National Pharmaceutical Regulatory Agency (NPRA)
Ministry of Health Malaysia

Lot 36, Jalan Prof Diraja Ungku Aziz, 46200 Petaling Jaya, Selangor.
Tel. No. : 03-78835400
Website : http://npra.gov.my

GUIDANCE DOCUMENT
FOREIGN GMP INSPECTION

10th Edition
November 2025

This guidance document is issued in accordance to Regulation 29, Control of Drugs and Cosmetics Regulations 1984.

NPRA Reserves the right to amend any part of the guidance document whichever it deems fit.

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1.0 INTRODUCTION

A company applying with the National Pharmaceutical Regulatory Agency (NPRA) for registration of a medicinal product in Malaysia must provide acceptable evidence to show that the manufacturer of the product follows an internationally accepted standard of Good Manufacturing Practice (GMP) and recognized by the authority in Malaysia.

The Control of Drugs and Cosmetics Regulations 1984 (CDCR) requires that the standard of manufacture and quality control of medicinal products manufactured outside Malaysia be taken into consideration before the products are registered with the authority namely Drug Control Authority (DCA). NPRA as the secretariat to the DCA is responsible for ensuring all manufacturers of registered products in Malaysia can provide acceptable evidence that the manufacturing premises conform to current GMP requirements. Hence, foreign manufacturers are also subjected to GMP conformity assessments through acceptable GMP evidence or GMP inspection.

Malaysia became the 26th member of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) since 1st January 2002. Hence, the current PIC/S Guide to GMP for Medicinal Products and its Annexes have been adopted as the standard used by NPRA to assess the GMP conformity of manufacturers.

2.0 DEFINITIONS/ABBREVIATIONS

CAPA	Corrective Action and Preventative Action
CDCR	Control of Drugs and Cosmetics Regulations 1984
DCA	Drug Control Authority
GDA	Good Manufacturing Practice Desktop Assessment
GMP	Good Manufacturing Practice
DiA	Good Manufacturing Practice Distant Assessment
RI	Remote Inspection
LIS	Listed Inspection Services under the ASEAN Sectoral Mutual Recognition Arrangement (MRA) on GMP Inspection of Manufacturers of Medicinal Products
MOH	Ministry of Health Malaysia
NDRA	National Drug Regulatory Agency

NPRA	National Pharmaceutical Regulatory Agency
PIC/S	Pharmaceutical Inspection Co-operation Scheme (Information on PIC/S Participating Authority can be accessed on the PIC/S website – www.picscheme.org)
PRH	Product Registration Holder
SMF	Site Master File
VMP	Validation Master Plan

3.0 OBJECTIVE

3.1 The objective of the foreign GMP inspection is to assess the conformance of foreign manufacturers to GMP requirements and ensure quality of products that are registered or in the process of registration/re-registration/change of manufacturing site with DCA of Malaysia and products manufactured for clinical trial purposes (investigational medicinal products). This activity is carried out with a view to strengthening the supervision and administration over imported products and foreign manufacturers as well as ensuring quality and safety of the imported products.

3.2 The purpose of this guidance is:

3.2.1 To provide information on the types of GMP evidence acceptable to the DCA of Malaysia.

3.2.2 To provide the requirements for an on-site inspection of manufacturing facility outside Malaysia where GMP evidence of the premise is not available or acceptable to the DCA of Malaysia.

3.2.3 To provide guidance on how to apply for an on-site foreign GMP inspection, the eligibility and application for GMP Desktop Assessment (GDA) for foreign manufacturers previously inspected by NPRA.

4.0 SCOPE

4.1 This guidance applies to all manufacturers of pharmaceutical products, which currently include products in the following categories: new drug products, biologics, generic products (scheduled and non-scheduled poisons), and sterile veterinary products located outside Malaysia.

5.0 ACCEPTABLE GMP EVIDENCE

5.1 One of the requirements to register an imported medicinal product in Malaysia is submission of acceptable documentary evidence of the GMP compliance of the manufacturer issued by a regulatory authority.

5.2 For pharmaceutical products, the requirements for GMP evidence submission are laid down in the following directives issued by the Director Pharmaceutical Services:

5.2.1 Bilangan 1 Tahun 2012 – Direktif Mengenai Syarat Pendaftaran Produk Farmaseutikal Dari Luar Negara Berkaitan Keperluan Amalan Perkilangan Baik (APB).

5.2.2 Bilangan 1 Tahun 2016 – Direktif Mengenai Keperluan Pemeriksaan Amalan Perkilangan Baik (APB) Luar Negara Bagi Tujuan Pendaftaran/ Pendaftaran Semula Produk Farmaseutikal Berdaftar dengan Pihak Berkuasa Kawalan Dadah (PBKD).

5.2.3 Bilangan 11 Tahun 2016 – Direktif Mengenai Penerimaan Pengesahan Pematuhan Amalan Perkilangan Baik (APB) Bagi Tujuan Pendaftaran Semula Produk Farmaseutikal Berdaftar dengan Pihak Berkuasa Kawalan Dadah (PBKD).

5.2.4 Bilangan 4 Tahun 2018 - Direktif Mengenai Penerimaan Pengesahan Pematuhan Amalan Perkilangan Baik (APB) Bagi Pengilang Farmaseutikal Bagi Tujuan Pendaftaran Baru/ Pendaftaran Semula Produk Farmaseutikal Berdaftar dengan Pihak Berkuasa Kawalan Dadah (PBKD).

5.2.5 Circular Letter Ref. No. NPRA-600-1/9/12 (7) dated 11 February 2021 - Pekeliling Berkenaan Pelaksanaan Prosedur Kerja Penilaian Desktop Bagi Aktiviti Pemeriksaan Amalan Perkilangan Baik (APB) Ke Atas Premis Pengilang Farmaseutikal Luar Negara.

(Directives accessible from NPRA website – http://npra.gov.my)

5.3 Based on the directives listed above, starting 1st of July 2018;

5.3.1 For pharmaceutical manufacturers **located on a site within jurisdiction of a PIC/S Participating Authority,** GMP evidence issued by the local NDRA is accepted.

5.3.2 For pharmaceutical manufacturers **located in an ASEAN member country**, GMP evidence issued by the local NDRA is accepted if the NDRA is included as a Listed Inspection Service under the ASEAN Sectoral Mutual Recognition Arrangement (MRA) for GMP Inspection of Manufacturers on Medicinal Products.

