QA.APP.GEN-32.05

|  |
| --- |
| Finished Pharmaceutical Product Questionnaire |

This questionnaire is used to collect information from vendors with regards to finished pharmaceutical products (FPPs) that fall in any of the categories below:

* Product has been reviewed and approved by Stringent Regulatory Agencies (including tentatively approved US FDA Anti-retrovirals for HIV/AIDS),
* Product is WHO prequalified,
* Product is manufactured in a facility that has been inspected and approved by the WHO in compliance with Good Manufacturing Practices (GMP).

Products that do not meet the above criteria may be considered on a case by case basis and may require additional documentation at the discretion of GHSC - QA.

*Instructions:*

*Fill out the information that is applicable to the product. Complete one questionnaire per product.*

*Complete the fields in this questionnaire as applicable.*

* *Tick or place an X in any of the blocks that are true/applicable.*
* *Add rows to tables to include requested information. Alternatively, you may attach information in a separate sheet using the same format requested.*
* *In some instances, it may be required to duplicate sections, copy the section and paste as needed. Alternatively, duplicate copies of the section may be completed and attached.*
* *Update the table of contents when completed.*

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# Applicant Information

*The information in this questionnaire can be shared confidentially between USAID | GHSC and partner organizations, WHO and The Global Fund for procurement purposes. If approved, the approval (including product identification, API and FPP manufacturing sites, and approved specifications) may also be shared with other procurement agencies. If applicant has any objections, mark an X in the box:*  objection to sharing information between USAID | GHSC and partner organizations.

|  |  |
| --- | --- |
| Request for Proposal Number |  |
| Questionnaire Submission Date *(DD/MON/YYYY)* |  |
| Company Name (Supplier)  (*name of company submitting bid*) |  |
| Physical address |  |
| Postal address |  |
| Telephone number |  |
| Fax |  |
| Website |  |
| e-mail |  |
| Link to product | *(Select all that apply)*  Marketing license holder  Distributor/wholesaler  Manufacturer  Other (Specify): |
| Provide contact information for each of the following: | |
| Technical Specifications and Quality Assurance | Name:  Telephone:  Cell phone:  E-mail: |
| Regulatory and patent | Name:  Telephone:  Cell phone:  E-mail: |
| General Inquiries | Name:  Telephone:  Cell phone:  E-mail: |

# Product Identification

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Active pharmaceutical ingredient(s) (use INN when applicable) |  | | | |
| Generic name of the product |  | | | |
| Brand name (if applicable) |  | | | |
| Finished Product Presentation  *(quantity of dosage-form units per pack)* |  | | | |
| Other pack sizes/dosage forms available (*Specify*). | | | |
| Manufacturer Unique Product  Identification Number |  | | | |
| Product Type | Single Pharmaceutical Entity | Fixed Dose Combination | Co-pack |
| Dosage form | Tablets | (Select all that apply)  Scored  Solid  Dispersible  Chewable  Buffered (Specify buffers): \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | (Select all that apply)  Film coated  Enteric coated  Sublingual  Bilayered  Delayed release  Controlled release |
| Capsules | (Select all that apply)  Enteric coated  Sublingual  Delayed release  Controlled release  Other (Specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| Injectable | Solution for injection  Powder for injection  Oily injection | | |
| Syrups/oral liquids | Solution  Suspension  Powder for solution  Powder for suspension | | |
| Oral powder |  | | |
| Implant |  | | |
| Other (*Specify*): | | | |
| Measuring Device | Syringe  Cup  N/A  Other (*Specify*): | | | |
| Strength per dosage form or unit |  | | | |
| Route of administration | Oral  Intramuscular (I.M.)  Intravenous (I.V.)  Subcutaneous (S.C.)  Other (Specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |
| Product Suitable for use in: | Zone I;  Zone II;  Zone III;  Zone IVa;  Zone IVb; Other (Specify)\_\_\_\_ | | | |
| Shelf-life | 24 months  36 month  48 months  60 months  Other (*Specify*) | | | |
| Packaging Type | Blister Pack  Bottle  Vial  Ampule  Other (*Specify*): | | | |
| Label Storage Requirements |  | | | |
| FPP Manufacturer and Manufacturing Site Address |  | | | |
| API Manufacturer and Manufacturing Site Address |  | | | |

