

**TENDER DOCUMENTS  
FOR  
SUPPLY AND DELIVERY OF  
ORAL CONTRACEPTIVE PILLS**

***TENDER NOTICE NO.  
CRS/USAID/OC-PILLS-1/2012***

**NEPAL CRS COMPANY**  
TOKHA ROAD, MAHADEV TAR, GONGABU  
GPO Box 842, Kathmandu, Nepal  
Phone: 977-1-4362-097, 4362-098  
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**February 2012**

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**PART I: TENDER NOTICE**

**TENDER NOTICE No.  
CRS/USAID/OC-PILLS-1/2012**

**NEPAL CRS COMPANY  
TOKHA ROAD, MAHADEV TAR, GONGABU,  
GPO Box 842, Kathmandu, Nepal**

**Notice Inviting Sealed Bids for the Supply and Delivery of  
Oral Contraceptive Pills**

(First, **Published on 11<sup>th</sup> February, 2012**)

1. Nepal CRS Company (CRS) has managed a contraceptive social marketing program in Nepal since 1978. Its mandate is to increase the commercial availability of high quality, affordable contraceptives and maternal/child health care products for middle and low-income Nepalese.

CRS has marketed low dose oral contraceptive pills under its own brand names Gulaf and Nilocon since 1983 with the objective of increasing availability at an affordable price and increasing use.

The US Government through USAID has supported the CRS's oral contraceptive pill social marketing programme.

2. The Managing Director of CRS invites sealed bids from manufacturers or their authorized representatives for the supply of 3 million cycles of low-dose oral contraceptive pills. Sealed bids from eligible Bidders must be received by 12.00 hrs on or before the 45<sup>th</sup> day (Monday, 26<sup>th</sup> March 2012) from the first day of publication of this bid notice in "The Rising Nepal" and in "The Himalayan Times". Interested eligible Bidders may obtain further information in respect of the bid documents from the office of CRS, Tokharoad, Mahadevtar, Kathmandu, Nepal, Telephone No 977-1-4362097 and 977-1-4362098, Telefax (977) 1 4362099 or email: kbr@crs.org.np
3. Bid documents comprising instructions to bidder, form of contract, bid forms with detail specifications and terms & conditions are available from the CRS office free of cost until the last date of bid submission. Alternatively, the bid documents can also be downloaded free of cost from the CRS website: [www.crs.org.np](http://www.crs.org.np)
4. Bids must be enclosed in sealed envelopes strictly according to the instructions given in the bid documents and should bear the words:  
**"Bid No. CRS/USAID/OC-PILLS-1/2012  
Supply and Delivery of Oral Contraceptive Pills**

Bids should include the original bid documents and a copy in separate envelopes.

5. Bids must be accompanied by earnest money deposit in the amount at least 2.5% of the total bid value and be valid for a period not less than 120 days from the closing of bids and in the form prescribed in the bid documents. Under normal circumstances successful Bidder(s) will be announced within 60 days from the date bids are opened and all such bidders must furnish a security for performance in the amount equal to 5% of the contract amount and in the form prescribed in the bid document.
6. All bids shall be opened publicly, in the presence of the Bidders and/or their representatives who choose to attend the public opening of the bid, at 13.00 hours in the above office on the day of the closing of bid (Monday, 26<sup>th</sup> March 2012).

7. Bids or modification of bids, from whatever cause arising, received after the closing of bids shall not be considered under any circumstances.
8. Bids should comply in all respects with the instructions to bidder included in the bid documents, in particular to those listed below. Non-compliance with these instructions will result in disqualification.
9. The Bidder must be a pharmaceutical company manufacturing oral contraceptive pills or its authorized representative. The offered products, namely, oral contraceptive pills, must be of the BP, USP standard or of a Pharmacopoeia standard recognized by the Department of Drug Administration (DDA) of Government of Nepal.
10. Goods delivered under the contract must fully comply with the technical specifications mentioned in the contract terms:
  - The supplier will manufacture and supply U.S. Food and Drug Administration (USFDA) or stringent regulatory authority (SRA) approved oral contraceptive pills to the Buyer.
  - Evidentiary proof must be provided of USFDA or SRA approval of product
  - Evidentiary proof must be provided that the Goods is manufactured in a cGMP site.

A stringent regulatory authority (SRA) is a drug regulatory body that closely resembles FDA in standards utilized in its operations. Currently, countries that participate in the International Conference on Harmonization (ICH) are considered as stringent regulatory authorities. The ICH regulatory bodies include: the USFDA; the Japanese Ministry of Health, Labor, and Welfare; the European Agency for the Evaluation of medicinal Products (EMA) centralized procedure; and the European Free Trade Area (represented by the Swiss Medic). The Canadian drug regulatory authority, the Therapeutic Products Directorate, Health Canada, is an observer to the ICH and is also considered a stringent regulatory authority. Other countries may be considered having a stringent regulatory body if they have implemented ICH guidelines and resemble the USFDA in operation, but would be considered on a case-by-case basis. Evidentiary proof must be provided of USFDA or SRA approval of product.

11. The oral contraceptive pills supplied under this Contract will bear the manufacturer's brand name and logo, if any, and its generic name. However, under CRS's social marketing programme, CRS will have the right to repack/over-pack the supplied oral contraceptive pills in other packaging bearing another brand name and logo chosen and owned by CRS.

The manufacturer agrees, without any reservation/qualification, to this right of CRS to repack/over-pack the oral contraceptive pills in another packaging and sell the oral contraceptive pills in Nepal under the brand name and logo chosen and owned by CRS. The manufacturer further agrees that the ownership of the brand name and the logo so used by CRS shall vest solely and exclusively with CRS and the same shall never be used by the manufacturer for any purpose whatsoever.

12. Award for the supply contract will be made from amongst those bidders who fully meet the requirements for eligibility, qualification and responsiveness of proposed supply as per bid documents and whose tendered unit prices are lowest evaluated.
13. Local representative companies or firms should accompany bid forms with letter of authorization from principals and attested copy of income tax certificates.

**Bid documents for the supply and delivery of oral contraceptive pills**

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14. All foreign bidders are required to indicate, if any, the name and address of their local agent together with a copy of the agreement for providing services in connection with this bid.
15. Interested bidders may obtain further information on the bid form and bidding documents at the above office.
16. CRS reserves all rights to reject any or all bids received or/and accept any bid or part of bid without assigning any reason whatsoever.

**PART II: INVITATION LETTER**

NEPAL CRS COMPANY  
TOKHA ROAD, MAHADEVSTAR, GONGABU, KATHMANDU  
Phone: 977-1- 4362097/98  
Fax: 977-1-4362099  
Email: kbr@crs.org.np

Date: February 11, 2012

Bid Notice No. **CRS/USAID/OC-PILLS-1/2012**

To,

.....  
.....

**Sub: Supply and Delivery of Oral Contraceptive Pills**

Dear Sir or Madam:

Nepal CRS Company (CRS) has managed a social marketing program in Nepal since 1978. Its mandate is to increase the commercial availability of high quality, affordable contraceptives and maternal/child health care products for middle and low-income Nepalese.

CRS has been marketing low dose oral contraceptive pills under its own brand names Nilocon and Sunaulo Gulaf since 1983 with the objective of increasing availability at an affordable price and increasing use.

The US Government through USAID has supported CRS's oral contraceptive pill social marketing program. CRS intends to procure 3 million cycles of low dose oral contraceptive pills.

Nepal CRS Company invites sealed bids from eligible manufacturers or their authorized representatives for the supply and delivery of three million cycles of oral contraceptive pills as per the bid documents attached herewith. Sealed bids must be submitted to us by 12.00 hrs on or before **26<sup>th</sup> March 2012**.

All instructions, terms, and conditions given in bid documents must be followed.

You are requested to take care in fulfilling the requirements of the bid documents and submission of the same. Substantial deviation from these requirements may cause rejection of bids.

Yours sincerely,

Krishna B. Rayamajhi  
Managing Director

## **PART III: INSTRUCTIONS TO BIDDER**

### **1 INTRODUCTION**

#### **1.1 Project Description**

Nepal CRS Company (CRS) has managed a contraceptive social marketing programme in Nepal since 1978 with the support of the United States Agency for International Development (USAID) and Government of the Federal Republic of Germany through KfW Entwicklungsbank (KfW) since 1998. Under this successful programme, oral contraceptives pills (OCs), condoms and oral rehydration salts (ORS) supplied by USAID and KfW are widely distributed throughout the country by CRS under its own brand names, extensively promoted through mass media and sold through retail outlets at affordable prices with a view to encouraging their use, particularly by rural couples.

CRS has been marketing low-dose OCs under its own brand names Sunaulo Gulaf and Nilocon since 1983 with the objective of increasing availability at an affordable price and increasing use.

The US Government through USAID has supported the OC social marketing programme.

CRS intends to procure 3 million cycles of low dose OCs over a period of three years. The twenty-eight (28) tablets included in monthly cycle packs shall consist of twenty-one (21) tablets containing estrogen and progestin and seven (7) tablets containing iron.

#### **1.2 Eligible Bidders**

The bid is open only to manufacturers of OCs or their authorized representatives with limitations to the nationalities described below.

Bidder will not be eligible, if:

- his participation is ruled out by sanctions issued by the UN Security Council
- the bidder is legally barred from the procurement process in Nepal on the ground of previous violation of regulations on fraud and corruption.

#### **1.3 Source, Origin and Nationality Requirements**

The authorized USAID Geographic Code (see AIDAR 752.225-70 Source, Origin and Nationality Requirements) is 935 for this procurement, which means products can be made in, and shipped from any country except Libya, Cuba, North Korea, Sudan, Syria, Iran, and Laos (or any other country that may be added to the list by the USG). Products may not contain any part-or ingredient manufactured in the foregoing excepted countries.

#### **1.4 Documents Establishing Bidder's Eligibility and Qualifications**

For the acceptance of the Bid, the Bidder should furnish documents establishing Bidder's eligibility to Bid and his qualifications to perform the contract. The Bidder shall provide such information in the forms prescribed in the bid documents.

#### **1.5 Eligible Goods and Services**

OCs to be supplied under this bid must be registered with the Department of Drug Administration (DDA) prior to pre-shipment inspection of the first consignment, and must also fully comply with other requirements and specifications given in the bid documents.

The manufactured OCs must be U.S. Food and Drug Administration (USFDA) or stringent regulatory authority (SRA) approved.

A stringent regulatory authority (SRA) is a drug regulatory body that closely resembles FDA in standards utilized in its operations. Currently, countries that participate in the International Conference on Harmonization (ICH) are considered as stringent regulatory authorities. The ICH regulatory bodies include: the USFDA; the Japanese Ministry of Health, Labor, and Welfare; the European Agency for the Evaluation of medicinal Products (EMA) centralized procedure; and the European Free Trade Area (represented by the Swiss Medic). The Canadian drug regulatory authority, the Therapeutic Products Directorate, Health Canada, is an observer to the ICH and is also considered a stringent regulatory authority. Other countries may be considered having a stringent regulatory body if they have implemented ICH guidelines and resemble the USFDA in operation, but would be considered on a case-by-case basis.