5.3.3 For pharmaceutical manufacturers **not located on a site within jurisdiction of a PIC/S Participating Authority**, GMP evidence issued by the following NDRA is accepted:

- any PIC/S Participating Authority
- any NDRA that has a cooperation agreement such as Mutual Recognition Agreement (MRA) with PIC/S.

5.4 As stipulated in Circular Letter Ref. No. NPRA-600-1/9/13 (31) Jld.1 dated 16 November 2023 - Arahan Pengarah Perkhidmatan Farmasi Bilangan 13 Tahun 2023, Direktif Berkenaan Pengemaskinian dan Pelaksanaan Guideline for Facilitated Registration Pathway (FRP), Revision 1, 2023, valid GMP Evidence issued by World Health Organization (WHO) may be deemed acceptable for WHO pre-qualified medicines/vaccines under the FRP mechanism, which is subject to further assessment by the Centre for Product and Cosmetic Evaluation, NPRA.

5.5 Apart from the GMP Evidence's issuing body, the documentary evidence provided must:

5.5.1 Have a validity period that is still current,

5.5.2 Provide the correct manufacturer's name and address of manufacturing site,

5.5.3 Specify the dosage form class OR the facility used to manufacture the dosage form was covered during the inspection.

5.6 The GMP evidence submitted shall be in the format of:

5.6.1 GMP Certificate

5.6.2 GMP Inspection Report

5.7 Where acceptable GMP evidence of the foreign manufacturer is not available or the documentation submitted is insufficient to demonstrate acceptable GMP standard, a GMP inspection shall be conducted by NPRA.

5.8 Submission of acceptable GMP evidence does not guarantee that GMP inspection will not be conducted by NPRA on the foreign manufacturer.

5.9 Foreign manufacturers who have been inspected by NPRA and have valid acceptable GMP status (3 years after the last inspection) may be eligible for GDA beginning in April 2021. This allows foreign manufacturers to extend their GMP status to facilitate the continuous regulatory process for new registration and renewal of medicinal products in Malaysia only. NPRA will not issue any GMP certificate for this purpose.

6.0 GENERAL REQUIREMENTS AND PROCEDURES FOR APPLICATION

APPLICATION FOR FOREIGN GMP INSPECTION

6.1 The application for a foreign GMP inspection should be made by a Malaysian registered company (PRH) acting on behalf of the foreign manufacturer.

6.2 The Malaysian registered company (PRH) shall authorize a responsible person (e.g. Chief Executive Officer, Managing Director or Regulatory Manager) to act as the liaison officer with NPRA for all arrangements pertaining to the proposed inspection.

6.3 The appointed liaison officer responsible for the application is required to submit the completed application form (N3-FR-11) with the processing fee of RM 5,000 and these documents:

6.3.1 A copy of Company/Business Registration Certificate (for PRH)

6.3.2 List of Building/Workshop/Line/Unit and dosage forms manufactured in each Building/Workshop/Line/Unit to be inspected.

6.3.3 Details of new products to be registered in Malaysia and/or existing registered products of renewal of product registration and/or existing registered products for change of manufacturing site

6.3.4 Site Master File

6.3.5 Validation Master File

6.3.6 Proposed flight route, including connecting flights (if any)

6.3.7 Hotel quotation [Name of hotel, hotel rate per night, hotel's official website, distance between hotel and manufacturing facility, accommodation during transits (if any)]

6.3.8 Entry requirements to the destination country for Malaysian citizens.

6.3.9 Declaration letter from Manufacturer stating that premises are ready to be inspected at any time.

6.3.10 Valid GMP Evidence (preferably GMP certificate/report issued by a PIC/S Participating Authority)

6.4 Any changes to the information on the application form must be notified in writing within one week of application submission.

6.5 If the application is successful, NPRA will write to the applicant and announce the proposed date, duration of inspection and estimated cost for inspection.

6.6 Prior to conducting the inspection, a meeting will be organized between the appointed GMP inspectors and the applicant for preparation of the inspection.

6.7 If the foreign manufacturer is also manufacturing registered products for other PRH, the applicant must ensure that all the other PRH are aware and understand that the outcome of the GMP inspection may affect the registration status of all the products manufactured at this facility.

6.8 Applicants must undertake the responsibility to ensure that application for new product / dosage form registration is submitted to Center for Product and Cosmetic Evaluation after submission of foreign GMP inspection application. Applicant must ensure that the application has been submitted for the screening process for new product / dosage form prior to inspection.

6.9 Screening for new product registration will only be accepted for evaluation if the applicant has provided proof of successful payment of the inspection fee of **RM 20,000.00**.

6.10 Failure to ensure the submission of product registration application prior to the inspection may result in cancellation of the application.

GOOD MANUFACTURING PRACTICE DESKTOP ASSESSMENT (GDA)

6.11 GDA is a process to extend the status of GMP for eligible foreign manufacturers, for the purpose of registration and/or registration renewal of medicinal products in Malaysia. The criteria for eligible applications are:

- Manufacturing sites inspected by NPRA previously with an acceptable GMP status for the same dosage form(s)
- Applicable for sterile and non-sterile facilities (excluding biopharmaceuticals)
- Application of N3-FR-11 is submitted at least 1 year before the expiry of GMP status (3 years after the last inspection date)

6.11 For every N3-FR-11 application received, NPRA will evaluate them for GDA eligibility. If eligible, PRH will be duly informed for further action. This is further explained in Process Flow for GMP Foreign Inspection (**Appendix 1**).

6.12 Currently, there are no additional processing fees imposed for eligible application. However, upon unsatisfactory GDA, the foreign manufacturers will be subjected to an on-site inspection. The scheduling of the inspection will be based on the date of complete N3-FR-11 application received by NPRA.

6.13 Upon satisfactory GDA, the GMP status validity will be extended for the next two years. For every on-site inspection, the foreign manufacturer may apply for GDA up to two times consecutively. For example, the last inspection conducted on 01/12/2017 will expire on 30/11/2020. With satisfactory GDA (first time), the GMP status will be extended to

30/11/2022. Then, PRH may apply for another GDA which will be due in 2021, in which a satisfactory GDA (second time) will be further extended to 30/11/2024. This process is further illustrated in **Appendix 2** of this document.

GMP DISTANT ASSESSMENT (DiA) - REMOTE INSPECTION (RI)

6.14 Starting from 1st of September 2021, Distant Assessment (DiA) which consists of Remote Inspection (RI) will commence whereby it will replace on-site foreign GMP inspection during the COVID-19 pandemic when border closure/travel restrictions are still in place.

