



**APPLICATION FORM FOR A LICENCE TO MANUFACTURE DRUGS, COSMETICS,  
HOUSEHOLD CHEMICAL SUBSTANCES AND MEDICAL DEVICES**

CHECKLIST

Applicant's check list		FDA double check
<input type="checkbox"/>	Covering Letter	<input type="checkbox"/>
<input type="checkbox"/>	Signed Declaration	<input type="checkbox"/>
<input type="checkbox"/>	Fully Completed Application	<input type="checkbox"/>
<input type="checkbox"/>	Site Master File	<input type="checkbox"/>
<input type="checkbox"/>	Environmental Protection Agency (EPA) Permit	<input type="checkbox"/>
<input type="checkbox"/>	Name and Address of Suppliers of Equipment	<input type="checkbox"/>
<input type="checkbox"/>	List of Equipment and their Capacity	<input type="checkbox"/>
<input type="checkbox"/>	Technical Management Agreement with any Organisation	<input type="checkbox"/>
<input type="checkbox"/>	Building Plans	<input type="checkbox"/>

**APPLICATION FORM FOR A LICENCE TO MANUFACTURE DRUGS, COSMETICS,  
HOUSEHOLD CHEMICAL SUBSTANCES AND MEDICAL DEVICES**

This form shall be completed in duplicate by, or for, each manufacturer, accompanied by the prescribed application fee to:

**The Chief Executive**

**Food and Drugs Authority**

**P. O. Box CT 2783**

**Cantonments, Accra**

**Note:** The license application form must be accompanied by an application letter, a site master file and an Environmental Protection Agency permit.

For extra information refer to guidelines for licensing manufacturing industries.

**FDA/DRI/DED/GL-LMI /2013/05**

**1. Details of Manufacturer**

a)Name of Business  
b)Postal Address:  
Tel  
Fax  
E-mail

**2. Location of proposed licensed premises**

a)Street Address:  
b) Postal Address (if different from business address above)  
Tel:  
Fax:  
E-mail

c) Additional manufacturing sites if any\*

*\* Manufacturing is defined as production of products or engaging in any part of the process of producing the product or bringing the products to their final stage. This includes processing, assembling, packaging, labeling, storage, sterilizing, testing or release for supply of the products or of any component or ingredient*

**3. Certificates**

Provide a certified true copy of Certificate of Incorporation and Certificate of Commencement of Business from Registrar General's Department.  
A separate application is required in respect of each premises except where a group of buildings on one or more sites are engaged in making the same kind of product under the same direct production and quality control management.

**4. Details of Manufacture**

a.) Product sub-category (*tick one or more boxes*)

- Active pharmaceutical ingredient
- Non-sterile drug
- Sterile drug
- Herbal product
- Homeopathic product
- Sterile device
- Non-sterile device
- Cosmetic product
- Household chemical substance

b.) Describe the range of dosage forms/types of devices to be manufactured (*tick the appropriate box(es)*)

- |  |                          |                                       |                          |
|--|--------------------------|---------------------------------------|--------------------------|
| Tablets  | <input type="checkbox"/> | Aerosol-dispensed Medication          | <input type="checkbox"/> |
| Capsules   | <input type="checkbox"/> | Powders (including oral and tropical) | <input type="checkbox"/> |
| Non-sterile ointments, (including creams, jellies, pastes)   | <input type="checkbox"/> | Medical gas                           | <input type="checkbox"/> |
| Liquid (including solutions, Suspensions, elixir, tinctures) | <input type="checkbox"/> | Chemical synthesis                    | <input type="checkbox"/> |
| Sterile non-injectables                                      | <input type="checkbox"/> | Plant/ animal extract                 | <input type="checkbox"/> |



**5. Contract Manufacture**

- a. Product stages of manufacture, excluding testing, which are to be contracted to another manufacturer.

Product/ Stage	Manufacturer	Address

- b. Testing contracted to the manufacturer

Nature of Test	Name of Testing Laboratory/Service	Address

- c. Products stages of manufacture, including testing, which are to be made or performed for another manufacturer.

Product	Manufacturer	Address

**6. Key Personnel**

6.1 Person in charge of production

Full Name \_\_\_\_\_ .

Position in the company \_\_\_\_\_ .

a. Relevant qualification

Name of Institution	Duration of Study	Certificates Awarded

b. Relevant Experience (*last job first*)

Name of Company	Duration	Position Held

6.2 Person(s) in charge of Quality/ Assurance.

Full Name \_\_\_\_\_ .

Position in the company \_\_\_\_\_ .

a. Relevant qualification

Name of Institution	Duration of Study	Certificates Awarded

b. Relevant Experience (*last job first*)

Name of Company	Duration	Position Held

**7. Specification of the Plant**

a. Equipment

Type	Number of Units	Specified Production Capacity
ō ō ö õ ö ö ö ö ö ö ö	ō ō ö õ ö ö ö ö .	ō ō ö õ ö ö ö ö ö ö ö ö ö ö ö ö ö ö .
ō ō ö õ ö ö ö ö ö ö ö	ō ō ö õ ö ö ö ö .	ō ō ö õ ö ö ö ö ö ö ö ö ö ö ö ö ö ö .
ō ō ö õ ö ö ö ö ö ö ö	ō ō ö õ ö ö ö ö .	ō ō ö õ ö ö ö ö ö ö ö ö ö ö ö ö ö ö .
ō ō ö õ ö ö ö ö ö ö ö	ō ō ö õ ö ö ö ö .	ō ō ö õ ö ö ö ö ö ö ö ö ö ö ö ö ö ö .
ō ō ö õ ö ö ö ö ö ö ö	ō ō ö õ ö ö ö ö .	ō ō ö õ ö ö ö ö ö ö ö ö ö ö ö ö ö ö .
ō ō ö õ ö ö ö ö ö ö ö	ō ō ö õ ö ö ö ö .	ō ō ö õ ö ö ö ö ö ö ö ö ö ö ö ö ö ö .
ō ō ö õ ö ö ö ö ö ö ö	ō ō ö õ ö ö ö ö .	ō ō ö õ ö ö ö ö ö ö ö ö ö ö ö ö ö ö .

*(Attach supplementary list where necessary)*





- b. Would any expatriate be employed?.....
- c. If Yes, how many? And what are their Nationalities?

õ  
õ õ

**10. Enclosures**

The following are to be submitted:

- a. Name and address of suppliers of equipment.
- b. Technical management agreement signed with any organization
- c. Building plans.

**11. State proposed date of commencement of business**

õ .

**12. Any additional information which applicant wishes to provide.**

õ  
õ  
õ  
õ  
õ  
õ õ

We hereby confirm that the answers given on this application form are true and correct to the best of our knowledge.

Name of Owner/ Director õ .

Signature õ ..

Date õ ..

Stamp õ .

Name of Qualified Person õ

Qualification õ õ õ õ õ õ õ õ õ õ õ õ õ õ õ õ õ õ õ .

Signature õ .

Date õ .

Stamp õ .

\*Witnessed by

Name õ .

Signature õ ..

Date õ ..

Stamp õ .

(\* Senior Civil/ Public Servant, Minister of Religion)