Evidentiary proof must be provided of USFDA or SRA approval of product.

### **1.6 Cost of Bid**

The Bidder shall bear all costs associated with the preparation and submission of the bid. CRS will, in no case be responsible or liable for these costs, regardless of the conduct or outcome of the bid process.

## **2 PREPARATION AND SUBMISSION OF BID DOCUMENTS**

### **2.1 The Bid Documents**

The commodities required, bid procedures and contract terms are prescribed in the bid documents. The bid documents include:

- i. PART I : TENDER NOTICE
- ii. PART II : INVITATION LETTER TO BID
- iii. PART III : INSTRUCTIONS TO BIDDER
- iv. PART IV : CONTRACT FOR THE SUPPLY AND DELIVERY OF ORAL CONTRACEPTIVE (OC) PILLS
- v. PART V: BILL OF QUANTITIES/ORDER LIST
- vi. PART VI: TECHNICAL SPECIFICATIONS
- vii. SAMPLE FORMS

The following documents and forms must be filled and completed by the Bidder as instructed:

- Form No. 1: Power of Attorney
- Form No. 2: Submission of Bid
- Form No. 3: Supplementary Information Required from the Bidder
- Form No. 4: Financial, Business and Technical Capability of the Manufacturer
- Form No. 5: Manufacturer's Authorization
- Form No. 6: Pharmaceutical Product Questionnaire
- Form No. 7: Earnest Money Deposit
- Form No. 8: Security for Performance Bond
- Form No. 9: Security for Advance Payment Bond

The Bidder is expected to examine all instructions, forms, terms, conditions, and specifications stated in the bid documents. Failure to furnish all information required by the bid documents or submission of a bid not substantially responding to the bid

documents in every respect will be at the Bidder's risk and may result in the rejection of the bid.

## **2.2 Clarification of Bid Documents**

A prospective Bidder requiring any clarification of the bid documents may notify the Buyer in writing or by email or fax at the Buyer's contact details indicated in the Invitation for bids. The Buyer will respond in writing to any request for clarification of the bid documents, which it receives not later than 10 days prior to the deadline for the submission of bids prescribed by the Buyer. Written copies of the Buyer's response including an explanation of the query but without identifying the source of inquiry will be sent to all prospective Bidders which have received the bid documents from CRS or who register their intention to submit a tender to CRS.

## **2.3 Amendment of Bid Documents**

At any time prior to the deadline for submission of bids, the Buyer may, for any reason, whether at its own initiative or in response to a clarification requested by a prospective Bidder, modify the bid documents by amendment.

The amendment will be notified in writing or by email or fax to all prospective Bidders that have received the bid documents from CRS or who register their intention to submit a tender to Nepal CRS, and will be binding on them.

In order to afford prospective Bidders reasonable time in which to take the amendment into account in preparing their bids, the Buyer may, at its discretion, extend the deadline for the submission of bids.

## **2.4 Language of Bid**

The bid prepared by the Bidder and all correspondences and documents, relating to the bid, exchanged by the Bidder and the Buyer, shall be written in English language. Provided that any printed literature furnished by the Bidder may be written in another language so long as accompanied by translation of its pertinent passages in which case, for purposes of interpretation of the bid, the English translation shall govern.

## **2.5 Bid Prices and Currencies**

The Bidder shall indicate on the appropriate Bill of Quantity attached to these documents, the unit price and total bid price of the Commodities it proposes to supply under the contract.

The prices shall be quoted, either in Nepalese currency or in an international trading currency, preferably in EURO or US Dollar. In case, currency of bid is not stated in the Bill of Quantities, all such bids will be evaluated based on Nepalese Currency.

During evaluation, bids will be compared by converting all bids in foreign currencies into equivalent Nepalese currency. For this purpose, all foreign currencies will be converted at the official selling rate on the **Fifteenth day** prior to the closing of bids (March 11, 2012), as published by **Nepal Rastra Bank**. Prices should be quoted in the following manner:

Prices indicated on the Bill of Quantities shall be entered separately in the following manner:

2.5.1 For commodities offered from within Nepal;

Total free arrival at designated destinations by road, consisting of:

The prices of commodities, quoted ex-factory, ex-warehouse or off-the-shelf, as applicable, including excise, sales and other taxes already paid or payable, to be shown separately.

Charges for inland transportation, insurance covering at least, pilferage, breakage, and non-delivery of the commodities and other local costs incidental to delivery of the Commodities to their final destinations.

2.5.2 For commodities offered from abroad;

Total DDU (delivered at designated place duty unpaid, according to INCOTERMS 2000) at designated destinations by sea/road/air.

All taxes, charges and other expenses on Bidder's account except Government of Nepal taxes, charges and other expenses within Nepal border.

2.5.3 The Buyer would assist the Bidder in providing all necessary tax exemption certificates; however, it would be the responsibility of the Bidder to supply the commodities at the final destinations within specified time. For reimbursement of duties and taxes paid in Nepal, authorized documentary evidence of such expenses should be submitted to the Buyer.

2.5.4 The commodities will be tendered only once for the entire programme period on a fixed price basis and the supply will follow the overall supply schedule as given in Part V of the bid documents.

2.5.5 Unit price quoted by the Bidder shall remain unchanged during the Bidder's performance of the contract and not subject to variation on any account. A bid submitted with an adjustable price quotation will be treated as non-responsive and rejected.

**2.6 Documents Establishing Bidder's Eligibility and Qualification:**

The Bidder shall furnish, as part of its bid, documents establishing the Bidder's eligibility to bid and its qualifications to perform the contract if its bid is accepted.

The documentary evidence of the Bidder's qualifications to perform the contract, shall establish to the Buyer's satisfaction that the Bidder or Bidder's principal in case of submission by an authorised representative, is a manufacturer of quality OCs, has the financial, technical and production or supply capability necessary to perform the contract that, in case the Bidder not being present within the Buyer's country, the Bidder is or will be represented by an agent in that country, who is equipped and able to perform the Supplier's obligations.

With the bid, the Bidder should provide following documentary information containing;

- Presence of properly signed form 1 (Power of Attorney), 2 (bid submission form) and 5 (Manufacturer's Authorization) as per Part VII, sample forms
- Evidence that the Bidder is either a primary manufacturer and does formulation, testing and packaging of OCs on its own premises or is the authorized representative of such primary manufacturer;
- Production history of the manufacturer, including products currently manufactured;
- Capacity of the factory and available capacity for this order;
- Regulatory compliance credentials and applicable national regulatory code;

- Other WHO standard GMP, USFDA /SRA and quality assurance certifications;
- Data to support claimed shelf life at tropical temperatures (see Part VI – technical specifications)
- Information about the Bidder's current financial situation as per Part VII, Form 4.
- Statement that the manufacturer is not presently excluded from supply of oral contraceptive by WHO or UNFPA for reasons of substandard quality or his participation is ruled out by sanctions issued by the UN Security Council.

## **2.7 Documents Establishing Conformity of the Offered Commodities to Bid Documents**

Bidder shall furnish documents establishing the conformity to the bid documents of the commodity, which the Bidder proposes to supply under the contract.

The documentary evidence of the commodities conformity to the bid documents may be in the form of literature, drawings and data, and shall furnish:

- i. A detailed description of the commodities and essential technical and performance characteristics;
- ii. A clause-by-clause commentary on the Buyers technical specifications demonstrating the commodities and services are substantially responsive to those specifications or a statement of deviations and exceptions to the provisions of the technical specifications.

## **2.8 Period of Validity of Bids**

The validity of bids should be at least for **Ninety (90) days** from the closing date of bids (June 24, 2012). A bid valid for shorter period than above will be rejected as non-responsive.

In exceptional circumstances the Buyer may solicit the Bidder's consent for an extension of the period of validity beyond 90 days. The request and the responses thereto shall be made in writing (or by fax). The bid bond provided under Clause 3.5 shall also be suitably extended. A Bidder may refuse the request without forfeiting its bid bond. A Bidder granting the request will not be required nor permitted to modify its bid.

## **2.9 Local Agents**

All foreign Bidders are required to indicate the name and address of their local agents, if any, together with a copy of agreement for providing services in connection with this bid.

## **2.10 Delivery Schedule**

All commodities should be delivered as per schedule, mentioned in the Bill of Quantities shown in PART V of bid documents.

Commodities manufactured in Nepal and India should be transported by road and those outside Nepal and India by surface transport or air at the Bidder's option, to meet the supply deadlines indicated in the bid documents.

### **2.11 Variation in Quantity**

The Buyer reserves the right to increase or decrease by up to twenty percent **(20%)** the quantity of Commodities specified in the Bill of Quantities without any changes in per unit price or other terms and conditions, by a written order given to the Supplier at least **120** days prior to the contractual delivery time.

### **2.12 Liquidated Damages**

If the Bidder fails in the delivery of the goods as scheduled, an amount at the rate of 0.05% per day of the value of undelivered goods will be charged as liquidated damages. In the event of the delivery schedule being delayed for more than 100 days, the Buyer may terminate the contract and forfeit all security for performance. The amount of liquidated damages shall, however, be subject to a maximum limitation of ten percent (10%) of the total contract sum.

### **2.13 Format and Preparation of Bid**

The original bid form and accompanying documents (as specified in Clause 2.1), clearly marked "Original Bid", plus one copy of the bid must be received by the Buyer at the date, time and place specified pursuant to Clauses 3.1 and 3.2. In the event of any discrepancy between the original and the copies, the original shall govern.

The original and all copies of the bid shall be printed, typed, or written in indelible ink and shall be signed by the bidder or a person or persons duly authorized to sign on behalf of the bidder. Such authorization shall be indicated by written power-of-attorney accompanying the bid. The person or persons signing the bid shall initial all pages of the bid, except for un-amended printed literature. The name and position held by each person signing must be typed or printed below the signature.

The bid shall contain no obliteration, erasures or overwriting except as necessary to correct errors made by the Bidder, in which case such corrections shall be initialled by the person or persons signing the bid.

## **3 SUBMISSION OF BIDS**

### **3.1 Sealing, Marking and Submission of Bids**

The bid shall comprise of sealed outer package with separate inner packages with original bid and copy of bid.

Marking of bids shall be as follows:

- (a) The inner and outer packages shall be addressed to the Buyer at the following - address;

**The Managing Director,  
Nepal CRS Company  
Tokha Road, Mahadevtar,  
Gangabu, Kathmandu, Nepal  
Telephone: (977) 1 4362097/98 Telefax: (977) 1 4362099**

And

- (b) The inner package containing the original bid shall bear the words  
**"Original Bid"**  
**"Bid Notice No. CRS/USAID/OC-PILLS-1/2012**  
Bid for the Supply and Delivery of **Oral Contraceptive Pills** and the words  
**"DO NOT OPEN BEFORE** (*date and time of opening of bids*)."
- (c) The inner package containing the copy of the bid shall bear the words  
**"Copy of the Bid"**  
**"Bid Notice No. CRS/USAID/OC-PILLS-1/2012 Bid for the Supply and Delivery of**  
**Oral Contraceptive Pills**  
and the words  
**"DO NOT OPEN BEFORE** (*date and time of opening of bids*)"

The documents to be clearly stamped either "Original" or "Copy."