6.15 On-site foreign GMP inspection will resume once COVID-19 pandemic has subsided.

6.16 This work process is only applicable to all foreign GMP inspection applications (N3-FR-11) pending for on-site inspection.

6.17 Foreign manufacturers eligible for GMP Desktop Assessment (GDA)are excluded from DiA as the GMP status of the manufacturer shall be confirmed following the completion of GDA.

6.18 Remote Inspection includes documentation review followed by virtual inspection in which:

- Documentation (e.g., filing commitments, site description, and key procedures) is requested by GMP inspector(s) for further evaluation. Requests and responses to questions are shared in written form (e.g., via email or on a document-sharing platform).

- In addition to sharing documentation, virtual inspection utilizes technologies such as live or real-time streaming video, screen-sharing, or other means of real-time communication. Virtual inspection may include virtual tour of aspects of the manufacturer, video communication and interview.

6.19 The payments involved with DiA work process include Processing Fee and Inspection Fee are as mentioned in para 6.23.1 & 6.23.2. Kindly note that both the fees are non-refundable under any circumstances.

6.20 For further information regarding Remote Inspection, kindly refer to Frequently Asked Questions (FAQs) on Foreign Good Manufacturing Practice (GMP) Inspections by NPRA during COVID-19 Pandemic through the following link: https://www.npra.gov.my.

TRANSPORTATION AND ACCOMMODATION

6.21 Travel arrangements include both ground travel and air travel. The applicant is expected to propose a suitable travel itinerary to NPRA (as reference) based on the following criteria:

- Preferred airline is Malaysian Airline (MAS).
- Flight is normally of the shortest distance from Kuala Lumpur to the point of destination and without transit. If transit is required due to unavailability of routes.
- The details of the transit destination and duration should be included.
- Flight class is Economy Class, with fare structure allowing for change of flight date and time without any penalty or charge.
- Arrangement of ground transportation (if any).

6.22 The information on accommodation will be required in the form of an official quotation or similar and satisfy the following criteria:

- Hotel details and room category as Standard Room.
- Reasonable distance between the hotel and the manufacturing facility (Please state the estimated duration to reach the manufacturing facility from the hotel).

PROCESSING FEE, INSPECTION FEE AND INSPECTION EXPENSES

6.23 The payment structure for foreign GMP inspection consists of three parts, in which all shall be borne by the applicant as follows:

6.24.1 Processing Fee (includes on-site, GDA & DiA):

- Payment of a processing fee of **RM 5,000.00** upon application.
- The processing fee is non-refundable.
- The payment shall be made using a bank draft / postal order. Alternatively, the payment can also be made directly at the Seksyen Kewangan, Akaun dan Hasil (SKAH) counter, NPRA via credit or debit cards.

6.24.2 Inspection Fee (only for on-site inspection & DiA):

- Payment of an inspection fee of **RM 20,000.00** upon issuance of invoice by NPRA.
- NPRA will issue an invoice to the company **once the inspection date is confirmed.**

- Payment of the inspection fee must be made at least **one (1) month before** the foreign inspection is conducted.

- The payment shall be made using a bank draft / postal order payable to:

  Name : BAHAGIAN REGULATORI FARMASI NEGARA, KEMENTERIAN KESIHATAN MALAYSIA

- Alternatively, the payment can also be made directly at the Seksyen Kewangan, Akaun dan Hasil (SKAH) counter, NPRA via credit or debit cards.

- The inspection fee is non-refundable under any circumstances.

6.24.3 Inspection Expenses (only for on-site inspection):

- The inspection expenses will cover all the expenses incurred to conduct the inspection. These include flight tickets, accommodation, and other associated expenses (such as allowances, insurance, etc.)

- The inspection expenses costing will be prepared by NPRA based on the eligibility of the inspectors as outlined in the Treasury Circular issued by the Malaysian Ministry of Finance.

- NPRA will calculate the inspection expenses using the information obtained from the applicant and inform the applicant accordingly.

- Payment for the inspection expenses shall be in the form of contribution to a trust fund established under the Malaysian Ministry of Health (MOH) namely *Akaun Amanah Penilaian, Pengiktirafan Akreditasi dan Pemeriksaan APB* (Main Code: 886341, Sub Code: 4001) through a **banker's check** made payable to:

  Name : KETUA SETIAUSAHA KEMENTERIAN KESIHATAN MALAYSIA

  Account No : 21401360003459

- In the event where foreign GMP inspection was conducted, remainder of the inspection expenses will be retained in the trust fund for future purposes as outlined in the *Arahan Amanah Penilaian, Pengiktirafan Akreditasi dan Pemeriksaan APB*.

- The inspection expenses will be refunded in the event where foreign GMP inspection cannot be conducted.

OUTCOME OF INSPECTION

6.25 The outcome of the GMP inspection will be tabled to the *Jawatankuasa Penilaian Pemeriksaan Premis dan Kajian (JKPPPK)* [Committee for the Evaluation of Premises and Research Inspection (CEPRI)].

6.26 The GMP inspection report will be issued to manufacturers through applicant e.g. PRH for on-site inspection and DiA in which the type of inspection conducted will be clearly mentioned. Meanwhile, for GDA, an official letter with the outcome of GDA will be issued.

6.27 For the on-site inspection and DiA, manufacturers may be required to submit a Corrective Action and Preventative Action (CAPA) report to NPRA for the non-compliances reported during the inspection within the time frame specified in the GMP report cover letter. The CAPA report will be presented to the JKPPPK meeting for further consideration.

6.28 GMP compliance status will only be concluded as acceptable when the actions outlined in the CAPA are considered satisfactory in addressing the non-compliances and the time frame needed to close all CAPA is not more than 6 months from the date of the inspection report issuance. If more than 6 months is required, the GMP compliance status will be concluded to be unacceptable. (Refer to **Appendix 4** for the CAPA summary report)

6.29 After the GMP compliance status is concluded as acceptable, the applicant may apply for a GMP certificate for the foreign manufacturer. The certificate shall be used administratively for product registration/re-registration/change of manufacturing site purposes with NPRA. This, however, is not applicable for GDA, whereby there will be no GMP certificate issued upon satisfactory GDA.

6.30 GMP certificate issued shall clearly specify the type of inspection (either on-site or RI inspection). The GMP validity for on-site inspection is 3 years and RI is 2 years.

