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**PREQUALIFICATION OF SUPPLIERS FOR NEGOTITAION OF ONCOLOGY & GENERAL DRUGS**

­­Applicants for prequalification need to fill out one form for part I-III. However, Part IV requires that separate forms be filled out for each product being offered for prequalification.

Information provided by potential suppliers seeking prequalification must be regarded as confidential information.

**I. BUSINESS INFORMATION**

1. Name of the company :

Year established :

Form of the company : Individual

Partnership

Corporation

Other (specify)

Legal Status :

Trade register number :

GST Number :

License Number :

(attach copy)

2. Address :

Telephone :

Email :

3. Type of activity carried out by the company

|  |  |  |  |
| --- | --- | --- | --- |
|  | Manufacturer |  | Wholesaler |
|  | Branded products |  | Branded products |
|  | Generic products |  | Generic products |
|  | Medical supplies |  | Medical supplies |
|  | Laboratory reagents |  | Laboratory reagents |
|  | Other products (specify below) |  | Other products (specify below) |



Indicate % of annual turnover:

Pharmaceutical formulations : %

Bulk drugs : %

Medical Supplies : %

Products manufactured for export

Sold only to the local market

Both

3. Annual sales turnover in the previous three years. Split export and domestic sales.

|  |  |  |  |
| --- | --- | --- | --- |
| Annual turnover | Domestic sales | Exports | Year |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**II. MANUFACTURING INFORMATION**

1. Total number of drugs manufactured (provide list of manufactured products).

2. 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*

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

YES NO

If “Yes”, give date of last inspection:

4. Date, number and expiry date of current business licence or permit.

Date :

Number :

Expiry Date :

5. Date, number and expiry date of manufacturing licence or permit

Date :

Number :

Expiry Date :



6. 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 Manufacture Address

(1)

(2)

(3)

Provide detailed information on the quality assurance procedures followed.

**III. QUALITY INFORMATION**

1. Do you maintain your own quality control laboratory?

YES NO

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

YES NO Certificate of Analysis

3. Are control samples of each batch retained?

YES NO

4. Do you have written cleaning procedures?

YES NO

5. Do you have written recall procedure?

YES NO

6. Are all quality control tests performed internally?

|  |  |  |
| --- | --- | --- |
| If “No,” tests performed by external laboratories | | |
|  |  |  |
| Tests | Laboratories | Address |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |



7. Do you keep samples of each batch?

YES NO

Indicate how long do you keep the samples: years

8. Attach a detailed account of the current quality assurance system in your company. A Quality Assurance manual or handbook may be submitted.

9. Describe your storage facilities:

**IV. PRODUCT INFORMATION**

1. Active Pharmaceutical Ingredient(s)

1. Trade Name of the product :

Dosage form: Tablets Capsules Ampoules Vial Others (specify)

Strength of the dosage unit:

Route of administration Oral IM IV SC Others (specify)

Please note the last date of submission of prequalification form

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 **VPS LAKESHORE HOSPITAL & RESEARCH CENTRE LTD.**

in making personal inspection of manufacturing facilities and records.

Name :

Designation :

Signature :

Date :

