INFORMATION REQUIRED FROM PHARMACEUTICAL FIRMS FOR REGISRATION

Part A: Details of the market Authorization holder (local agent)-

1. Name of Company: ……
2. Address and contact details of the company :
3. a) Registered office- Address: ……
   Telephone: ……
   Fax: ……..
   Facsimile: ……
   Email: ……
   b) Operations office- Address: ……
   Telephone: ……
   Fax: ……..
   Facsimile: ……
   Email: ……
   c) Ware house- Address: ……
   Telephone: ……
   Fax: ……..
   Facsimile: ……
   Email: ……
4. Are you licensed market authorization holder in Sri Lanka, if so attached the copy of the license.
5. As per regulation ; "Submit the declaration by the product license holder on contract manufacture
6. Copy of business registration:
7. Staff:
   Names of the Board of Directors:
   Responsible officers:
   a)Technical (Regulatory Affairs officer):
   b) Administration:
   (Full time, Part-time staff with qualifications and responsibilities)
8. Letter of appointment issued by head of the manufacturing site-

9. Details of the pharmacist who responsible for importing:
    - Name:
    - SLMC registration No:
    - Telephone: …….
    - Email: ……

10. Give details of premises, equipment and facilities for the handling ,storage and distribution of drugs which may import under his license are necessary to avoid deterioration of such drugs

11. Proposed post marketing surveillance plans:

12. Plan for recall procedure:

Part B-Business information on manufacturing company

1. Name of Company: ……
2. Address :
    - Head Office: .....
    - Manufacturing Plant: .....

    Indicate whether there are any other manufacturing plants:

    (Information on each manufacturing sites should be submitted separately, and will be evaluate and registered separately)
3. Nearest Airport:
4. Telephone:
5. Fax: …….
6. Telex: …….
7. Email: ……
8. Web site: .....
8. Contact person:
    - Telephone:
    - Email: ……

9. Year of Establishment: …….

10. Nature of the Company: Individual / Partnership/ Corporation

11. Names and Addresses of international pharmaceutical companies with whom there is collaboration or joint ventures, (if any):
12. Indicate whether any product completely or partly manufactured by other manufacturer for you.

13. Drug Manufacturing License Number issued by the Central Drug Authority and a copy of that certificate :
    To be valid for the date of submitted

14. Capital., Value of Authorized capital / Paid up capital/Reserves

15. Total sales turnover in the previous three years -each year separately. Split between export and domestic sale.

Year	Domestic	Export

(Proof documents for export & domestic sales)

(Also three drug registration certificate (translation copies to be certified by the Embassy of the issuing country) in your own country as a proof of domestic sales)

16. Countries to which your drugs are presently exported and the names of the drugs exported to each country.
    (At least three Copies of drug registration certificate from three deferent countries for three deferent years).

17. Names of pharmaceuticals and/ or raw materials actually manufactured and which are available for export.
    (Attached list)
18. Indicate whether the products are not marketed by you in your own country.
    (If yes give reasons)

19. Show pharmaceuticals and /or raw materials manufactured by other companies and marketed by you. Please give names of these companies, against items.
20. Certificates Good Manufacturing Practices and Certificates of Pharmaceutical Products according to W.H.O Certification Scheme.
    (Approved of central drug authority)

21. Site Master File

Following details to be submitted with site master file

21.1.1General Information

1	Brief Information on site (name, address, other site)	**Annexure**	
2	Pharmaceutical manufacturing activities as licensed by the Competent Authorities		
3	Any other manufacturing activities carried out on the site		
4	Name and extract address of the site, 24 hour telephone number ,fax, email, web site		
5	Direction from the airport to manufacturing plant:		
6	Does Government carry out inspections and controls with production of drugs in your country?		

21.1.2Personnel

7.	Organization chart	**Annexure**	
8.	Qualification, experience and responsibilities of key personnel Name ,designation and signature		
9.	Outline of arrangement for training programs		
10.	Health requirement for personnel engaged in production		
11.	Personal Hygiene requirement including clothing		

21.1.3Premises

		Annexure	
12.	*Site lay out of the manufacturing plant (authorized qualified engineering drawing with describing all areas)		
13.	*Brief description of ventilation system (schematic drawings of the system)		
14.	*Brief description of water system(schematic drawings of the system)		
15.	*Brief description on maintenance system		
16.	*Special area for handling of highly toxic ,hazardous and sanitizing materials		
17.	Cleaning procedures for manufacturing areas, equipment and machines		

