premises, equipment and utilities as well as the calibration of measuring devices.

d. Establish the sampling plans, testing of materials and product.

e. Establish a warehouse management program including receiving and storage of starting materials and finished products, as well as warehouse mapping.

f. Ensure personnel involved in manufacturing activities are healthy, adequately trained and qualified.

g. Have all the relevant procedures and records to prove that all activities are conducted accordingly.

For companies who procure/ transfer ownership of an existing GMP manufacturing business, it is the responsibility of the new owner to ensure that the GMP manufacturing facility complies with the current GMP and GDP requirements. The new owner must not rely solely on purported claims but is encouraged to self-assess the current state of the facility.

## 5.3 Submission of application form for inspection

Before submitting an application for inspection, manufacturers need to ensure that all the necessary renovations and installations are completed. Required documentations should also be updated and available.

The manufacturer may apply for a pre-licensing / initial inspection/ pre-approval inspection through the QUEST system once they are ready for inspection. Two documents are required to be submitted together during the application as follows:

a. Site Master File
b. Letter of approval for facility layout

A fee of RM 1000 is applicable for each inspection conducted within 1 day. However, if the inspection is expected to take more than 1 day due to complexity of the site, process and product, the fee will be revised according to the number of inspection days and number of inspectors. The manufacturer will be advised further for this scenario.

GMP Section will schedule the inspection upon satisfactory evaluation of the application and therefore, it is imperative for manufacturer to ensure that minimal Quality Management System as described in Appendix 1 are in place. Kindly refer to the Pre-Inspection Checklist: Pre-licensing / Initial / Pre-Approval Inspections (Appendix 1). The manufacturer is required to ensure the general points stated in Appendix 1 are met and the inspectors may request a completed checklist as in Appendix 1 to confirm that the manufacturer is able to meet the prerequisite requirements. **Please submit the filled Appendix 1 within 10 working days to the office of GMP Section after the submission of inspection application via QUEST System.**

In the event of unreadiness after submitting application for inspection in which evaluation of the Pre-Inspection Checklist was found incomplete, upon our discretion, the application may be rejected or withdrawn by the applicant, however, re-scheduling of inspection will not be considered. Please refer to Para 6 for terms of rejection and withdrawal.

### 5.4 Inspection and follow up actions

The pre-licensing / initial / pre-approval inspection will be scheduled by the assigned inspector. The manufacturer will be notified on the date and time of inspection by email or telephone.

Inspection will be conducted based on the abovementioned GMP and GDP guidelines stated and to determine if the manufacturer has a quality management system that is designed to manufacture the intended TMHS / cosmetics. The inspection also will verify the information that was submitted during the application of the inspection. After the inspection, the inspector(s) will issue a report to the manufacturer within a predetermined timeline.

An acceptable GMP status will be given if the manufacturer is able to comply with the required GMP principles and within the inspection scope. The inspected manufacturer is then subjected to routine GMP inspection by NPRA to ensure the compliance to GMP requirements are met and maintained.

Whereas, if the outcome was found to be Unacceptable because of a significant non-compliance with GMP, the manufacturer is required to conduct a complete Corrective Action and Preventive Action (CAPA) before submitting a new application (with payment). The CAPA report will be requested by NPRA as part of the preparatory document for the new inspection.

## 6. REJECTION, TERMINATION OR WITHRAWAL OF INSPECTION

Application for inspection shall be rejected if the manufacturer fails to submit satisfactory required documentation via QUEST System and Pre-Inspection Checklist within specified period. The applicant shall be notified accordingly of the rejection. In the event that the

manufacturer are unready for inspection ,the inspector may advise the application to be withdrawn by the applicant and a different application submitted when requirements are met.

The inspector, upon their discretion will have the right for any reason and at any time during the conduct of inspection period to terminate the inspection if the manufacturer was found to be not ready, provide false attestation of Appendix 1, have significant GMP non-compliance or in any situation where threat is detected / safety compromised.

## 7. OTHER INFORMATION

Inquiries relating to pre-licensing / initial / pre-approval GMP inspections of TMHS and cosmetics may be directed to the following contact:

GMP Section
Centre for Compliance and Quality Control
National Pharmaceutical Regulatory Agency
Ministry of Health Malaysia
Lot 36, Jalan Universiti, 46200 Petaling Jaya, Selangor.
Tel : (603)-78835400 or (603)-78835491
Email: gmp@npra.gov.my

## 8. ABBREVIATIONS

CAPA: Corrective Action and Preventive Action
GDP: Good Distribution Practice
GMP: Good Manufacturing Practice
NPRA: National Pharmaceutical Regulatory Agency
QMS: Quality Management System
TMHS: Traditional Medicines and Health Supplements

## REFERENCES:

1. Drug Registration Guidance Document (DRGD)
2. Guidelines on Good Manufacturing Practice for Traditional Medicines & Health Supplements, 1st Edition, 2008
3. Annex 1, Part 10; Guideline for Cosmetic Good Manufacturing Practice, Guideline for Control of Cosmetic Product in Malaysia February 2017 Rev.01.
4. Guideline on Good Distribution Practice, 3rd Edition, 2018
5. Site Master File, Third Edition, 2014
6. Annex 7 WHO Technical Report Series; Guidelines on Pre-approval Inspections
7. FDA Pre-Approval Inspections Compliance Program Guidance Manual,12 April 2010
8. PIC/S GMP Inspection Reliance Guidance; PI 048-1, 1 June 2018

# SENARAI SEMAK PRA-PEMERIKSAAN

***PRE-INSPECTION CHECKLIST***

# PEMERIKSAAN PRA-PELESENAN / AWAL / PRA-KELULUSAN

***PRE-LICENSING / INITIAL / PRE-APPROVAL INSPECTIONS***

## A. MAKLUMAT UMUM

***GENERAL INFORMATION***

| **Nama Pengilang** *Manufacturer Name* | **Alamat** *Address* |
|---|---|
| | |

| **Kategori Pengilang dan Bentuk Dos (Sila tandakan yang berkaitan)** *Category of Manufacturer and Dosage Form (Please tick where relevant)* | | | | **Pematuhan kepada Garis Panduan** *Compliance to Guideline* |
|---|---|---|---|---|
| **Ubat-ubatan Tradisional** *Traditional Medicines (TM)* | | **Suplemen Kesihatan** *Health Supplement (HS)* | | |
| ☐Tablet *Tablet*<br>☐Kapsul *Capsule*<br>☐Serbuk *Powder*<br>☐ Granul *Granule*<br>☐Cecair Internal *Internal Liquid* | ☐ Cecair Eksternal *External Liquid*<br>☐Separa Pepejal (Krim, Gel, Salap) *Semi-solid (Cream, Gel, Ointment)*<br>☐Lain-lain (sila nyatakan) *Others (please specify)*<br>_____ | ☐Tablet *Tablet*<br>☐Kapsul *Capsule*<br>☐Serbuk *Powder*<br>☐ Granul *Granule*<br>☐Cecair Internal *Internal Liquid* | ☐Cecair Eksternal *External Liquid*<br>☐Separa pepejal (Krim, Gel, Salap) *Semi-solid (Cream, Gel, Ointment)*<br>☐Lain-lain (sila nyatakan) *Others (please specify)*<br>_____ | • Guidelines on Good Manufacturing Practice for Traditional Medicines & Health Supplements, 1st Edition, 2008<br>• Good Distribution Practice, 3rd Edition, 2018. |
| **Cosmetics** | | | | • Annex 1, Part 10; Guideline for Cosmetic Good Manufacturing Practice<br>• Good Distribution Practice, 3rd Edition, 2018. |
| ☐Serbuk/Granul *Powder/Granule*<br>☐Sabun Buku *Bar Soap* | ☐Cecair Eksternal *External Liquid*<br>☐Ubat Gigi *Toothpaste* | ☐Separa pepejal (Krim, Gel, Salap) *Semi-solid (Cream, Gel, Ointment)* | ☐Lain-lain (sila nyatakan) *Others (please specify)*<br>_____ | |

**Jenis Pemeriksaan (Sila tandakan yang berkaitan)** ***Type of Inspection (Please tick where relevant)***

☒Pra-Pelesenan (Pengilang TMHS) *Pre-Licensing (TMHS manufacturers)*
☐Pemeriksaan Awal (Pengilang Kosmetik) *Initial Inspection (Cosmetic Manufacturers)*
☐Pra-Kelulusan (penambahan barisan pengilangan baru) *Pre-Approval (addition of new manufacturing line)*

