# SUPPLIER APPROVAL QUESTIONNAIRE

The purpose of this questionnaire is to allow us to identify a number of suitably qualified manufacturers and suppliers for Pharmaceutical Active Ingredients and Excipients, who will be invited to submit tenders for next three years period.

**Questionnaire Layout**

This form contains of four parts:

Part I Business Information Part II Manufacturing Information Part III Quality Information

Part IV Product Information

All information requested should be provided in the order and format of the parts.

Completed questionnaire may be sent through the post under registered cover or may personally be deposited in the box kept for this purpose on the ground floor at the State Pharmaceuticals Manufacturing Corporation, No 11, Sir John Kotelawala Mawatha, Kandawala Estate, Ratmalana, Sri Lanka.

* Only information provided as a direct response to the questionnaire will be evaluated.
* Marketing material should not be included.
* Supplementary documentation may be attached to the questionnaire where applicants have been directed to do so and such materials must be marked with the name of the organization and the question to which it relates.
* All questions must be answered.
* Please answer the questions specifically for your relevant firm not for the group if you are part of a group of Firms.
* Should you decide that you do not wish to continue with this application, please advise the procurement committee of your decision in writing at the earliest opportunity.
* The information you give will be treated as confidential.

Ensure that the completed questionnaire, together with all requested supporting documents, is returned in time to arrive by **30.09.2025** **(Closing date). Questionnaires received after this date will not be considered.**

# BUSINESS INFORMATION.

* + - 1. Name of company: Year established: Form of company:  Individual

 Partnership

 Corporation

 Other (specify)

Legal status: Trade register number: VAT number: License Number

*(attach copy)*:

* + - 1. Address:

Country: Telephone: Telefax: Telex: E-mail:

## Please attach the company organizational chart

* + - 1. Type of activity carried out by the company

 Manufacturer  Wholesaler

 Branded products  Branded products

 Generic products  Generic products

 Medical supplies

 API

 Medical supplies

 Excipient

 Laboratory reagents  Laboratory reagents

Other products *(specify below)*

Other products *(specify below)*

Indicate % of annual turnover:

Pharmaceutical % formulations:

Bulk drugs: %

Medical Supplies: %

Excipient %

* Products manufactured for export
* Sold only to the local market
* Both
	+ - 1. Names and addresses of international pharmaceutical companies, parent companies and/or subsidiaries and associated companies with whom there is collaboration or joint venture, if any:

Company Address

* + - 1. Employees:

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

* + - 1. Capital value of the company *(specify currency)*
1. Authorized capital:
2. Paid up capital:
3. Administration:
	* + 1. Annual sales turnover in the previous three years. Split export and domestic sales. *(specify currency)*

Annual turnover Domestic sales Exports Year

# MANUFACTURING INFORMATION.

* + - 1. Total number of Items manufactured:

## (provide list of manufactured products)

* + - 1. 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)

(1)

* + - 1. Provide details if pharmaceutical products and/or raw materials/ Excipients manufactured by your company are exported to other countries

Pharmaceutical product/raw material

(1)

(2)

(3)

Country Generic

Name

Trade Name

* + - 1. 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.*

* + - 1. 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:

* + - 1. Has your company been inspected by other governments, organizations or clients? Inspected by Year Outcome
			2. Date, number and expiry date of current business license or permit.

Date: Number: Expiry Date:

* + - 1. Date, number and expiry date of manufacturing license or permit.

Date: Number: Expiry Date:

* + - 1. If you are a Traderer /wholesaler, the following information should be obtained from the manufacturers of product you wish to offer.
1. Give full details on the manufacturer (company name and address), with product lists and brochures of the manufacturing plants, laboratories etc.

Manufacturer: Address:

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

 YES  NO

1. Or only occasionally on request?

 YES  NO

1. Number of specialized personnel involved in the manufacture of pharmaceuticals

*(exclude administrative personnel).*

Pharmacists: Chemists: Others:

* + - 1. A. Are the products manufactured by your company, manufactured under contract by other companies or repackaged?

 Manufactured

 Repackaged

 Manufactured under contract

1. 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)

1. 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)

* + - 1. 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.

* + - 1. 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

# QUALITY INFORMATION

* + - 1. Do you maintain your own quality control laboratory?

 YES  NO

* + - 1. Number of specialized personnel working in your quality control laboratory (excluding administrative personnel).

Pharmacists: Chemists: Others:

* + - 1. List names and addresses of quality control laboratories used in addition to or in lieu of your own laboratory.
			2. Are all raw materials completely tested prior to use or is a Certificate of Analysis accepted?

 YES  NO  Certificate of Analysis

* + - 1. Quality standards

 BP 

Edition

 JP 

Edition

USP Edition  EP Edition  IP 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

* + - 1. Are control samples of each batch retained?

 YES  NO

* + - 1. Do you have written cleaning procedures?

 YES  NO

* + - 1. Do you have a written recall procedure?

 YES  NO

* + - 1. Do you have a written procedure on how to deal with complaints?

 YES  NO

* + - 1. Name and title of the authorized person (s) responsible for batch release: Name: 

Title:

Experience in pharmaceuticals: years

( of change – should inform)

* + - 1. Name and qualification of the head of the Quality Control department: Name: 

Qualification: Experience in pharmaceuticals: years

( If change – should notify us)

* + - 1. Indicate if you perform quality tests conducted routinely:

 active starting materials

 non-active starting materials

 packaging materials

 intermediate products

 bulk products

 finished products

* + - 1. Are all quality control tests performed internally?

 YES  NO

If “No,” list tests performed by external laboratories:

Tests Laboratories Address

* + - 1. Explain process of approving sources for starting materials and describe basis for approving specifications of starting materials.
			2. Do you conduct tests on each container of the active starting material?

 YES  NO

If not, explain your way of sampling:

* + - 1. Do you test each container of non-active starting materials?

 YES  NO

If “No,” describe method of sampling:

* + - 1. Are you willing to reveal the sources of starting material? (Information will be deemed confidential)

YES  NO

* + - 1. Are stability tests routinely conducted for every product?

 YES c  NO

If “No,” state reason why not:

* + - 1. 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

* + - 1. Do you keep samples of each batch?

 YES  NO

Indicate how long do you keep the samples: years

* + - 1. Are these kept in the original containers?

 YES  NO

* + - 1. Do you carry out inspections or quality audits of your own suppliers?

 YES  NO

If “Yes,” describe audits in detail:

* + - 1. Describe your storage facilities:
		1. **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:

* + - 1. 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
			1. Regulatory Status in Other Countries

List other countries where the product is registered and currently marketed:

Product Country Trade Name

* + - 1. Validation

Are all your production processes validated?

 Yes  No

* + - 1. Do you use an approved manufacturing formula and processing instructions?

 Yes  No

* + - 1. 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

* + - 1. 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*

* + - 1. 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% |  |
| Period of time: |  not controlled 1 year  | 2 years  | other:3 years other: |

 in the same packaging as marketed

 in another packaging:

* + - 1. 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)**

* 1. **Copy of regulatory status product registration license etc**
	2. **Regulatory status in other country**