SOP No.	Revision	Issue date	Page 1 of .....
SOP-01-001	0	DD/MM/YYYY	Effective
date		Prepared by:	
			Reviewed by:
Standard Operating Procedure			Authorized by:

COSMETICS, DEVICES & DRUGS REGULATORY AUTHORITY PROCEDURES

STANDARD OPERATING PROCEDURE FOR REGISTRATION OF COMPANY PROFILES

Purpose:

Purpose of this document is to describe the procedure for registration of company profiles.

Scope:

This procedure applies …….

Responsibility:

Procedure

Step 1 – Dossier is submitted to pharmacist (1) by the applicant and

check with whether the acceptance criteria is met

Step 2 - Payment letter with a copy for processing is issued by the pharmacist (1).

Step 3- Payment are done by the applicant to the Shroff counter of the Ministry of Health. Applicant receives a yellow receipt for the payment by the shroff.

Step 4- The yellow receipt is date stamped at the CDDA, **entered in the particular register allocated to that subject** and submitted to the pharmacist (1) along with **application.** Two acknowledgement letters (Annexure A) should be attached with the dossier.

Step 5- On acceptance pharmacist (1) date stamps and signs in the acknowledgement letters, allocates a serial number to the dossier and an acknowledgement letter is returned to the applicant.

Step 6- The **application** is forwarded to the Chief Pharmacist. Chief Pharmacist allocates the dossier to the pharmacist (2) for evaluation.

Step 8- **Application** is submitted to D/MT&S for signature of duly completed format covering foregoing (Annexure "B").

Step 9 - D/MT&S signs the document and forwards to Senior Health Management Assistant.

Step 10 - Senior Health Management Assistant forwards the signed **approval letter (recommendation)** to the Health Management Assistant.

Step 11- Health Management Assistant handovers the document to applicant. If the document is not collected within two weeks, document should be posted to the applicant.

After evaluation applicant is informed the additional data needed or of its approval or rejection.

Note: After paying a fee, any document submitted to CDDA will not be returned.

ANNEXURE "A"

CP No…….

To be filled in duplicate.

ACKNOWLEDGEMENT OF APPLICATION FOR COMPANY PROFILE

1. Name of Applicant :……
2. Address :……

   ……

   ……

3. Name of the manufacturer :……

   ……

4. Address of the manufacturing plant :……

   ……

   ……

   ……

5. Processing fee:
   a. Payment receipt No. ……
   b. Date ……

Received the above application.

Date ……

……

Signature of the Receiving Officer

ANNEXURE "B"

120, Norris Canal Road,

Colombo 10.

(Date)

……..

……..

……..

COMPANY PROFILE – No: ……..

Name of the Local Agent:……

Address of the Local Agent :……..

Name of the Manufacturer :……

Address of the Manufacturer : ……

If approved, categories of product/s approved for registration:

External preparations

Oral liquids

Oral solids

Antibiotics – Beta lactams

Antibiotics – Non-beta lactams

Injections

Comments :……

……

……

……

……

Recommendation:

☐ The above company profile has been approved.

☐ Requested to forward the above information to facilitate the evaluation of the above Company Profile.

☐ The above company profile has been rejected.

……. ……..

Signature of the evaluator Date

…….. …….

Director/ CDDA Date

Note: This letter should be attached to each and every registration dossier and to the application for sample licence..

ANNEXURE "C"

INFORMATION REQUIRED FROM PHARMACEUTICAL FIRMS FOR REGISRATION

1. BUSINESS INFORMATION

1. Name of Company:. ……

a) Address :

b) Telephone :

Fax :…….

Telex :…….

2. Year of Establishment : …….

3. Form of Company : Individual / Partnership/ Corporation

4. Names and Addresses of international pharmaceutical companies with whom there is collaboration or joint ventures, if any :
5. Drug Manufacturing Licence Number issued by the Central Food and Drug Authority in India and a copy of that certificate :

6. Total number of employees:
   Technical: Scientific: Administration:

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

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

9. Countries to which your drugs are presently exported and the names of the drugs exported to each country.

10. Names of pharmaceuticals and/ or raw materials actually manufactured by you and which are available for export.

11. Indicate which are not marketed by you in your own country and give reasons.

12. Show pharmaceuticals and /or raw materials manufactured by other companies and marketed by you. Please give names of these companies, against items.

13. Certificates of Free Sale and Good Manufacturing Practices or Certificates of Pharmaceutical Products according to W.H.O Certification Scheme.

14. Have the drugs been exported to Sri Lanka Previously through: S.P.C./ Private importer

MANUFACTURING INFORMATION .

1. Full details enclosing product lists, brochures, (if available) of Manufacturing plants, laboratories etc.

2. Are products in the products list produced routinely ? or only occasionally on request ?

3. Number of specialized personnel involved in manufacture;

   Pharmacists : Chemists: Others:

4. Products actually manufactured, manufactured under contract are they repackaged ?

5. If any products are manufactured under contract, attach a list of such products showing the name and address of the manufacturer for each product.

6. If any products are repackaged, attach list of such products.

7. Are products you manufacture packaged by other companies ?
8. If yes, give in an annexure detailed information on the quality assurance procedures followed.

QUALITY CONTROL INFORMATION.

Do you maintain your own quality control laboratory ?

1. Number of specialized personnel in your quality control laboratory; excluding administrative personnel.
   Pharmacists: Chemists: Others:

2. Names and Address of quality control laboratories used in addition to or in lieu of your own laboratory.

3. Are all raw materials completely tested prior to use–or is a Certificate of Analysis accepted ?,

4. Which standards (Int.P.,BP,USP.etc) are used in quality control ?
   Are all recommended tested carried out?
   Are additional test carried out? If yes,, which tests?

5. Have bioavailability studies been carried out on any of your formulations?

If yes list products so tested been attach reports if approved by health authorities.

6. Are dissolution tests carried out routinely?

7. Are there performed stability tests for any of your products?

8. Are control samples of each batch retained?

9. Does your Government carry out inspections and controls with production of drugs in your country?.
10. Floor plan of the manufacturing premises.
11. Give date, number and expiry date of current manufacturing licence or permit.
12. Certificates issued by your Ministry of Health or official organization in to the effect that your company fulfils the requirements of Good Manufacturing Practices and local regulations.
13. Letter of appointment of local agent

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.

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

b) Certification by the Chamber of Commerce of Similar Organization.