**Tarikh Surat Kelulusan Pelan Susun Atur** ***Date of Layout Approval Letter:***

**No. Rujukan Surat Kelulusan Pelan Susun Atur** ***Reference number of layout approval:***

| B. PENGAKUAN KE ATAS MAKLUMAT YANG DISENARAIKAN SEBAGAI TAHAP KESEDIAAN PENGILANG<br>*PLEASE DECLARE THE INFORMATION LISTED BELOW AS AN INDICATION OF THE READINESS OF THE MANUFACTURER* | | | |
|---|---|---|---|
| **SISTEM PENGURUSAN KUALITI SECARA KESELURUHAN**<br>***OVERVIEW OF QUALITY MANAGEMENT SYSTEM*** | **Sila tandakan (Ya/Tidak)**<br>***Please Tick (Yes/No)*** | | **Catatan (jika perlu)**<br>**Nota: Dokumen lanjut perlu tersedia semasa pemeriksaan**<br>***Remarks (if required)*** *Note: More documents should be available upon request during inspection* |
| Kebiasaan dengan Garis Panduan APB?<br>*Familiarization with GMP Guideline?* | ☐ Ya / Yes | ☐ Tidak / No | |
| Pengasingan antara tugasan pengeluaran dan kawalan kualiti?<br>*Independency between production and quality control (QC)?* | ☐ Ya / Yes | ☐ Tidak / No | |
| **PERSONEL**<br>***PERSONNEL*** | **Sila tandakan(Ya/Tidak)**<br>***Please Tick (Yes/No)*** | | **Catatan (jika perlu)**<br>**Nota: Dokumen lanjut perlu tersedia semasa pemeriksaan**<br>***Remarks (if required)*** *Note: More documents should be available upon request during inspection* |
| Carta Organisasi diwujudkan?<br>*Organization chart available?* | ☐ Ya / Yes | ☐ Tidak / No | |
| Deskripsi tugas bagi personel utama didokumenkan?<br>*Documented job description of key personnel?* | ☐ Ya / Yes | ☐ Tidak / No | |
| Latihan APB / AEB dijalankan?<br>*GMP / GDP Training conducted?*<br>• Prosedur; Rekod Latihan<br>*Procedure; Training evidence / Record* | ☐ Ya / Yes | ☐ Tidak / No | |
| Pemeriksaan kesihatan dijalankan?<br>*Medical examination conducted?*<br>• Prosedur; Rekod Pemeriksaan kesihatan<br>*Procedure; Examination Record* | ☐ Ya / Yes | ☐ Tidak / No | |
| **PREMIS & PERALATAN**<br>***PREMISES & EQUIPMENT*** | **Sila tandakan (Ya/Tidak)**<br>***Please Tick (Yes/No)*** | | **Catatan (jika perlu)**<br>**Nota: Dokumen lanjut perlu tersedia semasa pemeriksaan**<br>***Remarks (if required)*** *Note: More documents should be available upon request during inspection* |
| Rekaan dan binaan membolehkan aktiviti pengilangan dan penstoran dijalankan dan mengelakkan risiko kontaminasi melalui:<br>*Building is designed and constructed to allow manufacturing and storage activities to be performed in a way that prevents contamination by way of:* | | | |
| • Bahan binaan yang bersesuaian?<br>*Suitable material of construction?* | ☐ Ya / Yes | ☐ Tidak / No | |
| • Permukaan yang licin, mudah dibersihkan dan tidak mengeluarkan habuk?<br>*Surfaces are smooth, easy to clean and do not shed particulate matter?* | ☐ Ya / Yes | ☐ Tidak / No | |
| • Kawasan / bilik khas dibina berdasarkan pelan susun atur yang diluluskan?<br>*Defined areas / rooms built according to approved layout?* | ☐ Ya / Yes | ☐ Tidak / No | |
| • Pencahayaan kawasan / bilik yang baik?<br>*Areas / rooms are well lit ?* | ☐ Ya / Yes | ☐ Tidak / No | |