*Above details to be authorized by designated qualified responsible person

21.2. Production

		Annexure
	Responsible person's name, designation, Qualification and experience	
1.	Type of actual product manufactured (Attached product list with product capacity)	
2.	Information about specially toxic or hazardous substances handled	
3.	Short description manufacturing activities (Are product manufactured routinely or Occasionally/Actually manufactured/ contract manufacturing[1]/loan license[2])	
4.	Whether Bio equivalence test are carried out if manufactured antibiotics, anti-epileptic drugs and slow release or modified release preparations	
5.	Details regarding manufacturing Vaccine (Whether supplier is prequalified by WHO? If yes WHO prequalification certificate and product list to be attached)	
6.	Details regarding manufacturing Bio Technological Products? (Whether they followed WHO guideline? product list to be attaché separately)	
7.	Indicate whether any product completely or partly manufactured by other manufacturer for you? (Product list with name and address of manufacturers)	
8.	Number of employees engaged production, storage and distribution (Pharmacist & Others)	
9.	Brief description of product operation (Flow sheets, charts ,specifying important parameters)	
10.	Brief description of equipment and machineries used in production? (Maintenance, Calibration& Validation)	
11.	Arrangement for the handling of starting materials ,packaging materials, bulk and finish products, including sampling, quarantine, release and storage	
12.	Arrangement for reprocessing or rework	
13.	Arrangement of the handling of rejected materials and product	
14.	Brief description of general policy for process validation	

Above details to be authorized by designated qualified responsible person in production.

21.3. Quality Control &Assurance

		Annexure
	Responsible person's name, designation, Qualification and experience	
1.	Number of specialized personnel in Quality Control &Assurance (Pharmacist, Chemist, Others))	
2.	Name and address of quality control laboratories used in addition to your own laboratory.	
3.	Description of quality control/Assurance system and activities of the department (Analytical testing, packaging component testing, biological & Microbiological testing)	
4.	Procedure of the release of finish product	
5.	Are raw materials completely tested prior to use?	
6.	Which standard are used in quality control?(BP/USP/IP etc) Are Additional test carried out?	
7.	Have Bio availability studies carried out on any of formulations? (List of product to be attached)	
8.	Are dissolution test carried out routinely	
9.	Are there performed stability test for any of the product	
10	Brief description of Laboratory equipment?(Maintenance, Calibration& Validation)	
11	Procedure for handling quality failures	

Above details to be authorized by designated qualified responsible person in Quality Control & Assurance.

21.4. Documentation, Distribution, Complain, Product Recall & Self inspection

	Responsible person's name, designation, Qualification and experience for each and every task to be given	**Annexure**
1.	Arrangement for the preparation revision and distribution of necessary documentation for manufacturer, including storage of master documents	
2.	Arrangement and recording system for distribution	
3.	Arrangement for the handling of complaint , product recall and Pharmacovigilence	
4.	Short Description of the self-inspection system	

Explanatory notes:

1. "A license which a Licensing Authority may issue to an applicant who does not have his own arrangements for manufacture but intends to avail him-self of the manufacturing facilities owned by a licensee".
2. This system prevails in many countries including developed countries. Contract manufacturer is a manufacturer who performs some aspect of manufacturing on behalf of the original manufacturer. This definition is included in the ICH and WHO Guidelines for GMP.

CERTIFICATION

I, the undersigned (full name of the person responsible)…….. Hereby declare that all the information given above is true, and I take the full responsibility for all consequences, which might arise from false or erroneous information. If required, I will cooperate with any official of the Ministry of Health and manufacturing facilities and records.

We hereby certify that the information given is true and that the company concerned fulfils the requirements of the local regulation concerning the manufacturing of pharmaceuticals.

……..

Head of the Company

Name /Designation /Signature

Annexure 1

Certification by the Ministry of Health or the official authority in charge of the control and inspection of pharmaceutical Manufacturing facilities.

(To be filled by authorized officer of above mentioned authority)

1. Name of Company:. ……

2. Address :
   Head Office: .....
   Manufacturing Plant: .....

3. Details on Manufacturing License:
   a. Manufacturing license No:
   b. Issuing date:
   c. Products which are approved for manufacture by the license:

4. Details of GMP Certificate:
   a) Certificate No
   b) Issuing Date
   c) Expiry date
5. Form of Company : Individual / Partnership/ Corporation
6. Attached Factory Layout :

   Satisfactory: Unsatisfactory:

7. Details on reporting:
   a. Quality failures-
   b. Adverse drug reactions -
   c. GMP violations-

We hereby certify that the information given is true and that the company concerned fulfils the requirements of the local regulation concerning the manufacturing of pharmaceuticals.

Name of the Authorized Officer:
Contact Details:

Signature/Date

Annexure- 2

Certification by the Chamber of Commerce or Similar Organization.

(To be filled by authorized officer of above mentioned organization)

1. Name of Company: . ……

2. Address :

   Head Office: .....

   Manufacturing Plant: .....

3. Membership details on manufacturing plant on your organization.

   Membership No-
   Issued date-

4. Details on total sales turnover in the previous three years of the manufacturing plant.

Year	Domestic	Export

We hereby certify that the information given is true and that the company concerned fulfills the requirements of the local regulation concerning the manufacturing of pharmaceuticals.

Name of the Authorized Officer:

Contact Details:

Signature/Date: