Application for the “Certificate of Good Manufacturing Practice for Pharmaceutical Products (GMP)”

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Service target and eligibility

Individuals/legal persons with an “Industrial Licence for Pharmaceutical Production” by the ISAF.

Application procedures and required documents

1. A completed IFM-3 “Certificate of Good Manufacturing Practice for Pharmaceutical Products (GMP)” application form;
2. The original of a valid Business Registration Certificate of the industrial licence holder, issued by the Commerce and Movable Property Registry (legal persons/corporates registered with the Registry are exempted from submitting this document);
3. Document(s) certifying the competence of an executive management member legitimately representing the

industrial licence holder (for legal person/corporate applicants); Proprietorship document of applicant (for individual applicants):

3.1. Copy of the Macao Resident Identity Card or other identification documents with holder’s signature sample (the original of the said identification documents must be presented for verification);

3.2. The original of the Certificate of No Criminal Conviction issued by the Identification Services Bureau (DSI) (usage of the certificate: to obtain the licence for engagement in professions or activities relating to pharmaceuticals; applicants can apply for this certificate at DSI, via self-service kiosks or the DSI website; the certificate issued by DSI will be delivered directly to ISAF).

4. Copy of the “Industrial Licence” or “Licence for Industrial Unit” (if applicable) issued by DSEDT (the original of the said documents must be presented for verification);
5. Photocopy of the “Industrial Licence for Pharmaceutical Production” issued by ISAF;
6. Photocopy of the “Certificate of Good Manufacturing Practice for Pharmaceutical Products (GMP)” issued by ISAF (if applicable);
7. Organisational chart of the pharmaceutical manufacturing plant and placement of key technical personnel, including technical supervisors, persons in charge of production and persons in charge of quality control:

   7.1. For legal person/corporate applicants, the organisational chart must be signed by the executive management members legitimately representing the industrial licence holder and the technical supervisor, with the effective date specified. For individual applicant, the organisational chart should be signed by the industrial licence holder and the technical supervisor, with the effective date specified.

   7.2. Key technical personnel should not have overlapping

responsibilities or double as other position(s) concurrently.

8. Relevant documents of the key technical personnel of the pharmaceutical manufacturing plant:
   8.1. Copy of academic qualification documents (the original must be presented for verification);
   8.2. Description of work experience;
   8.3. Description of relevant professional training;
   8.4. Assessment report on the capability of key technical personnel by the management of the pharmaceutical manufacturing plant.
9. The Declaration of Responsibility (5) by the technical supervisor(s) (available at the location of application or can be downloaded from the Health Bureau’s website);
10. Copy of the proof of legal employment of the staff of the pharmaceutical manufacturing plant, including all personnel involved in the production and quality control procedures (the originals must be presented for verification);
11. The site master file (please refer to the ‘Guidance for Compilation of Site Master File’);
12. Other supporting documents and information related to the application.

(Competent department: ISAF)