In addition to the information required in sub clauses (a), (b) and (c) above, the inner envelope shall indicate the name and address of the bidder to enable the bid to be returned unopened in case it is declared "Late" pursuant to Clause 3.3.

If the cover containing bid document is not sealed and marked as instructed above, no responsibility will be assumed for any misplacement of the bid, or premature opening of the envelope.

Samples of commodities accompanying the bid must be submitted in separately sealed packing.

### **3.2 Deadline for Submission of Bids**

Bids must be received by the Buyer at the address specified under Clause 3.1 no later than 12:00 hours noon, on or before the **45<sup>th</sup> day** (march 26,2012) from the first day of publication of notice inviting bids in the National Daily "The Rising Nepal" and in the DgMarket.

The Buyer may, at its discretion, extend this deadline for the submission of bids by amending the bid documents, in which case all rights and obligations of the Buyer and Bidders previously subject to the deadline will thereafter be subject to the deadline as extended.

### **3.3 Late Bids**

In no case will late submission of bids be allowed. Any bid received by the Buyer after the deadline for submission of bids prescribed by the Buyer will be rejected and returned unopened to the Bidder. Bids delivered through courier and post and received later than due date shall not be registered and returned unopened. The inner envelope shall indicate the name and address of the Bidder to enable the bid to be returned unopened in case it is declared "Late".

### **3.4 Modification and Withdrawal of Bids**

The Bidder may modify or withdraw its bid after the submission of the bid, provided that written notice of the modification or withdrawal is received by the Buyer prior to the deadline prescribed for the submission of bids.

The Bidder's modification or withdrawal notice shall be prepared, sealed, marked, and dispatched in accordance with the provisions of Clause 3.1 of the Instructions to Bidders. A

withdrawal notice may also be sent by fax but followed by a signed confirmation copy, received not later than the deadline for submission of bids.

No bid may be modified subsequent to the deadline for submission of bids. No bid may be withdrawn in the interval between the deadline for submission of bids and the expiration of the period of bid validity specified by the Bidder on the bid Form. Withdrawal of a bid during this interval may result in the Bidder's forfeiture of its bid security.

### **3.5 Bid Bond**

Bid bond in the amount at least equivalent to **2.5%** of the total bid price must accompany the bid. The bid bond shall be in favor of the Buyer and in the form as prescribed in Part VII of bid documents. All bid bonds issued by foreign-based banks must be endorsed by a bank operating in Nepal. Unacceptable deviations in the text of the bid bond from the one prescribed in Part VII of bid documents may cause disqualification of Bids.

The bid bond shall be valid for a period of not less than **one hundred and twenty (120) days (July 24, 2012)** from the date the Bids are due. Bids not accompanied by sufficient bid bond shall be rejected as non-responsive. If during the bid validity period, the Bidder withdraws his bid, the bid bond shall be forfeited and the bidder may be disqualified from further bidding with the Buyer.

An unsuccessful Bidder's bid bond will be discharged/returned as promptly as possible but not later than 60 days after the expiration of the period of bid validity.

The successful Bidder's bid bond will be discharged upon the Bidder executing the contract and furnishing the necessary performance security as prescribed in Part VII of Bid documents.

The bid bond may be forfeited if a Bidder withdraws its bid during the period of bid validity specified by the Bidder on the bid form or, in the case of a successful Bidder, if the Bidder fails to sign the contract or to furnish performance security as required by the contract.

### **3.6 Samples of the Proposed Supply**

The Bids must be accompanied with the samples of the commodities intended to be supplied to the Buyer.

The sample shall consist of one carton containing one hundred (100) monthly cycles of OCs as prescribed in PART VI section 1 of the technical specifications.

### **3.7 Bid Opening**

Bids shall be opened publicly, in the presence of the Bidders and/or their representatives, at **13.00 hour on March 26, 2012**, in the Buyer's office on the day of the closing of bid.

The bidders and/or their representatives participating in the bid opening must come with a proper authorization letter from the principal. The bidders' representatives who are present shall sign a register as evidence of their attendance. Bidders' names, addresses, and the names of their respective local agents, if any, shall be noted.

The bidders' names, list of items offered, list of samples submitted, prices of bids, any discount offered, modifications and bid withdrawals, and the presence or absence of

the requisite bid security, and such other details as the Buyer, at its discretion, may consider appropriate will be announced and recorded at the opening. Any bid price, discount, or alternative bid price, which is not read out and recorded at bid opening, will not be taken into account during evaluation of the bid.

The Buyer shall prepare minutes of the bid opening that contains a summary of the information of every bid read at bid opening.

### **3.8 Security for Performance**

Within fifteen days from the date of receipt of the notification of award from the Buyer, the successful Bidder shall furnish required security for performance in the amount equal to **5%** of the contract amount and attend the office of the Buyer for execution of contract agreement. If the successful Bidder fails to execute the contract or to furnish such a security, the bid bond shall be forfeited and the Bidder may be disqualified from further bid with the Buyer. In such event the Buyer may make the award to the next lowest evaluated Bidder or call for new Bids.

The security for performance shall be in favor of the Buyer or KfW and in the form of a performance bond as prescribed in Part VII of bid documents. The security for performance shall cover the entire contract duration and the warranty period whichever is longer. All performance bonds issued by foreign-based banks must be counter guaranteed by a bank operating in Nepal.

## **4 BID EVALUATION**

### **4.1 Clarification of Bids**

To assist in the examination, evaluation, and comparison of Bids, the Buyer may at its discretion ask the Bidder for any clarification of bid. The request for clarification and the response shall be in writing but no changes in the price or substance of the bid shall be sought, offered, or permitted except as required to confirm the correctness of arithmetical errors during evaluation of Bids.

The bids will be evaluated in the following order.

### **4.2 Preliminary Examination, Qualification and Determination of Technical Responsiveness of Bids**

The Buyer will examine the Bids to determine whether they are complete, whether any computational errors have been made, whether required guarantees have been furnished, whether the documents have been properly signed, and whether the Bids are generally in order.

The validity of bid must be at least for **90 days (until June 24, 2012)** from the closing of Bids (March 26, 2012). A bid valid for shorter period than the required minimum will be rejected as non-responsive.

bid must be accompanied with an earnest money deposit in the prescribed form and for an amount not less than **2.5%** of the total bid amount. Earnest money deposit of less than the required sum and valid for a period less than **one hundred and twenty (120) days** from the closing of Bids (until July 24, 2012) will be rejected as non-responsive.

Bids offering a delivery period in excess of **180 days** for the first year supply after signing of the contract will be rejected and not considered for further evaluation.

OCs to be supplied under this bid must be registered with the Department of Drug Administration (DDA) prior to shipment of the first consignment, and must also fully comply with other requirements of specifications given in the bid documents. Those Bidders who do not have their products registered at the time of tender submission but expect it to be done before the pre-shipment inspection, can also offer such commodities. However, the bidder must clearly state so in a letter during tender submission. Failure of the bidder to submit copies of DDA registration certificate at the time of tender submission and failure to announce the intention of submitting later during inspection will result in the disqualification of bid. Such bids will not be considered for further evaluation.

The supplier will manufacture and supply U.S. Food and Drug Administration (USFDA) or stringent regulatory authority (SRA) approved oral contraceptive to the Buyer. Evidentiary proof must be provided of USFDA or SRA approval of product failing which the bid will be rejected and not considered for further evaluation

Prior to the detailed financial evaluation, the Buyer will determine the technical responsiveness and qualification of the bid. A technically responsive bid is one which conforms to all the terms and conditions without material deviations and which also establishes Bidder's qualifications to supply and deliver the offered commodities within stipulated delivery schedule. Qualified bid offering conforming commodities is the one, which is responsive, and whose current products meet the requirements of the specifications when tested in an independent laboratory.

The Buyer may waive any minor nonconformity or irregularity in a bid, which does not constitute a material deviation.

The technical responsiveness of the Bids will be established when a bid is in full compliance with the qualification criteria mentioned in 2.6.

Offered commodities and samples thereof must comply with the requirements of the specifications.

All terms and conditions of the bid documents must be acceptable to the Bidder and any conditional bid will not be acceptable to the Buyer.

All non-substantial Bids will be rejected as non-responsive and shall be excluded from financial evaluation. A bid determined as substantially non-responsive will be rejected by the Buyer and may not subsequently be made responsive by the bidder by correction of the non-conformity.

### **4.3 Financial Evaluation and Comparison of Bids**

4.3.1 Only those bids determined as substantially responsive pursuant to Clause 4.2 will be considered by the Buyer for financial evaluation.

4.3.2 Arithmetical errors will be rectified on the following basis. If there is a discrepancy between the unit price and the total price per item that is obtained by multiplying the unit price and quantity, the unit price shall prevail and the total price per item will be corrected. If there is a discrepancy between the total amount and the sum of the total price per item, the sum of the total price per item shall prevail and the Total Amount will

be corrected. If the Bidder does not accept the corrections of the errors, his bid will be rejected.

4.3.4 Bids will be financially evaluated in the following manner

All substantially responsive bids will be compared for their price competitiveness. Comparison between quoted prices will be made as follows;

If all the Bidders are local Bidders then the bids shall be compared for their combined supply and delivery prices free arrival at the designated stores.

If all the Bidders are foreign Bidders then the bids shall be compared for their combined supply and delivery prices quoted on DDU basis at the designated stores.

If both kinds of Bidders are present then the foreign Bidders' delivery prices at the designated stores shall be compared with the local Bidders' ex-factory prices plus transportation and insurance cost free arrival to designated stores. Bids will be compared by converting all bids in foreign currencies into equivalent Nepalese currency. For this purpose, all **foreign currencies will be converted at the official selling rate on the fifteenth day prior to the closing of bids (March 11, 2012), as published by Nepal Rastra Bank.**

Bids will be evaluated and the contract will be awarded to lowest evaluated bidder.

**5 BUYER'S RIGHT TO ACCEPT ANY BID AND TO REJECT ANY OR ALL BIDS**

The Buyer reserves the right to accept or reject any bid, and to annul the bid process and reject all bids at any time prior to award of contract, without thereby incurring any liability to the affected Bidder or Bidders or any obligation to inform the affected Bidder or Bidders of the grounds for the Buyer's action.

**6 NOTIFICATION OF AWARD**

Prior to the expiration of the period of bid validity, the Buyer will notify the successful Bidder in writing by registered letter or by fax that its bid has been accepted. The notification of award will constitute the formation of the contract.

Upon furnishing of performance security by the successful Bidder, pursuant to Clause 3.8 of the Instructions to Bidders, the Buyer will promptly notify other unsuccessful Bidders and will discharge their bid bond.

**7 SIGNING OF CONTRACT**

At the same time as the Buyer notifies the successful Bidder that its bid has been accepted, the Buyer will send the Bidder the contract Form provided in the bid documents, incorporating all agreements between the parties.

Within 30 days of receipt of the contract Form, the successful Bidder shall furnish required security for performance in the amount equal to 10% of the contract amount, sign, date the contract, and return it to the Buyer.

Alternatively, the successful Bidder may choose to be present on a mutually agreed date for signing the contract in the Buyer's office.