| | | | |
|---|---|---|---|
| • Pengudaraan yang mencukupi? (sila rujuk Direktif Pelaksanaan Keperluan Sistem Air Terawat dan Pengudaraan Berpusat ke atas Pengilang Tradisional Rujukan: (3)dlm.BPFK/30/01/1.Bhgn2)<br>*Adequate ventilation? (please refer to Directive Pelaksanaan Keperluan Sistem Air Terawat dan Pengudaraan Berpusat for TM manufacturer Reference No.: (3)dlm.BPFK/30/01/1. Bhgn2)?* | ☐ Ya / Yes | ☐ Tidak / No | |
| • Kawasan / bilik mempunyai label / identifikasi?<br>*Labelling / identification of areas / rooms?* | ☐ Ya / Yes | ☐ Tidak / No | |
| • Ruangan bagi bahan dan peralatan yang mencukupi?<br>*Adequate space for material and equipment?* | ☐ Ya / Yes | ☐ Tidak / No | |
| Bangunan direka dan diselenggara untuk mengelakkan kontaminasi silang dengan:<br>*Building is designed and maintained to prevent cross-contamination by way of:* | | | |
| • Penyelenggaraan untuk memastikan premis sentiasa berkeadaan baik?<br>*Maintained proper state of repair?* | ☐ Ya / Yes | ☐ Tidak / No | |
| • Mewujudkan program kawalan makhluk perosak?<br>*Establish pest control program?* | ☐ Ya / Yes | ☐ Tidak / No | |
| Adakah kemudahan utiliti direka dan dibangunkan untuk menyokong aktiviti pengilangan?<br>Are the following *utilities is designed and built to support the manufacturing activities?* | | | |
| • Sistem Air<br>*Water System* | ☐ Ya / Yes | ☐ Tidak / No | |
| • Sistem Penyaman Udara<br>*Air-conditioning System* | ☐ Ya / Yes | ☐ Tidak / No | |
| • Udara Termampat (jika ada)<br>*Compressed Air (if applicable)* | ☐ Ya / Yes | ☐ Tidak / No | |
| • Kawalan habuk (jika berkaitan)<br>*Dust control (if relevant)* | ☐ Ya / Yes | ☐ Tidak / No | |
| Adakah peralatan direkabentuk, dibina, diletak, dikendali dan diselenggara dengan keadaan:<br>*Are the equipment is designed, constructed, arranged, operated and maintained in a manner that:* | | | |
| • Membenarkan pembersihan peralatan dan perkakas?<br>*Permits effective cleaning of equipment surface and utensils?* | ☐ Ya / Yes | ☐ Tidak / No | |

| | | | |
|---|---|---|---|
| • Siap dipasang (termasuk label, jika berkenaan) dan berfungsi?<br>*Installed (including labelling, where applicable) and functioning?*<br>• Kalibrasi (jika berkenaan)?<br>*Calibration (if applicable)?*<br>• Prosedur dan rekod berkaitan aktiviti penyelenggaraan/pembersihan<br>*Maintenance / cleaning procedures and records* | ☐ Ya / Yes<br>☐ Ya / Yes<br>☐ Ya / Yes | ☐ Tidak / No<br>☐ Tidak / No<br>☐ Tidak / No | |
| **DOKUMENTASI *DOCUMENTATION*** | **Sila tandakan (Ya/Tidak)**<br>***Please Tick (Yes/No)*** | | **Catatan (jika perlu)**<br>**Nota: Dokumen lanjut perlu tersedia semasa pemeriksaan**<br>***Remarks (if required)*** *Note: More documents should be available upon request during inspection* |
| Senarai induk bagi prosedur/arahan kerja berkaitan aktiviti yang dijalankan seperti pengilangan, pembungkusan, pelabelan penstoran, pengedaran dan kawalan kualiti disediakan?<br>*Are there master list of procedures/work instruction related to operations such as manufacturing, packing, labelling, storage, distribution and quality control?*<br><br>Adakah prosedur/arahan kerja yang disediakan sekurang-kurangnya termasuk: *Minimally, does these include:*<br>• Penerimaan bahan? *Receipt of materials?*<br>• Aktiviti kuarantin dan penstoran? *Quarantine & storage?*<br>• Sistem pemberian nombor kelompok? *Batch numbering system?*<br>• Pelepasan produk siap? *Release of finished product?*<br>• Operasi pemprosesan dan pengeluaran? *Processing and production operations?*<br>• Kawalan kualiti semasa proses dan produk siap? *In process QC and Finished product QC?*<br>• Pengedaran? *Distribution?*<br>• Pemulangan dan penolakan produk? *Returned and rejected products?*<br>• Panggil balik dan aduan? *Recalls and complaints?*<br>• Pembersihan & Sanitasi? *Housekeeping & sanitation?*<br>• Kejuruteraan & penyelenggaraan? *Engineering & maintenance?*<br>• Kelayakan & latihan? *Qualifications & trainings?*<br>• Pemeriksaan dalaman? *Self-inspection?* | ☐ Ya / Yes<br>☐ Ya / Yes | ☐ Tidak / No<br>☐ Tidak / No | |
| Dokumentasi tambahan termasuk buku log atau rekod yang seumpamanya? *Additional documentation includes log books, or other similar records?* | ☐ Ya / Yes | ☐ Tidak / No | |
| Spesifikasi bagi semua bahan? *Specifications available for all materials?* | ☐ Ya / Yes | ☐ Tidak / No | |
| Rekod Pengilangan Kelompok induk dan / atau Rekod Pembungkusan Kelompok *Master Batch Manufacturing Record and / or Batch Packaging Record available?* | ☐ Ya / Yes | ☐ Tidak / No | |

