National Pharmaceutical Regulatory Agency (NPRA)
Lot 36, Jalan Universiti
46200 Petaling Jaya, Selangor
Tel. No.: 03-78835400
Fax No.: 03-79571200
Website: http://npra.gov.my

GUIDANCE DOCUMENT

ON VERIFICATION OF

TRANSLATED

OFFICIAL DOCUMENT

JANUARY 2019

CENTRE FOR COMPLIANCE AND LICENSING
NATIONAL PHARMACEUTICAL REGULATORY AGENCY

TABLE OF CONTENT

INTRODUCTION:

Official documents issued by National Pharmaceutical Regulatory Agency (NPRA) are usually in national language (ie Malay language). However, to allow sharing of information such official documents may require translation and verification.

This guidance note is intended for use as a reference for foreign and local manufacturer that intends to submit a translated official document to Centre for Compliance and Licensing (CCL), NPRA for verification and endorsement.

OBJECTIVE

1. To provide guidance for the submission of translated official documents which are related to CCL for verification and endorsement.

2. To provide additional service to the industry for industrial development.

3. To avoid request not for official use by National Regulatory Authority (NRA) of importing countries.

SCOPE OF VERIFICATION:

1. Translated Good Manufacturing Practice (GMP) inspection report.

2. Translated relevant official letter issued by the CCL, NPRA.

GENERAL REQUIREMENTS:

1. CCL only accepts translations performed by an authorized / professional translator or translation body for the source of language (i.e Malay language) into English. The translator can also be those who are appointed / certified by the foreign embassy / high commissioner to Malaysia.

2. The following translation bodies which are recognized by CCL are as follows:

    i. The Institute of Language and Literature (Dewan Bahasa dan Pustaka)

    ii. Malaysian Institute of Translation and Books (Institut Terjemahan dan Buku Malaysia).

    iii. Malaysian Translators Association (Persatuan Penterjemah Malaysia)

3. CCL has the right to reject translations, which are deemed unacceptable (such as online translations, excessive grammatical and/or spelling errors, report misalignments, etc.).

4. Request for any translated document should be accompanied by an official letter / document by the applicant and/or country's regulator who is requesting such translation.

5. Applicant is required to submit their application via Borang Permohonan Verifikasi Terjemahan Dokumen Rasmi (BPFK-505) as attached in **Annex 1**.

6. The example of a translated GMP inspection report cover letter is as per **Annex 2**.

7. Please include a statement at the end of the translated document as part of each translation; Refer to **Annex 3**.

   '*I have examined the original document in the original language and verify that this is an accurate English translation of the original*' and will include;

   a. The date of translation
   b. Their signature and name
   c. Their professional title
   d. The accreditation details (such as registration number, if any)
   e. The official stamp or seal of the translator's accreditation organization
   f. Contact details

SUBMISSION OF APPLICATION

Each application should submit the following by hardcopy:

1. Borang Permohonan Verifikasi Terjemahan Dokumen Rasmi (BPFK-505)

2. Translation Acknowledgement

3. Translated document for verification and endorsement:
   a. Hard copy
   b. Soft copy in Compact Disc (CD) or dedicated USB Flashdrive (Both will not be returned).
   c. Font & Size : As per original document
   d. Compatible with Microsoft Word 97 – 2003 format

e. Accompanied with an official cover letter from the applicant and/or country's regulator who is requesting such translation.

Application can be submitted to:

Deputy Director
Centre for Compliance and Licensing
National Pharmaceutical Regulatory Agency (NPRA)
Lot 36, Jalan Universiti
46200 Petaling Jaya
Selangor.

ENQUIRIES

For further enquiries, kindly contact:

i. CCL Officer On Duty : 03-78018445 (gmp@npra.gov.my)
ii. En. Mohd Nasrul Mohamad Noor: 03-78018430 (nasrul@npra.gov.my)
iii. Pn. Alyaa Ismail: 03-78018432 (alyaa.ismail@npra.gov.my)

ANNEX 1

BPFK-505
v01.2019

Bahagian Regulatori Farmasi Negara
National Pharmaceutical Regulatory Agency (NPRA)
Lot 36, Jalan Universiti
46200 Petaling Jaya,
Selangor.