6.31 For inspection whose GMP compliance is concluded as unacceptable, the manufacturer is not required to submit a CAPA report as there will be no further consideration or appeal for the GMP compliance status of the manufacturer. Applicant is required to submit a new application for NPRA to conduct another inspection on the manufacturing facility.

7.0 REJECTION, TERMINATION OR WITHDRAWAL OF APPLICATION

REJECTION

7.1 NPRA has the right to reject an incomplete application, for example an application without supporting documents as mentioned in para 6.3 above.

TERMINATION

7.2 The application shall be terminated if payment of inspection fee is not made at least **1 (one) month before** the foreign inspection is conducted.

7.3 The estimated date of the inspection will be proposed by NPRA during the evaluation stage, upon receipt of a completed application form (N3-FR-11). The applicant and foreign manufacturer are responsible for making sure the premises are fully prepared and not under renovation or any other condition that may affect the GMP inspection conducted.

7.4 The applicant shall submit in writing, explaining the reason, to NPRA if there is a reason for postponing the inspection after the date of inspection has been confirmed.

7.5 NPRA has the authority to terminate the application if the applicant is not able to comply with the proposed date due to unavailability or unpreparedness of facility. Failure to commit to the inspection after the confirmed inspection date will result in application rejection and the processing fee is not refundable.

7.6 An application may also be terminated if it fails to fulfil the requirement outlined in para 6.8.

7.7 Application which has been terminated or rejected will go through the submission process once again as stated in para 6.0.

7.8 The applicant shall notify NPRA regarding withdrawal of application or any other changes in writing.

7.9 In cases where the application is withdrawn/terminated/rejected after payment for the inspection expenses has been made to the trust fund, applicant my request for a refund. Request for a refund can be made through an official letter to Center for Compliance and Quality Control together with proof of payment (payment receipt) as well bank account details. Applicants are advised to request for a refund within thirty (30) days of withdrawal.

7.10 The applicant is solely responsible for ensuring all documents are complete during submission for GDA. In the event of incomplete, missing documentation or unable to provide requested document within specific timeline, the GDA process may be terminated, leading to a decision to conduct on-site inspection.

8.0 GENERAL ADDITIONAL INFORMATION

8.1 The GMP inspection is subject to final approval by the Ministry of Health Malaysia.

8.2 The applicant shall arrange for adequate number of translators to be present during the on-site inspection, at the company's cost, if English or Bahasa Malaysia is not the language used in communication and documentation by the foreign manufacturer.

8.3 The applicant shall assign an individual from the PRH to accompany the GMP inspectors during the whole duration of the inspection.

8.4 The manufacturer must ensure that any translated version of the documentation that is provided to the GMP Inspector during the inspection is clear, legible, accurate and in an official manner in line with the manufacturer's documentation system.

8.5 The manufacturer shall operate and run production activities as usual during the inspection.

8.6 The number of inspectors appointed, and duration of inspection will be decided by NPRA depending on the nature of the products, size of premise and scope of inspection. In most circumstances, the minimum number of inspectors is three (3) and for a minimum duration of three (3) days.

8.7 Inspections are limited to one inspection per site for either sterile or non-sterile facilities. Inspections of multiple sites or to both sterile and non-sterile or to both biologics [drug product (DP) and drug substance (DS)] facilities will require separate applications.

8.8 NPRA adopts the PIC/S Guide to GMP for Medicinal Products and its annexes for the GMP inspection.

8.9 NPRA reserves the right to invalidate the GMP certificate issued to the manufacturer when evidence exists (such as product complaints, serious adverse events, etc.) or have reason to believe that the manufacturer is not complying with the GMP guidelines/requirements.

8.10 The same GMP certificate or GDA satisfactory status may be used by the same applicant for other product registration applications if the scope of manufacture is the same, provided the validity date of the GMP certificate or GDA is still current.

8.11 An acceptable GMP compliance of a manufacturer does not guarantee the manufactured product will be approved for registration in Malaysia.

8.12 Inquiries relating to foreign GMP inspection may be directed to the following contact:

Center for Compliance and Quality Control
National Pharmaceutical Regulatory Agency
Ministry of Health Malaysia
Lot 36, Jalan Profesor Diraja Ungku Aziz,
46200 Petaling Jaya, Selangor.