**8 LAWS GOVERNING THE CONTRACT**

The contract shall be subject to the contract laws of Nepal and the jurisdiction of the courts of Nepal for matters not specifically covered by this contract.

**PART IV: CONTRACT FOR THE SUPPLY AND DELIVERY OF ORAL CONTRACEPTIVE (OC) PILLS**

Whereas Nepal CRS Company, Tokha Road, Mahadevtar, Gangabu, Kathmandu, Nepal (hereinafter called the **Buyer**) had issued invitation for bid on February 11, 2012 for the yearly supply and delivery of Oral Contraceptive Pills (hereinafter called the **Commodity**) for the year 2012-2014 and \_\_\_\_\_ (hereinafter called the **Supplier**) has submitted his Bid No. **CRS/USAID/OC-PILLS-1/2012**, , dated \_\_\_\_\_ in response to this invitation for bids, now therefore, in accordance with the invitation to bid and Supplier's bid it is hereby agreed as follows:

**1. PARTS OF CONTRACT**

The following documents are by reference incorporated into this contract and together with the condition of this contract shall prevail in the following order;

- a) Conditions of this Contract
- b) Summary of order List / Bill of Quantities (Annex \_\_ )
- c) Specifications of Commodities (Annex \_\_ )
- d) Buyer's letter to Supplier dated \_\_\_\_\_ for award of supply contract. (Annex\_\_ )
- e) Supplier's Bid No. **CRS/USAID/OC-PILLS-1/2012** dated \_\_\_\_\_
- e) Performance Bond (Annex \_\_ )
- f) Advance Payment Bond (Annex\_\_\_\_\_ )

**2. PRICE OF SUPPLY**

The Supplier agrees to supply the Commodities at Central Warehouse of Nepal CRS Company, Tokha road, Mahadevtar, Gangabu Kathmandu, Nepal and the Buyer agrees to purchase the Commodities as stated in ANNEX \_\_ of this contract. The invoices shall state separately Nepalese import duties, taxes and other public charges, if included in the amounts invoiced.

It is agreed that the unit price of the Commodity is .....(Currency of bid) per cycle.

	<b>2012</b>	<b>2013</b>	<b>2014</b>	<b>Total</b>
<b>Quantity of OC Pill Cycles</b>	900,000 cycles	1,000,000 cycles	1,100,000 cycles	3,000,000 cycles
Supplier's DDU Price/Cycle at CRS Stores				
Supplier's Total Annual DDU Cost				

The total price for the Commodities including packing, insurance and transportation **at Central Warehouse of Nepal CRS Company at Tokha road, Mahadevtar, Gangabu Kathmandu, Nepal** amounts to the sum of \_\_\_\_\_ (In Words: \_\_\_\_\_ )

Prices charged by the Supplier for the Commodities delivered and services performed under the contract shall not, with the exception of any price adjustments authorized by the contract, vary from the prices quoted in its bid.

**3. DELIVERY SCHEDULE**

**3.1 Place of Delivery:**

The Commodities must be delivered at Central Warehouse of Nepal CRS Company at Tokha road, Mahadevtar, Gangabu Kathmandu, Nepal in accordance with the given delivery schedule.

**3.2 Delivery Period:**

Supply and delivery of Commodities shall be strictly carried out according to the prescribed delivery schedule. Commodities delivered after the respective schedules will be liable for liquidated damages as per Clause 16 of this contract.

**4. VARIATION IN QUANTITY / CHANGE ORDER**

The Buyer may, at least **120** days before the contractual delivery time, by a written order given to the Supplier, make changes within the general scope of the contract in any one or more of the following;

- (a) an increase or decrease in the supply quantity by up to **20%** .
- (b) the place of delivery; or
- (c) the method of shipment or packing.

If any such change causes an increase or decrease in the cost of, or the time required for the Supplier's performance of any part of the work under the contract, whether changed or not changed by the order, an equitable adjustment shall be made in the contract Price or delivery schedule, or both, and the contract shall accordingly be amended. Any claims by the Supplier for adjustment under this Clause must be asserted within thirty (30) days from the date of the Supplier's receipt of the Buyer's change order. However, for changes in quantities only within the limits as shown in clause 4(a), no adjustment in the unit price of Commodities will be made.

**5. TRANSPORTATION INSURANCE**

Transportation of the Commodities as laid down in the delivery at **Central Warehouse of Nepal CRS Company at Tokha road, Mahadevtar, Gangabu Kathmandu, Nepal** shall be the responsibility of the Supplier, and the cost thereof shall be included in the contract Price. Transport insurance will be taken out by the Supplier for the duration of the entire transport and shall be for an amount equal to 110% of the DDU value of the commodity, in freely convertible currency, if foreign exchange costs are involved. The provisions to be agreed upon are the Institute Cargo Clauses (A) All risks and, where necessary, the Institute War Clauses (Cargo) and the Institute Strikes Clauses (Cargo) of the London Institute of Underwriters in their version of 1982 or Comparable clauses.

**6. TRANSPORT DOCUMENTS**

Notice of transport shall be made by letter or fax to the following address:

The Managing Director,  
Nepal CRS Company  
Tokha Road, Mahadevtar, Gongabu,  
P.O. Box 842  
Kathmandu, Nepal.

Telephone: (977) 1 4362097/98 Telefax: (977) 1 4362099

Notice of transport shall contain the following information:

- a) Contract number
- b) Name and description of the Commodities
- c) Total quantity of the Commodities shipped/dispatched;
- d) Expected date/time of arrival of the Commodities at designated place of delivery;

Upon shipment and delivery the Supplier shall provide the following documents directly to the Buyer:

- i. Four copies of the Supplier's invoice showing description of commodity, quantity, unit price, total amount with separation of any customs duty, sales taxes or other similar taxes;
- ii. Original copy of consignment note as applicable;
- iii. Four copies of packing list identifying contents of each shipping carton/ package;
- iv. Two copies of manufacturer's guarantee certificate;
- v. Two copies of manufacturer's test certificates;
- vi. Inspection certificate issued by the nominated inspection agency, as applicable;
- vii. Certificate of origin of Commodity;
- viii. Receipt certifying that the goods have been received at the final delivery point as specified;

## **7. QUALITY OF COMMODITIES**

The Commodities shall be new and shall meet the quality required by the specifications. All Commodities supplied under this contract shall be suitable for delivery, storage and use under tropical conditions including high temperature, high humidity and natural storage conditions.

## **8. PACKAGING, MARKING AND LABELLING**

The Supplier shall provide such packing of the Commodities as is required to prevent its damage or deterioration during transit to the final destination as indicated in the contract. The packing shall be sufficient to withstand, without limitation, rough handling during transit and exposure to extreme temperatures, salt, and precipitation during transit and open storage.

The Supplier shall ensure that the Commodities are not exposed to temperatures exceeding 20°C - 25°C (68°F - 77°F) at any time during transit, causing accelerated deterioration of the commodity, compared to that at temperatures below 20°C - 25°C.

Packing case size and weights shall take into consideration where appropriate, the remoteness of the Commodity's final destination and the absence of the heavy handling facilities at all points in transit.

The packing, marking, and documentation within and outside the packages shall comply strictly with such special requirements as described below.

Each shipping carton/package shall have the following information printed in **BOLD LETTERS** on the outside and the size of the letters shall not be smaller than 2cm in height.

- a) Destination: **"Nepal CRS Company, Tokha Road, Mahadevtar, Gongabu, Kathmandu Nepal"**

- b) Name of Consignee:  
Contract Number: "**CRS/USAID/OC-PILLS-1/2012**"
- c) Name of Manufacturer:
- d) Name of the Drug/Commodity: "**Oral Contraceptive Pills**"
- e) Quantities of Commodities inside the Shipping carton/ package:
- f) Date of manufacture of Commodity: "**MM / YYYY**"
- g) Expiry date of Commodity: "**MM / YYYY**"
- h) Special Handling Instructions (as appropriate):
- i) Storage Instructions:  
" Protect Oral Contraceptive and Emergency Contraceptive Pills against exposure to:  
--Extreme heat above **20°C - 25°C (68°F - 77°F)**  
--Moisture  
--Direct Sunlight
- j) Up Arrow: "**↑**"
- k) Other instructions to shippers and warehouse personnel (as appropriate).

## **9. WARRANTY OF COMMODITIES AND EXPIRY DATE**

The Supplier warrants that the Commodities supplied under the contract is new, unused, of the most recent or current models and incorporate all recent improvements in formulations and Ingredients unless provided otherwise in the contract. The supplied Commodities must have remaining minimum of 48 months shelf life upon delivery to the final destination or must meet the specifications given in Part VI "Specification of Oral Contraceptive Pills" of the bid documents. The Supplier further warrants that the Commodities supplied under this contract shall have no defect arising from formulation, ingredients, and workmanship or from any act or omission of the Supplier that may develop under normal use of the supplied Commodities in the conditions obtaining in the country of final destination.

This warranty shall remain valid for minimum 48 month after the delivery and receipt of the Commodities at its final destination indicated in the contract.

The Buyer shall promptly notify the Supplier in writing of any claims arising under this warranty. Upon receipt of such notice, the Supplier shall, with all reasonable speed, replace the defective Commodities or parts thereof, without additional costs to the Buyer.

If the Supplier, having been notified, fails to replace the defective Commodities within 90 days, the Buyer may proceed to take such remedial action as may be necessary, at the Supplier's risk and expense and without prejudice to any other rights, which the Buyer may have against the Supplier under the contract.

## **10. INSPECTION AND ACCEPTANCE**

Before the Commodities are ready for packaging and dispatch after production, the Buyer or its representative shall have the right to inspect and/or test the Commodities to confirm its compliance with the provisions of the contract. All in-house technical and production data related to inspections and tests that may be conducted on the premises by the manufacturer shall be furnished to the inspectors, appointed by the Buyer, at no charge to the Buyer.

If the Buyer opts to carry out a pre-delivery inspection and quality assurance on the supplies through an independent third party, such an inspection agent appointed by the Buyer will visit the manufacturing premises of the Supplier and draw required number of random samples of oral contraceptive pills from every lot/batch manufactured under

the contract. These samples will be tested at an independent laboratory to ascertain full compliance of the Commodities with the specifications. Oral Contraceptive Pills of only those lots/batches, which comply, with the requirements of the specifications will be readied for shipment. The Supplier shall not dispute the results of the test conducted on such randomly drawn samples, nor shall supply the Commodities from the rejected lots/batches. The Supplier shall ensure the supply of the full contractual quantity, after taking of random samples

Once the acceptable commodities have been readied for shipment and delivery, a pre-shipment inspection will be carried out by the inspection agent to verify packaging and labeling requirements of the specifications. The Commodities will be shipped only after it has been cleared for shipment by the inspection agent. The Buyer shall notify the Supplier in writing of the identity of the agent or representative retained for these purposes.

Should the supply item fail to meet the requirements of the specifications, the Supplier shall replace the items within the time specified for delivery or extension granted. However, under such circumstances the Supplier will bear the extra costs incurred in connection with additional inspection, failing which the Buyer shall be entitled to recover all such additional costs from any payments due to the Supplier.

