

No. S.12012/17/2004-Supply  
Govt. Of India  
Ministry of Health & Family Welfare  
Department of Family Welfare

Nirman Bhawan, New Delhi-11  
Dated the 26<sup>th</sup> May 2004

**CORRIGENDUM**

Ref this Ministry tender notice even numbr dt 31.3.2004, and 12.5.2004, the **date of tender opening of Oral Polio Vaccine *has been deferrerd to 29.7.2004.***

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No. S.12012/17/2004-Supply

Govt. Of India

Ministry of Health & Family Welfare

Department of Family Welfare

Nirman Bhawan, New Delhi-11

Dated the 12<sup>th</sup> May 2004

**CORRIGENDUM**

Ref this Ministry tender notice even numbr dt 31.3.2004, the **date of tender opening of Oral Polio Vaccine *has been deferrerd to 27.5.2004.***

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No. S.12012/107/2003-Supply  
Govt. of India  
Ministry of Health & Family Welfare  
Department of Family Welfare

Nirman Bhawan, New Delhi-110011  
Dated 31<sup>st</sup> March 2004.

## TENDER NOTICE

### Subject: Supply of vaccines.

Offers in sealed covers are invited for and on behalf of the President of India to enter in to a Rate Contract for the supply during the year 2004-05 of following Vaccines on the terms and conditions given in the schedule to tender. Briefly, the particulars are as under:-

#### 1. Description of stores

Sl. No.	Item	Tentative Quantity to be procured for 2004-05
1.	Oral Polio Vaccine (OPV)	1293 lakh doses
2.	BCG Vaccine	482 lakh doses
3.	Measles Vaccines	320 lakh doses
4.	Diphtheria Tetanus Vaccine (DT)	330 lakh doses
5.	Tetanus Toxoid Vaccine(TT)	1375 lakh doses
6.	Diphtheria Pertusis Toxoid (DPT)	1293 lakh doses

#### 2. Technical Specifications

The detailed Technical Specifications are given in the tender document.

#### 3. Qualification Criteria for eligibility of firms

- Only domestic primary manufacturers are eligible to participate in the tender. (Primary manufacturer is a manufacturer that performs all the manufacturing and processing operations needed to produce goods in their appropriate dosage form, including processing, blending, formulating, filling, packing, labeling and quality testing).
- The bidder should have 2 years manufacturing and marketing experience of substantial quantities for these products in the country within a period of last 5 years duly supported by the documentary evidence and attested by their Chartered Accountant.
- The production capacity of the tenderer should be at least 10% of the requirement of the preceding year( \* ). This should be supported by a certificate from State Drug Authorities.
- The bidder must possess Good Manufacturing Practices (GMP)\* certificate for the manufacturing facility for 2 years or more, which should be valid on the date of tender opening.

e) Bidder should not have been convicted. This should be supported by a certificate from the State Drug Authorities.

\* The details are elaborated in the tender documents

**Note :** i. GOI reserves the right to increase or decrease the requirements, which depend on actual requirements and resources.

ii. Further details regarding eligibility criteria are given in the tender document.

4. The details of invitation to tender are given in the tender forms which can be obtained on payment of Rs 5000/- separately for each item, by demand draft drawn in favour of Secretary (FW) payable at New Delhi from;

Room No. 502 - A Wing`  
Department of Family Welfare  
Nirman Bhawan, New Delhi-110011

**5. Procedure for submission of offers.**

The procedure to be followed is given in detail in the tender documents.

**i) Completed tenders forms for item nos. 1,2 & 3 should be put in the tender box by 11.00 AM on 14.5.2004 . The bids will be opened on 14.5.2004 at 11.30 AM.**

**ii) Complete Tender forms for item No. 4,5 & 6 should be put in the Tender box at 1.00 PM on 14.5.2004 and will be opened on 14.5.2004 at 2.15 PM onwards.**

*Offer received after due date and time shall not be considered at all.*

No. S.12012/107/2003-Supply  
Govt. of India  
Ministry of Health & Family Welfare  
Department of Family Welfare

Nirman Bhawan, New Delhi-110011

Dated 31<sup>st</sup> March 2004.

## TENDER NOTICE

### **Subject: Supply of contraceptives and instruments**

Offers in sealed covers are invited for and on behalf of the President of India to enter in to a Rate Contract for the supply during the year 2004-05 of following Contraceptives and Instruments on the terms and conditions given in the schedule to tender document. Briefly, the particulars are as under:-

#### **1. Description of stores**

<b>Sl. No.</b>	<b>Item</b>	<b>Tentative Quantity to be procured for 2004-05</b>
1.	Condoms	1500 million pcs.
2.	Oral Contraceptive Pills	1200 lakh cycles
3.	Tubal Rings	40 lakh pairs
4.	Intra Uterine Device (Copper-T 380A)	80 lakh pcs.
5.	NSV instruments	10,000 sets

#### **2. Technical Specifications**

The detailed Technical Specifications are given in the tender document.

#### **3. Qualification Criteria for eligibility of firms**

a) Only domestic primary manufacturers are eligible to participate in the tender. (Primary manufacturer is a manufacturer that performs all the manufacturing and processing operations needed to produce goods in their appropriate dosage form, including processing, blending, formulating, filling, packing, labeling and quality testing).

b) The bidder should have 2 years manufacturing and marketing experience of substantial quantities for these products within a period of last 5 years duly supported by the documentary evidence and attested by their Chartered Accountant.

c) The production capacity of the tenderer should be at least 10% of the requirement of the preceding year( \* ). This should be supported by a certificate from State Drug Authorities.

d) The bidder must possess Good Manufacturing Practices (GMP)\* certificate for the manufacturing facility for 2 years or more, which should be valid on the date of tender opening.

e) Bidder should not have been convicted. This should be supported by a certificate from the State Drug Authorities.

\* The details are elaborated in the tender documents

**Note :** i. GOI reserves the right to increase or decrease the requirements, which would depend on actual requirements and resources.

iii. Further details regarding eligibility criteria are given in the tender document.

4. The details of invitation to tender are given in the tender forms which can be obtained on payment of Rs 5000/- separately for each item, by demand draft drawn in favour of Secretary (FW) payable at New Delhi from;

Room No. 502 - A Wing`  
Department of Family Welfare  
Nirman Bhawan, New Delhi-110011

5. **Procedure for submission of offers.**

The procedure to be followed is given in detail in the tender documents.

i) The sale of tender forms shall close on **13<sup>th</sup> May, 2004 at 11.00 AM for all items.**

ii) **Completed tenders forms for item nos. 1,2 &5 should be put in the tender box by 11.00 AM on 13.5.2004 . The bids will be opened on 13.5.2004 at 11.30 AM onwards.**

iii ) **The complete tender forms for item No 3&4 will be put in the Tender box by 1.00 PM on 13.5.2004 and will be opened at 2.15 PM onwards.**

*Offer received after due date and time shall not be considered at all.*

GOVERNMENT OF INDIA  
MINISTRY OF HEALTH & FAMILY WELFARE  
NIRMAN BHAVAN, NEW DELHI

**Tender Enquiry No.S.12012/ 18 /2004-Supply/RC/BCG Vaccine**

TIME AND DATE OF RECEIPT OF TENDERS IN THIS OFFICE BY **11.00 A.M. ON 14.05.2004**

TIME AND DATE OF OPENING OF TENDERS 11.30 **A.M on 14.05.2004**

THE TENDER SHALL REMAIN OPEN FOR ACCEPTANCE TILL **14.08.2004**

Item No.	Description of Stores	Unit	Rate figures words	(In terms of delivery F.O.R.)
1.	Freezed dried BCG Vaccine containing live bacteria, derived from culture of Bacillus Chalmette and Gurein intended for immunization of children against tuberculosis, to be administered by intredermal injection. It should meet the requirement of WHO for fried BCG Vaccine (WHO Technical Report Sl. 1979 No 638)	Ampoule of 20 dose		Tenderers to kindly read terms given below *
2.	Diluent for above i.e. Sodium Chloride Injection I.P. 0.9 W/V in 2.5 ml Ampoule.	Ampoule of 2.5 ml.		

LIFE 2 Years

Specification – As per Annexure A and IP (Latest)

Testing – Complete test protocols as per CDL Kasauli proforma.

Is Sales Tax extra?

Is Excise Duty extra ?

If yes, indicate the quantum of Sales Tax or Excise Duty applicable

\* The tenderer shall be responsible to arrange safe delivery, by air, rail or road, maintaining the cold chain, at the places to be mentioned in the supply order. The places of delivery are spread all over India. \* THE RATES QUOTED BY THE TENDERER SHOULD INCLUDE ALL COSTS FOR DELIVERY UP TO THE DESTINATION.

NOTE; Subject to the provision of Purchaser preference of the Govt. of India applicable for public sector undertaking of Govt. of India, the purchaser will not hold any negotiation with tenders except with the lowest tenders, if considered necessary. Hence all the tenderers are requested to quote their most competitive rates.

### **Qualification Criteria for eligibility of firms**

- a) Only domestic primary manufacturers are eligible to participate in the tender. (Primary manufacturer is a manufacturer that performs all the manufacturing and processing operations needed to produce goods in their appropriate dosages form, including processing, blending, formulating, filling, packing, labeling and quality testing).
- b) The bidder should have 2 years manufacturing and marketing experience of substantial quantities for this product within a period of last 5 years duly supported by the documentary evidence and attested by their Chartered Accountant.
- c) The production capacity of the tenderer should be at least 10% of the requirements of the preceding year ( 550 )[\*]. The bidders should be capable of producing the items, not only by enclosing the 'capacity certificate' but must also submit documents to prove that they have successfully supplied the BCG vaccine atleast equivalent to 10% of the annual off-take of the BCG vaccine by Deptt of Family Welfare, during the previous year(s). This should be supported by a certificate from State Drug Authorities.
- d) The bidder must possess Good Manufacturing Practices (GMP) certificate for the manufacturing facility for two years or more, which should be valid on the date of tender opening.
- e) Bidder should not have been convicted. This should be supported by a certificate from the State Drug Authorities.

**Note :** GOI reserves the right to increase or decrease the requirements, which is dependent on actual requirements and resources.

**[\*] Atleast 55 lakh doses.**

Signature of the tenders  
Name in Block letters and the capacity in  
Which the tender is signed  
Address in full

GOVERNMENT OF INDIA  
MINISTRY OF HEALTH & FAMILY WELFARE  
NIRMAN BHAVAN, NEW DELHI

**Tender Enquiry No.S.12012/ 19 /2004-Supply/RC/Measles**

TIME AND DATE OF RECEIPT OF TENDERS IN THIS OFFICE BY **11.00 A.M. ON 14.05.2004**

TIME AND DATE OF OPENING OF TENDERS 11.30 **A.M on 14.05.2004**

THE TENDER SHALL REMAIN OPEN FOR ACCEPTANCE TILL **14.08.2004**

Item No.	Description of Stores	Unit	Rate figures words	(In terms of delivery F.O.R.
1.	Indigenously manufactured MEASLES VACCINE (I.P) WITH DILUENT	Vial 2.5 ml of 5 dose each		Tenderers to kindly read terms given below *

LIFE 2 Years

Specification – As per Annexure A and IP (Latest)

Testing – Complete test protocols as per CDL Kasauli proforma.

Is Sales Tax extra?

Is Excise Duty extra ?

If yes, indicate the quantum of Sales Tax or Excise Duty applicable

\* The tenderer shall be responsible to arrange safe delivery, by air, rail or road, maintaining the cold chain, at the places to be mentioned in the supply order. The places of delivery are spread all over India. \* THE RATES QUOTED BY THE TENDERER SHOULD INCLUDE ALL COSTS FOR DELIVERY UP TO THE DESTINATION.

NOTE; Subject to the provision of Purchaser preference of the Govt. of India applicable for public sector undertaking of Govt. of India, the purchaser will not hold any negotiation with tenders except with the lowest tenders, if considered necessary. Hence all the tenderers are requested to quote their most competitive rates.

**Qualification Criteria for eligibility of firms**

- a) Only domestic primary manufacturers are eligible to participate in the tender. (Primary manufacturer is a manufacturer that performs all the manufacturing and

processing operations needed to produce goods in their appropriate dosages form, including processing, blending, formulating, filling, packing, labeling and quality testing).

b) The bidder should have 2 years manufacturing and marketing experience of substantial quantities for this product within a period of last 5 years duly supported by the documentary evidence and attested by their Chartered Accountant.

c) The production capacity of the tenderer should be at least 10% of the requirements of the preceding year ( 350 lakh doses)[\*]. The bidders should be capable of producing the items, not only by enclosing the 'capacity certificate' but must also submit documents to prove that they have successfully supplied the Measles vaccine atleast equivalent to 10% of the annual off-take of the Measles vaccine by Deptt of Family Welfare, during the previous year(s). This should be supported by a certificate from State Drug Authorities.

d) The bidder must possess Good Manufacturing Practices (GMP) certificate for the manufacturing facility for two years or more, which should be valid on the date of tender opening.

e) Bidder should not have been convicted. This should be supported by a certificate from the State Drug Authorities.

**Note :** GOI reserves the right to increase or decrease the requirements, which is dependent on actual requirements and resources.

[\* ] Atleast 35 lakh doses

Signature of the tenders  
Name in Block letters and the capacity in  
Which the tender is signed  
Address in full

GOVERNMENT OF INDIA  
MINISTRY OF HEALTH & FAMILY WELFARE  
NIRMAN BHAVAN NEW DELHI.

**DGS&D-242**

**Tender Enquiry No.S.12012/15/2003-Supply/RC/DT**

**Price per Tender set Rs.5000/- (Rupees Five thousand only)**

TIME AND DATE OF RECEIPT OF TENDERS IN THIS OFFICE BY **1.00 P.M. ON 14.05.2004**

TIME AND DATE OF OPENING OF TENDERS **2.15 PM on 14.05.2004**

THE TENDER SHALL REMAIN OPEN FOR ACCEPTANCE TILL **14.08.2004**

Item No.	Description of Stores	Unit	Rate figures words	(In terms of delivery F.O.R.
1.	DIPHTHERIA TETANUS TOXOID (DT) VACCINE	Vial of 10 dose each		Tenderers to kindly read terms given below **

LIFE : 2 Years

Specification – As per Annexure A and IP (Latest)

Testing – Complete test protocols as per CDL Kasauli proforma.

Is Sales Tax extra?

Is Excise Duty extra ?

If yes, indicate the quantum of Sales Tax or Excise Duty applicable

\*\* The tenderer shall be responsible to arrange safe delivery, by air, rail or road, maintaining the cold chain, at the places to be mentioned in the supply order. The places of delivery are spread all over India. \*\* THE RATES QUOTED BY THE TENDERER SHOULD INCLUDE ALL COSTS FOR DELIVERY UP TO THE DESTINATION.

NOTE: Subject to the provision of Purchaser preference of the Govt. of India applicable for public sector undertaking of Govt. of India, the purchaser will not hold any negotiation with tenders except with the lowest tenders, if considered necessary. Hence all the tenderers are requested to quote their most competitive rates.

**Qualification Criteria for eligibility of firms**

- a) Only domestic primary manufacturers are eligible to participate in the tender. (Primary manufacturer is a manufacturer that performs all the manufacturing and

processing operations needed to produce goods in their appropriate dosages form, including processing, blending, formulating, filling, packing, labeling and quality testing).

b) The bidder should have 2 years manufacturing and marketing experience of substantial quantities for this product within a period of last 5 years duly supported by the documentary evidence and attested by their Chartered Accountant.

c) The production capacity of the tenderer should be at least 10% of the requirements of the preceding year ( 338 lakh doses )[\*]. The bidders should be capable of producing the items, not only by enclosing the 'capacity certificate' but must also submit documents to prove that they have successfully supplied the DT Vaccine atleast equivalent to 10% of the annual off-take of the DT Vaccine by Deptt of Family Welfare, during the previous year(s). This should be supported by a certificate from State Drug Authorities.

d) The bidder must possess Good Manufacturing Practices ( GMP) certificate for the manufacturing facility for two years or more, which should be valid on the date of tender opening.

e) Bidder should not have been convicted. This should be supported by a certificate from the State Drug Authorities.

**Note :** GOI reserves the right to increase or decrease the requirements, which is dependent on actual requirements and resources.

[\*] Atleast 37 lakh doses.

Signature of the tenders  
Name in Block letters and the capacity in  
Which the tender is signed  
Address in full

GOVERNMENT OF INDIA  
MINISTRY OF HEALTH & FAMILY WELFARE  
NIRMAN BHAVAN NEW DELHI.

**DGS&D-242**

**Tender Enquiry No.S.12012/16/2004-SupplyRC//TT**

**Price per Tender set Rs.5000/- (Rupees Five thousand only)**

TIME AND DATE OF RECEIPT OF TENDERS IN THIS OFFICE BY **1.00 P.M. ON 14.05.2004**

TIME AND DATE OF OPENING OF TENDERS **2.15 PM on 14.05.2004**

THE TENDER SHALL REMAIN OPEN FOR ACCEPTANCE TILL **14.08.2003**

Item No.	Description of Stores	Unit	Rate figures words	(In terms of delivery F.O.R.
1.	TETANUS TOXOID (TT) VACCIINE	Vial of 10 dose each		Tenderers to kindly read terms given below *

LIFE : 3 Years

Specification – As per Annexure A and IP (Latest)

Testing – Complete test protocols as per CDL Kasauli proforma.

Is Sales Tax extra?

Is Excise Duty extra ?

If yes, indicate the quantum of Sales Tax or Excise Duty applicable

\* The tenderer shall be responsible to arrange safe delivery, by air, rail or road, maintaining the cold chain, at the places to be mentioned in the supply order. The places of delivery are spread all over India. \* THE RATES QUOTED BY THE TENDERER SHOULD INCLUDE ALL COSTS FOR ;DELIVERY UP TO THE DESTINATION.

NOTE: Subject to the provision of Purchaser preference of the Govt. of India applicable for public sector undertaking of Govt. of India, the purchaser will not hold any negotiation with tenders except with the lowest tenders, if considered necessary. Hence all the tenderers are requested to quote their most competitive rates.

**Qualification Criteria for eligibility of firms**

- a) Only domestic primary manufacturers are eligible to participate in the tender. (Primary manufacturer is a manufacturer that performs all the manufacturing and

processing operations needed to produce goods in their appropriate dosages form, including processing, blending, formulating, filling, packing, labeling and quality testing).

b) The bidder should have 2 years manufacturing and marketing experience of substantial quantities for this product within a period of last 5 years duly supported by the documentary evidence and attested by their Chartered Accountant.

c) The production capacity of the tenderer should be at least 10% of the requirements of the preceding year (726 lakh doses)[\*]. The bidders should be capable of producing the items, not only by enclosing the 'capacity certificate' but must also submit documents to prove that they have successfully supplied the TT Vaccine atleast equivalent to 10% of the annual off-take of the TT Vaccine by Deptt of Family Welfare, during the previous year(s). This should be supported by a certificate from State Drug Authorities.

d) The bidder must posses Good Manufacturing Practices (GMP) certificate for the manufacturing facility for two years or more, which should be valid on the date of tender opening.

e) Bidder should not have been convicted. This should be supported by a certificate from the State Drug Authorities.

**Note :** GOI reserves the right to increase or decrease the requirements, which is dependent on actual requirements and resources.

**[\*] Atleast 44 lakh doses.**

Signature of the tenders

Name in Block letters and the capacity in  
Which the tender is signed  
Address in full

GOVERNMENT OF INDIA  
MINISTRY OF HEALTH & FAMILY WELFARE  
NIRMAN BHAVAN NEW DELHI.

**DGS&D-242**

**Tender Enquiry No.S.12012/14/2004-Supply/RC/DPT**

**Price per Tender set Rs.5000/- (Rupees Five thousand only)**

TIME AND DATE OF RECEIPT OF TENDERS IN THIS OFFICE BY **1.00 P.M. ON 14.05.2004**

TIME AND DATE OF OPENING OF TENDERS **2.15 PM on 14.05.2004**

THE TENDER SHALL REMAIN OPEN FOR ACCEPTANCE TILL **14.08.2004**

Item No.	Description of Stores	Unit	Rate in figures and words	Terms of delivery F.O.R.
1.	DIPHTHERIA PERTUSIS TOXOID (DPT) VACCINE	Vial of 10 dose each		Tenderers to kindly read terms given below *

LIFE : 2 Years

Specification – As per Annexure A and IP (Latest)

Testing – Complete test protocols as per CDL Kasauli proforma.

Is Sales Tax extra?

Is Excise Duty extra ?

If yes, indicate the quantum of Sales Tax or Excise Duty applicable

\* The tenderer shall be responsible to arrange safe delivery, by air, rail or road, maintaining the cold chain, at the places to be mentioned in the supply order. The places of delivery are spread all over India. \* THE RATES QUOTED BY THE TENDERER SHOULD INCLUDE ALL COSTS FOR DELIVERY UP TO THE DESTINATION.

NOTE: Subject to the provision of Purchaser preference of the Govt. of India applicable for public sector undertaking of Govt. of India, the purchaser will not hold any negotiation with tenders except with the lowest tenders, if considered necessary. Hence all the tenderers are requested to quote their most competitive rates.

## **Qualification Criteria for eligibility of firms**

- a) Only domestic primary manufacturers are eligible to participate in the tender. (Primary manufacturer is a manufacturer that performs all the manufacturing and processing operations needed to produce goods in their appropriate dosages form, including processing, blending, formulating, filling, packing, labeling and quality testing).
- b) The bidder should have 2 years manufacturing and marketing experience of substantial quantities for this product within a period of last 5 years duly supported by the documentary evidence and attested by their Chartered Accountant.
- c) The production capacity of the tenderer should be at least 10% of the requirements of the preceding year (780 lakh doses)[\*]. The bidders should be capable of producing the items, not only by enclosing the 'capacity certificate' but must also submit documents to prove that they have successfully supplied the DPT Vaccine atleast equivalent to 10% of the annual off-take of the DPT Vaccine by Deptt of Family Welfare, during the previous year(s). This should be supported by a certificate from State Drug Authorities.
- d) The bidder must possess Good Manufacturing Practices (GMP) certificate for the manufacturing facility for two years or more, which should be valid on the date of tender opening.
- e) Bidder should not have been convicted. This should be supported by a certificate from the State Drug Authorities.

**Note :** GOI reserves the right to increase or decrease the requirements, which is dependent on actual requirements and resources

**[\*] Atleast**

Signature of the tenders  
Name in Block letters and the capacity in  
Which the tender is signed  
Address in full

GOVERNMENT OF INDIA  
MINISTRY OF HEALTH & FAMILY WELFARE  
NIRMAN BHAVAN NEW DELHI.

**DGS&D-242**

**Tender Enquiry No.S.12012/17/2004-Supply/RC/OPV**

**Price per Tender set Rs.5000/- (Rupees Five thousand only)**

TIME AND DATE OF RECEIPT OF TENDERS IN THIS OFFICE BY **11.00 A.M. ON 14.5.2004**

TIME AND DATE OF OPENING OF TENDERS **11.30 AM on 14.5.2004**

THE TENDER SHALL REMAIN OPEN FOR ACCEPTANCE TILL **14.08.2003**

Item No.	Description of Stores	Unit	Rate in figures and words	Terms of delivery F.O.R.
1.	Oral Polio Vaccine in vial of 20 doses and each of 0.1ml with pre-steriled dropper	Vial of 20 dose each		Free delivery to consignee all over India

Is Sales Tax extra?

Is Excise Duty extra ?

If yes, indicate the quantum of Sales Tax or Excise Duty applicable

a) Specifications:

1. As per IP(latest) – 1996 and Annexure –A attached

**2. OPV BULK CONCENTRATE**

- i. All OPV supplies against this tender must be blended from WHO approved bulk concentrate.
- ii. In support of (i) above, tenderers must submit a certificate from National Controlling Authority of the manufacturer of bulk concentrate.

### **3. Requirement of Blenders**

The manufacturers who blend the vaccine from bulk concentrate must have valid, WHO GMP certificate on the date of tender opening. Such WHO GMP certificate must be enclosed with the tender duly attested Drug Authority.

4. The vials should be provided with Vaccine Vial Monitor (VVM) which must be in stage I at the destination point.

- b). Testing – Complete test protocols as per CDL, Kasauli proforma.
- c). LIFE : 2 Years

The tenderer shall be responsible to arrange safe delivery, by air, rail or road, maintaining the cold chain, at the places to be mentioned in the supply order. The places of delivery are spread all over India. \* THE RATES QUOTED BY THE TENDERER SHOULD INCLUDE ALL COSTS FOR DELIVERY UP TO THE DESTINATION.

NOTE: Subject to the provision of Purchaser preference of the Govt. of India applicable for public sector undertaking of Govt. of India, the purchaser will not hold any negotiation with tenders except with the lowest tenders, if considered necessary. Hence all the tenderers are requested to quote their most competitive rates.

### **Qualification Criteria for eligibility of firms**

- a) Only domestic primary manufacturers are eligible to participate in the tender. (Primary manufacturer is a manufacturer that performs all the manufacturing and processing operations needed to produce goods in their appropriate dosages form, including processing, blending, formulating, filling, packing, labeling and quality testing).
- b) The bidder should have 2 years manufacturing and marketing experience of substantial quantities for this product within a period of last 5 years duly supported by the documentary evidence and attested by their Chartered Accountant.
- c) The production capacity of the tenderer should be at least 10% of the requirements of the preceding year (1350 lakh doses) [\*]. The bidders should be capable of producing the items, not only by enclosing the 'capacity certificate' but must also submit documents to prove that they have successfully supplied the OPV atleast equivalent to 10% of the annual off-take of the OPV Vaccine by Deptt of Family Welfare, during the previous year(s). This should be supported by a certificate from State Drug Authorities.
- d) Bidder should not have been convicted. This should be supported by a certificate from the State Drug Authorities.

**Note :** GOI reserves the right to increase or decrease the requirements, which is dependent on actual requirements and resources. .

**[\*] Atleast 140 lakh doses.**

Signature of the tenders  
Name in Block letters and the capacity in  
Which the tender is signed

Address in full

## INSTRUCTIONS FOR FILLING THE TENDER

The tender consists of two parts. Part A consists of technical and commercial terms and conditions and part B form for submitting the price offered by the tenderer. The part A and part B of the offer must be sealed in separate covers and covers clearly marked as **'part A containing the techno-commercial bid' and part B containing the price bid'**, respectively. The two covers then must be enclosed in one cover and sealed again, and the name and address of the tenderer, the tender No. and the date and time of opening must be clearly marked on the cover and put in the tender box, before the due date and time i.e 1.00 PM on 13.05.2004. The purchaser shall open the cover containing the Technical and Commercial offer (part A) on the due date and time for opening i.e. 2.15 PM on 13.05.2004.

### Tender Samples

Tenderers are requested to submit 150 pairs of Tubal Rings alongwith 75 cms of tubing material used for the manufacture of tubal rings, duly sealed alongwith their tender.

### Evaluation of offers

The Technical and Commercial offer of the firms contained in part A shall be first evaluated. The offers from only those tenderers

- a) Who satisfy the eligibility criteria given in the tender form and
- b) Whose Tender Samples, are found to conform to the tender enquiry specifications and
- c) Who have submitted certificate from the Drugs Authority that the material used for the manufacture of the tubal rings is of medical grade as specified in ISI 3009 : 2000.

Tenderer not satisfying anyone or more conditions mentioned above shall not qualify for further consideration. The envelopes containing prices (Part B) of only those firms who become qualified for further consideration as above shall be opened, after giving suitable notice to such qualifying tenderers.

Part A

*(The forms contained herein give the details of the terms and conditions of this invitation to tender/bid and should be filled and signed and enclosed in a sealed envelope and it must be clearly and boldly mentioned on the envelope that it contains the techno- commercial tender/bid. The envelope should also clearly mention the tender No and the date and time of opening. The failure of the tenderer to comply with these requirement may result in a mix-up with the price bid and in that event the offer shall be liable to be ignored summarily).*

Government of India  
Ministry of Health and Family Welfare,  
Room No.502 "A" Wing,

Nirman Bhavan, New Delhi-110011.  
Dated

.04.2004  
DGS&D-242

Schedule to Tender No.S.12012/23/2004-Supply/RC-Tubal Rings

**Price per Tender set Rs.5000/- (Rupees Five thousand only)**

Time and date of receipt of Tender-----**1.00 P.M on 13.05.2004.**

Time and date of opening of tecno-commercial bid----**2.15 PM on----  
13.05.2004**

Time and date of opening of price bid----- Will be informed later on  
Tender shall remain valid for acceptance -----**13.08.2003.**

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<b>Item No.</b>	<b>Description of stores</b>	<b>Unit</b>
1	Tubal Rings	pair

**2. Specifications** :IS1 3009:2000

Against this enquiry, the procurement decision as well as the subsequent supply in pursuance to such decision shall be on the condition that tubal rings are manufactured out of the material specified in the IS1 3009: 2000 and the finished tubal rings conform to ISI 3009:2000. The supplier shall furnish a certification from the Drug Authority that the rings offered by him have been manufactured out of medical grade tubing, as specified in IS1 3009:2000. Such certificate shall also be furnished with each batch offered for inspection by successful tenderer.

Negotiation: Subject to the provisions of Purchase preference policy of the Govt. of India applicable for public sector undertaking of Govt. of India, the purchaser will not hold any negotiation with tenderers except with the lowest tenderer, if considered necessary. Hence all the tenderers are required to quote their most competitive rates.

3. . Places of delivery:-The tenderer shall be responsible to arrange safe delivery of the required quantity of stocks at the place to be mentioned in the supply order. The places of delivery are spread all over India. THE RATES QUOTED BY THE TENDERER IN PART B OF THE TENDER/BID SHOULD INCLUDE ALL COSTS FOR DELILVERY UP TO THE DESTINATION., DULY INSURED ON WAREHOUSE TO WAREHOUSE BASIS.

4. QUANTITY : This tender enquiry is for entering into rate contract with the suppliers for the period 1.4.2004 to 31.3.2005. There is no commitment on the part of the purchaser for buying any specific quantity. However, the quantities for which orders are placed during the currency of the contract must be supplied by the successful tenderers.

## 5. Tender Samples

Tenderers are requested to submit 150 pairs of Tubal rings along with 75 cms of tubing material used for the manufacture of tubal rings, duly sealed along with their tender.

## 6. Qualification Criteria for eligibility of firms

- a) Only domestic primary manufacturers are eligible to participate in the tender. [Primary manufacturer is a manufacturer that performs all the manufacturing and processing operations needed to produce goods in their appropriate dosages form, including processing, blending formulating, filling, packing, labeling and quality testing].
- b) The bidder should have 2 years manufacturing and marketing experience of substantial quantities for this product within a period of

last 5 years duly supported by the documentary evidence and attested by their Chartered Accountant.

- c) The production capacity of the tenderer should be at least 10% of the requirements of the preceding year [\*]. This should be supported by a certificate from State Drug Authority.
- d) The bidder must possess GMP certificate for the manufacturing facility, for two years or more which should be valid on the date of tender opening.
- e) Bidder should not have been convicted. This should be supported by a certificate from the State Drug Authorities.
- f) Valid Income Tax Certificate, the date of issue of which should not be earlier than one year from the date of opening.
- g) Drugs License for manufacture and sale of the item.
- h) A certificate from the Drugs authority to confirm that the tubal rings offered are manufactured out of medical tubing as given in the IS 13009:2000.
- i) Each page of this tender should be signed and returned in token acceptance of the terms and conditions of the tenderer.

**Note :** GOI reserves the right to increase or decrease the requirements, which is dependent on actual requirements and resources.

**[\*] Atleast 3 lakh pairs.**

## **7. Performance Security**

Within 30 days of issue of supply order, the successful bidder shall be required to furnish performance security which shall be 10% of the value of the quantity for which the supply order is placed. The performance security shall be in the form of Bank guarantee (in the form annexed II) or irrevocable Letter of Credit or cashier's cheque.

In case, the Performance Security is not submitted within 30 days of placement of supply order, the supply order will be liable to be cancelled and procurement in such an event will be made at the risk and expense of the supplier.

The proceeds of the performance security shall be payable to the purchaser to compensate for any loss resulting from the suppliers failure to complete its obligations under the contract.

**8. Procedure for inspection**

Before declaring the tubal rings against any batch as acceptable, the inspecting officer shall get the samples from every batch tested. For this purpose, alongwith each lot of tubal rings, the firms are required to send 75cms of tubing out of which the batches in the lot have been manufactured. Also, alongwith each such lot, a certificate from the Drug Authority to confirm that the rings have been manufactured out of medical grade tubing (as specified in the ISI 3009:2000)should be furnished.

Signature of the tenderer  
Name in Block Letters and the capacity in  
Which the tender is signed.

Address in full:

## Part B

(To contain only the price)

(The form contained herein for the price bid should be filled and signed and enclosed in a sealed envelope and it must be mentioned in clear and bold letters on the envelope that it contains price bid. The envelope should also clearly mention the tender No and name of the item. The failure of the tenderer to comply with these requirements may results in a mix-up with the techno commercial bid and, in that event , the offer shall be liable to be ignored summarily.)

Government of India  
Ministry of Health & Family welfare  
Room No. 502 A Wing

Nirman Bhawan, New Delhi-11

Schedule to Tender No.S.12012/23 /2004-Supply/RC-Tubal Rings

Time and date of receipt of Tender----- **1.00 P.M on 13.05.2004.**

Time and date of opening of tecno-commercial bid----**2.15 PM on----  
13.05.2004**

Time and date of opening of price bid----- Will be informed later on  
Tender shall remain valid for acceptance -----13.08.2004.

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<b>Item No.</b>	<b>Description of stores</b>	<b>Unit</b>	<b>Rate (In Figure &amp; Words)</b>	<b>Terms of Delivery</b>
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<b>1.</b>	<b>Tubal Rings</b>	<b>Pair</b>		
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Specifications : ISI 3009: 2000

1. Against this enquiry, the procurement decision as well as the subsequent supply in pursuance to such decision shall be on the condition that tubal rings are manufactured out of the material specified in the ISI 3009: 2000 and the finished tubal rings conform to ISI 3009: 2000 . The supplier shall furnish a certificate from the Drug Authority that the rings offered by him have been manufactured out of medical grade tubing as specified in ISI-3009-2000. Such certificate shall also be furnished with each batch offered for inspection by successful tenderer.

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2. i) Rates quoted will remain firm and fixed for all the supply order placed till the last day of the validity of Rate contract. However, the statutory variation if any will be to the purchaser's accounts.
- ii) Is Sales Tax extra?
- iii) Is Excise Duty extra?
- iv) If yes, indicate the quantum of Sales Tax or Excise Duty applicable.
- v) Discount if any.
- vi) \* The tenderer shall be responsible to arrange safe delivery of the required quantity of stocks at the places anywhere in India, to be mentioned in the order. **THE RATES QUOTED BY THE TENDERER SHOULD INCLUDE ALL COSTS FOR DELIVERY UP TO THE DESTINATION., DULY INSURED ON WAREHOUSE TO WAREHOUSE BASIS.**

**Negotiation: Subject to the provision of Purchase preference policy of the Govt. of India applicable for public sector undertakings of Govt. of India, the purchaser will not hold any negotiation with tenderers except with the lowest tenderer, if considered necessary. Hence all the tenderers are required to quote their most competitive rates.**

3. Places of delivery: -

The tenderer shall be responsible to arrange safe delivery of the required quantity of stocks at the places to be mentioned in the supply order. The places of delivery are spread all over India. **THE RATES QUOTED BY THE TENDERER IN PART B OF THE TENDER/BID SHOULD INCLUDE ALL COSTS FOR DELIVERY UPTO THE DESTINATION., DULY INSURED ON WAREHOUSE TO WAREHOUSE BASIS.**

4. Quantity : This tender enquiry is for entering into rate contract with the suppliers for the period **1.4.2004 to 31.3.2005**. there is no commitment on the part of the purchaser for buying any specific quantity. However, the quantities for which orders are placed during the currency of the contract must be supplied by the successful tenderers.

## **5. Tender Samples**

**Tenderers are requested to submit 150 pairs of Tubal Rings alongwith 75 cms of tubing material used for the manufacture of tubal rings, duly sealed along with their tender.**

Signature of the tenderer  
Name in Block Letters and  
the capacity in which the tender is signed.

Address in full

nsv

## INSTRUCTIONS FOR FILLING THE TENDER

The tender consists of two parts. Part A consists of technical and commercial terms and conditions and part B form for submitting the price offered by the tenderer. The part A and part B of the offer must be sealed in separate covers and covers clearly marked as '**part A containing the techno-commercial bid**' and **part B containing the price bid**', respectively. The two covers then must be enclosed in one cover and sealed again, and the name and address of the tenderer, the tender No. and the date and time opening must be clearly marked on the cover and put in the tender box, before the due date and time i.e 11.00 AM on 13.05.2004. The purchaser shall open the cover containing the Technical and Commercial offer (part A) on the due date and time for opening i.e. 11.30 AM on 13.05.2004.

### **Evaluations of offers**

The technical and Commercial offer of the firms contained in part A shall be first evaluated . The offers from only those tenderers.

- a) whose Tender Samples, are found acceptable by a team consisting of experts in the Department of Family Welfare .shall only qualify for further consideration. Tender not satisfying any one or more conditions mentioned above shall not qualify for further consideration. The envelopes containing prices (Part B) of only those firms who becomes qualified for further consideration as above shall be opened, after giving suitable notice to such qualifying tenderers

## Part A

*(The forms contained herein give the details of the terms and conditions of this invitation to tender/bid and should be filled and signed and enclosed in a sealed envelop and it must be clearly and boldly mentioned on the envelope that it contains the techno- commercial tender/bid. The envelope should also clearly mention the tender No and the date and time of opening. The failure of the tenderer to comply with these requirement may result in a mix-up with the price bid and in that event the offer shall be liable to be ignored summarily).*

Government of India  
Ministry of Health and Family Welfare,  
Room No.503 "A" Wing,

Nirman Bhavan, New Delhi-110011.

Schedule to Tender No.S.12012/24/2004-Supply/RC-NSV

**Price per Tender set Rs.5000/- (Rupees Five thousand only)**

Time and date of receipt of Tender----- **11.00 A.M on 13.05.2004.**

Time and date of opening of tecno-commercial bid----**11.30 AM on 13.05.2004**

Time and date of opening of price bid----- Will be informed later on

Tender shall remain valid for acceptance **13.8.2004**

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Quantity	____ Sets with 3.5mm diameter (Ring) Extra Cutaneous and ___ sets with 4 mm internal diameter Ring Extra Cutaneous. The detailed specification are given in Annexure-I
Places of delivery	Family Welfare Depot, Nirman Bhawan, New Delhi.

The tenderers shall be responsible to arrange safe delivery of the required quantity of stocks to the above mentioned depot. THE RATES QUOTED BY THE TENDERER IN PART B OF THE TENDER/BID SHOULD INCLUDE ALL COSTS FOR DELIVERY UP TO THE DESTINATION , DULY INSURED ON WARE HOUSE TO WAREHOUSE BASIS.

### **TENDER SAMPLE**

Alongwith their offer tender should submit duly sealed tender sample comprising of one set of each of the two items mentioned in the tender enquiry.

### **Qualification Criteria for eligibility of firms**

- a) Only domestic primary manufacturers are eligible to participate in the tender. (Primary manufacturer is a manufacturer that performs all the manufacturing and processing operations needed to produce goods in their appropriate dosages form, including processing, blending, formulating, filling, packing, labeling and quality testing).
- b) The bidder should have 2 years manufacturing and marketing experience of substantial quantities for this product within a period of last 5 years duly supported by the documentary evidence and attested by their Chartered Accountant.
- c) The production capacity of the tenderer should be at least 10% of the requirements of the preceding year (7000 sets). The bidders should be capable of producing the items, not only by enclosing the 'capacity certificate' but must also submit documents to prove that they have successfully supplied the NSV Instruments atleast equivalent to 10% of the annual off-take of the NSV Instruments by Deptt of Family Welfare, during the previous year(s). This should be supported by a certificate from State Drug Authorities.
- d) The bidder must posses Good Manufacturing Practices (GMP) certificate for the manufacturing facility for two years or more, which should be valid on the date of tender opening.
- e) Bidder should not have been convicted. This should be supported by a certificate from the State Drug Authorities.
- f) Alongwith their offer tender should submit duly sealed tender sample comprising of one set of each of the two items mentioned in the tender enquiry.

**Note :** GOI reserves the right to increase or decrease the requirements, which is dependent on actual requirements and resources.

Signature of the tenderer  
Name in Block Letters and the capacity in  
Which the tender is signed  
.Address in full:

## Part B

(To contain only the price)

*(The forms contained herein for the price bid should be filled and signed and enclosed in a sealed and it must be mentioned in clear and bold letters on the envelope that it contains price bid. The envelope should also clearly mention the tender No and name of the item. The failure of the tender to comply with these requirements may results in a mix-up with the techno commercial bid and in that event, the offer shall be liable to be ignored summarily.)*

Government of India  
Ministry of Health and Family Welfare,  
Room No.503 "A" Wing,  
Nirman Bhavan, New Delhi-110011.

### **Schedule to Tender No.S.12012/24/2004-Supply/RC-NSV**

Time and date of receipt of Tender----- **11.00 A.M. on 13.05.2004.**

Time and date of opening of tecno-commercial bid----**11.30 AM on 13.05.2004**

Time and date of opening of price bid----- Will be informed later on

Item No.	Description of stores	Unit	Quantity	Rate (In Figure & Words)	Terms of Delivery
1.	No Scalpel Vasectomy Instruments with; a) 3.5 mm internal diameter ring Extra Cutaneous Vas Fixation Forceps and; b) Vas Dissection Forceps	Set			
2.	No Scalpel Vasectomy Instruments with; a) 4 mm internal diameter ring Extra Cutaneous Vas	Set			

Fixation Forceps  
and,  
b) Vas Dissection  
Forceps

The detailed specifications are given in Annexure I

Tenderer should quote most competitive rates. No second opportunity to quote rates by way of negotiation or counteroffer will be given to the tenders.

Is Sales Tax extra?

Is Excise Duty extra?

If yes, indicate the quantum of Sales Tax or Excise Duty applicable.

Signature of the tenderer  
Name in Block Letters and the capacity in  
Which the tender is signed. Address in full:

## FOR NSV ONLY

**IN ADDITION TO THE GENERAL CONDITIONS OF CONTRACT GIVEN IN FORM DGS7D –68 (REVISED) AND DGS&D 69 (REVISED), THE FOLLOWING SPECIAL CONDITIONS OF CONTRACT SHALL BE APPLICABLE , AND WOULD HAVE AN OVER-RIDING EFFECT OVER THE GENERAL CONDITIONS. IN CASE OF ANY CONFLICT BETWEEN THE TWO**

1. Delivery Period: Within two months of placement of order. Inspection Authority: The Deputy Commissioner (RSS), Ministry of Health and Family Welfare, Nirman Bhavan, New Delhi.
2. Inspecting Officer and procedure for inspection:-

Representative of the Deputy Commissioner(RSS) will carry out the inspection of the stocks.

i) Procedure for inspection

- a) Before declaring the instruments as acceptable, the inspecting officer shall draw samples from the lots offered for inspection for visual and laboratory tests. Only instruments which are found to meet the specification in all respects, will be accepted

have the right to impost any condition which may be necessary to safeguard Government interest.

3.1 **Inspection Authority:** The Drug Controller General of India.

3.2 **A. Inspecting Officer:**

To be specified in the order. However, the Director General,. Medical Stores Depot of the area concerned, or the District Health/Family Welfare Officer of the district/the district Immunisation Officer is generally authorised to carry out the inspection.

3.4 **B. For Manufacturers abroad**

In case of imported stocks, the representative of Drugs Controller of India shall draw the samples on the arrival of the goods at the Airport of entry into India., and that stocks shall be allowed entry only after clearance by the representative of the Drugs Controller of India at the Airport.

### 3.5 Pre-inspection by the suppliers:-

Manufacturers/contractors should satisfy themselves that the stores are in accordance with the terms of the contract and fully conform to the required specifications before tendering them for inspection to the inspecting officer nominated under the terms of the contract. If the inspector finds that the pre-inspection has not been carried out, or on examination of any sample from any portion of the consignment if the material are not found to fully conform to the particulars governing the supply, the entire consignment shall be reected.

A declaration by the contractor that necessary pre-

Government of India  
Ministry of Health & Family Welfare  
Department of Family Welfare  
Nirman Bhawan, New Delhi

Tender Enquiry NO. S.12012/ 22 /2004-Supply/RC/OCPs

**Price per Tender set Rs.5000/- (Rupees Five thousand only)**

**TIME AND DATE OF RECEIPT OF TENDERS – By 11.00 A.M on 13.5.2004**

**TIME AND DATE OF OPENING OF TENDERS – By 11.30 A.M on 13.5.2004**

**THE TENDER SHALL REMAIN OPEN FOR ACCEPTANCE– 13.8.2004**

Description of stores	Unit	Rate (in Rs.) for tableting ( <i>Raw material will be provided by the Government</i> )	Rate(In Rs.) with Finish Product ( <i>Raw material will not be provided by Government</i> )	Terms of delivery of dispatch	F.O.R Station
1. Mala 'D' – Fully packed.	<b>Cycles</b>			<b>Tenderers to kindly read terms given below.*</b>	
2. Mala'N' – Fully packed.	<b>Cycles</b>				
3. OCP (other Brands)- (Packed upto strip stage only) ii) Supply of Physicians samples on free door delivery basis only.	<b>Cycles</b>				

**\* (As per specifications attached at Annexure 'A' & B)**

**Special Note: i)** Rates quoted will remain firm and fixed for all the supply orders placed till the last date of the validity of the Rate contract. However, statutory variation, if any, will be to the purchaser's account.

- ii) Discount if any
- iii) Is Sales Tax extra?
- iv) Is Excise Duty extra?
- v) If yes, indicate the quantum of sales tax on Excise Duty applicable.

\* The tenderer shall be responsible to arrange safe delivery, by road at the places to be mentioned in the supply order. The places of delivery are spread all over India. \* THE RATES QUOTED BY THE TENDERER SHOULD INCLUDE ALL COSTS FOR DELIVERY UP TO THE DESTINATION.

## **B. Negotiation**

Subject to the provisions of Purchase Preference Policy of Govt. of India applicable for Public Sector Undertaking of Govt. of India the purchaser will not hold any negotiation with the tenderers except to the lowest tenderer, if considered necessary. Hence, all the tenderers are required to quote their most competitive rates.

Note. It should be the responsibility of the manufacturer to order as well as to provide the master case as per the specifications. In other words. The manufacturing companies shall be responsible for organising at their expense the packaging material up to the blister (pills) stage as well as the master case.

### **Qualification Criteria for eligibility of firms**

- a) Only domestic primary manufacturers are eligible to participate in the tender. (Primary manufacturer is a manufacturer that performs all the manufacturing and processing operations needed to produce goods in their appropriate dosage form, including processing, blending, formulating, filling, packing, labeling and quality testing).
- b) The bidder should have 2 years manufacturing and marketing experience of substantial quantities for this product within a period of last 5 years duly supported by the documentary evidence and attested by their Chartered Accountant..
- c) The production capacity of the tenderer should be at least 10% of the requirement of the preceding year (\*). The bidders should be capable of producing the items, not only by enclosing the 'capacity certificate' but must also submit documents to prove that they have successfully supplied the Oral Contraceptive Pills atleast equivalent to 10% of the annual off take of the OCPs by the Department of Family Welfare during the previous year(s). This should be supported by a certificate from State Drug Authorities.
- d) If the active ingredient has not been supplied by Govt. of India for the past supplies, the bidder should furnish documentary evidence of quantity procured of the active ingredient by enclosing document e.g
  - i) Air Way bill.
  - ii) Proforma invoice
  - iii) Bill of lading

- iv) Proof of payment
- v) Certificate from the Supplier, of these materials etc.
  
- e) The bidder must possess Good Manufacturing Practice (GMP) certificate for the manufacturing facility for two years or more, which should be valid on the date of tender opening.
- f) Bidder should not have been convicted. This should be supported by a certificate from the State Drug Authorities.

**Note :** GOI reserves the right to increase or decrease the requirements, which is dependent on actual requirements and resources.

(\*) At least 100 lakh cycles

Signature of the tenders  
Name in Block letters and the capacity in  
Which the tender is signed.  
Address in full:

Government of India  
Ministry of Health & Family Welfare  
Department of Family Welfare  
Nirman Bhawan, New Delhi

Tender Enquiry NO. S.12012/ 21 /2004-Supply/RC/Condom

**Price per Tender set Rs.5000/- (Rupees Five thousand only)**

**TIME AND DATE OF RECEIPT OF TENDERS – By 11.00 AM on 13.5. 2004**

**TIME AND DATE OF OPENING OF TENDERS – By 11.30 A.M on 13.5.2004**

**THE TENDER SHALL REMAIN OPEN FOR ACCEPTANCE – upto 13.8.2004**

<b>Description of the Stores</b>	<b>Unit per 100 pieces</b>	<b>Rate per A Type</b>	<b>Unit B Type</b>
1. Nirodh (condom) with teat end and lubricated for single use for new 10 paisa service charge scheme (life three years) (fully packed)			
2. New Lubricated Nirodh (condom) ---3's pack (life 3 years) with teat end and lubricated for single use for commercial distribution). i. upto strip pack stage – Note xxx ii. fully packed i.			
3. <b>Deluxe Nirodh</b> (condom) with teat end pink coloured lubricated for single use for commercial distribution (life 3 years) i. upto strip stage – Note xxx ii. fully packed			
4. Super Deluxe Nirodh (condom) with teat end and lubricated in four different colours each, barring natural latex colour, for single use for commercial distribution. i. upto strip stage ---Note xxx ii. fully packed.			

**Technical Specification: As per Schedule 'R' of Drugs & Cosmetics Rule**

**Note\*\***

1. 'A' Type denotes the 170 mm length condoms in squeeze pack condition (strip size minimum 70 mm length x minimum 30 mm width as per Specification Schedule 'R' of Drugs & Cosmetics Act.
2. 'B' Type denotes 180 mm length condoms in non-squeeze pack condition (strip size 54 mm minimum length and width as per Specification Schedule 'R' of Drugs & Cosmetics Act.
3. Tenderers should quote for item 1 in 'A' type pack only. For item No.2 to 4, tenderers may quote both 'A' type and 'B' type packs.
- 4 a) **CONDOMS SHOULD CONFORM TO THE SPECIFICATIONS LAID DOWN IN THE SCHEDULE 'R' OF DRUGS AND COSMETIC RULES.**

b) **The wallets as well as the cartons and the prices printed on them should strictly conform to the provisions contained in D.I.R (packed and commodities order 1987). However, as of now, 'Maximum retail price Rs/ --- per---- condom, inclusive all taxes', should be stipulated on the wallets and cartons for commercial scheme.**

**Note xxx**

- a) For condoms upto strip-packed stage, the manufacturer should also include the cost of outer packing.
- b) The brand name of the product will be mentioned in the supply order.
- c) The packing materials viz. Wallet catch covers and inner cartons will be provided by the purchaser.
- d) The colour of the condom art-work of the foil and specification for painting colour on the outer carton will be indicated in the supply order.

**Negotiation: Subject to the Provision of Purchaser preference of the Govt. of india applicable for public sector undertaking of Govt. of India, the purchaser will not hold any negotiation with tenderers except with the lowest tenderer, if considered necessary. Hence all the tenderers are requested to quote their most competitive rates.**

**Qualification Criteria for eligibility of firms**

- a) Only domestic primary manufacturers are eligible to participate in the tender. (Primary manufacturer is a manufacturer that performs all the manufacturing and processing operations needed to produce goods in their appropriate dosages form, including processing, blending, formulating, filling, packing, labeling and quality testing).
- b) The bidder should have 2 years manufacturing and marketing experience of substantial quantities for this product within a period of last five years duly supported by the documentary evidence and attested by their Chartered Accountant.
- c) The production capacity of the tenderer should be at least 10% of the requirement of the preceding year (\* ). This should be supported by a certificate from State Drug Authorities.

d) The bidder must possess Good Manufacturing Practice (GMP) certificate for the manufacturing facility for two years or more, which should be valid on the date of tender opening.

e) Bidder should not have been convicted. This should be supported by a certificate from the State Drug Authorities.

**Note :** GOI reserves the right to increase or decrease the requirements, which is dependent on actual requirements and resources.

Signature of the tenders  
Name in Block letters and the capacity in  
Which the tender is signed.  
Address in full:

**Note:\* At least 100 million pcs. of Condoms**

Government of India  
Ministry of Health & Family Welfare  
Department of Family Welfare  
Nirman Bhawan, New Delhi

**DGS&D -242**

Tender Enquiry No.S.12012/20/2004-Supply/RC/Copper-T-380A

**Price per Tender Set Rs.5000/- (Rupees Five thousand only)**

TIME AND DATE OF RECEIPT OF TENDERS IN THIS OFFICE BY **1.00 P.M. ON 13.5.2004.**

TIME AND DATE OF OPENING OF TENDERS ----- **2.15 P.M on 13.5.2004**

THE TENDER SHALL REMAIN OPEN FOR ACCEPTANCE -----TILL **13.8.2004**

2. Price schedule

Description of stores	Unit	Rate/unit (Figures & words)	Terms of delivery
1.Intra-Utrine Contraceptive Devices Copper-T 380-A As per specification Annexure-A & B attached with these tender documents.			Please quote rates for free delivery to consignees by road transportation.

2. 1 Is Sales Tax extra ?

2.2 If yes, indicate the quantum of Sales Tax or Excise Duty applicable.

3. THE PURCHASER WILL NOT RECOMMEND ANY CASE FOR WAIVER TO CUSTOM DUTY ON ANY OF COMPONENTS OR RAW MATERIALS OR PACKING MATERIAL USED IN MANUFACTURE OF COPPER-T. THE TENDERERS ARE REQUESTED TO KEEP THIS IN VIEW WHILE GIVING THEIR MOST COMPETATIVE RATES.

#### **4. Qualification Criteria for eligibility of firms**

- a) Only domestic primary manufacturers are eligible to participate in the tender. (Primary manufacturer is a manufacturer that performs all the manufacturing and processing operations needed to produce goods in their appropriate dosages form, including processing, blending, formulating, filling, packing, labeling and quality testing).
- b) The bidder should have 2 years manufacturing and marketing experience of substantial quantities of this product within a period of last 5 years duly supported by the documentary evidence and attested by their Chartered Accountant.
- c) The production capacity of the tenderer should be at least 10% of the requirements of the preceding year [\*]. The bidders should be capable of producing the items, by enclosing the 'capacity certificate' supported by State Drugs Authorities.
- d) The bidder must possess Good Manufacturing Practices (GMP) certificate for the manufacturing facility for two years or more, which should be valid on the date of tender opening.
- e) Bidder should not have been convicted. This should be supported by a certificate from the State Drug Authorities.

**Note:** GOI reserves the right to increase or decrease the requirements, which is dependent on actual requirements and resources.

**[\*] Atleast 7 lakh pieces**

Signature of the tenders  
Name in Block letters and the capacity in which the tender is signed.  
Address in full.

**ITEM NO. 1**

**DETAILS OF SPECIFICATION FOR 10 PAISA SERVICE CHARGE SCHEME**

1. Nirodh Condom with teat end, lubricated for single use for Supply Scheme [life 3 years].
2. Details of lubrication and lubricant
  - a. Quantity of lubricant - 200mg minimum
  - b. Details of lubricant - Silicon Oil [Dimethyl Poly Siloxane]
  - c. Viscosity - 200-350 CTSK
  - d. Properties - Non-toxic and non-irritant to skin
3. Each Nirodh [condom] is to be strip packed individually and 2 strip of each 5 foiled Nirodh are to be packed in a polythene pouch of 150 gauge, duly printed with the various instructions required under Standards of Weights & Measures Act 1976 and rules made under the law. The design and drawing of the polythene pouch should be in conformity with the artwork to be provided to the suppliers. 'Service fee leviable Re 1 for 10 condoms' will be printed on pouch [instead of 'Free Supply' earlier].
  - 3a. STRIP : 4 Ply Laminated Foil  
Material : 40/42 gsm GIP(glassine) paper/0.009mm aluminium foil/ heat seal coating /Acid Copolymer of polyethylene  
Size of each strip  
A Type : Strip size for squeeze pack, 70+2mm length x minimum 30mm width.  
Printing : In 2 colours dark tan and red on one side only, as per artwork to be given to the suppliers. "Service fee leviable – RE 1 for 10 condoms" will be printed (instead of 'Free Supply' earlier.).
  - 3b. CARTON : To contain 50 polythene pouches of 10 pcs. Each – total 500 pcs. in one carton. The words "Service fee of Re 1 for 10 condoms" will be printed (instead of 'not for sale').  
Material : 450gsm or above heavy duty gray board one side smooth surface to be used.  
Printing : As on existing carton in red colour.
4. **Specification for packing material for outer box**  
Narrow flue corrugated card board boxes of 7 ply, each ply of 150 gsm virgin Kraft paper of which outer ply to be alkali resistant [chemically treated or bitumined against white ants and other insects]. Outer layer will be 60 + 40 + 60 gsm and corners reinforced with 3" wide gummed cloth tapes in dark tan colour as per write up as in previous supplies. Inside to be lined with polythene liner.

Each box should contain 12 cartons of 50 pouch x 10nos. of Nirodh i.e. 6000pcs.

As per above specification the total GSM is as follows:

Out of 7 plies 6 inner plies (1 to 6 plies)		
150 gsm each	-	900
7 <sup>th</sup> out ply 160gsm x 1	-	160
<b>Total</b>	-	<b>1060</b>
Extra GSM for corrugation for 3 plies (@35%)	-	158
<b>G. Total</b>	-	<b>1218</b>

Bursting strength not less than 19 KGs/sq. cm.

Note:

1. Name of the form should be printed on the tape pasted on the card board for sealing purpose.
2. "Not for export outside India" must be printed on the wallet, cartons and corrugated card board boxes.
3. Leaflet illustrating how to use condoms must be enclosed in each pouch of ten condoms.
4. Condom width and length specification and whether the packing is of A type or B type must be mentioned on individual package (wallets) and the cartons.

ITEM NO. 2

SPECIFICATION FOR PACKING MATERIAL FOR NEW LUBRICATED NIRODH  
COMMERCIAL SCHEME

1. Nirodh Condom with teat end, lubricated for single use for commercial distribution [life 3 years].
2. Details of lubrication and lubricant
  - a. Quantity of lubricant - 200mg minimum
  - b. Details of lubricant - Silicon Oil [Dimethyl Poly Siloxane]
  - c. Viscosity - 200-350 CTSK
  - d. Properties - Non-toxic and non-irritant to skin
3. Each New Lubricated Nirodh [condom] is to be strip packed individually and 3 such strip packed Nirodh are to be packed in a wallet. 50 wallets in a carton in 2 rows (25 wallets in one row). Each row separated with 2 piece of 400 gsm grey board and 40 cartons in a card board box. Each wallet should contain an instruction leaflet printed in English and Hindi.

Details of the packing material and their size and printing are as follows:-

- 3a. **STRIP**
  - Material : 4 Ply Laminated Foil  
40/42 gsm GIP(glassine) paper/0.009mm aluminium foil/ heat seal coating /Acid Copolymer of polyethylene
  - Size of each strip
  - A Type : Stripe size for squeeze pack, 70+2mm length x minimum 30mm width.
  - B Type : Stripe size for non-squeeze type pack, minimum 54mm length x minimum 34mm width.
  - Printing : In 2 colours, canary yellow base, and bright red words. The glassine shall have the letters NIRODH printed obliquely. The printing of letters shall be in English, one line alternating with Hindi in the second line and having the red triangle, interspersed between two letters in the same line.
- 3b. **Wallets (catch Cover)**
  - Material : 250 gsm white duplex board burst factor 16/18 with brightness factor 76. Preferably board from Bhadrachalam, orient, sirpur and Balakrishna in the same order of priority.
  - Size
  - A Type : Size of the wallet{catch cover} should have a minimum dimension of 70mm x 60mm
  - B Type : Size of the wallet{catch cover} should have a

Printing : minimum dimension of 78mm x 68mm  
Printing on wallet should be in four colours on off set press. The wallets should have a finishing of double coat scuff proof, varnish cut and creased. The offset printing should be done based on the artwork supplied.

THE WALLET SHOULD BEAR A PRICE OF Rs..... FOR THREE

3c. CARTON : Cartons shall be made of 150gsm micro flute material which shall have four colour off set printing on 150gsm pulp board. It should be finished with double coat, scuff proof, varnished, cut creased and side seam glue. Each carton will contain 150pcs. 150 wallets of 3 pcs. each.

Size  
A Type : Size of the carton should have a minimum dimension of 181x150x79mm

B Type : Size of the carton should have a minimum dimension of 250x150x79mm. The size of carton should be as per the specifications given and should be such as to pack 50 condoms and the printing should be on the space on the art work supplied.

In the side panel of the carton the following particulars should be indicated;

Caution: Store properly to protect from heat, direct sun light and mechanical damage.

All the specifications of the strip, wallet and carton will be as per the engineering drawings and specifications.

#### 4. **Specification for packing material for outer box**

Narrow flute corrugated card board boxes of 7 ply, each ply of 150 gsm virgin Kraft paper of which outer ply to be alkali resistant [chemically treated or bituminsed against white ants and other insects]. Outer layer will be 60 + 40 + 60 gsm and corners reinforced with 3" wide gummed cloth tapes in green. The outside printing should be in double colour as per write up as in previous supplies. Inside to be lined with polythene liner.

Each box should contain 40 cartons of 50 wallets x 3 nos. of new lubricated Nirodh (i.e. 6000 pcs.)

As per above specification the total GSM is as follows:

Out of 7 plies 6 inner plies (1 to 6 plies)		
150 gsm each	-	900
7 <sup>th</sup> out ply 160gsm x 1	-	160
<b>Total</b>	<b>-</b>	<b>1060</b>
Extra GSM for	-	158
corrugation for 3 plies		
(@35%)		

**G. Total - 1218**

Bursting strength not less than 19 KGs/sq. cm.

Caution: Store properly to protect from heat, direct sun light and mechanical damage.

Note:

1. Name of the form should be printed on the tape pasted on the card board for sealing purpose. The strap should be in green colour.
2. "Not for export outside India" must be printed on the wallet, cartons and corrugated card board boxes.
3. Condoms width and length, specification and whether the packing is of A type or B type must be mentioned on individual package (wallets) and the cartons.

ITEM NO. 3

SPECIFICATION FOR PACKING MATERIAL FOR DELUXE NIRODH - PINK  
LUBRICATED CONDOMS

1. Nirodh Condom with teat end, lubricated for single use for commercial distribution [life 3 years].
2. Details of lubrication and lubricant
  - a. Quantity of lubricant - 200mg minimum
  - b. Details of lubricant - Silicon Oil [Dimethyl Poly Siloxane]
  - c. Viscosity - 200-350 CTSK
  - d. Properties - Non-toxic and non-irritant to skin
3. Each Deluxe Nirodh [condom] is to be strip packed individually and 5 such strip packed Deluxe Nirodh after keeping in a polythene pouch are to be packed in a wallet, 20 wallets in a carton. 40 cartons in a card board box. Details of the packing material and their size and printing are as follows. Each wallet should contain an instruction leaflet printed in English and Hindi alongwith pictorial. The leaflet is to be printed in black and white on 80gsm crème owe paper of size 8.25"x5.25".
  - 3a. **STRIP**

Material	:	4 Ply Laminated Foil
	:	40/42 gsm GIP(glassine) paper/0.009mm aluminium foil/ heat seal coating /Acid Copolymer of polyethylene.
Size of each strip		
A Type	:	Stripe size for squeeze pack, 70+2mm length x minimum 30mm width.
B Type	:	Stripe size for non-squeeze type pack, minimum 54mm length x minimum 54mm width.
Printing	:	In 2 colours, blue and red on glassine as per existing design.
  - 3b. **Wallets- box type**

Material	:	250 gsm duplex board printed in four colours and laminated (as per existing design).
Size		
A Type	:	Suggested dimension for the wallet (box type) is 75x50x13. However, all the five strips in the polythene pack and the instruction leaflet should fit well in the wallets (exact size to be approved by the Ministry)
B Type	:	Size of the wallet{catch cover} should have a minimum dimension of 120 x 83mm

THE WALLET SHOULD BE BEAR A PRICE OF Rs. 3.00 FOR FIVE CONDOMS

3c. CARTON : 3 ply flute 100x100x250 duplex board top open.  
Printing in four colours.

Size

A Type : Suggested dimension of the carton are 145x120x80mm. 20 wallet should fit well in the carton. (exact size to be approved by the Ministry)

B Type : Size of the carton should have a minimum dimension of 185x125x85mm.

Wallet & Carton should bear the following printing matter'

Superior quality, conforming to International Standard, Electronically tested, lubricated pink coloured condoms, subsidized price.

In the side panel of the carton the following particulars should be indicated;

Caution: Store properly to protect from heat, direct sun light and mechanical damage.

All the specifications of the strip, wallet and carton will be as per the engineering drawings and specifications to be provided to the supplier.

4. **Specification for packing material for outer box**

Narrow flue corrugated card board boxes of 7 ply, each ply of 150 gsm virgin Kraft paper of which outer ply to be alkali resistant [chemically treated or bituminsed against white ants and other insects]. Outer layer will be 60 + 40 + 60 gsm and corners reinforced with 3" wide gummed cloth tapes in green colour. The outside printing should be in double colour as per write up as in previous supplies. Inside to be lined with polythene liner.

Each box should contain 40 cartons of 20 wallets x 5 nos. of Deluxe Nirodh (i.e. 4000 pcs.). Suggested dimension is 490x300x410. However, all the 40 cartons should fit well in the box(exact size to be approved by the Ministry).

As per above specification the total GSM is as follows:

Out of 7 plies 6 inner plies (1 to 6 plies)		
150 gsm each	-	900
7 <sup>th</sup> out ply 160gsm x 1	-	160
<b>Total</b>	-	<b>1060</b>
Extra GSM for	-	158
corrugation for 3 plies		
(@35%)		
<b>G. Total</b>	-	<b>1218</b>

Bursting strength not less than 19 KGs/sq. cm.

Printing: The following matter should be printed on each outer box.

Caution: Store properly to protect from heat, direct sun light and mechanical damage.

Note:

1. Name of the form should be printed on the tape pasted on the card board for sealing purpose. The strap should be in black colour.
2. "Not for export outside India" must be printed on the wallet, cartons and outer board boxes.
3. Condoms width and length, specification and whether the packing is of A type or B type must be mentioned on individual package (wallets) and the cartons.

ITEM NO. 4

SPECIFICATION FOR PACKING MATERIAL FOR SUPER DELUXE MULTI  
COLOURED LUBRICATED CONDOMS

1. Nirodh Condom with teat end, lubricated and multi-coloured for single use for commercial distribution [life 3 years].
2. Details of lubrication and lubricant
  - a. Quantity of lubricant - 200mg minimum
  - b. Details of lubricant - Silicon Oil [Dimethyl Poly Siloxane]
  - c. Viscosity - 200-350 CTSK
  - d. Properties - Non-toxic and non-irritant to skin
3. Each condom is to be strip packed individually and 4 such strips containing condoms of four different colours are to be kept in a polythene pouch and such polythene pouch of four different colour condoms are to be packed in a wallet and 25 such wallet in a carton. 50 cartons in a card board box.
  - 3a. **STRIP**

Material	:	4 Ply Laminated Foil
	:	40/42 gsm GIP(glassine) paper/0.009mm aluminium foil/ heat seal coating /Acid Copolymer of polyethylene
Size of each strip		
A Type	:	Strip size for squeeze pack, 70+2mm length x minimum 30mm width.
B Type	:	Strip size for non-squeeze type pack, minimum 54mm length x minimum 34mm width.
Printing	:	Printing to be carried out in 2 colours, maroon background and reverse letterings as per previous supplies.
  - 3b. **Wallets catch cover**

Material	:	250 gsm duplex board laminated with 12 micron film, burst factor 16/19 brightness 76 Badhrachalam/Orient Sirpur/Balakrishna in the order of preference.
Size		
A Type	:	Size of the wallet (catch cover) should have a minimum dimension of 90x75mm
B Type	:	Size of the wallet (catch cover) should have a minimum dimension of 90x75mm. Each wallet should contain Super Deluxe different colour condoms.

Printing	:	To be carried out in 5 colours in by offset process (photo in 4 colours maroon as per previous supply)
a. Front Panel	:	<ul style="list-style-type: none"> <li>i. Multicoloured condoms</li> <li>ii. “Made specially for the Govt. of India”</li> <li>iii. Hindi words –</li> </ul>
B. Back Panel	:	Prices to be charged to Rs. .... for ..... pcs.
3c. CARTON	:	300 gsm white duplex board duly varnished with burst factor 16/19 brightness 76 Badhrachalam/Orient Sirpur/Balakrishna in the order preference.
Size		
A Type	:	Size of the carton should have a minimum dimension of 155x81x70mm
B Type	:	Size of the carton should have a minimum dimension of 220x81x70mm.
Printing	:	To be carried out in five colours.

All other matters as per pervious supplies.

4. **Specification for outer boxes**

Narrow flute corrugated card board boxes of 7 ply, each ply of 150 gsm virgin Kraft paper of which outer ply to be alkali resistant [chemically treated or bituminsed against white ants and other insects]. Outer layer will be 60 + 40 + 60 gsm and corners reinforced with 3” wide gummed cloth tapes in red colour with the undermentioned printing outside. Inside to be lined with polythene liner.

Each box should contain 50 cartons of 25 wallets x 4 ms. of Super Deluxe Nirodh (i.e. 5000 pcs.).

As per above specification the total GSM is as follows:

Out of 7 plies 6 inner plies (1 to 6 plies)		
150 gsm each	-	900
7 <sup>th</sup> out ply 160gsm x 1	-	160
<b>Total</b>	-	<b>1060</b>
Extra GSM for	-	158
corrugation for 3 plies		
(@35%)		
<b>G. Total</b>	-	<b>1218</b>

Bursting strength not less than 19 KGs/sq. cm.

Printing: The following matter should be printed on each outer box.

Caution: Store properly to protect from heat, direct sun light and mechanical damage.

Note:

1. Name of the form should be printed on the tape pasted on the card board for sealing purpose. The strap should be in red colour.
2. "Not for export outside India" must be printed on the wallet, cartons and outer boxes.
3. Condoms width and length, specification and whether the packing is of A type or B type must be mentioned on individual package (wallets) and the cartons.

**SPECIFICATION FOR LATEX RUBER CONDOMS**

1. **Dimensions**

- i. Length: The length when unrolled (excluding teat) shall be net less than 170mm/180mm with width  $49 \pm 2\text{mm}$  /  $53 \pm 2\text{mm}$  measured as per details in para 2 below.
- ii. Width: The width of a condom when laid flat and measured at any point within 85mm from the open end shall be;
  - a.  $49 \pm 2\text{mm}$
  - b.  $53 \pm 2\text{mm}$
- iii. Single wall thickness: the single wall thickness of a condom when measured at three points, one at  $30 \pm 2$  mm from open end,  $30 \pm 5\text{mm}$  from the closed and excluding the reservoir tip and at the mid distance between these two points shall be from 0.045mm to 0.075mm.

2. **Freedom from Holes:**

Statistical sampling from quality control assessment of the finished product in respect of water leakage test shall be done in accordance with the plan set out in Appendix I. Condom shall show no evidence of water leakage when tested as follows:-

Unroll the condom and fit the open end on a suitable mount. The condom is thus suspended open end upwards. Fill it with 300ml water at room temperature and inspect it after a period of atleast 1 minute for leakage upto 25mm from the open end. If, because of distension of the condom, the water does not extend to 25mm from the open end, raise the closed end until water level reaches the distance. After atleast 1 minute, inspect the newly-wetted part of the condom for leakage.