Tel : (60)-378835400

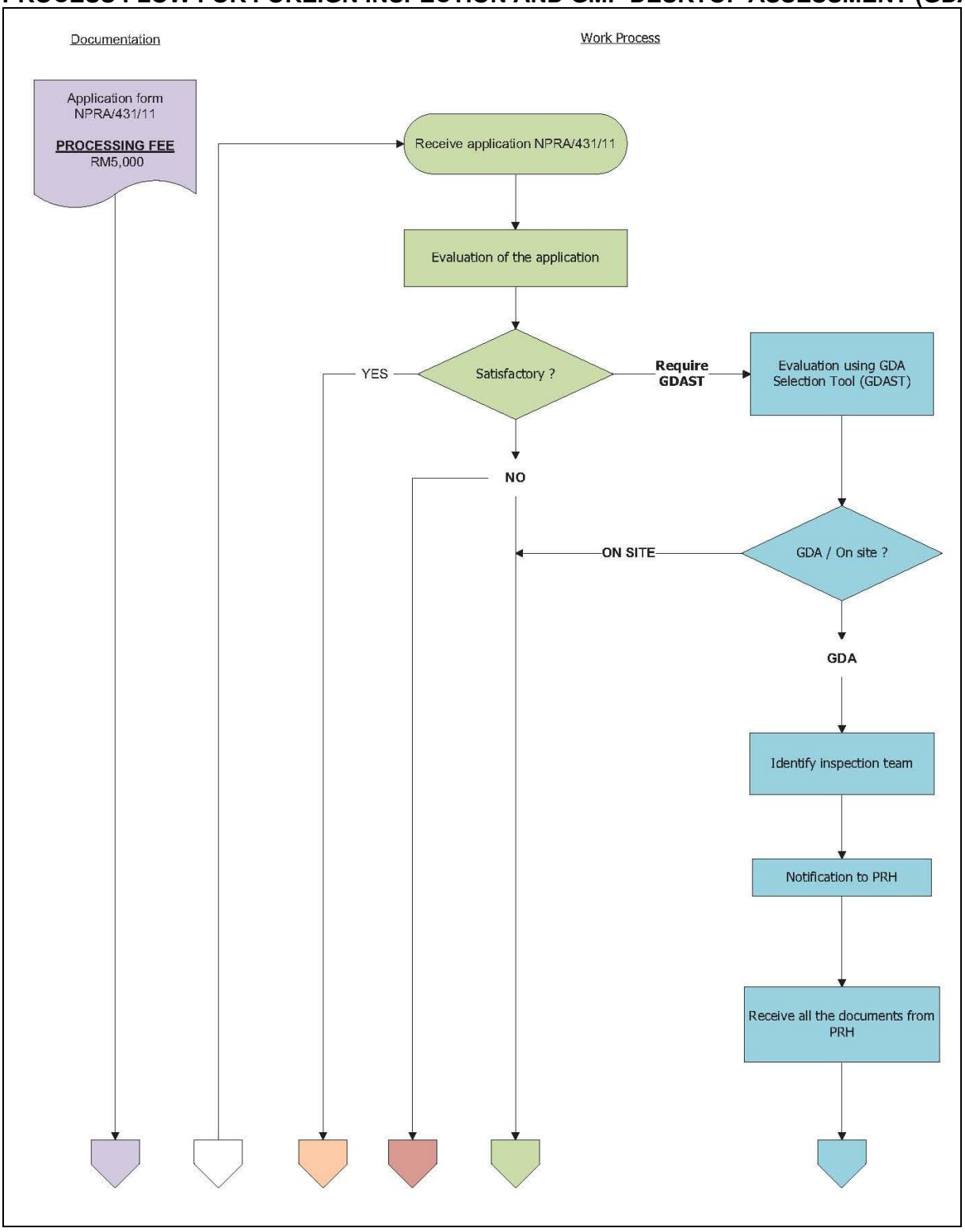
9.0 FORM

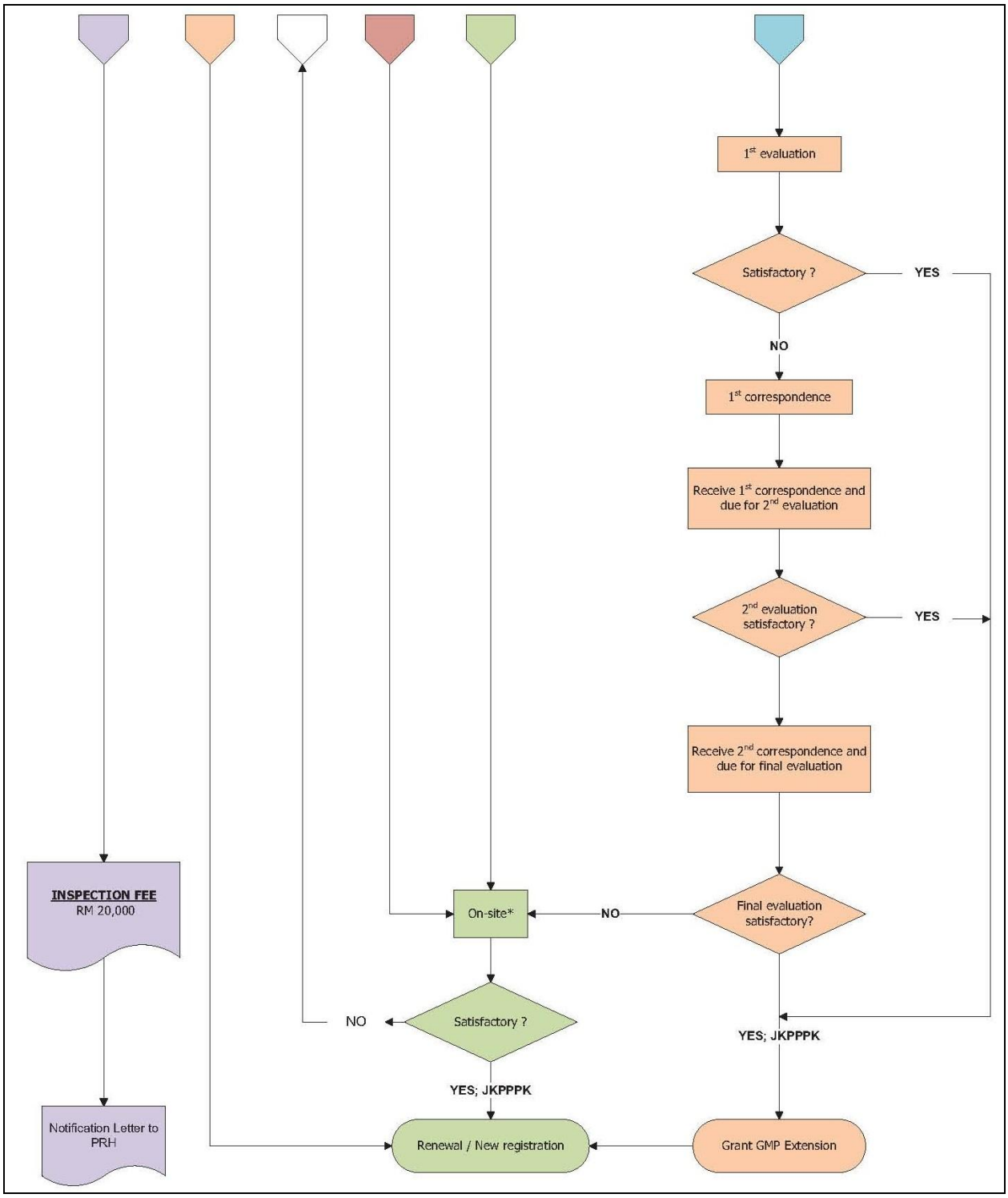
N3-FR-11 - Foreign GMP Inspection Application Form *(downloadable via NPRA website – http://npra.gov.my.)*

