Company	Address
_____	_____
_____	_____
_____	_____

5. Employees:

Total: _____
Management: _____
R&D _____
Sales _____
Administrative _____
Others *(specify):* _____

6. Capital value of the company *(specify currency)*
   (a) Authorized capital: _____
   (b) Paid up capital: _____
   (c) Administration: _____

7. Annual sales turnover in the previous three years. Split export and domestic sales. *(specify currency)*

Annual turnover	Domestic sales	Exports	Year

II. MANUFACTURING INFORMATION.

1. Total number of Items manufactured: _____
   (provide list of manufactured products)
2. Are all manufacturing operations (processing, packaging, labeling) carried out internally?
   ☐ YES ☐ NO

If "No," attach a list of pharmaceuticals and/or raw materials/ Excipients manufactured by other companies and marketed by you. Please give the names of the companies, for each item.

	Product	Manufacturer	Address
(1)			
(2)			
(3)			

3. Provide details if pharmaceutical products and/or raw materials/ Excipients manufactured by your company are exported to other countries

Pharmaceutical product/raw material	Country	Generic Name	Trade Name
(1)			
(2)			
(3)			

4. Does your company have GMP certification?

☐ Yes *(attach a copy of the GMP certificate if any)*
Certified by: _____

☐ No

Indicate if your company has other types of certification

☐ ISO Type of ISO certification: _____

☐ WHO Certification Scheme

☐ Others *(specify)* _____

Attach Certificates of Good Manufacturing Practices (GMP, ISO or Certificates of Pharmaceutical Products according to WHO. Certification Scheme covering each item you propose to export.

5. Does your Government carry out inspections and controls on the production of drugs in your country?

☐YES ☐NO

If "Yes", give date of last inspection: _____

6. Has your company been inspected by other governments, organizations or clients?

Inspected by	Year	Outcome

7. Date, number and expiry date of current business license or permit.

Date: _____

Number: _____

Expiry Date: _____

8. Date, number and expiry date of manufacturing license or permit.

Date: _____

Number: _____

Expiry Date: _____

9. If you are a Traderer /wholesaler, the following information should be obtained from the manufacturers of product you wish to offer.

A. Give full details on the manufacturer (company name and address), with product lists and brochures of the manufacturing plants, laboratories etc.

Manufacturer: _____

Address: _____

B. Are the products in the product list produced routinely by the company?

☐ YES ☐ NO

C. Or only occasionally on request?

☐ YES ☐ NO

D. Number of specialized personnel involved in the manufacture of pharmaceuticals *(exclude administrative personnel)*.

Pharmacists: _____

Chemists: _____

Others: _____

10 A. Are the products manufactured by your company, manufactured under contract by other companies or repackaged?

- ☐ Manufactured
- ☐ Repackaged
- ☐ Manufactured under contract

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

	Product	Manufacturer	Address
(1)			
(2)			
(3)			

C. If any products are repackaged, attach a list of such products with the name and address of the manufacturer for each product.

	Product	Manufacturer	Address
(1)			
(2)			
(3)			

11 Do other companies package any of the products you manufacture?

☐ YES ☐ NO

If any products are repackaged, attach a list of such products with the name and address of the manufacturer for each product.

	Product	Manufacturer	Address
(1)			
(2)			
(3)			

Provide detailed information on the quality assurance procedures followed.

_____

_____

_____

_____

_____

12 Do you manufacture beta-lactam antibiotics?

☐ YES ☐ NO

If "Yes," are these production facilities in a separate building?

☐ YES ☐ NO

13 Production site

Are the production premises located in the same place as the main office?

☐ Yes ☐ No

If not, state address of the production premises: _____

Address: _____

_____

_____

If there are >1 production site, give description of production site as follows:

Production site

Address

No. Of products

Production capacity

Quality of in process water

List the products from the different production sites:

Production site Products

III. QUALITY INFORMATION

1. Do you maintain your own quality control laboratory?
   ☐ YES ☐ NO
2. Number of specialized personnel working in your quality control laboratory (excluding administrative personnel).
   Pharmacists: _____
   Chemists: _____
   Others: _____

3. List names and addresses of quality control laboratories used in addition to or in lieu of your own laboratory.
   _____
   _____
4. Are all raw materials completely tested prior to use or is a Certificate of Analysis accepted?
   ☐ YES ☐ NO ☐ Certificate of Analysis
5. Quality standards
   ☐ BP Edition ☐ USP Edition ☐ EP Edition ☐ IP Edition
   ☐ JP Edition ☐ CP Edition ☐ Other:

   Are all recommended tests carried out?
   ☐ YES ☐ NO
   If "No," state reason why not
   _____
   Are additional tests carried out?
   ☐ YES ☐ NO
   If "No," state reason why not
   _____

6. Are control samples of each batch retained?
   ☐ YES ☐ NO
7. Do you have written cleaning procedures?
   ☐ YES ☐ NO
8. Do you have a written recall procedure?
   ☐ YES ☐ NO
9. Do you have a written procedure on how to deal with complaints?
   ☐ YES ☐ NO

10 Name and title of the authorized person (s) responsible for batch release:

Name: _____

Title: _____

Experience in pharmaceuticals: _____ years

(of change – should inform)

11 Name and qualification of the head of the Quality Control department:

Name: _____

Qualification: _____

Experience in pharmaceuticals: _____ years

(If change – should notify us)

12 Indicate if you perform quality tests conducted routinely:

- ☐ active starting materials
- ☐ non-active starting materials
- ☐ packaging materials
- ☐ intermediate products
- ☐ bulk products
- ☐ finished products

13. Are all quality control tests performed internally?

☐ YES ☐ NO

If "No," list tests performed by external laboratories:

Tests	Laboratories	Address
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

14. Explain process of approving sources for starting materials and describe basis for approving specifications of starting materials.