Note: Air leakage test is deleted from requirements.

3. **Bursting Volume and Pressure Test:**

Sample condoms shall be tested for bursting volume and pressure test. Statistical sampling for this test shall be done in accordance with the plan set out in Appendix-II.

Condom shall not leak or burst at a volume of less than that specified or pressure less than 1.0kpa(gauge), when test as in Appendix-IIA both before and after oven conditioning as specified in Appendix-III. Bursting volume minimum limit in litres shall be equal to

$$= \frac{(\text{Mean condom width in mm})^2}{151.8} \text{ rounded to the nearest 0.5 litres.}$$

**Note:** Tensile test is deleted from requirements.

4. **Integrity of Individual Package Seals:**

Sample condoms in individual packages shall be placed in a sealed, transparent container (such as laboratory bell jar) and subjected to a vacuum of  $50 \pm 10\text{kpa}$  (gauge) for a period of one minute.

Condom packages that do not inflate and remain inflated for the period of the test shall be deemed non-compliers. In doubtful cases, the test may be repeated and both the inflation and deflation of packages may be observed on application and removal of vacuum.

An AQL of 2.5 will be applied in assessing the results of this test. 50 samples of condoms shall be tested for integrity test of individual package seals. The compliance limit or acceptance number shall be not more than 3 condoms.

## Appendix – I

### Sampling plan for Quality Control of Condoms at Manufacturer's Level/Purchaser's Level

#### **Batch Size : 35001 to 1.50 lakhs**

Single Sampling Plan

Sample Size: 200	AQL -	0.25
	AC -	1
	R -	2

#### **Batch Size : 1.50 lakhs to 5 lakhs**

Sample Size: 315	AQL -	0.25
	AC -	2
	R -	3

#### **Batch Size : Over 5 lakhs**

Single Sampling Plan

Sample Size: 500	AQL -	0.25
	AC -	3
	R -	4

Note: AQL means Acceptance Quality Level.

AC means Acceptance Number i.e. the maximum allowable number of defectives for acceptance of the Batch.

R means Rejection Number i.e. the minimum number of defectives for rejection of the Batch.

## Appendix – II

### Sampling plan for Bursting Volume and Pressure Test

#### **Batch Size : 35001 to 1.50 lakhs**

Single Sampling Plan

Sample Size: 200	AQL -	1.5
	AC -	7
	R -	8

#### **Batch Size : 1.50 lakhs to 5 lakhs**

Single Sampling Plan

Sample Size: 315	AQL -	1.5
	AC -	10
	R -	11

#### **Batch Size : Over 5 lakhs**

Single Sampling Plan

Sample Size: 500	AQL -	1.5
	AC -	14
	R -	15

Note: AQL means Acceptance Quality Level.

AC means Acceptance Number i.e. the maximum allowable number of defectives for acceptance of the Batch.

R means Rejection Number i.e. the minimum number of defectives for rejection of the Batch.

## Appendix – IIA

### Determination of Bursting Volume and Pressure

#### 1. Principle

Inflation of a constant length of the condoms with air and recording the volume and pressure at the moment of bursting.

#### 2. Apparatus:

- 2.1 Apparatus suitable for inflating the condom with clean air at a specified rate and provided with equipment for measuring volume and pressure.
- 2.2 Suitable mount for fitting the condoms to the apparatus.
- 2.3 Rod, 140mm in length having a smooth sphere 20mm in diameter at its top for hanging the unrolled condom when fixed to the apparatus.

#### 3. Procedure:

- 3.1 Unroll the condom, hang it on the rod (2.3), affix to the mount (2.2) and inflate with air at a rate of 0.4 to 0.5 litre/sec (24 to 30 litres/min.)
- 3.2 Measure and note the bursting volume, in litres rounded to the nearest 0.5 litre and the bursting pressure, in kilopascals rounded to the nearest 0.1kpa.

**Oven Conditioning**

1. **Principle of the method:**

The test consists in subjecting test samples to control deterioration by air at an elevated temperature and at atmospheric pressure after which Burst Volume and Pressure limits are measured.

2. **Apparatus:**

The air oven shall be of such a size that the total volume of the test samples does not exceed 10% of the free air space of the oven. Provision shall be made for slow circulation of air in the oven of not less than three changes and not more than ten changes per hour. The temperature of the oven shall be thermostatically controlled so that the test samples are kept within  $\pm 2^{\circ}\text{C}$  of the specified ageing temperature. A thermometer shall be placed near the centre of the ageing test samples to record the actual ageing temperature.

Note: Copper or Copper alloys shall not be used for the material of construction of the oven prescribed.

3. **Test Samples:**

The foil limitations of individual packages should remain in tact throughout all laboratory handling including oven conditioning.

4. **Test Reports:**

The test report shall include the following particulars;

- a. the identification of the sample.
- b. The bursting volume and bursting pressure of each tested condom.
- c. The date of testing.

**STANDARDS FOR COPPER-T 380A**

**Definition:** Copper-T 380A is a T shaped intrauterine device having a copper color on each of the horizontal arms and a copper wire wound on to the vertical arm with dimensions as shown in figure I, with a plastic mono filament tied to the ball end of the vertical arm of the T. The T shall be dispensed with a plastic insertion tube and a solid rod having dimensions as shown in figure I, to facilitate insertion of the device in to the uterine cavity.

**1.1** This standards, cover the shape dimensions, manufacturing specification and the finished product specifications required for intra uterine contraceptive device Copper-T 380A and its components.

**2. References:**

**2.1** The following standards contain provisions which through reference in this text, constitute provisions of this standards. At the time of publications, the edition indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below:

<b>IS No.</b>	<b>Title</b>
<b>3395:1997</b>	: Low density. Poly Ethylene (LDPE) and Linear Low Density Poly Ethylene (LLDPE) – materials for moulding & extrusion (2 <sup>nd</sup> Version)
<b>13360(part4/SecI): 1995</b>	: Plastics-methods of testing : part 4 Rheological properties: Section 1 determination of the melt mass flow rate (MFR) and the melt volume flow rate (MVR) of thermo plastics.

**3. Procedure/specification for testing during manufacture:**

**3.1 Shape and dimensions**

**3.1.a** The shape and dimensions of Copper-T 380A components are shown in Figure I.

**3.1.b** The flange as shown in figure shall be positioned so as to be at  $70\pm 5$ mm from T end on the insertion tube. The dimension of the flange given in the figure I are for guidance only.

**3.2 Mass of Copper wire and collar**

**3.2a Mass of Copper wire:**

The mass of the copper wire wound on the vertical frame of the T shall be  $176\pm 11$ mg – Sampling Plan: Single Plan General Inspections level II – AQL 1%

**3.2.b Mass of Copper Collar-**

The mass of each copper collar fitted on the horizontal arm shall be  $68.7 \pm 3$  mgs -  
Sampling Plan: Single Plan General Inspections level II – AQL 1%

### **3.3 Materials for Copper-T components**

#### **3.3.a T**

The T shall be made of a compound obtained by blending low density poly ethylene (see IS 3395) and barium sulphate (20-24%) quality of BaSO<sub>4</sub> IP grade. The low density poly ethylene shall pass the extractable test as per Method A and shall have melt mass flow rates between 1.8 to 2.2 g—per 10 minutes when tested according to the method in IS 13360 (part 4/Sec. 1). The blend of LDPE and BaSO<sub>4</sub> shall meet the requirements of the implantation test as per methods.

**3.3.a.1** The lower end of the vertical arm of the T shall not deviate by more than 3mm from the central axis.

#### **3.3.b. Solid Rod**

The solid rod shall be made of polypropylene with approximately 0.5% pharmaceuticals grade titanium dioxide.

**3.3.b.1** The solid rods with following shape structures shall be accepted:

- a. Rod without having ball or fin
- b. Rod with ball
- c. Rod with fin

#### **3.3.c Insertion tube**

The insertion tube shall made of high density poly ethylene which shall pass the extractable tests as per pharmacopoeia requirements. The polyethylene shall be tested at the manufacturing stage. It shall have a melt mass flow rate between 0.6 to 0.8 g/10 minute when tested according to the method given in IS 13360(part4/Sec.1).

**3.3.c.1** It is optional to have the marking on scale in cm on the insertion tube with a pharmaceutical grade material so that it does not produce any toxic effects when in contact with the body fluids.

#### **3.3.d. Flange**

The flange shall be made of ply vinyl chloride containing approx. 1% titanium di oxide and pharmacopeial grade “blue” or “yellow” (IP grade).

### 3.3.e. Tie (Thread)

The tie shall be made of high density polyethylene with approx. 1% titanium di oxide (IP grade) or iron oxide to give white or dark colour respectively. The material shall pass implantation test when tested as per Method B. The tie shall be monofilament.

### 3.3.f. Copper wire/Copper Collar

The material of copper wire and copper collar shall be 99.99% pure and no other individual element shall be more than 50ppm. The manufacturer shall ascertain the purity of copper wire and copper collar used.

## 3.4 Dimensions

	Specification	AQL	Sampling Plan
<b>3.4.a T frame</b>			
Horizontal arm length	31.6mm-32.3mm	4%	Single plan General inspection Level II
Horizontal arm diameter	1.5mm-1.7mm	1.5%	-do-
Vertical arm length	35.7mm-36.2mm	4%	-do-
Vertical arm diameter	1.4mm-1.6mm	1.5%	-do-
<b>3.4.b Suture</b>			
Diameter	0.25± 0.05mm	4%	-do-
<b>3.4.c Copper Wire</b>			
Diameter of Copper Wire	0.25± 0.005mm	2.5%	-do-
<b>3.4.d Copper Collar</b>			
Length	4.9 – 5.15mm	4%	-do-
Outer diameter	2.17 – 2.22mm	1.5%	-do-
Inner diameter	1.65-1.7mm	2.5%	-do-
<b>3.4.e Insertion Tube</b>			
Length	203-208mm	1%	-do-
Inner diameter	3.6-3.8mm	1%	-do-
Outer diameter	4.3-4.5mm	1%	-do-
<b>3.4.f Solid Road</b>			
Length of the stem	188-193mm	1%	-do-
Tip diameter	2.5-2.8mm	1%	-do-
Stem diameter	2.3-2.6mm	1%	-do-
<b>3.4.g Flange</b>			
Hole diameter	Approx. 4.14mm		

### **3.5 Flange Displacement force**

Moulded flanges selected at random after 24 hours of moulding when assembled on insertion tubes selected at random and allowed to age for 24 hours shall show a displacement force between 180-630 gms. This test should not be carried out in the finished product - Sampling Plan: Single Plan General Inspections level II – AQL 2.5%.

### **3.6 Flexibility**

The standard flexibility test measures the deflection in mm when a 20gm weight is applied to the cross arm of the T for 30 seconds at a distance of 12mm from the stem of the T. T units are subjected to the test between 24 and 96 hours after moulding. Before measurements are made the Ts are equilibrated for at least 6 hours at within  $\pm 1.5^{\circ}\text{C}$  of the temperatures they will encounter during measurements. Measurements made at other than  $24^{\circ}\text{C}$ , but within the range  $20^{\circ}\text{C} - 29^{\circ}\text{C}$ , may be corrected by subtracting 0.125 units for each degree above  $24^{\circ}\text{C}$  and adding a similar amount for each degree below. Sample 50 units of moulded Ts from each batch. Not more than 5 of the 50 samples shall show a flexibility of less than 4.8mm or more than 6.5mm. None shall show a flexibility above 7.0mm. A batch shall be defined as units made with a single moulding mixture and in an uninterrupted manner except for momentary turn off.

### **3.7 Memory**

Memory is measured in terms of recovery after acute flexation. The horizontal arms are folded and inserted to a depth of 6.35mm in a hole of 4mm diameter. They are allowed to remain in this position for 5 minutes and then removed and allowed to recover their shape under zero load for 1 Minute. The recovery of the arms must be such that the tips of the arms are not displaced by more than 5mm from the horizontal. Test shall be conducted on 10 pcs. from a batch and if the average recovery is greater than 5.5mm then reject. If between 5 and 5.5mm then sample another 10 units and the average of the 20 tested shall be below 5mm.

## **4. Standards for the finished product**

### **4.a Amount of Copper wire**

The weight of the wire on the T arm shall be between 165-187mg. Sampling plan Single Plan General Inspections level II – AQL 1%.

**4.a.1** The ends of the copper wire shall be round and shall not have any sharp point at the edges and the end of the wire shall not protrude out more than 0.25mm from the outer surface of the copper wire winding on T-Sampling Plan: Single Plan General Inspections level II – AQL 0.65%.

### **4.b Dimension and position of the copper collar**

The outer diameter of the copper collar on the finished product shall be smooth and shall be between 2.05 – 2.11mm and shall be positioned at a distance of  $5.4 \pm 0.4\text{mm}$  from the ends of

the horizontal arm of the T - Sampling Plan: Single Plan General Inspections level II – AQL 1.5%.

#### **4.c Length of the Tie**

The length of the Tie attached to the T arm shall be 100mm minimum from the ball end of the T - Sampling Plan: Single Plan General Inspections level II – AQL 2.5%.

#### **4.d Strength of the Tie**

Place the IUD in the tensile machine. The upper part of the IUD in the upper clamp and thread at a distance of 5cm from the attachment of the lower clamp. Apply the force steadily at a separation speed of  $3.3 \pm 0.3$ mm/sec ( $200 \pm$  mm/min.). The thread shall not come out of the T or break a load of less than 9.5N - Sampling Plan: Single Plan General Inspections level II – AQL 0.65%.

#### **4.e Pouch Burst Strength**

Select one pouch at random from each 800 units of finished goods or at least a total of 32 units. Apply 60 mm Hg or equivalent air pressure inside the pouch section extending approximately 20cm beyond the added seal. The pouch shall hold the pressure for 30 seconds. No seal may open. If one opens repeat the sampling procedure. Not more than total of one seal may open in the combined sampling.

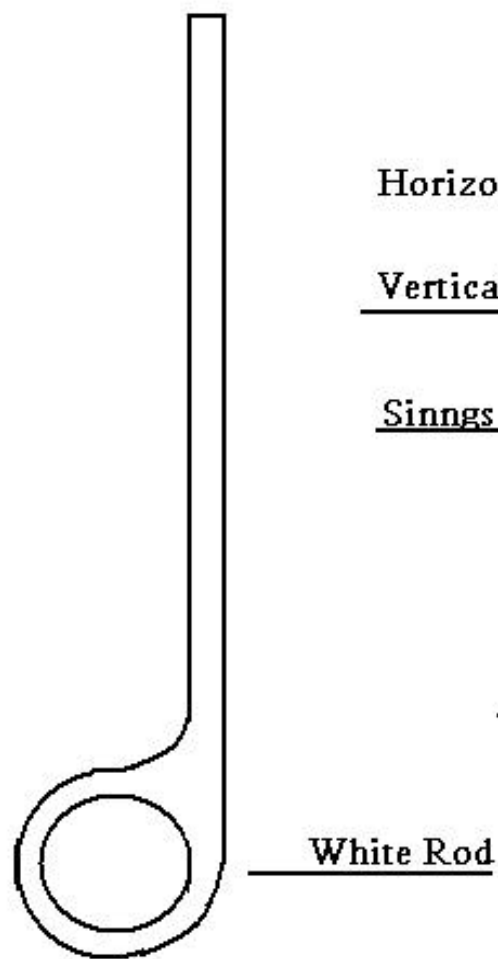
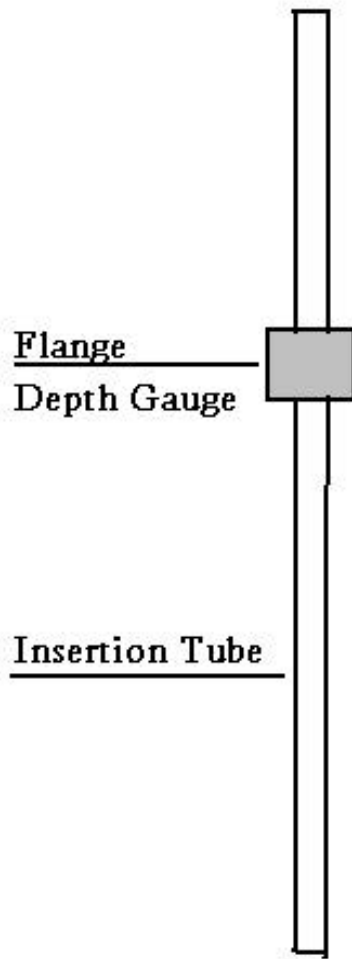
#### **4.f Copper Collar Pull force**

The Copper Collar on the finished product shall withstand a minimum pull force of 5N or 500 gm when a force is steadily applied at the rate of  $200 \pm 20$ mm/min. Sampling Plan: Single Plan General Inspections level II – AQL 4%.

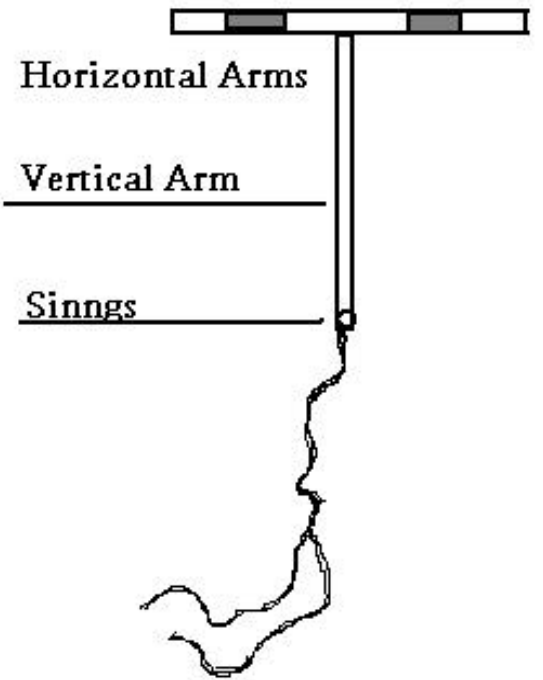
#### **4.g Sterility**

The device shall meet the requirements of the sterility test as specified in the latest Indian Pharmacopoeia.





