

**NI/UNICEF joint TECHNICAL QUESTIONNAIRE FOR PHARMACEUTICAL  
MANUFACTURERS**

*Note to applicant: This questionnaire must be completed for each manufacturing site involved in the supply of the products to NI-UNICEF. Please also note that answers are not limited to the space provided in the questionnaire. If necessary, attach answers in a separate document.*

**1. GENERAL INFORMATION**

- Name, address, telephone, email, 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 Drug 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 Drug Regulatory Authority:
  
- Please attach a copy of the last inspection report by the National Drug Regulatory Authority if it can be made available for review by NI/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 from other Regulatory Authorities or International Organisation if it can be made available for review by NI/UNICEF on a confidential basis. Comments (if any):

## 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 and be reminded this questionnaire must be completed for each manufacturing site involved in supply of products to NI/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 product time and size?  Yes  No

#### 4.7. Beta-lactames

Do you manufacture penicillins 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 three years:

#### 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		
Other, specify		
Other, specify		

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

1

2

3

Other, (please specify):

## **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). Comments (if any):
  - 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. Comments (if any):

### **5.2. Documentation**

- The following product documentation must upon request be available for all products offered to NI/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 requested 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 Active Pharmaceutical Ingredients (APIs) are manufactured in accordance with GMP?

## 6. GMP INSPECTION

- Can NI/UNICEF or any other representative designated by NI/UNICEF perform an inspection of the Manufacturing site?  Yes  No
- Can the National Drug 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 NI/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 NI/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:**