_____
_____
_____
_____

15. Do you conduct tests on each container of the active starting material?

☐ YES ☐ NO

If not, explain your way of sampling: _____

_____

16. Do you test each container of non-active starting materials?

☐ YES ☐ NO

If "No," describe method of sampling: _____

_____

17. Are you willing to reveal the sources of starting material? (Information will be deemed confidential)

☐ YES ☐ NO

18 Are stability tests routinely conducted for every product?

☐ YES c ☐ NO

If "No," state reason why not: _____

_____

19 For each batch, what are the check procedures that are routinely done:

- ☐ Batch numbers and control numbers of each component
- ☐ Weighed quantities double checked and signed off for each component
- ☐ Acceptance record of each component
- ☐ Date and time of each stage of production
- ☐ Identification of equipment used
- ☐ Name of persons in charge at each stage
- ☐ In-process control results
- ☐ Environment control results
- ☐ Remarks on production incidents
- ☐ Comments on not following the master formula
- ☐ Yield and reconciliation
- ☐ Packaging material batch numbers
- ☐ Line clearance sign off
- ☐ Result of QC of end product
- ☐ Inspection checks and test results, dates and signatures of inspecting

20 Do you keep samples of each batch?

☐ YES ☐ NO

Indicate how long do you keep the samples: _____ years

21 Are these kept in the original containers?

☐ YES ☐ NO

22 Do you carry out inspections or quality audits of your own suppliers?

☐ YES ☐ NO

If "Yes," describe audits in detail:

_____

_____

_____

_____

23 Describe your storage facilities:

_____

_____

_____

IV. Product Information (Please fill up one form for each product)

1. Active Pharmaceutical Ingredient(s) _____

_____

_____

Indicate if product has any of the following:

☐ Certificate of Suitability to the European Pharmacopoeia (CEP)
Certificate No.: _____
☐ The CEP is in our possession (including annex if any)

☐ Drug Master File (DMF)
registered in *(country)*: _____
registration no.: _____
☐ The full or open part of the DMF is in our possession
☐ The full or open part of the DMF is in possession of the manufacturer
Manufacturer: _____
Country: _____

2. Regulatory Status in Country of Origin

☐ Product registered in country of origin and routinely manufactured and marketed
License no: _____ year issued: _____

☐ Product registered in the country of origin but not currently marketed
License no: _____ year issued: _____

☐ Product registered for export only
License no: _____ year issued: _____

☐ Product not registered

3. Regulatory Status in Other Countries
List other countries where the product is registered and currently marketed:

Product	Country	Trade Name
_____	_____	_____
_____	_____	_____
_____	_____	_____

4. Validation

Are all your production processes validated?

☐ Yes ☐ No

5. Do you use an approved manufacturing formula and processing instructions?

☐ Yes ☐ No

6. Finished Product Specification

☐ BP ☐ USP Edition ☐ IP
☐ JP ☐ Any other

Attach a copy of the finished product specifications

Are you willing to provide necessary information (analytical methods) for the tests to be replicated by another control laboratory?

☐ Yes ☐ No

7. Limits in % for the assay in active ingredient(s):

☐ 95-105% ☐ 90-110 %
☐ Other: _____

Additional specifications to those in the pharmacopoeia:

_____

_____

Attach a copy of the model certificate of analysis for batch release

8. Stability

Stability testing data available: ☐ Yes ☐ No

Type and conditions of satisfactory testing (without significant change):

- ☐ accelerated testing
- ☐ 40°/75% RH/6 months
- ☐ other:
- ☐ in the same packaging as marketed
- ☐ in another packaging:
- ☐ real time testing

Temperature: ☐ ambient ☐ 25°C ☐ 30°C ☐ other: __

Relative humidity: ☐ 45% ☐ 60% ☐ 70%
☐ not controlled ☐ other: _____

Period of time: ☐ 1 year ☐ 2 years ☐ 3 years ☐ other: __
☐ in the same packaging as marketed
☐ in another packaging: _____

9. Label and Insert Information

Shelf life: ☐ 2 years ☐ 3 years ☐ 4 years
☐ 5 years ☐ other: _____

Storage conditions (e.g. Store below 30°- Protect from light):

_____

_____

Package insert: ☐ Yes ☐ No

Attach a copy of the label and package insert

CERTIFICATION

I, the undersigned (full name of the person responsible)

Name _____

Designation _____

Hereby declare that all the information given above is true, and I take the full responsibility for all consequences that might arise from false or erroneous information. If required, I will cooperate with any official of the State Pharmaceuticals Manufacturing Corporation of Sri Lanka in making personal inspection of manufacturing facilities and records.

Name _____
Designation _____
Signature _____
Date _____

Following documents should be send along with the Manufacture/supplier Questionnaire

1 Copy of manufacture license
2 copy of total number of items manufactured
3 Copy of valid GMP certificate/s
4 Copy of Business license or Permit
5 Copy of Manufacturing license
6 Copy of other certifications if (ISO ,WHO etc)
7 Under the Product information Page 12 of 15

1 submit the Copy of the all necessary documents (drug master file, CEP-certification of suitability to the European pharmacopoeia

2 Copy of regulatory status product registration license etc

3 Regulatory status in other country