# FPP Manufacturer Information

## FPP Manufacturer Identification

* *Attach a copy of the FPP Manufacturer Site Master File*

|  |  |
| --- | --- |
| Manufacturer Name |  |
| Physical address: |  |
| Postal address |  |
| Telephone number |  |
| Fax |  |
| Website |  |
| e-mail |  |

## FPP Manufacturing Activities

|  |  |  |  |
| --- | --- | --- | --- |
| Business Name | Activity | License No. | Address   * *Include plot/unit/production line information if applicable)* * *Identify SRA vs Non SRA unit/production lines* |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

## FPP Good Manufacturing Practice (GMP) Inspections

* *Attach recent/valid GMP certificates/letter (Country of Origin, SRA, WHO, other) for each business listed*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Business Name | Authority | GMP Certificate No. | Date Issued  *(DD/MON/YYYY)* | Valid until  *(DD/MON/YYYY)* |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

# Finished Pharmaceutical Product

*(Reproduce section 5.0 for each FPP component (eg. placebo))*

## Product Formulation

* *Attach a copy of the product formulation that includes the qualitative and quantitative composition (including active ingredient(s), overages if any and all excipients). Please also indicate the standard for each ingredient (e.g. BP, Ph. Eur., USP or in-house). Include a product formulation list for each individual FPP component (e.g. placebos, co-packaged products).*

## FPP Specifications

* *Attach a copy of the release and shelf-life specifications for the Finished Pharmaceutical Product. Please also indicate the standard for specification (e.g. BP, Ph. Eur., USP or in-house)*
* *Attach a copy of the in-house analytical methods (if any), and include the analytical validation reports.*

|  |  |  |  |
| --- | --- | --- | --- |
| Standard | Edition | Year Published | Explain specifications that are additional to those in the pharmacopoeia. |
|  |  |  |  |
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## Method of Manufacture and Process Validation

* *Attach a flow diagram and brief narrative describing the manufacturing and control process of this product with relevant parameters.*
* *Attach a copy of Certificate of analysis of the of the last year or 10 consecutive lots per manufacturing site released (whichever is greater)*

|  |  |
| --- | --- |
| Manufacturing methods for each standard lot size have been validated. | |
| Specify the lot size of the validated lots (minimum and maximum size) |  |
| Specify the reference number for the process validation report |  |
| Specify the manufacturing dates of the validated lot (*LOT ID: (DD/MON/YYYY))* |  |
| Validation reports are not available. | |
| Specify the reference number for the process validation protocol |  |

## Sterile Aspects of the Product

*(Complete this section only for sterile products.)*

* *Attach the data on validation of the sterile aspects of the product including recent medical fill validation data as applicable.*

|  |
| --- |
| Describe the method of sterilization used including conditions such as temperature, time, pressure, if applicable: |
|  |

## FPP Container Closure, Packaging and Labeling

* *Attach a copy of the container closure specifications (include reference to compendia or in-house methods)*
* *Attach a copy of the specifications of the primary and secondary packaging components (include reference to compendia or in-house methods)*
* *Attach a copy of the primary packaging and secondary packaging artwork.*
* *Attach a copy of the package insert/leaflet*
* *Attach a copy of the patient information leaflet*

|  |
| --- |
| Describe the Container Closure Design Characteristics and describe the evaluation of the attributes to establish suitability (protection, compatibility, safety and performance/drug delivery).  *(Container closure design refers to the sum of packaging components that together contain and protect the dosage form. This includes primary packaging components and secondary packaging components, if the latter are intended to provide additional protection to the drug product).* |
|  |
| Describe the materials used for primary packaging, the specifications and the quality control measures (physical characteristics and chemical composition) that are used to ensure consistency in the packaging components; include reference compendia or in-house methods. |
|  |
| Describe the materials used for secondary packaging, the specifications and the quality control measures (physical characteristics and chemical composition) that are used to ensure consistency in the packaging components; include reference compendia or in-house methods. |
|  |
| Primary packaging label language:  English  French  Portuguese  Spanish  Other (Specify): |
| Secondary packaging label language:  English  French  Portuguese Spanish  Other (Specify): |
| Package Insert/ Leaflet language:  English  French  Portuguese  Spanish  Other (Specify): |
| Patient Information Leaflet language:  English  French  Portuguese  Spanish  Other (Specify): |
| For oral powder for suspension and powder for injection, specify if any of these are included on the product label:  In use period (*Specify*):  Storage Conditions (*Specify*): |

## FPP Shelf-life and Storage Conditions

* *Attach report for accelerated and long-term stability studies completed, status report for any ongoing stability studies and protocol for any planned stability studies. Verify that information includes: type and material of container; conditions (temperature/relative humidity/duration of stability study); number of lots involved in the study (minimum of three); lot sizes for each lot tested; date of beginning of the study; and study conclusions.*
* *Attach stability data and storage conditions after reconstitution (For oral powder for suspension and powder for injection)*

|  |  |
| --- | --- |
| Stability testing data for this product is available.  The stability data available is for a product of the same formula, same API source(s), manufactured in the same site and packed in the same packaging materials declared for the product that will be shipped. If not, describe the differences: | |
| Stability testing studies are ongoing. Specify the studies that are ongoing: | |
| Stability testing studies are planned. Specify the studies that are planned:  . | |
| Shelf-life as it appears on the packaging | 24 months  36 months  48 months  60 months  Other *(Specify*): |
| Storage conditions for this product as they appear on the packaging |  |
| Product suitable for use in: | Zone I  Zone II  Zone III  Zone IVa  Zone IVb  Other (Specify)\_\_\_\_ |

For oral powder for suspension and powder for injection, or injection that may be further diluted, or multi-dose containers provide in-use stability data and storage conditions after reconstitution and/or dilution.

Indicate the period (hours/days) until which the product is stable after reconstitution and/or dilution based on the available in-use stability data.

# Active Pharmaceutical Ingredient(s)

*(Reproduce section 5.0 for each API)*

## API Details and Manufacturer Identification

|  |  |
| --- | --- |
| API Name/INN (if any) |  |
| Manufacturer Name |  |
| Physical address: (Specify units and block if existing) |  |
| Postal address |  |
| Telephone number |  |
| Fax |  |
| Website |  |
| e-mail |  |

## API Manufacturing Activities

|  |  |  |  |
| --- | --- | --- | --- |
| Business Name | Activity | License No. | Address   * *Include plot/unit/production line information if applicable)* * *Identify SRA vs Non SRA unit/production lines* |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

## API Good Manufacturing Practice (GMP) Inspections

* *Attach recent/valid GMP certificates/letter (Country of Origin, SRA, WHO, other) for each business listed*

|  |  |  |  |
| --- | --- | --- | --- |
| Authority | Inspection Date  *(DD/MON/YYYY)* | GMP Certificate No. | Valid until  *(DD/MON/YYYY)* |
| [Country of origin] |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

## API Specifications

* *Attach a copy of the in-house analytical methods (if any), and include the analytical validation reports.*
* *Attach a certificate of analysis (3) of API from the API manufacturer and the FPP manufacturer*

|  |  |  |  |
| --- | --- | --- | --- |
| Standard | Edition | Year Published | Explain specifications that are additional to those in the pharmacopoeia. |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

## API Regulatory and Licensing Status

* *Attach a copy of the certificate of suitability to the EU Pharmacopoeia (CEP) and its annexes, a WHO Prequalification CPQ or a copy of the Drug Master File (DMF), as it applies.*

|  |  |  |
| --- | --- | --- |
| CEP: A Certificate of Suitability to the monograph of the European Pharmacopoeia (CEP) is available | | |
|  | CEP Number: |  |
|  | Issue Date: *(DD/MON/YYYY)* |  |
|  | Valid Until: *(DD/MON/YYYY)* |  |
| CPQ: A WHO API Prequalification Certificate | | |
|  | CPQ Number: |  |
|  | Issue Date: *(DD/MON/YYYY)* |  |
|  | Valid Until: *(DD/MON/YYYY)* |  |
| DMF: A Drug Master file (DMF) is available and provided (Open and Restricted parts) | | |
| Other (Specify): | | |

|  |  |  |
| --- | --- | --- |
| API is WHO Prequalified | | |
|  | Issue Date: *(DD/MON/YYYY)* |  |
| API is NOT WHO Prequalified. *Explain* | | |

# Safety and Efficacy and/or Therapeutic Equivalence

*Complete section 6.1 for FPPs approved by Stringent Regulatory Authorities (see SRA definition on Section 7.3); for Generic products, complete section 6.2.*

## For FPPs approved by Stringent Regulatory Authorities

* *This requirement may be fulfilled by providing a public assessment report, such as the Scientific Discussion of the European Public Assessment Report (EPAR), issued by a Stringent Regulatory Authority (SRA), or assessment report(s) issued by the reference SRA or WHO Prequalification Programme.*

|  |
| --- |
| Provide a summary of pharmacology, toxicology and efficacy of the product |
|  |

## For Generic Product: Therapeutic Equivalence Information

### Therapeutic Equivalence Strategy

|  |  |
| --- | --- |
| Therapeutic equivalence is demonstrated by: | |
|  | In vivo bioequivalence studies |
|  | In vitro dissolution tests according to conditions described in WHO BCS classification document (WHO Technical Report Series, No. 937)  By other method (*Specify*): |

### Test Product

|  |
| --- |
| The product used in therapeutic equivalence study is essentially the same as the one that will be supplied (same materials from the same suppliers, same formula and same manufacturing method). |
| There are differences in the product used in therapeutic equivalence study from the one that will be supplied. Explain: |

### Reference Product

|  |  |
| --- | --- |
| Generic Name |  |
| Dosage form |  |
| Strength |  |
| Brand/Trade Name |  |
| Manufacturer |  |
| Manufacture site |  |
| Lot number |  |
| Expiry date: *(DD/MON/YYYY)* |  |

### In Vivo Equivalence Study Details

* *Provide a copy of the In Vivo Equivalence Study Protocol and Report*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study Title/Protocol # | |  | | |
| Study Period | |  | | |
| Contract research organization Information | | | | |
|  | CRO Name |  | | |
|  | CRO Inspection Status | SRA | [Agency Name] | [ Inspection Date *(DD/MON/YYYY)*] |
|  | WHO |  |  |
|  | PIC/S |  |  |
|  | None | | |
| Country of study | |  | | |
| Number of volunteers | |  | | |
| Bio batch size | |  | | |
| Bio batch number | |  | | |
| Bio Batch API source | |  | | |
| Study Conclusion/ (include Study Report Identification Number) | |  | | |

### In Vitro Dissolution Test Details

* *Provide a copy of the In Vitro Dissolution Test Protocol and Report*

|  |  |
| --- | --- |
| Study Title |  |
| Study Period |  |
| Laboratory name (name) |  |
| Laboratory study director (name) |  |
| Contact details of laboratory |  |
| Study protocol identification number |  |
| Study Report Identification Number |  |
| F2 similarity factor value (standard 50-500%) |  |
| F1 (Difference factor) value |  |
| Study Conclusion |  |

### By another method

* *Provide a copy of the Method Test Protocol and Report*

|  |  |
| --- | --- |
| Describe method in detail: | |
| Study Title |  |
| Study Period |  |
| Performance name and location |  |
| Study Protocol identification number |  |
| Study Report Identification Number |  |
|  |  |
| Study Conclusion |  |