No. Tel. *Tel. No.* : 03-78835400
No. Faks. *Fax No.* : 03-79571200

Laman Web *Website* : http://npra.gov.my

Untuk Kegunaan PKP Sahaja
For CCL Use Only

Tarikh Diterima
Date Received

No. Rujukan Permohonan:
Application Reference No.:

BORANG PERMOHONAN VERIFIKASI TERJEMAHAN DOKUMEN RASMI

APPLICATION FOR THE VERIFICATION OF TRANSLATED OFFICIAL DOCUMENTS

ARAHAN *INSTRUCTIONS*

1. Sila isikan borang permohonan ini dalam 2 salinan: salinan asal (kegunaan pejabat) dan salinan pemohon.
   Please fill in this application form in 2 copies: original copy and applicant copy.
2. Sila tanda (✓) pada kotak yang berkenaan.
   Please tick (✓) the appropriate boxes.
3. Borang permohonan yang telah lengkap diisi hendaklah dikemukakan ke:
   The completed application form should be submitted to:

   Timbalan Pengarah
   Pusat Komplians dan Pelesenan
   Bahagian Regulatori Farmasi Negara
   Lot 36, Jalan Universiti
   46200 Petaling Jaya
   Selangor.

Nota:
a. Hanya borang permohonan yang lengkap diisi akan diproses oleh **Pusat Komplians dan Pelesenan, NPRA.**
Note:
a. *Only completed application form with confirmed payment will be processed by* ***Centre for Compliance and Licensing, NPRA.***

Pengesahan Permohonan (kegunaan pejabat sahaja) ***Application Verification (for office use only)***	
Status Permohonan *Application Status*	☐ **Lengkap** *Completed* ☐ **Tidak Lengkap** *Not Completed*
Nama Pegawai Bertugas *Name of Officer-on-duty*	
Tandatangan Pegawai Bertugas *Signature of Officer-on-duty*	
Tarikh Permohonan Lengkap *Application Completed Date*	

Lampiran : SENARAI SEMAK PERMOHONAN*Attachment:Application Checklist*	
Sila lengkapkan senarai semak permohonan. *Please complete the application checklist*	**Sila tanda (√)** *Please Tick (√)*
1) Bahagian I, II dan III telah lengkap diisikan dengan sewajarnya. *Part I, II and III were filled in properly*	☐
2) Dokumen-dokumen yang perlu dilampirkan adalah seperti yang berikut: *Documents to be attached are as below:*	
a) Salinan dokumen yang telah diterjemahkan untuk tujuan verifikasi (hardcopy) *A copy of the translated document to be verified (hardcopy)*	☐
b) Salinan dokumen yang telah diterjemahkan untuk tujuan verifikasi (softcopy) *A copy of the translated document to be verified (softcopy)*	☐
c) Surat iringan permohonan verifikasi penterjemahan *Cover letter for application for translation verification*	☐
d) Annex 3 – Pengesahan penterjemahan *Annex 3 – Translation Acknowledgement*	☐

Permohonan tidak dipertimbangkan sebagai permohonan lengkap sekiranya lampiran-lampiran yang berkaitan tidak dilampirkan dengan sewajarnya. *Application will not be considered as completed application if the relevant attachments are not submitted properly.*

BAHAGIAN I : BUTIR-BUTIR PEMOHON & SYARIKAT *PART I : DETAILS OF APPLICANT & COMPANY*			
Nama Pemohon *Applicant Name*			
No. Kad Pengenalan *I.C. No.*			
Jantina *Gender*	☐ Lelaki *Male*	☐ Perempuan *Female*	
Jawatan *Position*			
Nama syarikat *Company's Name*			
Telefon (Pejabat) *Telephone (Office)*		**Telefon bimbit** *Handphone*	
Faksimili *Fax*		**Emel** *Email*	
Alamat premis perniagaan/premis pengilangan *Address of business premise/manufacturing premise*			
Alamat surat menyurat [Jika berlainan daripada alamat di atas] *Correspondence address* [*If different from the address above*]			