The Buyer, at its discretion, may not choose to test the commodities prior to its delivery if such commodities have been produced in the countries of European Union, North America, Japan or Australia.

The Buyer's right to inspect, test and where necessary, reject the Commodities after the arrival in the Buyer's country, shall in no way be limited or waived by reason of the Commodities having previously been inspected, tested and passed by the Buyer or its representatives prior to the shipment from the country of origin.

Providing always that replacement is possible, the Supplier shall refund to the Buyer all amounts paid on account or recovery may be made from the security for performance.

Nothing in this clause, in any way, releases the Supplier from any warranty or other obligations under this contract. Buyer's failure to inspect and accept or reject supplies shall not relieve the Supplier from responsibility nor impose liability on Buyer, for non-conforming supplies.

## **11. SAMPLES OF THE PROPOSED SUPPLY**

The Supplier shall furnish one set of the sample of the Commodity per lot/batch, approved for supply (as reference sample), with the actual shipment. One set of sample shall consist of one carton containing one hundred (100) monthly cycles of OCs and shall meet other packing and marking requirements as prescribed in PART VI section 1 of the technical specifications.

## **12. PAYMENTS**

Payment of the contract price for the drugs/commodities purchased hereunder shall be made in the following manner;

- a) Foreign currency cost will be paid at the prices and in the currency as mentioned in the bid.
- b) 20% of the annual supply cost may be paid after signing of contract and within 45 days of receipt of a commercial invoice and upon submission of a bank guarantee for the equivalent amount and currency in the form prescribed in PART VII, Form-9 of

the tender documents. Validity of advance payment bond shall be until either last lot has been delivered or until complete recovery of advance has been made, whichever is later. The Buyer will adjust such advance by percentage deductions from future payments against delivery of the Commodities on a pro rate basis.

- c) 70% of the cost will be paid to the Supplier pro rata as per value of invoice provided that the pre-shipment, if any, and post-shipment quality inspection reports conforms to the required specifications of OCs and upon presentation of required documents by the Supplier including acknowledgements of the receipt of the OCs from the Buyer's Central Warehouse at Tokha Road, Mahadevtar, Gongabu, Kathmandu.
- d) Alternatively, 90% of the price for the Commodities delivered shall be paid upon receipt of the total consignment as shown in the delivery schedule against submission of a commercial invoice, the documents specified in Clause 6, and the acceptance certificate (in quantity and quality) of the Commodities by the Buyer.
- e) The remaining 10% of the cost will be retained by the Buyer as retention money, which would be paid to the Supplier upon Certificate of Completion of annual supply lots and acceptance from the Buyer.
- f) While making above payments, any Government of Nepal taxes due on behalf of the Supplier shall be deducted as and when applicable.

The Supplier's request for payments shall be made to the Buyer in writing, accompanied by a commercial invoice describing, as appropriate, the Commodities delivered and services performed, and by shipping and other documents submitted as required pursuant to Clause 6 of the contract, and upon fulfillment of other obligations stipulated in the contract.

The Buyer shall make payments promptly within sixty (60) days of submission of an invoice/claim by the Supplier.

### **13. RELEASE OF CLAIMS**

After completion of all obligations of interest and prior to final payment, the Supplier shall furnish to the Buyer, a release of all claims against the Buyer arising out of the contract.

### **14. SECURITY FOR PERFORMANCE**

Within 30 days of the Supplier's receipt of notification of award of the contract, the Supplier shall furnish performance security to the Buyer in the amount of 5% of the contract sum. The Buyer will release fifty percent (50%) of the amount stated in the performance security after the Supplier has completed his supply obligations in full quantity and the supplies have been accepted by the Buyer following post-shipment inspection. The remaining 50% of the performance security will be discharged by the Buyer and returned to the Supplier within thirty days following the date of completion of the Supplier's performance and/or warranty obligations.

The proceeds of the performance security shall be payable to the Buyer as compensation for any loss resulting from the Supplier's failure to complete its obligations under the contract. The performance security shall be denominated in the currency of the contract or in a freely convertible currency acceptable to the Buyer, and shall be in the form of a guarantee, issued by a bank or insurance company located in the Buyer's country or abroad, but endorsed by a local Bank acceptable to the Buyer, and in the form provided in Part VII of the tender documents.

**15. DELAYS IN THE SUPPLIER'S PERFORMANCE**

Delivery of the Commodities and performance of the services shall be made by the Supplier in accordance with the time schedule specified in the contract.

If at any time during performance of the contract, the Supplier or its sub-contractor(s) should encounter conditions impeding timely delivery of the Commodities and performance of services, the Supplier shall notify the Buyer in writing of the fact of the delay, its likely duration and its cause(s) within two weeks from the beginning of such delay.

As soon as practicable after receipt of the Supplier's notice, the Buyer shall evaluate the situation and may at its discretion extend the Supplier's time for performance, in which case the extension shall be ratified by the parties by amendment of the contract. The Buyer's finding thereupon shall be final and conclusive subject only to the Supplier's right of appeal under the arbitration clause of the contract.

A delay, without giving any reason, by the Supplier in the performance of its delivery obligation, shall render the Supplier liable to any or all of the following sanctions:

- i. forfeiture of its performance security,
- ii. imposition of liquidated damages, and / or
- iii. termination of the contract for default.

**16. LIQUIDATED DAMAGES**

All quantities of Commodities shall be delivered to the CRS warehouse not later than the annual supply deadlines shown in PART V: Bill of Quantities.

If the Supplier fails to deliver any or all of the Commodities or perform the services within the time period(s) specified in the contract, the Buyer shall, without prejudice to its other remedies under the contract deduct from the contract Price, as liquidated damages, a sum equivalent to 0.05 % percent of the value of delayed or undelivered goods for each day of delay until actual delivery or performance. Deduction of liquidated damages will be subject to a maximum of 10 percent of the contract price. Once a delay of 100 days is reached, the Buyer may consider the termination of the contract.

**17. TERMINATION FOR DEFAULTS**

The Buyer may, without prejudice to any other remedy for breach of contract, by written notice of default sent to the Supplier, terminate the contract in whole or in part:

- i. If the Supplier fails to deliver any or all of the Commodities within the time period(s) specified in the contract, or any extension thereof granted by the Buyer pursuant to the Clause 15 of the contract; or
- ii. If the Supplier fails to perform any other obligation(s) under the contract.

In the event the Buyer terminates the contract in whole or in part, pursuant to Clause 17, the Buyer may procure, upon such terms and in such manner, as it deems appropriate, Commodities similar to those undelivered and the Supplier shall be liable to the Buyer for any excess costs for such similar Commodity. However, the Supplier shall continue performance of the contract to the extent not terminated. A breach by the Supplier will result in the forfeiture of the Supplier's security for performance.

**18. FORCE MAJEURE**

The parties of this contract shall not be liable or under any obligation to meet claims for any failure or omission to carry out any of their respective obligations under this contract if such failure or omissions arises from natural disasters, fires, floods, epidemics, quarantine restrictions and freight embargoes strikes, riots, civil commotion or war from any cases generally accepted as force majeure.

If because of any legislation, decrees, or orders of the government or any of the causes mentioned above either of the parties is prevented from fulfilling its obligations, then either party may give notice thereof to the other, and the obligation of both parties shall be suspended.

Notwithstanding the provisions of Clauses 15, 16 and 17 of the contract, the Supplier shall not be liable for forfeiture of its performance security, liquidated damages or termination for default, if and to the extent that, its delay in performance or other failure to perform its obligations under the contract is the result of an event of Force Majeure.

If a Force Majeure situation arises, the Supplier shall promptly notify the Buyer in writing of such condition and the cause thereof. Unless otherwise directed by the Buyer in writing, the Supplier shall continue to perform its obligations under the contract as far as is reasonably practical, and shall seek all reasonable alternative means for performance not prevented by the Force Majeure event.

In case of Supplier's failure to perform his contractual obligations due to force majeure a certificate is to be issued by the local Chamber of Commerce or similar institution, certifying the existence of an event of force majeure preventing the Supplier from fulfilling his contractual obligations.

Parties to this contract shall not be entitled to any compensation for damages or loss due to such force majeure.

**19. ASSIGNMENTS / SUB-CONTRACTS**

The Supplier shall not assign, in whole or in part, its obligations to perform under the contract, except with the Buyer's prior written consent. Subcontracts, if accepted by the Buyer, must comply with the provisions of all Clauses of this contract.

The Supplier shall notify the Buyer in writing sufficiently in advance of all sub-contracts to be awarded under the contract if not already specified, and seek Buyer's consent. However, such notification shall not relieve the Supplier from any liability or obligation under the contract.

**20. SUSPENSION OR TERMINATION**

The Buyer may at any time terminate the contract by giving written notice to the Supplier, without compensation to the Supplier, if the Supplier becomes bankrupt or otherwise insolvent, provided that such termination will not prejudice or effect any right of action or remedy which has accrued or will accrue thereafter to the Buyer.

The Buyer, may by written notice sent to the Supplier, terminate the contract, in whole or in parts, at any time for its convenience. The notice of termination shall specify that termination is for the Buyer's convenience, the extent to which performance of the work under the contract is terminated, and the date upon which such termination becomes effective. The Commodities that are complete and ready for shipment within thirty days after the Supplier's receipt of notice of termination shall be purchased by the Buyer at the contract terms and prices. For the remaining Commodities the Buyer may elect;

- i. To have any portion completed and delivered at the Contract terms and prices; and / or
- ii. To cancel the remainder and pay to the Supplier an agreed amount for partially completed Commodity, materials and parts previously procured by the Supplier.

**21. ARBITRATION / RESOLUTION OF DISPUTES**

The Buyer and the Supplier shall make every effort to resolve amicably by direct informal negotiation any disagreement or dispute arising between them under or in connection with the Contract.

If, after thirty days from the commencement of such informal negotiations, the Buyer and the Supplier have been unable to resolve amicably a Contract dispute, either party may require that the dispute be referred for resolution to the formal mechanisms as specified hereunder. These mechanisms may include, but are not restricted to, conciliation mediated by a third party, adjudication in an agreed national or international forum, and / or international arbitration.

- i. In the case of dispute between the Buyer and the Supplier which is a national of the Buyer's country, the dispute shall be referred to adjudication / arbitration in accordance with the laws of the Buyer's country; and
- ii. In the case of dispute between the Buyer and a foreign Supplier, the dispute shall be settled by arbitration in accordance with the provisions of the UNCITRAL Arbitration Rules.

**22. BANKRUPTCY**

If the Supplier commits any act of bankruptcy or goes into liquidation except for reconstruction purpose, or if its business is carried on by a receiver such receiver, liquidator, or any person in whom the contract may become vested shall forthwith give notice thereof in writing to the Buyer and shall for one month, during which he shall take all reasonable steps to prevent stoppage of performance of the contract, have the option of carrying out the contract subject to his or their providing such guarantees as may be required by the Buyer, but not exceeding the value of the work for the time being which remain unexecuted.

