Industrial Licence for Pharmaceutical Production

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Service target and eligibility

Individuals or legal persons (companies) with an Industrial Licence by DSEDT to perform pharmaceutical production.

Application procedures and required documents

1. A completed IFM-1 “Industrial Licence for Pharmaceutical Production” application form
2. The original of valid Business Registration Certificate of the industrial licence holder, issued by the Commerce and Movable Property Registry (legal person/corporate applicants 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 Certificate of Criminal Record 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. A certified true 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. A photocopy of the “Industrial Licence for Pharmaceutical Production” issued by ISAF (if any)
6. 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:
   6.1. 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 must be signed by the industrial licence holder and the technical supervisor, with the effective date specified
   6.2. Key technical personnel should not have overlapping responsibilities or double as other position(s) concurrently
7. Relevant documents of the key technical personnel of the pharmaceutical manufacturing plant:
   7.1. Copy of academic qualification documents (the original must be presented for verification)
   7.2. Description of work experience
   7.3. Description of relevant professional training
   7.4. Assessment report on the capability of key technical personnel by the management of the pharmaceutical manufacturing plant
8. The Declaration of Responsibility (5) by the technical

supervisor(s)

9. 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 (the originals must be presented for verification);
10. Documents and information involved in the application for the “Industrial Licence for Pharmaceutical Production”:
    10.1. Floor plan and construction standard of the production site(s)
    10.2. Description and test reports of the manufacturing facilities and equipment
    10.3. Environmental standard and surveillance report of the production site(s)
    10.4. Description and test reports of the quality control facilities and equipment
    10.5. Design drawings, operation standards and test reports of the air-conditioning system, temperature and humidity control system and other auxiliary systems
    10.6. Design drawings, operation standards and test reports of the industrial water treatment and supply system
    10.7. Pharmaceutical production list (including production formula, volume of production, technical procedure of production, name of product and dose form), as well as the proposed production and sales plan
    10.8. Material procurement and quality control management
    10.9. Records and the table of contents of standard operating protocol
    10.10. Arrangement of commissioned production as well as arrangement of on-site supervision on the commissioned production activities (if any)
    10.11. Arrangement of commissioned inspection (if any)
11. Other supporting documents and information related to the application

Remarks:

The floor plan mentioned in 10.1 of the “Application procedures and required documents” should specify the dimensions and scale and indicate the personnel flow and material flow. A floor plan typically includes rooms or physically isolated areas for the following activities:

1. Delivery and collection;
2. Storage of qualified, inspection pending and unqualified materials and finished products
3. Separate routes for personnel flow and material flow;
4. Changing room;
5. Production;
6. Inner packaging;
7. Outer packaging;
8. Weighing of raw materials;
9. Weighing of finished products;
10. Intermediate control;
11. Storage of semi-finished products;
12. Storage of wastes;
13. Separate cleaning and storage of production instruments;
14. Cleaning and storage of cleansing equipment for the premises;
15. Staff hygiene;
16. Administration;
17. Quality control;
18. Installations of auxiliary facilities and equipment;
19. Other activities related to pharmaceutical production.

For more information, please click  here。

(Competent department: ISAF)