10.0 END OF DOCUMENT

APPENDIX 1

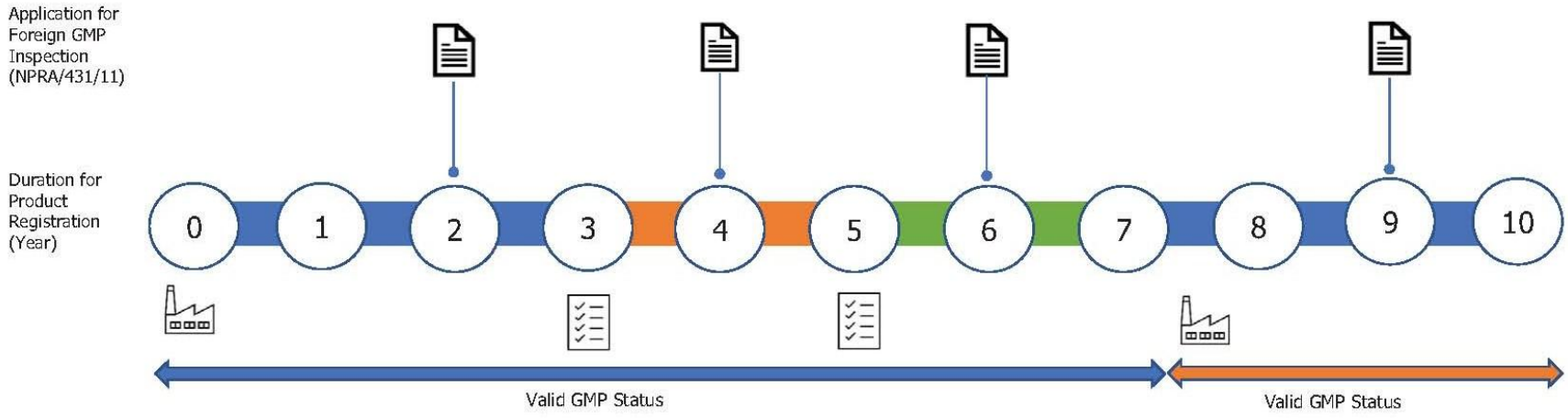
PROCESS FLOW FOR FOREIGN INSPECTION AND GMP DESKTOP ASSESSMENT (GDA)




1st evaluation
Satisfactory ?
YES
NO
1st correspondence
Receive 1st correspondence and due for 2nd evaluation
2nd evaluation satisfactory ?
YES
Receive 2nd correspondence and due for final evaluation
INSPECTION FEE
RM 20,000
On-site*
NO
Final evaluation satisfactory?
NO
Satisfactory ?
YES; JKPPPK
YES; JKPPPK
Notification Letter to PRH
Renewal / New registration
Grant GMP Extension

APPENDIX 2

ILLUSTRATION OF GDA EXTENSION (3 CASES)

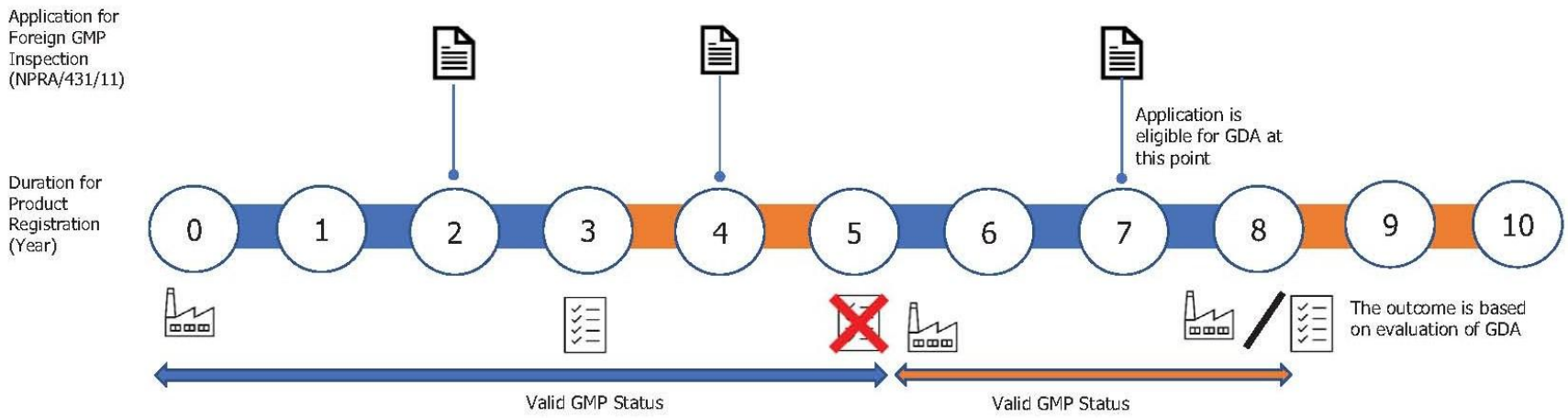


Case 1: Satisfactory GDA status based on application in the 2nd and 4th year of the product registration period

LEGEND:

Application NPRA 431/11 | On-site Inspection | GDA Approval

NOTE: A 2-year extension of GMP validity period will be granted for each satisfactory GDA assessment where a site inspection needs to be conducted after the second GMP validity period extension is granted.

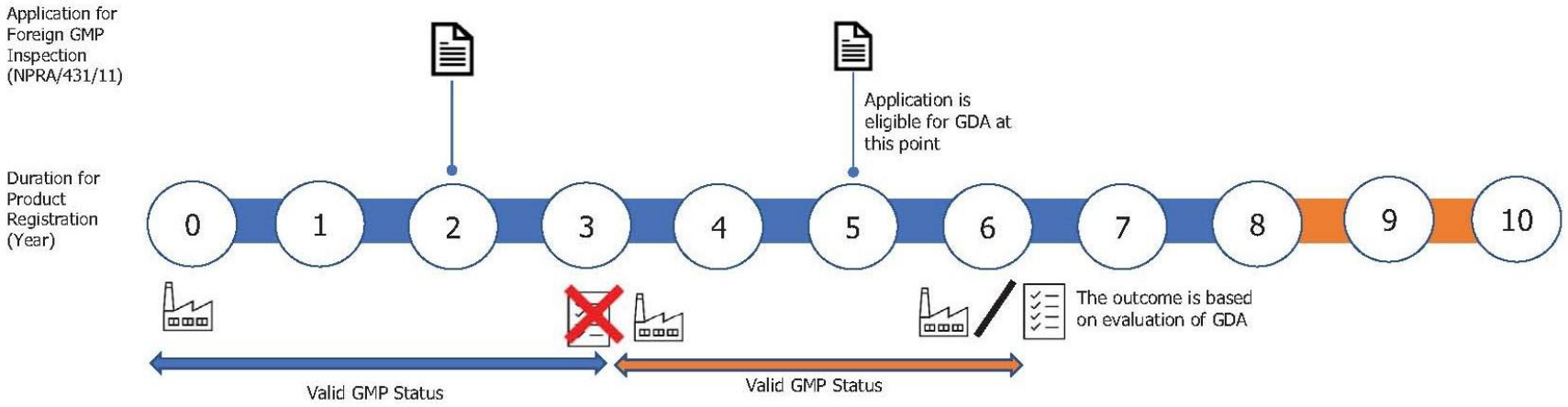


Case 2: GDA status is satisfactory based on application in Year 2. However, the status is unsatisfactory in Year 4 during the tenure of product registration.

LEGEND:

Application NPRA 431/11 | On-site Inspection | GDA Approval

NOTE: A site inspection must be carried out if the GDA assessment is not satisfactory following the application in the 4th year.



Case 3: GDA status is not satisfactory based on the application in the 2nd year of the product registration period

LEGEND:

Application NPRA/431/11 On-site Inspection GDA Approval

NOTE: A site inspection must be carried out if the GDA assessment is not satisfactory following the application in the 2nd year.

APPENDIX 3

Description for Pre-Assessment of GDA

No.	GDA Parameters of Pre-assessment	Categories	Description
1.	Number of employees.	• more than 150 employees • 50 – 150 employees • less than 50 employees	The total number of manufacturing personnel (permanent) – including QA, QC and Warehouse.
2.	The maximum number of different processes from manufacturing to distribution processes that are in use at the site	• More than 7 processes • 4 – 6 processes • 1 – 3 processes	The maximum total number of manufacturing up to distribution processes for different dosage forms (number of dosage forms). Larger numbers generally give rise to more complexity.
3.	The level of dedication of equipment and facilities that is in place at the site (e.g.: No dedication, partial dedication, full dedication).	• No dedication • Partial dedication • Full dedication	Dedication of facility for different dosage forms / categories of products. *No dedication indicates all manufacturing processes using the same equipment and utilities. Example: manufacturing of general products.* *Whereas, full dedication may indicate different equipment and utilities are used to manufacture different categories of products, such as soft gel that is sensitive to humidity.* *Campaign manufacturing considered partial dedication. Other than that, for a manufacturing site consists of a totally dedicated block for Penicillin / Cephalosporin and another block that manufactures steroid by campaign, it is considered partial dedication.* *Hence, manufacturing blocks with less dedicated areas will take precedence over the total dedicated area.*
4.	Involvement of Real Time Release Testing (RTRT)	• Real Time Release Testing (RTRT) activities • No Real Time Release Testing (RTRT) activities	Any Real Time Release Testing (RTRT) is practiced by the manufacturer. Kindly refer to the latest Annex 17 PIC/S GMP Guide.
5.	Complexity of products manufactured	• Complex product type (low concentration / high	Complex products are being manufactured such as *highly potent products that may require special*

No.	GDA Parameters of Pre-assessment	Categories	Description
		potency, sustained release, biological) • Normal product • Repacking only	*manufacturing / storage requirements.*
6.	The maximum number of unit operations in a non-sterile manufacturing process (e.g.: dispensing, mixing, granulate, drying, coating, blister, packing, testing, IPQC)	• More than 6 processes • 4 – 5 processes • Less than 3 processes	The total number of each process within the manufacturing process for the intended product *Example: Dispensing – Blending – Milling – Drying – Tableting – Coating – Blistering is considered as 7 units of operation for manufacturing processes.*
7.	Involvement of repackaging activities (e.g.: primary, secondary).	• Packing of products for clinical trials, primary repack • Secondary repack • No repack activities	For the intended product
8.	Engagement of sub-contract activities (e.g.: contract lab, transport). *Can tick more than one*	• Subcontracting of processes / stages of manufacturing, primary packaging and QC • Subcontracting services: contract lab, transport etc. • No subcontracting	
9.	The maximum number of components in a product include final pack (e.g.: vial, diluent, syringe, leaflet).	• More than 4 components • 2 – 3 components • 1 component (primary packaging)	For the intended product. For example, a pack of a tablet product may have a blister strip and a patient information leaflet within it which is considered 2 components.
10.	Any product with specific storage requirement. *Can tick more than one*	• Cold chain, shorter shelf life • Specified storage requirement • No specific storage requirement	

APPENDIX 4

Ringkasan Penilaian Tindakan Pembetulan dan Pencegahan (CAPA) / CAPA Summary Report

NPRA	PEMERIKSAAN AMALAN PERKILANGAN BAIK LUAR NEGARA
	RINGKASAN PENILAIAN TINDAKAN PEMBETULAN DAN PENCEGAHAN (CAPA)

Nama Syarikat *Name of Company*	
Alamat *Address*	
Alamat Stor (sekiranya berkenaan) *Warehouse Address (if applicable)*	
Nombor laporan *Report reference number*	
Pemeriksa *Inspectors*	
Tarikh Pemeriksaan *Date of Inspection*	
Tarikh Penutupan CAPA *Date of CAPA Closure*	

Ringkasan Penemuan:
Summary of Findings:

Bil. *No.*	**Bil. Penemuan Pemeriksaan** *No. of Findings*	**Bil. Penemuan yang Belum Selesai selepas penilaian CAPA 1** *No. of Incompleted Findings after review of first CAPA*	**Bil. Penemuan yang Belum Selesai selepas penilaian CAPA 2** *No. of Incompleted Findings after review of second CAPA*	**Bil. Penemuan yang Belum Selesai selepas penilaian CAPA 3** *No. of Incompleted Findings after review of third CAPA*
Kritikal *Critical*				
Major *Major*				
Minor *Minor*				
Tarikh CAPA diterima *Date CAPA received*				
Tarikh CAPA Disemak *Date CAPA reviewed*				

Nota:

(i) Berdasarkan Prosedur Kualiti: Pemeriksaan Amalan Pengilangan Baik (No. Dokumen: N3-PK-39):
   a. Status pematuhan APB hanya akan disimpulkan sebagai 'Memenuhi Keperluan APB' untuk pengilang luar negara apabila tindakan yang dinyatakan dalam CAPA dianggap memuaskan dalam menangani ketidakpatuhan dan jangka masa yang diperlukan untuk menyelesaikan semua CAPA tidak melebihi enam (6) bulan dari tarikh pengeluaran laporan pemeriksaan.

b. Bagi memastikan penilaian pematuhan dilakukan ke atas pengilang luar negara dalam tempoh yang bersesuaian, Pemegang Pendaftaran Produk perlu diingatkan oleh pemeriksa untuk menghantar laporan CAPA sekurang-kurangnya lima (5) hari sebelum tarikh akhir penghantaran laporan CAPA.

