**TECHNICALQUESTIONNAIRE FOR PHARMACEUTICAL MANUFACTURERS**

To be completed and returned to UNICEF Supply Division, Quality Assurance Centre, Freeport, DK-2150 Nordhavn, Denmark, with all requested documents attached.

This information is requested in addition to the information requested through the registration at United Nations Global Market Place. [www.ungm.org](http://www.ungm.org).

Further information about UNICEF’s purchase of pharmaceutical products and general quality requirements can be found on <http://www.unicef.org/supply/index_suppliers.html>

**1. GENERAL INFORMATION**

Name, address, telephone, email, fax, Internet address of the company:

**2.** **AFFILIATES**

If the company is owned by another company, or belongs to a group of companies, please indicate your position within the structure:

**3.** **REGULATORY ISSUES**

3.1. **Good manufacturing practice**

Indicate the GMP standards (WHO, PIC-S/EU, FDA or other) with which the company complies:

3.2. **Manufacturing licence for medicinal products**

Please list the pharmaceutical dosage forms you are licensed to manufacture by the National Regulatory Authority and attach a copy of the Manufacturing licence(s) or GMP certificate (it must indicate dosage forms manufactured):

3.3. **Inspection**

Date of last inspection by the National Regulatory Authority:

Please attach a copy of the last inspection report if it can be made available for review by UNICEF on a confidential basis.

Names of all other Regulatory Authorities and International Organisations who have inspected the company. Please also state the outcome of the inspection:

Please attach a copy of the last inspection report if it can be made available for review by UNICEF on a confidential basis.

**4.** **MANUFACTURING**

4.1. **Manufacturing site**

Please state all addresses at which manufacturing of pharmaceutical products takes place, and indicate which year the factory was built (complete one questionnaire for each site):

4.2. **Personnel**

Please indicate the name and the education of the following key staff:

* Managing director:
* Production Manager:
* Quality Assurance Manager:
* Number of personnel in total:
* Number of personnel in production:
* Number of personnel in quality control:

4.3. **Ventilation system**

Please indicate whether the manufacturing areas are equipped with controlled ventilation systems:

Yes No

4.4. **Quality Control**

* Chemical laboratory in-house contracted out
* Biological laboratory in-house contracted out
* Microbiological laboratory in-house contracted out

4.5. **Contract manufacture**

Please indicate if you undertake contract manufacture for other companies:

Yes No

Do you subcontract to other companies?

Yes No

If yes, please list products and/or services:

This questionnaire must be completed by each contract manufacturer involved in supply of products to UNICEF.

4.6. **Sterile products:**

Do you manufacture sterile products?

Yes No

Which Method of sterilisation is used:

Is aseptic manufacturing processes simulated with media fills twice a year for each product time and size?

Yes No

4.7**. Beta-lactames**

Do you manufacture penicillin’s or other beta-lactam products?

Yes No

If yes, does this production take place in separate buildings?

Yes No

4.8. **Recalls**

Do you have a recall procedure? Yes No

Please indicate significant product complaints and any recalls the last threeyears:

4.9. **Production capacity**

|  |  |  |
| --- | --- | --- |
| Product | No of units per year | Last years' production - units |
| Tablets |  |  |
| Capsules |  |  |
| Ampoules |  |  |
| Vials, liquids |  |  |
| Vials, dry powder |  |  |
| Vials, lyophilized |  |  |
| Ointments |  |  |
| Liquids |  |  |
| Powder for oral suspensions |  |  |
| Suppositories |  |  |
| Penicillin, tablets/capsules |  |  |
| Penicillin, powder for oral suspension |  |  |
| Penicillin, powder for injection |  |  |
| Sachets |  |  |
| Other, specify |  |  |

Is production capacity figures based on one or more shifts? (Tick in appropriate box)

1  2  3

**5.** **PRODUCTS**

5.1 **Product licences**

Please enclose a list of all products manufactured by your company and authorised for sale on the domestic market (country of origin).

For each licensed product, please categorise as follows:

The product is marketed on the domestic market.

The product is licensed but not marketed on the domestic market.

The licence is for export only

Kindly also list licences for each product held in other countries:

Please indicate how much in percentage your export is of the total production:

Please also list the name of any contract manufacturer, when a product not is fully manufactured by your company

If possible, please attach an indicative price list.

5.2. **Documentation**

The following product documentation must upon request be available for all products offered to UNICEF:

* Product composition - master formula
* Batch manufacturing record
* Starting materials specification
* Finished product specification
* Validation report
* Stability report
* Packaging and labelling specifications
* Annual Product Review

Please indicate if this documentation is NOT available for any of the products on the list mentioned above in point 5.1.

5.3. **Samples**

Are you willing to provide samples of finished products and batch documentation (on a confidential basis) if requested? Yes No

5.4. **Starting materials**:

Indicate approved starting material sources for the company's major products and indicate if approved DMFs or Certificates of suitability of the Monograph of the European Pharmacopoeia are available:

How is it ensured that only active pharmaceutical ingredients, manufactured in accordance with GMP, are used in poducts?.

**6.** **GMP INSPECTION**

Can UNICEF or any other representative designated by UNICEF perform an inspection of the Manufacturing site? Yes No

Can the National Regulatory Authority participate as observers in the audit?

Yes No

Please attach a Site Master File (PIC-S format). If not attached please indicate why it is not attached:

May UNICEF share the inspection report with its partners WHO Geneva, MSF France, ICRC Geneva and PIC-S member states upon request? (Your company will be notified in case the report is shared.) Yes No

**7.** **OTHER INFORMATION**

Contact person for UNICEF:

Email:

Add any other information:

I hereby certify that the information given in this questionnaire and the attachments is correct.

**Date:**

**Title:**

**Name:**

**Signature:**