**23. CONFLICTS OF INTEREST**

Any bribe, commission, gift or advantage given, promised or offered by or on behalf of the Supplier or its partner, agent or servant, or any one on its behalf to any person on its behalf, in relation to the obtaining or to the execution of this or any other contract with the Buyer shall, in addition to any criminal liability which it may incur, subject the Supplier to the cancellation of this and all other contracts and also to payment of any loss or damage resulting from any such cancellation. The Buyer shall then be entitled to deduct the amount so payable from any money otherwise due to the Supplier under this or any other contract payable under this clause shall be referred to arbitration.

**24. CONTRACT DOCUMENTS AND MATTERS TO BE TREATED AS CONFIDENTIAL**

All documents, correspondence, decisions, and orders concerning the contract shall be considered as confidential and restricted in nature by the Supplier and he shall not

divulge or allow access to them by any unauthorized person.

**25. RULING LANGUAGE**

This contract is made in English language and all correspondence and other documents pertaining to the contract, which are exchanged by the parties, shall be written in the same language.

**26. CONTRACT AMENDMENTS**

No variation in or modification of the terms of the contract shall be made. However, should circumstances arise that require amendments to this contract, these shall be agreed upon between the parties in writing.

**27. TAXES AND DUTIES**

The Supplier shall be entirely responsible for all taxes, stamp duties, license fees, and other such levies imposed outside the Buyer's country. The cost of such taxes, etc. shall be included in the quoted prices.

The Supplier shall not be responsible for any taxes, duties, etc., incurring in the Buyer's country. The Buyer will obtain necessary tax and duty exemption certificates from the concerned agencies of the Government. Any government imposed taxes or duties paid by the Supplier in the Buyer's country will be reimbursed by the Buyer upon presentation of original receipts of such payments. The invoice shall state separately Nepalese import duties, taxes and other public charges, to be reimbursed by the Buyer.

**28. LAWS GOVERNING THE CONTRACT**

The contract shall be subject to the laws of Nepal and the jurisdiction of the courts of Nepal. Unless specifically otherwise provided for in this contract, the contract shall be construed according to the general contract laws of Nepal.

**29. BRAND NAME AND LOGO**

The Commodities supplied under this contract will bear the Supplier's brand name and logo, if any, and its generic name. However, under the Buyer's social marketing programme the Buyer will have the right to repack/over-pack the supplied OCs in another packaging bearing another brand name and logo chosen and owned by the Buyer.

The Supplier agrees, without any reservation/qualification, to this right of the Buyer to repack/over-pack the OC pills in another packaging and sell the OCs in Nepal under the brand name and logo chosen and owned by the Buyer. The Supplier further agrees that the ownership of the brand name and logo so used by the Buyer shall vest solely and exclusively with the Buyer and the same shall never be used by the Supplier for any purpose whatsoever.

**30. NOTICES**

Any notice given by one party to the other pursuant to the contract shall be sent in writing or by telegram or telex/cable/fax and confirmed in writing to the address specified for that purpose.

A notice shall be effective when delivered or on the notice's effective date, whichever is later. For the purposes of all notices, the following shall be address of the Buyer and the Supplier;

BUYER:                      Managing Director, Nepal CRS Company  
Tokha road, Mahadevtar, Gangabu, Kathmandu, Nepal

SUPPLIER:                      \_\_\_\_\_

Signed in Two Originals.

\_\_\_\_\_  
FOR THE SUPPLIER:

\_\_\_\_\_  
FOR THE BUYER  
Mr. Krishna B. Rayamajhi  
Managing Director,  
Nepal CRS Company

**PART V : BILL OF QUANTITIES /ORDER LIST**

**A : Time schedule for supply and delivery of Oral Contraceptive (OC) Pills**

Nepal CRS Company Tokha Road, Mahadevtar, Gangabu P.O.Box No. 842 Kathmandu, Nepal	Bill of Quantities/ Order List Number of Oral Contraceptive and Emergency Contraceptive Pills to be supplied  3 million cycles of Oral Contraceptive pills
---	--

DELIVERY SCHEDULE	For 2012, 180 days after signing of supply contract	For 2013, 180 days after reconfirmation of order by the Buyer	For 2014, 180 days after reconfirmation of order by the Buyer	Total
OC PILLS IN CYCLES	900,000	1,000,000	1,100,000	3,000,000

The annual quantity of the Pills as per this contract will be supplied and delivered within 180 days of the Buyer's order for delivery.

Nepal CRS Company,  
**Bid documents for the supply and delivery of oral contraceptive pills**

---

**B: Bill of Quantities /Order List**

Currency of Bid.....

**B.1: Unit Price and cost of supply and delivery of Oral Contraceptive (OC) Pills**

Quantity of OC Pill (Cycles)	2012	2013	2014	Total
	900,000 CYCLES	1,000,000 CYCLES	1,100,000 CYCLES	3,000,000 CYCLES
Supplier's DDU Price/Cycle at Kathmandu (in figure)				
Supplier's DDU Price/Cycle at Kathmandu (in words)				
Supplier's DDU Cost of Entire Quantity of OC Pills (in figure)				
Supplier's DDU Cost of Entire Quantity of OC Pills (in words):				
.....				
.....				

## **PART VI: TECHNICAL SPECIFICATIONS FOR ORAL CONTRACEPTIVE PILLS (OC)**

### **1. SPECIFICATIONS FOR ORAL CONTRACEPTIVE PILLS (OC)**

The contractor will manufacture and supply to Nepal CRS Company the quantities of oral contraceptives listed in the Commodity List in accordance with the specifications listed in this section, which offer a minimum description of the supplies required.

Tablets will be of the shape and dimensions of the manufacturer's normal, standard commercial tablet. Each tablet may bear the identifying imprint(s) of its manufacturer. Colors of contraceptive and iron tablets may be similar to manufacturer's normal, standard commercial tablet.

**Name of Drug** : Oral Contraceptive Pills

#### **Composition Per table of OC:**

The twenty-eight (28) tablets included in monthly cycles shall consist of twenty-one (21) tablets containing estrogen and progestin and seven (7) tablets containing iron with the following amounts of active ingredients:

**Estrogen** - The estrogen portion of the combined pills will contain 30-35 mcg. of ethinylestradiol.

**Progestin** - The progestin portion of the combined pill will contain 150 mcg. of levonorgestrel.

**Iron Tablets** - The combination pill pack will also contain iron in the seven (7) placebo pills per cycle such as 75 mg. of ferrous fumerate (equivalent to 25 mg. of elemental iron)

**Standard:** BP, USP, EP or any other pharmacopoeia recognized by the Department of Drug Administration (DDA) of Government of Nepal (GoN)

**Shelf-life:** The shelf life of the commodities provided will be at least five years from the date of granulation. At the time of delivery to CRS warehouse, there shall be at least four years remaining until the expiration date as shown on each monthly cycle package. Documentation substantiating product shelf life must be provided.

#### **Packaging, Packing and Marking:**

Packaging, packing and marking shall be similar or equal to the following specifications.

Each tablet shall be individually enclosed in a transparent blister package formed of PVC, with a minimum thickness of .01905 cm. (+/- .001905 cm.) or .0075 inch, backed with aluminum foil, minimum thickness .0018 cm. (.0007 inch). If a supplier wishes to provide a thicker PVC or foil or add a card to either the front or back of the package (in addition to the minimum PVC or foil), this would be acceptable.

The size of the package shall be 6.00 cm. x 9.00 cm. (+/- 0.25 cm.), or 2 3/8 inches x 3 1/2 inches (+/- 1/8 inch).

#### **Mounting**

Tablets shall be mounted in four (4) rows of seven (7) tablets per row. For low-estrogen combination pills, the contraceptive tablets shall precede the iron tablets.

**Printing**

Although the desired placement of certain information is indicated below it is the supplier's responsibility to obtain USFDA and/or SRA approval of monthly cycle package. Such approval must be obtained prior to commencement of delivery.

**Words:** On the front of each monthly cycle pack above the first row of the tablets and in the left hand corner, the brand name of the product shall be printed in precision full registration. In parenthesis, in reduced lettering and below the trade or brand name, shall be printed (Family Planning Pills). The manufacturer's name and address shall be printed on the pack. Sequence of administration shall be clearly indicated by an arrow/line pathway on the unit. The tablet formulation must be printed on the pack and may be printed on the top of the reverse side. On the bottom of the reverse side the following must be printed:

**Take one oral contraceptive (OC) pill every day to best prevent pregnancy. OCs do not prevent AIDS (HIV Infection) or other sexually transmitted diseases.  
See a health care provider for any questions or concerns.**

**Numbers:** The month and year of expiration and the lot/control number shall be shown in English numerals; e.g., expiration 6/2014 will indicate product-expires in June 2014. The full four-digit number is required for the year of expiration. Embossing is acceptable for these numbers, but must be easily legible.

**Color:** Background color shall be the natural color of the aluminum foil on the face. The reverse of the unit will not be inked except for the necessary printing. The manufacturer shall be responsible for the choice of color of the stripe across the top with the brand name.

**One Hundred Cycle Inner Box:** The inner box must hold 100 cycles of oral contraceptives. Each inner box must contain at least 5 leaflets containing instructions for use of oral contraceptive of the instructions in picture by the Supplier.

The inner boxes (100 cycles of oral contraceptives) shall be constructed of board plasticized on its inner surface and of sufficient strength and rigidity so that the box will retain its shape through every stage of the supply chain.

The inner boxes will be marked in a legible manner to show the contents and to facilitate identification in case of subsequent query.

The following information shall be included in the inner box marking:

- Lot identification number
- Month and year of manufacture (including the words Date of Manufacture, Month, Year) in English. The year will be written as a four-digit number and the month as a two-digit number.
- Month and year of expiry (including the words Expiry Date, Month, Year) in English. The year will be written as a four – digit number and the month as a two – digit number.
- Manufacturer's name and registered address
- Number of cycles of oral contraceptives in the box
- Instruction for storage:
  - “Protect against exposure to:
    - Moisture
    - Direct Sunlight
    - Store at controlled room temp 20°C to 25°C (68°F to 77°F)”

**Color:** Printing required for Low-Estrogen Combination Pill packaging for social marketing program for the product name, lot number and date of expiration which shall be in black.

**Quantity in a shipping carton:** Twenty (20) 100-cycle cartons will be packed in each shipping carton.

**Requirements:** The oral contraceptive pills to be supplied under this contract will be packed and protected to prevent damage or deterioration during transportation and storage..The carton will be manufactured of a standard heavy-duty material appropriate for Nepal where high heat and humidity is prevalent, that will withstand export handling and rough treatment, and ensure the safety, efficacy and quality of the product. Once the contractor selects a shipping carton size, that size will remain constant throughout the life of the contract.