### Copper - T





**Inspection**

- a) The mode of offering supply and procedure adopted for sampling will be governed by specification No.IS:12418(Part-4) 2000.
- b) A packing slip indicating the quantity of the contents in the box should invariably be kept in each box by the manufacturer/supplier. Quantities withdrawn from the boxes as samples for test should be indicated in the packing slip contained therein.
  - i) ISI specification is meant to be a reference to the latest issue of the said specification.

ISI specifications are priced publication and can be procured on payments from the Bureau Standards Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi-2 or from any of the regional offices.

**DESCRIPTION AND SPECIFICATIONS**

1. Product Formulation (each tablet)

- i) Free Distribution Programme : Mala-N – Packed as per 2 below:
  - a) 21 tablets containing Harmones as under:  
Levonorgestrel I.P. - 0.15 mg  
Ethinylloestradiol I.P. - 0.03 mg.
  - b) 7 tablets containing Ferrous Fumerate I.P - 60 mg.
- ii) Social Marketing Programme (Mala-D) – Packed as per 2 below:
  - a) 21 tablets containing Harmones as under:  
Levonorgestrel I.P - 0.15 mg.  
Ethinylloestradiol I.P - 0.03 mg.
  - b) 7 tablets containing Ferrous Fumerate I.P - 60 mg.
- iii) Other private Brands of Marketing Companies :- Packed upto strip stage.
  - a) 21 tablets containing harmones as under:  
Levonorgestrel - 0.15 mg  
Ethinylloestradiol I.P - 0.03 mg.
  - b) 7 tablets containing Ferrous Fumerate I.P. – 60 mg.

Tablets in all the three packing as above should conform to IP standards (Disintegration time as per IP)

2. Packaging insert, Logo Brand Name – Mala etc. will be same for both the products under the two schemes except for colour scheme and printing of 'Free Supply – Not for Sale' both on the catch cover and on the strip of pills under the Free- Distribution Scheme. To distinguish the two brands Mala-N or Mala-D will be printed on both the strip and the catch cover respectively. Samples of each is enclosed.

3. Tableting: The OCP strip will have 28 tablets constituting of twenty one oral Pills with active ingredients as mentioned above and seven Ferrous Fumerate tablets . The tablets will be coated and packed in 'Blister packs' only.

4. Colour Scheme:

As per sample attached – but actual printing material and colour scheme has to be got approved by the supplier as per clause 10.

Catch Cover

a) Free Scheme – The paper of Mala-N catch cover will be Meplitho 95 dimension will be 110 x 65 + 65 + 40 mm. The paper will be of 120 GSM.

B) Social Marketing Scheme \_ The paper of Mala-D catch cover will be Chemo-art of good quality. Its dimension will be 110x 65+65+40 mm. The paper will be of 140 GSM. For physician samples, the strip will bear inscription 'Physician Samples - Not for Sale' and the same will be inscribed on the catch cover also.

5. Packaging insert/instructions leaflets:

It should be both in English and Hindi and four Regional Languages. The size of leaflet should be 290x220 ± 5mm on good quality white prints paper of 48 GSM.

6. Supply of Bulk Drug

The active ingredients (with 5% allowable wastage) viz. Levonorgestrel and Ethinyloestradiol will be supplied for both the items by the Department of Family welfare from their New Delhi Depot against Bank Guarantee for the cost of ingredients. The other ingredients and packing materials will have to be arranged by the supplying firms.

7. Carton

i)Free Distribution (Mala-N) 100 cycles each (in plain carton) and ten such cartons in a corrugated box to fit in the Outer box. The paper of the inner box will be the same as of the outer box. The Outer box should be conforming to specifications indicated in the attached Annexure 'A' . The size of inner box will be 350 x225x 70 mm.

ii)Social Marketing : 10 cycles in a carton with five sides marking as on catch cover and bottom plain and 100 such cartons in a outer corrugated box.

iii) The size and specification of the Outer box will be as per Annexure 'B'

8. Paper for wallet/catch cover/carton:

- i) Both for wallet/catch cover for free Scheme (Mala-N)-Maplitho.,
- ii) Paper for carton for Social Marketing – GSM 250- Duplex Board.
- iii) The size of carton will be 115 x 75x70 mm.

9. Brand Name i.e. Mala- 'Mala-N' or Mala-'D' , Name of manufacturer, date of manufacturer etc, and batch number should be indicated on both the catch covers and strip.

10. Approval of packaging materials

Samples of strips, catch cover, carton etc, will have to be approved in advance.

**SPECIFICATION FOR OUTER CORRUGATED BOX FOR MALA ‘N’-‘D’  
TABLETS**

Paper	:	Virgin Kraft												
Ply	:	7												
G.S.M. Liner	:	160 (Outer line bituminised) 120 120												
Flute	:	120 120												
Dimension	;	<table><thead><tr><th></th><th>L</th><th>W</th><th>H</th></tr></thead><tbody><tr><td>Mala-N</td><td>470</td><td>370</td><td>390</td></tr><tr><td>Mala-D</td><td>475</td><td>390</td><td>370</td></tr></tbody></table>		L	W	H	Mala-N	470	370	390	Mala-D	475	390	370
	L	W	H											
Mala-N	470	370	390											
Mala-D	475	390	370											
No. of Inter leaving Board	:	Two of 3 ply of 120 G.S.M each.												
Nature of Flute	:	Narrow												
Direction of Flute	:	Vertical												
Puncture Resistance	:	NLT 45 C ozs inch/Tear inch												
Bursting Strength	:	NLT 15 kg/m <sup>2</sup> .												
Nature of Gum	:	Starch based												
Style	:	Universal												
Burst factor	:	NLT 20												
Stappling	:	NLT 20												

The box shall be of single piece with double stappling using flat wire of mild steel or galvanised materials, at once corner only as per – ISP 10066 – 1981. The body joint shall have overlapping of minimum 40 mm and spacing of stappling should not be more than 60 mm. The first and last stappling should not be put at a distance of more than 25 mm from end.

.....

Note: For Mala'D', the above specifications will be followed except that the size of the box will be 475x365x345mm.

SIZE OF PACKAGING MATERIAL OF MALA 'N' & MALA 'D'

1. Mala 'N'

<u>S.No.</u>	<u>Name of Material</u>	<u>Size</u>
i)	Leaflet	290x220 mm
ii)	Catch Cover	110x65+65+40 mm
iii)	Inner Box	350x225x70 mm
iv)	Outer Box	470x370x390 mm L W H

2. Mala 'D'

i)	Leaflet	290x220 mm
ii)	Catch Cover	110x65+65+40 mm
iii)	Carton	115x75x70 mm
iv)	Outer Box	475x390x370 L W H

SPECIFICATIONS FOR ITEM NO 1 OF THE TENDER ENQUIRY

Two instruments are required for performing NSV. They are

1. Extra Cutaneous vas fixation forceps.
2. Vas dissection forceps.

The specifications for Extra Cutaneous Vas fixation forceps are :

Weight	21.905 G
Length (Ratchet to Tip)	11.6 cms
Length (Box joint to Tip)	4.0 cms
Locking grooves	2
Internal Diameter of Ring	3.5 mm
Slit between blades (length)	6 mm
Slit distance	0.6 mm
Thickness of Ring	0.8 mm

The specifications for vas dissection forceps\* are as follows:

Weight	18.565 G	Range 18-20 G
Length (Ratchet to Tip)	9.8 cms	Ranges upto 10 cms
Length (Lock to tip)	2.6 cms	Range 2.6-3 cms
Ratchets	3	
Tip angle	45 on plane	
Inside surfaces of blades	Smooth	

Instrument must have box joint.

Both the Instruments must be packed in sets of two ( i.e. two extra cutaneous vas fixation forceps and two vas dissection forceps must be packed together).

## SPECIFICATIONS FOR ITEM NO.2 OF THE TENDER ENQUIRY

Two instruments are required for performing NSV. They are

1. Extra Cutaneous vas fixation forceps.
2. Vas dissection forceps.

The specifications for Extra Cutaneous Vas fixation forceps\* are:

Weight	21.905 G
Length (Ratchet to Tip)	11.6 cms
Length (Box joint to Tip)	4.0 cms
Locking grooves	2
Internal Diameter of Ring	4 mm
Slit between blades (length)	6 mm
Slit distance	0.6 mm
Thickness of Ring	0.8 mm

The specifications for vas dissection forceps\* are as follows:

Weight	18.565 G	Range 18-20 G
Length (Ratchet to Tip)	9.8 cms	Ranges upto 10 cms
Length (Lock to tip)	2.6 cms	Range 2.6-3 cms
Ratchets	3	
Tip angle	45 on plane	
Inside surfaces of blades	smooth	

Instrument must have box joint.

Both the instruments must be packed in sets of two (i.e. two extra cutaneous vas fixation forceps and two vas dissection forceps must be packed together).

\* The specification of metal used for manufacture of the instruments.

The metal should be light weight surgical alloy, non staining, corrosion free, non-rusting and should be able to withstand the temperature of auto-claving. It should not be reflecting light (surface should not be shiny) with buff coating. It should not be brittle.

## Vaccines

### **SPECIFICATION FOR D.P.T. VACCINE AS PER I.P. (Latest)**

#### **PACKING**

- 1. In 5ml rubber capped vials with yellow colour Aluminium caps i.e. 10 doses vials. Then one box containing 50 vials and finally securely packed in 7 ply card board cartons or suitable wooden packing cases to avoid any breakage/loss in transit.**
2. All the containers and other outer containers will be marked with the words 'CGS SUPPLY, NOT FOR SALE' in English and Hindi and all labels on containers i.e. bottle cartons, tubes etc., as well as outer droppers should be marked with the words 'CGS SUPPLY, NOT FOR SALE' in bold red letters in English.
3. Any other particulars required under Drugs and Cosmetics Act., 1940.

## **SPECIFICATION FOR TT VACCINE**

As per I.P. (Latest)

### **PACKING & MARKING**

1. Box containing 50 vials and finally securely packed in 7 ply card board cartons of suitable wooden cases to avoid any breakage loss in transit.
2. All the containers and other outer containers will be marked with the words 'CGS SUPPLY NOT FOR SALE' in English and Hindi and all labels on containers i.e. bottle, cartoons, tubes etc. as well as outer dropper should be marked with the words CGS S SUPPLY NOT FOR SALE' in bold red letter in English and Hindi.
3. Any other particulars required under Drugs & Cosmetics Act., 1940.
4. The vials should have Aluminium Caps of Green colour on outer surface. Inner surface of the caps should not be coloured.

## SPECIFICATION FOR DT VACCINE

### **As per I.P. (Latest)**

#### PACKING & MARKING

In 5ml rubber capped vials with lime colour. The Aluminium caps should not be coloured from inside, caps as caps may be used with approval of the Inspecting Officer 10 doses vial in box containing 50 vials to be finally securely packed in 7 ply card board cartons of suitable wooden packing cases to avoid any breakages loss in transit.

#### **Despatch Instructions:**

1. The stores should be dispatched by Air/rail freight prepaid insulated delivery van/passenger train with the attendant as per the instructions in the supply order. The consignee may be informed of the likely date of despatch well in advance.
2. All the containers and other outer containers will be marked with the words 'CGS SUPPLY NOT FOR SALE' in English and Hindi and all labels on containers i.e bottle, cartoons, tubes etc. as well as outer dropper should be marked with the words CGS SUPPLY NOT FOR SALE' in bold red letters in English and Hindi.
3. Any other particulars required under Drugs &Cosmetics Act., 1940.

## **SPECIFICATIONS OF ORAL POLIO VACCINES**

1. The preparation shall contain 1 Molar Magnesium Chloride as stabilizer. The colour of the vaccine should be pink. Such dose must consist of 2 drops to conform to the I.P. requirements.

The supplier should specify on the vials numbers of drops to be administered which will contain required amount of virus per dose. Pre-sterile droppers should be supplied with the vial/plastic tube.

3. **Packing:** Vaccine should be supplied in 20 doses vials/plastic tube with pre-sterile dropper packed in cardboard box containing 50 vials/plastic tube, 20 such boxes must be packed in thermocole boxes containing sufficient dry ice to maintain a temperature of  $-20^{\circ}\text{C}$ . The dry ice should be sufficient to maintain temperature of  $-20^{\circ}\text{C}$  for about 100 hrs.
4. **Expiry Date:** The life of the vaccine must be 2 years if stored at  $-20^{\circ}\text{C}$  and should not be older than  $1/6^{\text{th}}$  of total life at the time of tendering.
5. **Protocol and Testing:** Complete Test Protocol along with samples of all batches should be sent to the Head of the Polio Vaccine testing laboratory i.e. Central Drugs Laboratory at Central Research Institute, Kasauli-173205 by the Inspecting Officer duly sealed and signed by him or his authorized representative. The Vaccine should be dispatched to the consignee only on clearance from the Central Drugs Laboratory at Central Research Institute, Kasauli. The vaccine will be released on the basis of Protocol Scrutiny and Testing of the vaccine by Central Research Institute, Kasauli.
6. Each batch should be accompanied with a certificate from the manufacturer that the vaccine meets the I.P. requirements.

### **Despatch**

The vaccine should be dispatched preferably by Air, Rail or Road transport may be used if accompanied by attendant. Vaccine should be sent in thermocol boxes with dry ice maintaining temperature below  $-20^{\circ}\text{C}$ . The consignee should be intimated well in advance by Registered letter/Telegram/Telephone, so that vaccines are collected from airport immediately after arrival. Copy of the communication from the supplying firm should be endorsed to the Asstt. Commissioner(I) and Dy. Director(Supply), Ministry of Health & Family Welfare, Nirman Bhavan, New Delhi for information.

## Measles

## Annexure-A

### SPECIFICATION AND PACKING DETAILS OF MEASLES VACCINE IN 5 DOSE VIALS

1. Name of the Vaccine	Vaccinum Morbillorum Vivum (Measles Vaccine)
2. Grade	As per I.P. (In packing of 5 dose vial)
3. Dose	0.5 ml contained not less than 1,000 CCID/50 virus particles per dose.
4. Potency	Measles Vaccine should be in consonance with the requirement stipulated for potency in the monograph of Measles Vaccine of IP.
5. Diluent	Each vial of Measles Vaccine should be accompanied with one ampoule containing 2.5 ml. Of distilled water (pyrocen free) specially prepared for diluting Measles Vaccine.
6. Life of Measles	24 months when stored at 2c to 8c.
7. Packing of Vaccine	The vaccine should be supplied in packing of 50 vials well packed in cardboard boxes of 3 ply Ten/Twenty such cardboard boxes packing i.e. 500/1000 vials will be further packed in a bigger size thermocole box, duly cooled with ice packs, covered with polythene sheets, to avoid leakage of the box containing the vaccine. The ice packs will be packed at the top, centre and the bottom of the thermocole box.

## **BCG VACCINE [FREEZE-DRIED]**

Bacillus Calmette – Guerin Vaccine

BCG Vaccine [Freeze-dried] is a preparation containing live bacteria obtained from a strain derived from the bacillus of Calmette and Guerin and known to protect human beings against tuberculosis. The vaccine is prepared immediately before use by reconstitution from the dried vaccine with a suitable diluent as per manufacturer's instructions.

The vaccine is produced on the basis of the seed-lot system.

The strain which is of uniform composition is selected and maintained so as to preserve its stability, its power to sensitise human beings to tuberculin, its ability to protect laboratory animals against tuberculosis and to retain its relative non-pathogenicity for human beings and laboratory animals. The seed lot is maintained in a freeze-dried form at a temperature not exceeding  $-20^{\circ}$  and is revived by transplanting on to a suitable medium. The cultures for harvesting are done on liquid medium and the harvested growth is separated by filtration in the form of a "cake". The "cake" is homogenized in a grinding flask and suspended in a suitable sterile liquid medium designed to be preserved as determined by an appropriate method. The suspension is distributed into its final sterile containers and freeze-dried under conditions designed to prevent microbial contamination, particularly by virulent tubercle bacilli. The containers are sealed so as to prevent contamination or deterioration of the final vaccine. The vaccine contains no antimicrobial agent.

**Category:** Active immunizing agent.

**Dose:** Prophylactic, by intracutaneous injection as a single, 0.1ml.

**Description:** White pellet or powder which, when reconstituted, yields an opalescent and homogenous suspension.

**Storage:** Store in light-resistant glass containers at a temperature between  $2^{\circ}$  and  $8^{\circ}$ . The vaccine should be used immediately after reconstitution.

**Labelling:** The label states (1) the number of viable particles; (2) the name and volume of the liquid to be used for reconstituting the vaccine; (3) the storage conditions; (4) the date after which it is not intended to be used; (5) that any portion of the reconstituted vaccine not used immediately should be discarded; (6) that the vaccine should not be exposed to light before or after reconstitution.

## STANDARDS

*The vaccine reconstituted as stated on the label complies with the following requirements.*

**Identification: A:** Examined microscopically in stained smears, the bacilli exhibit the characters of an authentic strain of the bacillus of Calmette and Guerin.

**B :** Colonies grown on a suitable solid culture medium have a characteristic appearance and conform to the test for colony-forming units [CFU], Appendix 9.3.  
**Extraneous micro-organisms:** Complies with the tests for sterility, Appendix 9.5, except that there may be growth of the organism from which the vaccine was prepared.

**Stability:** Determine the number of culturable units in the reconstituted vaccine by a colony count on solid medium using a method appropriate to the vaccine being examined. [It is not possible to specify the value for the number of culturable units per dose since this will vary according to the seed lot and the method of manufacture used]. Incubate half of the vaccine at 4° and the other half at 37° for 28 days. Determine the number of culturable units in the two samples as before. The number of culturable units in the two samples as before. The number of culturable units in the sample kept at 37° is not less than 20% of that in the vaccine kept at 4°.