# FPP Regulatory and licensing status

## Licensing Status

* *Attach a copy of the licenses that apply*

|  |  |  |
| --- | --- | --- |
| Product registered and currently marketed in the country of manufacture | | |
|  | Country: | Issuing Agency: |
|  | License Number: | Valid Until *(DD/MON/YYYY)*: |
| Product registered but NOT marketed in the country of manufacture | | |
|  | Country: | Issuing Agency: |
|  | License Number: | Valid Until *(DD/MON/YYYY)*: |
| Product registered for export only | | |
|  | Country of origin: | Issuing Agency: |
|  | License Number: | Valid Until *(DD/MON/YYYY)*: |
| Product NOT registered in the country of manufacture. *(Please clarify):* | | |

## Certificate of Pharmaceutical Product (CPP)

* *Attach a certificate of pharmaceutical product according to the WHO Certification Scheme (WHO Technical Report Series, No. 863). An earlier version is not acceptable.*

|  |  |  |
| --- | --- | --- |
| A Certificate of Pharmaceutical Product is available | | |
|  | Country: | Issuing Agency: |
|  | CPP Number: | Valid Until *(DD/MON/YYYY)*: |
| A Certificate of Pharmaceutical Product is NOT available. *(Please explain):* | | |

## Stringent Regulatory Authority (SRA) Approval Status

* *Provide copies of SRA approval/registration*

|  |  |  |
| --- | --- | --- |
| Product is approved by a SRA.  *Tick this box also for HIV ARVs that received US FDA tentative approval.*  Stringent Drug Regulatory Authority (SRA) includes:   1. the U.S. Food and Drug Administration, the Japanese Ministry of Health, Labor, and Welfare and the European Agency for the Evaluation of Medicinal Products (EMEA) centralized procedure; or 2. SwissMedic or Health Canada 3. European Union member states admitted prior to 1996 (Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom).   Reference: ADS 312 Additional Help Document, 22 November 2013 (<http://www.usaid.gov/sites/default/files/documents/1864/ADS312AdditionalHelpDocument.pdf> )  For each SRA country provide the following information: | | |
| Country/Issuing Agency | License Number | Valid Until  *(DD/MON/YYYY)* |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
| Product submitted for registration in a SRA. Awaiting registration approval.  Provide the following information for each country where product is submitted: | | |
| Country/Agency | Submission date  *(DD/MON/YYYY)* | Expected approval date  *(DD/MON/YYYY)* |
|  |  |  |
|  |  |  |
|  |  |  |

## WHO Prequalification Status

* *Provide a copy of the relevant WHO Prequalification acceptance letter signed by the company or provide a copy of the WHO acceptance letter for product dossier review signed by the company.*
* *Provide a recent as well as historical deficiency letters issued by the WHO Prequalification Programme in relation to the specific product dossier*

|  |  |  |
| --- | --- | --- |
| Product is in the list of WHO prequalified products. | | |
| Product submitted for WHO prequalification, but not yet prequalified*.* | | |
|  | Date of Submission *(DD/MON/YYYY)*: | WHO reference number: |
| Product not submitted for WHO prequalification, but is manufactured in a facility that has been inspected and approved by the WHO in compliance with Good Manufacturing Practices (GMP)  *(Provide Rationale for not submitting product for prequalification in instances where a WHO Expression of Interest has been released.)* | | |

## Registration status

* *Provide copies of latest proof of registration for all countries listed*

|  |  |  |  |
| --- | --- | --- | --- |
| List all countries where this product has been registered and is currently marketed. | | | |
| *Country* | *Agency* | *Registration Number* | *Valid Until*  *(DD/MON/YYYY)* |
|  |  |  |  |
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# Product Quality Incidents and Recalls

Provide a listing and summary of incidents and recalls associated with this product for the past 3 years.

|  |
| --- |
|  |

# Samples for Technical Evaluation

As part of the product assessment activities GHSC-QA may request samples of API and/or of the FPP for laboratory analysis.