**Labeling on the shipping carton:**

The exterior shipping carton shall be marked with information about the contents in a clearly legible manner. The information shall include:

- Destination: *Central Warehouse of Nepal CRS company, Tokha road, Mahadevtar, Gangabu Kathmandu Nepal*
- Name of Consignee: *Managing Director  
Nepal CRS Company,  
Tokha Road, Mahadevtar,  
Gongabu, Kathmandu Nepal*  
Contract Number : **CRS/USAID/OC-PILLS-1/2012**
- LOT identification number:
- Month and year of manufacture (including the words Date of Manufacture, Month, Year) in English. The year shall be written as a four – digit number and the month as a two digit – number.
- Month and year of expiry (including the words Expiry Date, Month, Year) in English. The year will be written as a four- digit number and the month as a two-digit number.
- Name and address of manufacturer/supplier
- Name of the commodity
- Quantity of Oral Contraceptive contained in the carton
- Instruction for storage and handling as follows:  
" Protect against exposure to:  
--Moisture  
--Direct Sunlight  
-- Store at controlled room temperature. 20°C to 25°C (68°F to 77°F )
- Up Arrow (↑)

The marking on the exterior of the shipping cartons has to be done in big letters, not less than 2cm in height.

## **2. INSPECTION AND ACCEPTANCE**

The Buyer or its representative shall have the right to inspect and / or to test the Commodities to ascertain its conformity to the contract before delivery. For this purpose the Buyer shall appoint an agent to carry out pre-shipment inspections on his behalf. The Buyer will forward the name and address of such an agent(s) to the Supplier soon after signing of supply contract.

Thereafter the Supplier shall notify the Buyer and the agent for pre-shipment inspection well in advance indicating the time and place the Commodities is ready for inspection. Upon such notification by the Supplier the inspection agent shall carry out the pre-shipment inspection for all Commodities ready for supply to the Buyer.

The inspection agent appointed by the Buyer will visit the manufacturing premises of the Supplier and draw required number of random samples of oral contraceptive pills from each lot/batch manufactured under the contract. These samples will be tested at an independent laboratory to ascertain full compliance of the Commodities with the specifications. OCs of only those lots/batches, which fully comply, with the requirements of the specifications will be readied for shipment. The Supplier shall not dispute the results of the test conducted on such randomly drawn samples, nor shall he supply the Commodities from the rejected lot(s)/batch (es).

Once the samples from the readied commodities for shipment have passed the prescribed set of tests, a pre-shipment inspection will be carried out by the inspection agent to verify packaging and labelling requirements of the specifications. The Commodities shall be shipped only after the consignment has been approved and certified for delivery. The Supplier shall ensure the supply of the full contractual quantity, after taking of random samples.

Should the supplied Commodities fail to meet the requirements of the specifications, the Supplier shall replace such Commodities within the time specified for delivery or extension granted. However, under such circumstances the Supplier will bear the extra costs incurred in connection with additional pre-shipment inspection, failing which the Buyer shall be entitled to recover all such additional costs from any payments due to the Supplier.

Upon arrival of Commodities at the designated store the Buyer shall carry out post-shipment inspection of all supplied Commodities to ensure that the Commodities have arrived in an acceptable condition.

The Buyer, at its discretion, may not chose to test the commodities prior to its delivery if such commodities have been produced in the countries of European Union, North America, Japan or Australia.

The Buyer's right to inspect, test and, where necessary, reject the Commodities after the arrival in the Buyer's country, shall in no way be limited or waived by reason of the Commodities having previously been inspected, tested and passed by the Buyer or its representative prior to the shipment from the country of origin. Nothing in this Clause in any way release the Supplier from any warranty or other obligations under this contract. Providing always that replacement is possible, the Supplier shall refund to the Buyer all amounts paid on such account or recovery may be made from the security for performance.

**PART VII: SAMPLE FORMS**

**Form No. 1: Power of Attorney**

I ....., certify that I am .....Secretary  
(or other authorized official) of the corporation, organized under the laws of .....  
..... and that.....who signed the above bid is  
authorized to bind the corporation by authority of its governing body.

\_\_\_\_\_  
(Secretary/Authorized Official)

Date:

**Form No. 2: Submission of Bid**

*[The Bidder shall fill in this Form in accordance with the instructions indicated. No alterations to its format shall be permitted and no substitutions shall be accepted.]*

Date: *[ insert: **date of bid** ]*

*[ Purchaser insert: **name** ]*

*[ Purchaser specify: "Tender No.: **CRS/USAID/OC-PILLS-1/2012***

*[ insert: **name of Contract** ]*

To: *[ Purchaser insert: **Name and address of Purchaser** ]*

Dear Sir or Madam:

Having examined the Bidding Documents, including Addenda Nos. *[ insert **numbers** ]*, the receipt of which is hereby acknowledged, we, the undersigned, offer to supply and deliver the Goods under the above-named contract in full conformity with the said Bidding Documents for the sum of:

*[ insert: **amount of local  
currency in words** ]*

*[ insert: **amount of local  
currency in figures** ]*

*[ insert: **amount of foreign  
currency in words** ]*

*[ insert: **amount of  
foreign currency in  
figures** ]*

(hereinafter called "the Total Bid Price") or such other sums as may be determined in accordance with the terms and conditions of the contract. The above amounts are in accordance with the Price Schedules attached herewith and are made part of this bid.

We undertake, if our bid is accepted, to deliver the Goods in accordance with the delivery schedule specified in the Schedule of Requirements.

If our bid is accepted, we undertake to provide an advance payment security and a performance security in the form, in the amounts, and within the times specified in the bidding documents.

We agree to abide by this bid, for the bid validity period specified in the bid documents and it shall remain binding upon us and may be accepted by you at any time before the expiration of that period.

Until the formal final contract is prepared and executed between us, this bid, together with your written acceptance of the bid and your notification of award, shall constitute a binding contract between us. We understand that you are not bound to accept the lowest or any bid you may receive.

Commissions or gratuities, if any, paid or to be paid by us to agents relating to this bid, and to contract execution if we are awarded the contract, are listed below:

Nepal CRS Company,  
**Bid documents for the supply and delivery of oral contraceptive pills**

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Name and Address of Agent	Amount and Currency	Purpose of Commission or Gratuity
_____	_____	_____
_____	_____	_____

Dated this [ *insert: **number*** ] day of [ *insert: **month*** ], [ *insert: **year*** ].

Signed: \_\_\_\_\_

Date: \_\_\_\_\_

In the capacity of [ *insert: **title or position*** ]

Duly authorized to sign this bid for and on behalf of [ *insert: **name of Bidder*** ]

**Form No. 3: Supplementary Information Required from the Bidder**

*(Bidder must give specific **answers against each of the following questions. Bidder is liable to be disqualified if the particulars** asked below are not furnished. For details, additional sheets may be used.)*

1. Is bidder a manufacturer, authorized agent or dealer, which ? .....  
.....  
.....
2. Whether the Pills offered conform to particulars and specifications quoted in the tender schedule, and if not, details of the deviations must be stated. Provide the product dossier and site master file for the product being offered. ....  
.....  
.....  
.....  
.....
3. Does the manufacturer have a GMP or equivalent certificate for quality assurance? If yes, provide a copy of GMP site certificate. ....yes / no  
  
.....yes / no  
  
Does the manufacture have USFDA or SRA approval for the product and the manufacturing site? If yes, provide document of FDA or SRA product approval.
4. Guaranteed delivery period (after contract signing) .....  
...
5. Whether letter of authority from the manufacturer is enclosed, if applicable? .....yes / no
- 6(a) Are the Pills prices inclusive of all taxes in manufacturer's country? .....yes / no
- 6(b). Are the Pills prices exclusive of all taxes in Buyer's country (Nepal)? .....yes / no
7. In case of direct bid offer from manufacturer

**Bid documents for the supply and delivery of oral contraceptive pills**

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- (a) Does the bidder have any agent in connection with this contract? .....yes / no
- (b) If yes, indicate:
  - (i) The name and address of the Agent .....
  - (ii) What services the agent will render? .....
  - (iii) The amount of remuneration included in the quoted price for the Agent? .....

(Signature of the Bidder)

(Date)

**Form No. 4: Financial, Business Capability of the Manufacturer**

[Bidder must provide copies of **Audited Balance Sheets** of the manufacturer(s), (duly certified by the Auditor and Corporate Principal / Secretary) as proof of stated turnover and/or financial capability of the manufacturer(s). Non-submission of stated documents would automatically cause disqualification of the bids.]

Name and Address of Manufacturer:

.....

Telephone No: .....Fax:.....Telex

.....

1. Latest Profit & Loss Statement from ..... to .....  
filed with ..... on .....  
(Attach a certified copy of Balance Sheets)

2. Net Sales: (attach certified copies of Balance Sheets)

- a. Current Period .....
- b. During the last Financial Year .....
- c. During the year before last Financial Year .....

3. Net Profit before Tax: (attach certified copies of Balance Sheets)

- a. Current Period .....
- b. During the last Financial Year .....
- c. During the year before last Financial Year .....

The Profit and Loss Statements have been certified through  
.....  
by.....

4. Manufacturer's financial arrangements (check appropriate item)

- a. Own Resources.....
- b. Bank Credits .....
- c. Others specify .....

5. Certificate of Financial soundness from the Manufacturer's Banker (attach a certified copy).

\_\_\_\_\_  
(Signature of the Bidder)

\_\_\_\_\_  
(Date)

**Form No. 5: Manufacturer's Authorization**

*[The Bidder shall require the Manufacturer to fill in this Form in accordance with the instructions indicated. This letter of authorization should be on the letterhead of the Manufacturer and should be signed by a person with the proper authority to sign documents that are binding on the Manufacturer. The Bidder shall include it in its bid, if so indicated in the BDS.]*

Date: *[insert: **date** (as day, month and year) of Bid Submission]*

Tender No.: *[insert: **number of bidding process**]*

Alternative No.: *[insert: **identification No if this is a Bid for an alternative**]*

To: The Buyer

WHEREAS

We *[insert: **complete name of Manufacturer**]*, who are official manufacturers of *[insert: **type of goods manufactured**]*, having factories at *[insert: **full address of Manufacturer's factories**]*, do hereby authorize *[insert: **complete name of Bidder**]* to submit a bid the purpose of which is to provide the following Goods, manufactured by us *[insert: **name and or brief description of the Goods**]*, and to subsequently negotiate and sign the contract.

We hereby extend our full guarantee and warranty in accordance with Clause 9 of the PART IV Conditions of contract, with respect to the Goods offered by the above firm.

We also agree, without any reservation/qualification, to the right of the Buyer to repack/over-pack the OCs in another packaging and sell the OCs in Nepal under the brand name and logo chosen and owned by the Buyer. We further agree that the ownership of the brand name and the logo so used by the Buyer shall vest solely and exclusively with the Buyer and the same shall never be used by us for any purpose whatsoever.

Signed: *[insert: **signature(s) of authorized representative(s) of the Manufacturer**]*

Name: *[insert: **complete name(s) of authorized representative(s) of the Manufacturer**]*

Title: *[insert: **title**]*

Duly authorized to sign this Authorization on behalf of: *[insert: **complete name of Bidder**]*

Dated on \_\_\_\_\_ day of \_\_\_\_\_, \_\_\_\_\_ *[insert: **date of signing**]*

**Form No. 6: - Pharmaceutical Product Questionnaire**

**I Product Identification**

Active pharmaceutical ingredient(s) (use INN if any): .....

Generic name of the product: .....

Dosage form:  Tablets  Capsules  Ampoules  Vials  Other: ....

Strength per dosage unit: .....

Route of administration:  Oral  IM  IV  SC  Other

Amp/vial size:  2ml  5ml  10ml  25ml  Other

Description of primary packaging materials: .....