**Absence of virulent mycobacteria:** At least six tuberculin-negative guinea-pigs, all of the same sex, each weighing between 250 and 400 grams are used. A dose of BCG organisms corresponding to at least 50 human doses of vaccine intended for intra-dermal injection shall be injected into each guinea-pig by the subcutaneous or intra-muscular route. The animals shall have been maintained on a diet that is free from added substances such as antibiotics that might interfere with the test. The guinea-pigs will be observed for at least 6 weeks.

At the end of the observation period, the animals shall be sacrificed and examined post-mortem for macroscopic evidence of progressive tuberculosis disease. Similarly, any animals that die before the end of the observation period shall be subjected to post-mortem examination. The vaccine will pass the test if none of the guinea-pigs shows evidence of progressive tuberculosis disease and if at least 2/3<sup>rd</sup> of them survive the observation period. Should more than one third of the guinea-pigs die during the observation period [and freedom from the progressive tuberculosis disease is verified] the test shall be repeated on at least 6 more tuberculin-negative guinea-pigs. If on the second occasion more than 1/3<sup>rd</sup> of the animals fail to survive the observation period, the vaccine will not pass the test. If evidence of progressive tuberculosis is seen, the vaccine will be rejected.

**Skin reactivity:** Inject intracutaneously into each of four guinea-pigs weighing not less than 250g in a volume of 0.1ml, one, one-tenth and one-hundredth of the human dose of the vaccine being examined and of the *standard preparation of BCG vaccine*. The vaccine passes the test if the skin reaction produced with the injections for the vaccine being examined within 4 weeks do not differ markedly from those produced by the standard preparation.

**Potency:** Carry out the test on at least five containers. Reconstitute the vaccine as for human use with the diluent stated on the label and carry out the *test of colony-forming units [CFU]*, Appendix 9.3. The validity of the test must be determined by carrying out the test on a preparation of known potency.

**Government of India**

Ministry of Health & Family Welfare  
Department of Family Welfare  
(SSM Division)

Nirman Bhavan, New Delhi-110011.

Dated . 2004.

**Tender Enquiry No.S.12012/ /2004-Supply/RC**

To

Dear Sir,

On behalf of the President of India, I invite you to tender for supply of stores detailed in this schedule attached to the tender form enclosed.

2. The conditions of contract which will govern any contract made are contained in pamphlet No.DGS&D 1001 " General terms and conditions of contract governing Rate Contract". as amended upto date and those contained in the Phamphlet No.DGS&D-229 containing the various instructions to tenders quoting against the tender enquiries issued by the DGS&D subject to the following:

Para(1) of Form DGS&D-68 (Revised) may be substituted by the following:

- i) "Secretary" means the Secretary of M/O Health & FW or the Department of F.W. and includes an Additional Secretary, Joint Secretary or Dy. Secretary in this Ministry or Department and any other officer who is authorised for the time being to execute relevant contract relating to purchase and supply of stores on behalf of the purchaser.
- ii) All rights reserved or and exercisable by the DGS&D as contained in pamphlet DGS&D-229 shall vest in the Secretary, Family Welfare.

1. The above price pamphlets and the list of corrections thereto can be obtained on payment from the under-mentioned officers

- a) DGS&D, New Delhi and its Regional Offices at Mumbai, Madras, Calcutta.

4. If you are in a position to quote for supply in accordance with the requirements states in the attached schedule DGS&D form 242, form DGS&D 68 A and 69 A attached herewith should be duly filled in signed and returned to this office. You must also furnish with your tender all the information called for as indicated in pamphlet No. DGS&D 229 mentioned in para 2 above. A list of questions which should be answered is attached, which should also be returned with the tender, failing which your tender will be liable to be ignored and not considered.

This tender is not transferable.

Yours faithfully,

Dy. Director (S)  
For and on behalf of the PRESIDENT OF INDIA

Note : **Tender box is placed at Family Welfare Depot, Near gate no 7 Nirman Bhawan. New Delhi**

**IN ADDITION TO THE GENERAL CONDITIONS OF CONTRACT GIVEN IN FORM DGS&D-1001 AS AMENDED TO DATE, THE FOLLOWING SPECIAL CONDITIONS OF CONTRACT SHALL BE APPLICABLE, AND WOULD HAVE AN OVER-RIDING EFFECT OVER THE GENERAL CONDITIONS, IN CASE OF ANY CONFLICT BETWEEN THE TWO.**

1. Tenderers should furnish performance statement alongwith quotations. The cut off date for the performance is 31.3.2004. They are requested to enclose one copy of consolidated drawl statement with their quotation as on the cut-off date duly certified by the Inspector/their Chartered Accountant.

**2. PERFORMANCE CRITERIA**

- 2.1 Firms holding the rate contracts will be considered for the fresh R/C/, if otherwise eligible, against the tender inquiry only if their performance against the current R/C held by them is considered satisfactory. For this purpose, the purchase expects that the contractor should have supplied on or before 31.3.2004 minimum 85% of the stores which were due to be supplied by him upto 31.3.2004 as per original delivery period agreed upon against the current R/C.
- 2.2 In addition to above, firms who held R/C immediately preceding to the current one should not have a backlog exceeding 5% of the total quantities ordered against such previous R/C on 31.3.2004.
- 2.3 It is further expected that there will be no backlog in respect of earlier contracts to the ones referred above.
- 2.4 Firms not satisfying the criteria mentioned above may not qualify for the award of the R/C, the purchaser however reserves the right to consider also firms who have executed supplies even to a lower extent.

**3. INSPECTION**

- 3.1 Every single batch proposed to be supplied against the tender should be tested at an approved laboratory and cleared by the Inspecting Officer after inspection.

**3.2 Life at the time of inspection.**

At the time of offering for inspection, the stocks offered for inspection should not have crossed more than 1/6<sup>th</sup> of the total life, and should

have a total shelf life not less than \_\_\_\_\_ years from the date of manufacturer. The firms should not tender any stock older than 1/6<sup>th</sup> of total life for inspection without the prior approval of Department of Family Welfare. While giving such approval, the Department of Family Welfare will have the right to impose any condition which may be necessary to safeguard Government interest.

3.3 Inspection authority: The Drugs Controller General of India.

3.4 Inspecting Officer:-

To be specified in the supply order. However, the Assistant Director General, Medical Stores Depot of the area concerned, or the District Health/Family Welfare Officer of the District/the District Immunisation Officer is general authorized to carry out the inspection.

3.5 Pre-inspection by the suppliers:-

Manufacturerers/contractors should satisfy themselves that the stores are in accordance with the terms of the contract and fully conform to the required specifications before tendering them for inspection to the inspecting officer nominated under the terms of the contract. If the inspector finds that the pre-inspection has not been carried out, or on examination of any sample from any portion of the consignment if the materials are not found to fully conform to the particulars governing the supply, the entire consignment shall be rejected.

A declaration by the contractor that necessary pre-inspection has been carried out on the stores tendered for inspection will be submitted along with the challan. Test protocols for tests carried out will be submitted along with the offer for inspection.

#### **4. Warranty**

If at any time during the shelf life of the stores, the samples drawn from the batches in stock are declared not conforming to specifications, the Purchaser shall stop the use of the quantity in stock and the supplier shall replace or cause to replace within a period of 2 months the quantity remaining unused.

The above Warranty will also apply to replacement batches.

If the supplier fails to replace the quantity within two months on being called upon to do so, action in terms of Default Clause shall be taken against the supplier.

## **5. Packing and Marking:-**

The stores should be packed as per details given in Annexure A.

Each pack/vial will have the following printed in indelible ink across each label.

### **'CGS Not for Sale.'**

The packing will also be marked as under

- i) Nomenclature of the stores.
- ii) Manufacturers name and address and Licence No.
- iii) Date of manufacture. Expiry and Batch No.
- iv) Quantity contained therein.
- v) Inspection Note No. and Date.
- vi) Any other particulars required under the Drugs and Cosmetics Act of India and the Rules framed there under.

## **6. Tender Validity:**

Tenderers should note the period for which the offers should remain open for acceptance. The offers of those firms who have not kept the validity open till the period stipulated in the tender enquiry, will be treated unresponsive and will be ignored without making any back reference. Discounts given by the firms for any shorter validity than required in the tender document will not be considered and the offers will be considered for rates for full validity only.

6.2 Tenderers may note that in the absence of mention of the date upto which the offer has been kept valid; it will be deemed to be valid for the period specified in the schedule to tender enquiry.

6.3 If the date up to which the offer is to remain valid for acceptance is or is declared a closed holiday for Government Offices, the offer shall remain open for acceptance till the next working day.

## **7. Vague offer:-**

Offers qualified by vague and indefinite expression such as subject to acceptance or subject to the prior sale, will not be considered and will be summarily ignored.

**8. Telegraphic/Letter-head offers .**

Telegraphic or offers on letter-head shall be summarily ignored.

**9. Payment terms**

- i) The payment of 100% of price of the stores of each consignment thereof will be made after receipt and acceptance of the stores by the consignee in good condition. Bills are to be supported with inspection note issued by the Inspector and consignee's Receipt Certificate on copy No.1,2 & 5 of the Inspection Note.
- ii) 98% of the price of the stores of each consignment thereof shall be paid on proof of dispatch to the consignee or delivery to an interim consignee, if any and on production of a valid Inspection Note issued by the Inspector. A Photostate copy of Railway receipt duly attested by the contractor, postal receipts bill of lading or consignment note under which the goods charged for in the bill are dispatched by rail, post, sea or air respectively and copy of the letter with which such receipt, postal receipt, bill of lading or consignment note is forwarded to the consignee shall be furnished with the bill.
- iii) In the case of local delivery and in case of stores dispatched by road advance 98% payment may be allowed on proof of Inspection and delivery to the consignee, the proof of delivery being a provisional certificate from the consignee on copy No.1 of the Inspection Note. The balance 2% will be payable on final acceptance by the consignee on copy No.2 & 5 of the Inspection note as recorded in his final receipt certificate.

**10. PERIOD OF THE Rate CONTRACT**

- (I) the period of the Rate Contract shall be 1.4.2004 to 31.3.2005 or one year from date of concluding of Rate Contract. The tenderers are requested to quote for supply against the orders placed during the validity of the rate contract.
- (II) Delivery Schedule

Tenderers should indicate monthly rate of supply against the R/C.

**11. The purchaser:-**

The President of India

**12. DRAWALS**

The combined estimated draws are expected to be Rs. \_\_\_\_\_ crores approximately. This is only an estimate, and implies no commitment whatsoever on the part of the purchaser.

13. The purchaser reserves the right to enter into parallel rate contracts with one or more tenderers or to place adhoc contracts simultaneously, or at any time during the currency of the rate contract, with one or more suppliers.
14. The successful tenderers shall maintain stock of the items at the stations indicated by them and shall make deliveries against the supply orders from such stocks as and when required. Upon receipt of an order from any officer authorized to place, the purchaser will within seven days intimate to such officer the quantity which can be supplied within the delivery period specified therein and the time required to the balance quantity. If the successful tenderer fails to give such intimation within seven days time as aforesaid, he shall be deemed to have agreed to supply the stores within the delivery date stipulated in the supply order.

**15. Cancellation on failure to supply/Default clause.**

- (i) If the supplier fails to commence deliveries as scheduled or to deliver the quantities ordered on him within the delivery period stipulated in the contract, it shall be discretion of the purchaser either (a) to extend the delivery period or (b) to cancel the contract in whole or in part (for the unsupplied quantities) without any show-cause notice. In the event of extension, liquidated damage, will be applicable.
- (ii) If the purchaser decides to cancel the contract, the more of repurchase will be at the desecration of the Purchaser. The supplier shall be liable to any loss by way of extra expenditure or other incidental expensed which the purchaser may sustain on account of such repurchase at the risk and cost of the supplier.
- (iii) In addition to action in sub-para (ii) above, the purchaser may debar the defaulting supplier from future orders for a maximum period of three years. In any case, the supplier will stand debarred for future contracts for the period till the extra expenditure on account of cancellation and repurchase in terms of actions at (ii) above is paid by the supplier or recovered

from his bills for supply against any of the orders with the purchaser or his authorized consultants/agents.

**16. Liquidated damages**

If the supplier fails to deliver any or all of the goods within the time period(s) specified in the contract, the purchaser shall, without prejudice to its other remedies under the contract, deduct from the contract price, as agreed liquidated damages and not by way of penalty, a sum equivalent to 0.5% of the delivered price of the delayed goods or unperformed services for each week of delay until actual delivery or performance, upto a maximum deduction of 10% of the delayed goods or services at contract price. The purchaser may consider termination of the contract without any further notice if deliveries do not start till 2 weeks after scheduled commencement of deliveries.

**17. PURCHASE PREFERENCE**

The policy of purchase preference to Central Public Sector Undertaking, as prescribed by the Govt. of India from time to time will be applicable.

18. The Contract shall be governed by the Arbitration clause-24 of DGS&D-68 ( Revised) amended upto date. The nominee of the Secretary (FW) shall be the Arbitrator. The court of law located in Delhi shall have the jurisdiction to decide the case in the event of any disputes, if the tenders does not agree to the Arbitration clause.

**19. THE FOLLOWING DOCUMENTS SHOULD BE ENCLOSED ALONG WITH THE OFFERS. IF ANY OF THE DOCUMENTS ARE NOT ENCLOSED WITH THE OFFER, THE OFFER WILL BE LIABLE TO BE IGNORED WITHOUT FURTHER REFERENCE TO THE TENDERS.**

a. Valid income Tax Clearance Certificate , the date of issue of which should not be earlier than one year from the date of opening.

b. Drugs Licence for manufacture and sale of the item on date of Tender opening.

c. Each page of this tender should be signed and returned in token of acceptance of the terms and conditions of the tender enquiry by the Authorised signatory of the company.

20. **Negotiation:** The purchaser will not hold any negotiation with tenders except with the lowest tenderer, if considered necessary. Hence all the tenders are required to quote their most competitive rate.

Signature of the Tenderer\_\_\_\_\_

Name in Block Letters\_\_\_\_\_

Capacity in which tender is signed\_\_\_\_\_

Address in full\_\_\_\_\_

Full Name and address of the  
Tenderer. In addition post Box  
Box No. If any should be quoted  
In all communications to this

Contractor's Telegraphic  
Address \_\_\_\_\_  
Telephone No. \_\_\_\_\_  
Code \_\_\_\_\_ used

Office \_\_\_\_\_

From

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

To

Dy. Director,  
Ministry of Health & Family Welfare  
Department of Family Welfare  
Supply Division 'A' Wing (520-A Room No.),  
Nirman Bhavan, New Delhi-110011.

Dear Sir,

I/We hereby offer to supply the stores detailed in the schedule hereto or such portion thereof as you may specify in the acceptance of Tender at the price given in the said schedule and agree to hold this offer open till \_\_\_\_\_. I/We shall be bound by a communication of acceptance dispatched within the prescribed time.

2. I/We have understood the instructions to Tenderers in the booklet DGS&D – 229 and Conditions of Contract in the Form No.DGS&D-68 (Revised) included in the pamphlet entitled “Conditions of Contract governing contracts placed by the Central Purchase Organisation of the Govt. of India” and have thoroughly examined the specifications drawing and/or pattern quoted in the schedule hereto and am/are fully aware of the nature of the stores required and my/our offer is to supply the stores strictly in accordance with the requirements.

3. The following pages have been added to an form part of this tender \_\_\_\_\_.

Yours faithfully,

\*(Signature of Tenderer)

Here paste coupon in cases  
Where couples are supplied  
Contractors in payment

Address \_\_\_\_\_

Dated \_\_\_\_\_

Signature of witness \_\_\_\_\_

Address \_\_\_\_\_

**Note: Strict compliance with para of DGS&D 230 is essential.**



**RATE CONTRACT**

**TENDER NO.**

**From**

\_\_\_\_\_  
\_\_\_\_\_

**To**

Dy. Director (Supply)  
M/o Health & Family Welfare  
Room No. 503-A  
Nirman Bhawan, New Delhi – 110 011

Dear Sir,

I/We hereby offer to supply the stores detailed in the schedule(s) annexed or such portion thereof as you may determine in strict accordance with the General and Special Conditions of Contract referred to below and Specification (s) and details mentioned at the price(s) quoted in the said Schedule (s) the delivery terms during the period being ---- stated therein.

2. I/We undertake that this offer shall not be retracted or withdrawn for and during ..... days from the date on which the tender is to be opened but may be accepted at any time during the above mentioned period. I/We shall be bound by a communication of acceptance dispatched within the prescribed time.

3. Free samples of the under-mentioned articles were submitted to the Inspecting Officers specified in the schedule(s) as follows:-

**Article**

**Submitted to**

**Date**

---

\*To be scored out by tenderers where not necessary.

4. In the even of our tender being accepted, I/We hereby authorize Sarvashri.....# my/our bankers/agents in India to receive payment and declare that payment to them will be completed and final acquittance.

The following pages have been added to and from part of this tender.

Yours faithfully,

\$Signature of tenderer

\*Paste coupon here in case where coupons have been issued to Tenderers on payment.

Address.....

Dated.....

Signature of witness.....

Address.....

---

\*To be completed only by firms who are unable to receive payment in rupees in India direct.

#Give Name and Full Address

\$Strict compliance with para 3 of D.G.S. & D-230 is essential.

**TENDER NO.**

Full name and address of the tenderer. In addition to Post Box, if any, should be quoted in all communication to this office.

Contractor's Telegraphic  
Address.....  
.....  
Telephone No.....  
Code used.....

**From**

\_\_\_\_\_  
\_\_\_\_\_

**To**

Dy. Director (Supply)  
M/o Health & Family Welfare  
Room No. 503-A  
Nirman Bhawan, New Delhi – 110 011

Dear Sir,

I/We hereby offer to supply the stores detailed in the schedule hereto or such portion thereof as you may specify in the Acceptance of Tender at the price given in the said schedule and agree to hold this offer open till..... I/we shall be bound by a communication of acceptance dispatched within the prescribed time.

2. I/We have understood the instructions to Tenderers in the booklet DGS&D 229 and conditions of contract in the Form No. DGS&D 68 (Revised) included in the pamphlet entitled "Conditions of Contract governing contracts placed by the Central Purchase Organisation of the Government of India" and have thoroughly examined the specification drawing and/or pattern quoted in the schedule hereto and am are fully aware of the nature of the stores required and my/our offer is to supply stores strictly in accordance with the requirements.