BAHAGIAN II : BUTIR-BUTIR PERMOHONAN *PART II:DETAILS OF APPLICATION*		
Skop verifikasi *Verification scope*	☐ Surat rasmi *Official letters* ☐ Surat iringan laporan pemeriksaan *Cover letter for inspection report* ☐ Lain-lain *Others*	☐ Laporan pemeriksaan Amalan Perkilangan Baik (APB) *Good Manufacturing Practice (GMP) Inspection Report*
Tujuan verifikasi *Reason for verification*	☐ Keperluan daripada pihak berkuasa regulatori luar negara (Sila kepilkan surat daripada pihak regulatori luar negara tersebut) *Request from foreign regulatory authority (Please attach request letter from foreign regulatory authority)* Sila nyatakan *Please specify :* _____ _____	☐ Lain- lain *Others* Sila nyatakan *Please specify :* _____ _____

BAHAGIAN III : PENGESAHAN (SYARIKAT/PERTUBUHAN) *SECTION III: CERTIFICATION (COMPANY/ESTABLISHMENT)*	
Saya mengesahkan dan bersetuju bahawa ***I confirmed and agreed that*** i) Pemohon adalah seorang *kakitangan/pemilik di syarikat yang tersebut di atas. *The applicant is an *employee/owner of the above-mentioned company.* ii) Pihak syarikat hendaklah sentiasa bersedia untuk memberi kerjasama dalam mengemukakan maklumat tambahan yang diperlukan dari semasa ke semasa bagi tujuan penilaian. Sekiranya tiada sebarang maklum balas diterima daripada pihak syarikat dalam tempoh masa yang ditetapkan, permohonan akan dicadangkan untuk ditolak dan fi pemprosesan tidak akan dikembalikan. *The company should be co-operative in providing any additional information required from time to time for the purposes of evaluation. If the company did not provide any feedback to the officer within the specified time frame, this application will be proposed to be rejected and the processing fee is not refundable.* iii) Semua maklumat dan lampiran yang diberikan adalah benar dan tepat. *All the information and attachment provided are true and accurate.*	**Tandatangan *Pemilik/Pengurus/Pengarah Syarikat & Cop Syarikat** *Signature of *Company's Owner/Manager/Director& Company Stamp* **Nama** *Name* **Tarikh** *Date*

*Sila potong yang tidak berkenaan
**Please strikethrough those that are not relevant*

ANNEX 2

Your Ref. :
Our Ref. : KKM/NPRA.PKP/600-2/4/2 ( )Jld.2
Date : <DD Month YYYY>

Managing Director
<Company Name>
<Company Address 1>
<Company Address 2>
<Attn.: Company Person-In-Charge>

Sir/Madam,

ROUTINE GOOD MANUFACTURING PRACTICE (GMP) INSPECTION REPORT FOR PHARMACEUTICAL MANUFACTURING PREMISE

With reference to the routine GMP Inspection that has been conducted at your premise on **<Date>**, attached herewith the report of the inspection for your perusal.

2. In principal, the level of GMP compliance of the premise is **ACCEPTABLE.** The company is required to take the necessary corrective actions and preventive actions on the deficiencies identified during the inspection, and stipulated clearly the **time frame** required for the corrective action and preventive action to be taken. The feedback shall be submitted to this Centre **within 30 days from the date of this letter** using the format attached with the report number: **GMP300/Record-10/yy/xxx**

3. Please be informed that compliance to Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) guidelines should not only focused on the inspection findings. Instead, your company is responsible to ensure the compliance towards all the requirements of the current GMP and GDP guidelines at all times.

4. For further information, please do not hesitate to contact the officer **<Inspector Name>** (**<Phone Number>/<Email Address>**).

Your co-operation and attention on this matter is highly appreciated.

Thank you.

Yours faithfully,

-sign-
(MUHAMMAD LUKMANI IBRAHIM)RPh. 1046
Deputy Director
Head Centre for Compliance and Licencing
p.p. Director
National Pharmaceutical Regulatory Agency
Ministry of Health Malaysia

ANNEX 3

TRANSLATION ACKNOWLEDGEMENT

Document Title	**:**
Document Reference (If Applicable)	**:**
Document Date	**:**

I HAVE EXAMINED THE ORIGINAL DOCUMENT IN THE ORIGINAL LANGUAGE AND VERIFY THAT THIS IS AN ACCURATE ENGLISH TRANSLATION OF THE ORIGINAL.

Signature	**:**
Full Name	**:**
Date	**:**
Professional Designation/ Title	**:**
Accreditation Details	**:**
Contact details	
Office	**:**
Email	**:**
Official Stamp	**:**