# Checklist of Attachments

FPP Manufacturer Information

FPP Manufacturer Site Master File

Recent/valid GMP certificates/letter (Country of Origin, SRA, other)

Finished Pharmaceutical Product

Copy of the FPP formulation (verify that all requirements specified in Item 4.0 are included)

Release and shelf-life specifications for the FPP

In-house FPP analytical and validation reports

FPP Certificate of Analysis of the last year or 10 consecutive lots per manufacturing site released (whichever is greater)

Flow diagram and brief narrative describing the manufacturing and control process of this product with relevant parameters.

Data on validation of the sterile aspects of the product including recent media fill validation data, as applicable.

Attach a copy of the container closure specifications (include reference to compendia or in-house methods)

Attach a copy of the specifications of the primary and secondary packaging components (include reference to compendia or in-house methods)

Package insert/leaflet

Patient information leaflet

Primary Packaging Artwork

Secondary Packaging Artwork

Protocol and report for accelerated and long-term stability for each FPP presentation

Status report for any ongoing stability studies

Protocol for any planned stability studies

Stability data and storage conditions after reconstitution (For oral powder for suspension and powder for injection)

API Regulatory and Licensing Status

Recent/valid GMP certificates/letter for each business involved in API manufacturing

Certificate of analysis (3) of API from the API manufacturer and the FPP manufacturer

API In-house analytical methods and validation reports

Copy of the certificate of suitability to the EU Pharmacopoeia (CEP) and its annexes

Copy of WHO Prequalification CPQ

Copy of Drug Master File (DMF) Open and Restricted Parts

Safety and Efficacy and/or Therapeutic Equivalence

Public Assessment Report

In vivo Equivalence Study Protocol

In vivo Equivalence Study Report

In vitro Dissolution Study Protocol

In vivo Dissolution Study Report

Other Method: Equivalence Study Protocol

Other Method: Equivalence Study Report

FPP Regulatory and Licensing Status

Certificate of Pharmaceutical Product (CPP)

WHO Prequalification approval letter signed by your company

WHO acceptance letter for product dossier review including WHO reference number assigned for this specific product

Provide a recent as well as historical deficiency letters issued by the WHO Prequalification Programme in relation to the specific product dossier.

FPP Registration and Marketing Documentation (SRA, Country of Origin and all other)

Authorization and Commitment

Copy of Power of Attorney (in instances where a manufacturer authorizes a distributor to submit the questionnaire)

Authorization to share information

Commitment

# Authorization and Commitment

## Authorization for sharing information with other Agency(ies)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| I, the undersigned [ENTER FULL NAME], confirm that the company has no objection to the information contained herein being shared with USAID | GHSC and partner organizations, WHO and The Global Fund. If approved, the approval (including product identification, API and FPP manufacturing sites, approved specifications and publicly available information) may also be shared with other procurement agencies. | | | | |
|  |  |  |  |  |
| Name |  | Signature |  | Date *(DD/MON/YYYY)* |
| Full title/Position |  | Company name |  |  |
|  |  |  |  |  |

## Commitment

* *Provide a copy of a power of attorney in instances where a manufacturer authorizes a distributor to submit the questionnaire.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| I, the undersigned (ENTER FULL NAME), certify that:  The product offered is identical in all aspects of manufacturing and quality to that US FDA approved product (NDA/ANDA: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) including, formulation, method and site of manufacture, sources of active and excipient starting materials, quality control of the product and starting material, packaging, shelf-life and product information. The following exceptions apply: (Describe)  or  The product offered is identical in all aspects of manufacturing and quality to that registered and marketed in [SPECIFY COUNTRY / Registration No.] including, formulation, method and site of manufacture, sources of active and excipient starting materials, quality control of the product and starting material, packaging, shelf-life and product information. The following exceptions apply: (Describe)  I, the undersigned (ENTER FULL NAME), certify that the information provided above is accurate, correct, complete, up-to-date and true at the time of submission.  If any changes occur to the information provided after submission of this product questionnaire, the manufacturer/supplier undertakes to provide the relevant update as soon as possible. | | | | |
|  |  |  |  |  |
| Name |  | Signature |  | Date *(DD/MON/YYYY)* |
| Full title/Position |  | Company name |  |  |
| Company seal/stamp |  |  |  |  |