| **PENGELUARAN** ***PRODUCTION*** | **Sila tandakan (Ya/Tidak)** ***Please Tick (Yes/No)*** | | **Catatan (jika perlu)** **Nota: Dokumen lanjut perlu tersedia semasa pemeriksaan** ***Remarks (if required)*** *Note: More documents should be available upon request during inspection* |
|---|---|---|---|
| Produk/bahan dilindungi daripada kontaminasi mikrobial dan lain-lain kontaminasi pada setiap langkah pemprosesan? *Product/materials protected from microbial and other contamination at all stage of processing?* | ☐ Ya / Yes | ☐ Tidak / No | |
| Semua bahan, bekas bahan pukal, peralatan pengilangan utama dan bilik berlabel / mempunyai identifikasi? *All materials, bulk containers, major items of equipment and rooms be labelled or identified?* | ☐ Ya / Yes | ☐ Tidak / No | |
| Pembekal yang diluluskan dikenal pasti? *Approved supplier program available?* | ☐ Ya / Yes | ☐ Tidak / No | |
| Kawalan ke atas bahan dan produk dikuarantin / ditolak / dipulangkan ada diwujudkan? *Control of quarantine / rejected / returned materials and products in place?* | ☐ Ya / Yes | ☐ Tidak / No | |
| Kawalan ke atas persekitaran di kawasan pengeluaran / penstoran dikenal pasti? *Environmental control in production / storage identified?* | ☐ Ya / Yes | ☐ Tidak / No | |
| Prosedur dan aktiviti pensampelan diwujudkan? *Sampling procedure / activities is considered?* | ☐ Ya / Yes | ☐ Tidak / No | |
| Tatacara pengendalian dan kawalan ke atas stok bahan / produk dikenal pasti? *Stock handling and stock control for material / products established?* | ☐ Ya / Yes | ☐ Tidak / No | |
| **KAWALAN KUALITI** ***QUALITY CONTROL*** | **Sila tandakan (Ya/Tidak)** ***Please Tick (Yes/No)*** | | **Catatan (jika perlu)** **Nota: Dokumen lanjut perlu tersedia semasa pemeriksaan** ***Remarks (if required)*** *Note: More documents should be available upon request during inspection* |
| Makmal dan peralatan bagi tujuan aktiviti kawalan kualiti disediakan? *Availability of laboratory and equipment for QC testing?* | ☐ Ya / Yes | ☐ Tidak / No | |
| Pengujian kawalan kualiti ke atas produk siap dikenal pasti? *QC testing for finished product has been identified?* | ☐ Ya / Yes | ☐ Tidak / No | |
| Kawasan penyimpanan bagi sampel retensi ditentukan? *Storage area for retention sample?* | ☐ Ya / Yes | ☐ Tidak / No | |
| **AKTIVITI PENGILANGAN DAN ANALISA SECARA KONTRAK** ***CONTRACT MANUFACTURING & ANALYSIS*** | **Sila tandakan (Ya/Tidak)** ***Please Tick (Yes/No)*** | | **Catatan (jika perlu)** **Nota: Dokumen lanjut perlu tersedia semasa pemeriksaan** ***Remarks (if required)*** *Note: More documents should be available upon request during inspection* |
| Aktiviti pengilangan secara kontrak dipertimbangkan? *Contract manufacturing is considered?* | ☐ Ya / Yes | ☐ Tidak / No | |
| Aktiviti pengujian analisa secara kontrak dipertimbangkan? *Contract testing is considered?* | ☐ Ya / Yes | ☐ Tidak / No | |
| **ADUAN DAN PANGGIL BALIK PRODUK** ***COMPLAINTS & PRODUCT RECALLS*** | **Sila tandakan (Ya/Tidak)** ***Please Tick (Yes/No)*** | | **Catatan (jika perlu)** **Nota: Dokumen lanjut perlu tersedia semasa pemeriksaan** ***Remarks (if required)*** *Note: More documents should be available upon request during inspection* |
| Prosedur disediakan? *Procedure available?* | ☐ Ya / Yes | ☐ Tidak / No | |
| Rekod berkaitan aduan dan panggil balik produk disediakan? *Record for complaints & product recall available?* | ☐ Ya / Yes | ☐ Tidak / No | |