(ii) Status penutupan CAPA akan dikemaskini dari semasa ke semasa dalam Mesyuarat PREMTEK dan JKPPPPK.

Note:

(i) Based on Quality Procedure: Inspection of Good Manufacturing Practices (Document No.: N3-PK-39):

a. GMP compliance status will only be concluded as Acceptable for overseas manufacturers when the actions specified in the CAPA are considered satisfactory in dealing with non-compliances and the time required to complete all CAPAs does not exceed six (6) months from the date of the inspection report.

b. In order to ensure the compliance of the overseas manufacturers are completed within a stipulated period, the Product Registration Holder will be reminded by the inspector to send the CAPA report at least five (5) days before the deadline for sending the CAPA report.

(ii) CAPA closure status will be updated from time to time in PREMTEK and JKPPPPK Meetings.

NPRA	PEMERIKSAAN AMALAN PERKILANGAN BAIK LUAR NEGARA
	RINGKASAN PENILAIAN TINDAKAN PEMBETULAN DAN PENCEGAHAN (CAPA)

No. Penemuan *No. of Findings*	**Tindakan CAPA (Sila kemukakan dokumen sokongan)** *Corrective Action and Preventive Action Taken (please provide supporting documents)*	**Maklum Balas Pemeriksa** *Inspectors Comments*
1.1	**CA1:** Rujukan dokumen sokongan: (sila sertakan pautan/ *softcopy*) *Reference of supporting documents: (please provide a link or softcopy attachment)* **Jangka Masa Tindakan Pembetulan Selesai**: *Time taken to complete Corrective Action:* **PA1:**	**Status: Selesai/ Belum Selesai (Nyatakan dokumen tambahan yang perlu diminta)** *Status: Completed/ Not Completed (State additional supporting documents to be requested)*
1.1	**CA2:** **Jangka Masa Tindakan Pembetulan Selesai**: *Time taken to complete Corrective Action:* **PA2:**	**Status: Selesai/ Belum Selesai (Nyatakan dokumen tambahan yang perlu diminta)** *Status: Completed/ Not Completed (State additional supporting documents to be requested)*
1.2	**CA1:** **Jangka Masa Tindakan Pembetulan Selesai**: *Time taken to complete Corrective Action:* **PA1:**	**Status: Selesai/ Belum Selesai (Nyatakan dokumen tambahan yang perlu diminta)** *Status: Completed/ Not Completed (State additional supporting documents to be requested)*
Untuk diisi oleh Pegawai Pemeriksa *To be filled by the Inspector*		
Perkara yang Perlu Disemak dalam Pemeriksaan Akan Datang: *Scope to be reviewed in the next inspection:*		
Kesimpulan: *Conclusion:*		
Tandatangan Ketua Pemeriksa: *Signature of Lead Inspector:*		

REVIEW HISTORY

VERSION	REVIEW DATE	DESCRIPTION OF REVIEW
7	25/01/2021	1. Include the Review History 2. Update term 'Center for Compliance and Licensing' to 'Center for Compliance and Quality Control' 3. Update term 'Center for Product Registration' to 'Center for Product and Cosmetic Evaluation' 4. Update NPRA address to Lot 36, Jalan Profesor Diraja Ungku Aziz 5. Update telephone number to 03-7883 5400 6. Include term 'GDA - Good Manufacturing Practice Dekstop Assessment' 7. Revise para 3.2.3 to add '…the eligibility and application for GMP Desktop Assessment (GDA) for foreign manufacturers previously inspected by NPRA.' 8. Include new circular under para 5.2 – Circular Letter Ref No. NPRA-600-1/9/12 (7) dated 11 February 2021 – Pekeliling Berkenaan Pelaksanaan Prosedur Kerja Penilaian Desktop Bagi Aktiviti Pemeriksaan Amalan Perkilangan Baik (APB) Ke Atas Premis Pengilang Farmaseutikal Luar Negara. 9. Additional para 5.8, 6.8, 6.10, 6.11, 6.12, 6.13, 6.17, 6.18. 10. Revise para 6.21 to add '…This, however, is not applicable for GDA, whereby there will be no GMP certificate issued upon satisfactory GDA.
8	17/08/2021	1. Removal of fax number from cover page. 2. Alignment adjustment throughout the document. 3. Update Table of Contents under item 6 with 'Good Manufacturing Practice Distant Assessment (DiA)'. 4. Include terms 'DiA - Good Manufacturing Practice Distant Assessment' and 'RI - Remote Inspection' under 2.0 Definitions/Abbreviations. 5. Addition of para 6.14 – 6.20. 6. Revise para 6.23.1 from 'includes GDA' to 'includes on-site, GDA & DiA'. 7. Revise para 6.23.2 from 'only for on-site inspection' to 'only for on-site inspection & DiA'. 8. Revise para 6.25 and 6.26 to add in 'and RI'. 9. Addition of para 6.29.
9	20/02/2023	1. Revise para 6.17 from 'BPFK-501' to 'N3-FR-11'.

VERSION	REVIEW DATE	DESCRIPTION OF REVIEW
		2. Revise para 6.3 from 'BPFK-501' to 'N3-FR-11' and amend list of supporting documents. 3. Revise para 6.11 to 6.13 from 'BPFK-501' to 'N3-FR-11'. 4. Revise para 6.8 to 'Applicant must ensure that the application has been submitted for the screening process for new product / dosage form prior to inspection.' 5. Added para 6.9 to 'Screening for new product registration will only be accepted for evaluation if the applicant has provided proof of successful payment of the inspection fee of RM20,000.00.' 6. Revise para 7.3 from 'BPFK-501' to 'N3-FR-11'. 7. Change the application form number under item 9.0 Forms from 'BPFK-501' to 'N3-FR-11'. 8. Revise Appendix 1 and Appendix 2 from 'BPFK-501' to 'N3-FR-11'. 9. Revise Para 4.1 to 'This guidance applies to all manufacturers of pharmaceutical products, which currently include products in the following categories: new drug products, biologics, generic products (scheduled and non-scheduled poisons), and sterile veterinary products located outside Malaysia.'
10	28/11/2025	1. Change 'BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN' to 'BAHAGIAN REGULATORI FARMASI NEGARA' in Para 6.24.2. 2. Addition of Para 5.4.