Description of secondary packaging materials: .....

**II. Manufacturer of the product**

Name, address and activities of the manufacturer(s) (or contract manufacturer(s)):

Name	Physical address	Telephone no, fax no and email contact details	Activity(e.g. packaging)

Are all sites listed licensed by the relevant Authority to perform the activity?

Yes  No

Has the manufacturing method for each standard batch size been validated?

Yes  No

List the standard batch size quantities: .....

**I. Supplier identification (to be filled in if not identical to that indicated in question II)**

Name: .....

Address: .....

Telephone no: .....

Facsimile no: .....

Email contact details: .....

Link with the product:

Marketing license holder  Distributor  Manufacturer  Other: ....

**II. Regulatory situation (licensing status) in the country of manufacturer**

Product registered and currently marketed: License number.....

Offeror should complete one pharmaceutical product questionnaire for each offered commodity as indicated in supply schedule.

Product registered for marketing in the country of manufacturing but not currently marketed:  
License number: .....

Product registered for export only: license number.....

Product not registered (please clarify):  
.....  
.....

*Please attach a Certificate of Pharmaceutical Product according to the WHO Certification Scheme (WHO Technical Report Series No 863. Earlier version is not acceptable.)*

**III. Finished Product Specifications**

BP Edition     USP Edition .....  International Pharmacopoeia Edition  
 Other.....

*Please attach a copy of the finished product specification, if different from Bp, USP or International Pharmacopoeia Specification*

Limits in % for the assay in active ingredient(s):  
 95-105%     90-110%     Other: .....

Additional specifications to those in the pharmacopoeia (e.g. dissolution, syringe ability):  
.....

*Please attach a copy of the model certificate of analysis for batch release*

Are you willing to provide necessary information (analytical method) for the tests to be replicated by another control laboratory?

Yes     No

**IV. Stability**

Stability testing data available:

Yes     No

If yes type and conditions of testing

Accelerated testing     40°C/75%RH/6 months     Other: .....

In the same packaging as specified under point I:     Yes     No

Real time testing temperature:

ambient     25°C     30°C     Other: .....

Relative Humidity:

non controlled     45%     65%     Other: .....

Period of time:

1 year     2 years     3 years     Other: .....

In the same packaging as specified under point I (page 1):  Yes  No

Can a stability report be forwarded within one week of being requested?  Yes  No

Was the stability testing done on a product of the same formula, manufactured on the same site and packed in the same packaging material as the product that will be supplied?

Yes  No

**V. Label and insert information**

(In case more than one label/leaflet is used, please replicate this question)

Shelf- life (years):  2  3  4  5  Other: .....

Storage conditions (e.g. do not store above 30°C-protect from light):  
.....

Label language:

Bilingual English/French  English  French  Other: .....

Package insert:  Yes (attach a copy)  No

**VIII. Samples**

Can free non returnable samples be obtained upon request within one week from being requested?  Yes  No

**IX. Therapeutic equivalence**

Demonstrated:

By in-vivo bioequivalence studies, Reference product: .....

Number of volunteers: ..... Country of study: ..... Performed year: .....

By another method claimed by the supplier/manufacturer (please describe briefly):  
.....  
.....  
.....

By in-vitro dissolution tests Reference product: .....

Not demonstrated  not relevant  Unknown

Can a copy of the report be obtained upon request within one week from being requested?

Yes  No

Is the product used in the trial or test essentially the same as the one that will be supplied (same materials from the same suppliers, same formulas, and same manufacturing method)?

Yes  No

**X. Active Pharmaceutical Ingredient(s) (APIs)**

(In case more than one active ingredient is used, please replicate this question)  
Do specifications and standard test methods exist for each API and excipient?

Yes  No

Each API used (in INN if any):

Has a certificate of suitability to the European Pharmacopoeia (CEP)  
Certificate no: .....

The CEP is in our possession (including annex if any).....  
 The CEP is in possession of the finished product manufacturer (including annex if any)

Has a Drug Master File (DMF)  
Registered in: (country)..... registration number

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 finished product manufacturer  
Quality Standard:

BP  USP  EP  International Pharmacopoeia

Other (e.g. "in-house", specify: ).....

No Pharmacopoeia monograph exists\*

\*If there is no monograph in a recognized Pharmacopoeia, then the following information should be provided and evaluated:

- Chemical structure;
- If relevant, the isomeric nature of the active ingredient, including stereo chemical configuration (e.g. racemate, pure (S)- isomer, 50/50 mixture of (Z)- and (E)-isomers;
- The solubility of the active ingredient in water at 25 or 30°C
- The solubility of the active ingredient in other solvents such as ether, ethanol, acetone and buffers if different pH (if the active ingredient is acidic or basic)
- Other relevant physicochemical characteristics of the active ingredient such as partition coefficient (usually octanol/water) and the existence of polymorphs;
- Copies of infrared, nuclear magnetic resonance (proton and C-13), ultraviolet and mass spectra;
- Information on the chemical stability of API and on physicochemical stability if relevant (e.g. formation of a hydrate, change of polymorphic form)

Manufacturer (name, physical address +country): .....

.....  
.....  
GMP certified: Yes (attach a copy of the GMP certificate if any) No Unknown  
Certified by: .....

**XI. Commitment**

I, the undersigned.....

.....  
(position in the company ,e.g. General Manager, Authorised Person, Responsible Pharmacist)

Acting as responsible for the company (name of the company), certify that the information provided (above) is correct and true  
(Check the following boxes as applicable :)

And I certify that the product offered is identical an all aspects of manufacturing and quality to that marketed in.....(country of origin),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;

And I certify that the product offered is identical to that marketed in.....  
(Name of country), except: .....

.....  
(e.g. formulation, method and site of manufacture, sources of active and exipient starting materials, quality control of the finished product and starting material,packaging,shelf-life,indications ,product information)

Date: ..... Signature: .....

**Form No. 7: Bid Bond**

**Bid Bond (in the form of Bank Guarantee)**

*[The Bank shall fill in this Bank Guarantee Form in accordance with the instructions indicated.]*

\_\_\_\_\_  
*[Bank's Name, and Address of Issuing Branch or Office]*

**Beneficiary:** \_\_\_\_\_ *[Name and Address of Purchaser]*

**Date:** \_\_\_\_\_

**BID GUARANTEE No.:** \_\_\_\_\_

We have been informed that *[name of the Bidder]* (hereinafter called "the Bidder") has submitted to you its bid dated (hereinafter called "the Bid") for the execution of *[name of contract]* under Invitation for Bids No. *[IFB number]* ("the IFB").

Furthermore, we understand that, according to your conditions, bids must be supported by a bid guarantee.

At the request of the Bidder, we *[name of Bank]* hereby irrevocably undertake to pay you any sum or sums not exceeding in total an amount of *[amount in figures]* (*[amount in words]*) upon receipt by us of your first demand in writing accompanied by a written statement stating that the Bidder is in breach of its obligation(s) under the bid conditions, because the Bidder:

(a) has withdrawn its Bid during the period of bid validity specified by the Bidder in the Form of Bid; or

(b) having been notified of the acceptance of its Bid by the Purchaser during the period of bid validity, (i) fails or refuses to execute the contract Form; or (ii) fails or refuses to furnish the performance security, if required, in accordance with the Instructions to Bidders.

This guarantee will expire: (a) if the Bidder is the successful bidder, upon our receipt of copies of the contract signed by the Bidder and the performance security issued to you upon the instruction of the Bidder; or (b) if the Bidder is not the successful bidder, upon the earlier of (i) our receipt of a copy of your notification to the Bidder of the name of the successful bidder; or (ii) twenty-eight days after the expiration of the Bidder's Bid.

Consequently, any demand for payment under this guarantee must be received by us at the office on or before that date.

This guarantee is subject to the Uniform Rules for Demand Guarantees, ICC Publication No. 458.

\_\_\_\_\_  
*[signature(s)]*

**Form No. 8: Security for Performance, in the Form of Performance Bond**  
(To be submitted in the currency of bid)

*(The bank, as requested by the successful Bidder, shall fill in this form in accordance with the instructions indicated)*

Date: *[insert date (as day, month, and year) of Bid Submission]*  
Tender No. and title: *[insert no. and title of bidding process]*

Bank's Branch or Office: *[insert complete name of Guarantor]*

**Beneficiary:** *[insert complete name of Purchaser]*

**PERFORMANCE GUARANTEE No.:** *[insert Performance Guarantee number]*

We have been informed that *[insert complete name of Supplier]* (hereinafter called "the Supplier") has entered into Contract No. *[insert number]* dated *[insert day and month]*, *[insert year]* with you, for the supply of *[description of Goods and related Services]* (hereinafter called "the Contract").

Furthermore, we understand that, according to the conditions of the Contract, a Performance Guarantee is required.

At the request of the Supplier, we hereby irrevocably undertake to pay you any sum(s) not exceeding *[insert amount(s) in figures and words]* upon receipt by us of your first demand in writing declaring the Supplier to be in default under the Contract, without cavil or argument, or your needing to prove or to show grounds or reasons for your demand or the sum specified therein.

This Guarantee shall expire no later than the *[insert number]* day of *[insert month]* *[insert year]*, and any demand for payment under it must be received by us at this office on or before that date.

This guarantee is subject to the Uniform Rules for Demand Guarantees, ICC Publication No. 458, except that subparagraph (ii) of Sub-article 20(a) is hereby excluded.

*[signatures of authorized representatives of the bank and the Supplier]*

**Form No. 9: Security for Advance Payment**

(in the form of Advance Payment Bond)

*[The bank, as requested by the successful Bidder, shall fill in this form in accordance with the instructions indicated.]*

Date: *[insert date (as day, month, and year) of Bid Submission]*  
tender No. and title: *[insert number and title of bidding process]*

*[bank's letterhead]*

**Beneficiary:** *[insert legal name and address of Purchaser]*

**ADVANCE PAYMENT GUARANTEE No.:** *[insert Advance Payment Guarantee no.]*

We, *[insert legal name and address of bank]*, have been informed that *[insert complete name and address of Supplier]* (hereinafter called "the Supplier") has entered into Contract No. *[insert number]* dated *[insert date of Agreement]* with you, for the supply of *[insert types of Goods to be delivered]* (hereinafter called "the Contract").

Furthermore, we understand that, according to the conditions of the Contract, an advance is to be made against an advance payment guarantee.

At the request of the Supplier, we hereby irrevocably undertake to pay you any sum or sums not exceeding in total an amount of *[insert amount(s) in figures and words]* upon receipt by us of your first demand in writing declaring that the Supplier is in breach of its obligation under the Contract because the Supplier used the advance payment for purposes other than toward delivery of the Goods.

It is a condition for any claim and payment under this Guarantee to be made that the advance payment referred to above must have been received by the Supplier on its account *[insert number and domicile of the account]*

This Guarantee shall remain valid and in full effect from the date of the advance payment received by the Supplier under the Contract until *[insert date]*.

This Guarantee is subject to the Uniform Rules for Demand Guarantees, ICC Publication No. 458.

\_\_\_\_\_  
*[signature(s) of authorized representative(s) of the bank]*