| **PEMERIKSAAN DALAMAN** ***SELF-INSPECTION*** | **Sila tandakan (Ya/Tidak)** ***Please Tick (Yes/No)*** | | **Catatan (jika perlu)** **Nota: Dokumen lanjut perlu tersedia semasa pemeriksaan** ***Remarks (if required)*** *Note: More documents should be available upon request during inspection* |
|---|---|---|---|
| Prosedur disediakan? *Procedure available?* | ☐ Ya / Yes | ☐ Tidak / No | |

## C. PENGESAHAN *ATTESTATION*

- ✓ Saya memahami bahawa senarai semak di atas mengesahkan tahap ketersediaan syarikat pengilang untuk diperiksa dan bukan senarai lengkap berkaitan perkara yang akan disemak semasa pemeriksaan. *I hereby understand the checklist above is to declare the readiness of the manufacturing facility to be inspected and is a non-exhaustive list that will be covered during inspection.*
- ✓ Saya telah membaca dan memahami keperluan-keperluan yang dinyatakan dalam garisan panduan APB yang berkaitan dengan produk yang dikilangkan.
  *I have read and understand the requirement of relevant GMP guideline appropriate to my product*
- ✓ Saya memahami bahawa NPRA hanya akan menjalankan pemeriksaan sekiranya penilaian yang dilakukan mendapati pengilang dianggap sesuai untuk diperiksa.
  *I understand that NPRA will only conduct inspection after evaluation of the manufacturer is deemed fit for inspection*
- ✓ Saya memahami bahawa permohonan pemeriksaan berkemungkinan ditolak / ditarik semula / dihentikan mengikut budi bicara NPRA.
  *I understand that inspection application maybe rejected / withdrawn / terminated under sole discretion of NPRA*

| **TANDA TANGAN PEMOHON** ***SIGNATURE OF APPLICANT*** | **NAMA PEMOHON** ***NAME OF APPLICANT*** |
|---|---|
| | |

## D. UNTUK KEGUNAAN PEJABAT

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|---|---|---|---|---|---|
| Tarikh penerimaan permohonan dari Sistem QUEST : | | Tarikh penyerahan senarai semak pra-pemeriksaaan kepada pengilang (pengilang dikehendaki menyerahkan senarai semak yang dilengkapkan) : | | | |
| Tarikh lengkap senarai semak pra-pemeriksaan : | | Bil. hari bekerja penerimaan senarai semak lengkap dari tarikh terima permohonan: | ..... hari | Keputusan pemeriksaan dijalankan: | ☐Ya<br>☐Tidak diperiksa |
| Tarikh pemeriksaan dijadualkan (hanya setelah senarai semak yang lengkap didapati memuaskan): | | Nyatakan sebab pemeriksaan tidak dapat dijalankan : | | | |

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