3. The following pages have been added to and form part of this tender.....

\*Paste coupon here in case where coupons have been issued to Tenderers on payment.

Address.....

Dated.....

Signature of witness.....

Address.....

---

\*Note- Strict compliance with para 3 of DGS\*&D – 230 is essential.

**LIST NO. 1**

TENDERERS SHOULD FURNISH SPECIFIC ANSWERS TO ALL QUESTIONS GIVEN BELOW. TENDERERS MAY PLEASE NOTE THAT IF THE ANSWERS SO FURNISHED ARE NOT CLEAR AND OR ARE EVASIVE. THE TENDER WILL BE LIABLE TO BE IGNORED

1. Tender No..... Due for opening on.....
2. Offer is open for acceptance till.....
3. Whether the stores offered fully conform to the technical particulars and Specifications/Drawings, specified by the Purchaser in the schedule to Tender. If not mention here details of deviation
4. Brand of Store Offered
5. Name and address of Manufacturer
6. Station of manufacturer
7. Please confirm that you have offered packing as per tender enquiry requirements. If not indicated deviations.
8. Gross weight of consignment  
New weight of each item
9. What is your Permanent Income Tax  
A/c No.
10. Confirm whether you have attached your letters/current ITCC or photo copy thereof
11.
  - a. Indicate whether you are LSU or SSI
  - b. Are you registered with DGS&D for the item quoted? If so, indicate whether there is any monetary limit on registration.
  - c. If you are a small scale unit registered with NSIC under Single Point Registration Scheme, whether there is any monetary limit.

- d. In case the item in the tender is to be as per Defenec Specification, state whether your registration with DGS&D or NSIC under Single Point covers, the Defense Specification
  - e. In case you are registered with NSIC under Single Point Registration Scheme for the item quoted. Conform whether you have attached a photocopy of the registration certificate indicating the items for which you are registered.
- 12.
- a. If you are not registered either with NSIC or with DGS&D, please state whether you are registered with Directorate of Industries of State Government concerned.
  - b. If so, confirm whether you have attached a copy of the certificate issued by Director of Industry.
13. Please indicate:-
- Name & Full address of you Banker
14. Please furnish details of Equipment quality control in the prescribed proforma [Appendix D of DGS&D-230 (to be given by firms not registered with DGS&D/NSIC under the Single Point Registration Scheme)]
15. Please furnish your performance statement in the prescribed format (DGS&D – 230)
16. Please state whether you have submitted the Tender Sample (if called for in the Tender Enquiry). If so on what date. Please also state if you have remitted Testing Fee and if so or what date.

17. Please state whether you agree to submit advance sample, if called upon to do within the specified period of 21 days.
18. Please indicate guaranteed date by which date delivery can be completed. Also indicate monthly rate of Supplies and also time required for commencement of Supplies from the date of receipt of formal order/approval of advance sample.
19.
  - i. The Indian Companies Act, 1956
  - ii. The Indian Partnership Act, 1932 (please also give name of partners).
  - iii. Any act, if not, who are the owners. (Please give full names and address).
20. Whether the tendering firm is/are;
  - i. Manufacturer
  - ii. Manufacturer's authorized agents
  - iii. Holders in stock of the stores tendered for

Note: If manufacturer's agents, please enclose with tender the copy of manufacturer's authorization.

21. If stores offered are manufactured in India, please state whether all the raw materials, components etc. used in their manufacture are also produced in India. If not give details of materials, components etc. that are imported and their break up of the indigenous and imported components together with their value and proportion it bears to the total value of the store should also be given.

22. State whether raw materials are held in stock sufficient for the manufacture of stores.
23. Please indicate the stocks in hand at present time:
- i. Held by you against this enquiry
  - ii. Held by M/s  
.....  
over which you have secured an option.
24. Do you agree to sole arbitration by an Officer in the Ministry of Law to be appointed as arbitrator by the DGS&D as provided in clause 24 of the General conditions of contract form DGS&D-68 (Revised) (Your acceptance or non-acceptance of this clause will not influence the decision of the tenderer. It should, however, be noted that an omission to answer above question will be deemed as an acceptance of the clause)
25. Please state whether the transit insurance clause as in clause 20 of DGS&D – 230 is acceptable to you.
26. Please state whether the inspection clause is acceptable to you
27. For Partnership firms state whether they are registered or not registered under Indian Partnership Act, 1932. Should the answer to this question by a partnership firm be in the affirmative, please state further:-
- a. Whether by the partnership agreement, authority to refer disputes concerning the business of the partnership to

arbitration has been conferred on the partner who has signed the tender.

- b. If the answer to (a) is in the negative, whether there is any general power of attorney executed by all the partners of the firm authorized the partner who has signed the tender to refer dispute concerning business of the partnership to arbitration.
- c. If the answer to either (a) or (b) is in the affirmative have you already furnished a copy of either the partnership agreement or the general power of attorney as the case may be to DGS&D? Please quote the reference to the communication by which this was done.

Note:- 1. if a copy of neither the partnership agreement nor the general power of attorney has previously been furnished in the DGS&D please attach to the tender a copy of either document in when reliance is placed for authority of partners or the partner signing the tender attested by Notary Public or its execution would be admitted by affidavit on a properly stamped paper by all the partners.

2. Whether authority to refer disputes to arbitration has not been given to the partner signing the tender the tenders must be signed by every partners of the firm.

- 28. i. Whether the price tendered by you is to the test of your knowledge and belief, not more that the price usually charged by you for stores of same nature/class or description to any private

purchaser either foreign or as well as Govt. purchaser. If not state the reasons thereof, if any also indicate the margin of difference.

- ii. In respect of indigenous for which there is a controlled price fixed by law, the price quoted shall not be higher than the controlled price, and if the price quoted exceeds the controlled price the reasons thereof should be stated.

- 29.
  - i. Holding valid Industrial licence(s) registration certificate under the Industrial Development and Regulation Act, 1981. If so, please give particulars of Industrial Income Registration Certificate.
  - ii. Exempted from the licensing provision of the Act, for the manufacture of item quoted against the tender. If so, please quote relevant orders and explain your position.
  - iii. Whether you possess the requisite license for manufacture of the stores, and/or for the procurement of raw materials belonging to any controlled category required for the manufacture of the store? In the absence of any reply it would be assumed that no license is required for the purpose of raw materials and/or that you possess the required license.

- 30. State whether business dealings with you have been banned by Min./Deptt. of Supply.

31. Please confirm that you have read all the instructions carefully and have complied with accordingly.

Signature of Witness:

Signature of tenderer

Full Name & address of witness in Block letters

1. Full name and address of the person signing (in Block Letters)

2. Whether signing as proprietor/partner constituted attorney duly authorized by the Company.

**ADDITIONAL QUESTIONS FOR DRUGS AND MEDICINES**

*Tenderers are requested to indicate clearly the following-*

1. Confirm specifically whether stores offered are to T/E specification.
2. Confirm specifically whether packing offered is to specification.
3. What is the amount of raw material included in the finished product in case where raw material price is controlled by Governmental/STC.
4. Are you the manufacturer? If not, indicate name of manufacturer.
5. Are you offering you branded product? What is the name of the brand.
6. Category in which the Drug falls as defined in D.P.C.O 1979 (amended up to date) i.e. whether Cat.I/Cat.II/Cat.III/Cat.IV
7. If Drug falls in Cat.I or Cat.II, indicate the name of the leader firm and Leader prices.
8. If the drug falls in Cat.III, what is the MRP fixed by Govt.
9. Whether the drug is essential or non-essential?
10. What is the discount allowed over MRP in terms of DPCO norms

.

11. Element of price variation clause,  
if any.

Signature of Tenderers.

**ADDL. QUESTIONS FOR R/C AND RGC/TENDER ENQUIRIES**

1. (FOR MANUFACTURING FIRMS)

(I) what is your installed capacity?

(ii) What is your working capacity?

(iii) What is the existing load?

(iv) What portion of your capacity are you prepared to reserve and allocate to this Rate Contract?

(v) Are you

(i) holding valid industrial licensers Registration license/registration certificates under the Industries (Development and Regulation) Act, 1951. If so please give particulars of Industrial Licenses/Registration Certificates.

(ii) exempted from the licensing provisions of the act for the manufacture of items) quoted against the tender. If so, please quote relevant orders and explain your position.

**(FOR SOLE AGENTS/STOCKISTS)**

(I) what is your present stock ?

(ii) what is the volume or orders (including Govt and others) pending with you at present ?

(iii) What is the rate of flow of stocks ?

(iv) What is the rate of issue ?

(i) What stock will you maintain at each important centre in India.

(ii) What is the time and rate required for replenishment of the stock as these centers ?

Are you required as small scale unit with the NSIC ? If so, indicate your current Registration number and date and the period up to which the registration will be valid.

Signature of Tenderers

Date \_\_\_\_\_

***Note : Complete items wise tender documents with details and specifications are available in Room No 502-A Nirman Bhawan on payment through bank draft in favour of secretary (FW) Min of Health & Family Welfare Nirman Bhawan, New Delhi-110011***



## **Additional general conditions for NSV Instruments only**

IN ADDITION TO THE GENERAL CONDITIONS OF CONTRACT GIVEN IN FORM DGS&D –68 (REVISED) AND DGS&d-69 (REVISED), THE FOLLOWING SPECIAL CONDITIONS OF CONTRACT SHALL BE APPLICABLE, AND WOULD HAVE AN OVER –RIDING EFFECT OVER THE GENERAL CONDITIONS IN CASE OF ANY CONFLICT BETWEEN THE TWO

1.	Delivery Period:	Within two months of placement of order.
2.	Inspection Authority:	The Deputy Commissioner(RSS), Ministry of Health and Family Welfare, Nirman Bhavan, New Delhi.

### 3. Inspecting Officer and procedure for inspection:

- i. Inspecting Officer: Representative of the Deputy Commissioner (RSS) will carry out the inspection of the stocks.
- ii. Procedure for inspection
  - a) Before declaring the instruments as acceptable the inspecting officer shall draw samples from the lots offered for inspection for visual and laboratory tests. Only instruments which are found to meet the specification in all respects will be accepted.

### 4. Pre-inspection by the suppliers:

- a) Manufacturers/contractors should satisfy themselves that the stores are in accordance with the terms of the contract and fully conform to the required specifications before tendering them for inspection to the Inspection Officer nominated under the terms of the contract. If the inspector finds that the pre-inspection has not been carried out or on examination of any sample from any portion of the consignment if the materials are not found to fully conform to the particulars governing the supply, the entire consignment shall be rejected.
- b) A declaration by the contractor that necessary pre-inspection has been carried out on the stores tendered for inspection will be submitted along with the challan.

5. Warranty Clause: - The contractor shall be fully responsible for the manufacturer's Warranty in respect of proper design, quality and workmanship of Equipment 12 months from the date of receipt of stores by the consignee or 18 months from the date of dispatch whichever is earlier and inter-alia furnish the manufacturer's warranty as under:

“ We warranty that everything supplied by us shall be free of all defects and faults in materials workmanship and manufacture and shall be of highest grade quality accepted standards for the materials of the type ordered and in full conformity with the

specifications and if operated properly, we shall be fully responsible for its efficient operation”.

The warranty shall survive notwithstanding the fact that the goods/stores/articles may have been inspected, accepted and payment thereof made by the purchaser.

If any part is found to be defective through faulty workmanship or through normal type of failure during the warranty period requires to be replaced, will be replaced free of charge and dispatch directly by the manufacturers to the consignee.

6. Quantity tolerance

The purchaser reserves the right to place orders for additional quantity upto 25% on successful tenderers on the rates offered by them at the time of placement of contract or during the currency of the contract. If slab rates are quoted then the tenderer shall supply the additional quantity in respect of each slab at the respective rate for the slab.

7. Packing and marking: The instruments should be packed to withstand the hazards of the sea/rail/air transport as per clause –12 (packing) of General Conditions of DGS&D-68 ® and every precaution should be taken to avoid loss or damage in transit. Consignment should be marked with the order no. and date and the name of the consignee.

8. Tender validity:

Tenderers should note the period for which the offers should remain open for acceptance. The offers of those firms who have not kept the validity open till the period stipulated in the tender enquiry, will be treated unresponsive and will be ignored without making any batch reference. Discounts given by the firms for any shorter validity than required in the tender document will not be considered and the offers will be considered for rates for full validity only.

Tenderers may note that in the absence of mention of the date up to which the offer has been kept valid, it will be deemed to be valid for the period specified in the schedule to tender enquiry.

If the date up to which the offer is to remain valid for acceptance is or is declared, a closed holiday for Government Offices, the offer shall remain open for acceptance till be next working day.

9. Vague offers: -

Offers qualified by vague and indefinite expressions such as subject to acceptance or subject to the prior sale, will not be considered and will be ignored without any back reference.

10. Telegraphic/Letter head offers.

Telegraphic or offers on letter head shall be summarily ignore.

#### 11. Payment terms:

Payment for 90% cost of the stock shall be made after the Inspecting Officer named in the contract certifies the consignment as acceptable and the provisional receipt by the consignee. The remaining 10% payment shall be made after the consignee certifies the receipt of the stock in good condition.

#### For Imported stores

The Principals/Foreign manufacturers will be paid 100 per cent of the net F.O.B/F.A.S price excluding the Indian Agents commission on presentation of the following documents.

4 copies	Commercial invoice
1 copy	packing list
1 copy	Non-negotiable Bill of Lading
1 copy	High Commission of India Supply Wing Certificate of inspection ( if applicable)

and certificate from the supplier confirming that the original shipping documents etc. have been dispatched in accordance with the requirements of the A/T

80% commission may be paid to the Indian Agent on proof of payment to the foreign supplier/principals and the balance 20% on receipt of store by the consignee in good condition.

#### 12. BID SECURITY

A Bid security of Rs.1,00,000/- may be furnished along with the tender documents. If tenderer withdraws the bid within the validity of the bid or fails to submit performance security after the award of the contract, the bid security shall be forfeited. The bid security shall be denominated in rupees of US Dollar and shall be in one of the following forms .

- a) Bank guarantee or irrevocable letter of Credit issued by a bank located in India on the form Annexure-II
- b) Banker's cheque or demand draft drawn in favour of the " Secretary(Family Welfare) Ministry of Health & Family Welfare.

#### 13. PERFORMANCE SECURITY

Within 30 days of award of the contract, the successful bidder shall be required to furnish performance security which shall be 10% of the value of the quantity for which the contract is awarded to the successful bidder. The performance security shall be in the form of Bank guarantee (in the form annexed iii) or irrevocable Letter of Credit or cashier's cheque.

The proceeds of the performance security shall be payable to the purchaser to compensate for any loss resulting from the supplier;s failure to complete its obligations under the contract.

14. The contract shall be governed by the Arbitration Clause and the nominee of the Secretary(Family Welfare) shall be the arbitrator. The Courts of Law located in Delhi shall alone have the power to decide the case in the event of any disputes, if the tenderer does not agree to the Arbitration clause.

14.1 Liquidated damages

If the supplier fails to deliver, any or all of the goods within the time period(s) specified n the contract, the purchaser shall, without prejudice to its other remedies under the contract deduct from the contract price, as agreed liquidated damages and not by way of penalty, a sum equivalent to 0.5% of the delivered price of the delayed goods or unperformed services for each week of delay until actual delivery or performance upto a maximum deduction of 10% of the delayed goods or services at contract price. The purchaser may consider termination of the contract without any further notice if deliveries do not start till 2 weeks after scheduled commencement of deliveries.

15. THE FOLLOWING MUST BE ENCLOSED ALONG WITH THE OFFERS. IF ANY OF THE FOLLOWING ARE NOT ENCLOSED WITH THE OFFER, THE OFFER WILL BE IGNORED WITHOUT ANY BACK REFERENCE TO THE TENDERER.

- a. Valid Income Tax Certificate, the date of issue of which should not be earlier than one year from the date of opening.
- b. Valid registration Certificate for registration with DGS&D or NSIC or Director of Industries
- c. Tender Samples as required in the enquiry
- d. Each page of this tender should be signed and returned in token acceptance of the terms and conditions of the tender.

Signature of the Tenderer

Witnesses

Name and address 1) \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
2) \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_



**ADDITIONAL QUESTIONS FOR DRUGS AND MEDICINES**

*Tenderers are requested to indicate clearly the following-*

1. Confirm specifically whether stores offered are to T/E specification.
2. Confirm specifically whether packing offered is to specification.
3. What is the amount of raw material included in the finished product in case where raw material price is controlled by Governmental/STC.
4. Are you the manufacturer? If not, indicate name of manufacturer.
5. Are you offering you branded product? What is the name of the brand.
6. Category in which the Drug falls as defined in D.P.C.O 1979 (amended up to date) i.e. whether Cat.I/Cat.II/Cat.III/Cat.IV
7. If Drug falls in Cat.I or Cat.II, indicate the name of the leader firm and Leader prices.
8. If the drug falls in Cat.III, what is the MRP fixed by Govt.
9. Whether the drug is essential or non-essential?
10. What is the discount allowed over MRP in terms of DPCO norms

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11. Element of price variation clause,  
if any.

Signature of Tenderers.

**ADDL. QUESTIONS FOR R/C AND RGC/TENDER ENQUIRIES**

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(ii) What is your working capacity?

(iii) What is the existing load?

(iv) What portion of your capacity are you prepared to reserve and allocate to this Rate Contract?

(v) Are you

(i) holding valid industrial licensers Registration license/registration certificates under the Industries (Development and Regulation) Act, 1951. If so please give particulars of Industrial Licenses/Registration Certificates.

(ii) exempted from the licensing provisions of the act for the manufacture of items) quoted against the tender. If so, please quote relevant orders and explain your position.

**(FOR SOLE AGENTS/STOCKISTS)**

(I) what is your present stock ?

(ii) what is the volume or orders (including Govt and others) pending with you at present ?

(iii) What is the rate of flow of stocks ?

(iv) What is the rate of issue ?

(i) What stock will you maintain at each important centre in India.

(ii) What is the time and rate required for replenishment of the stock as these centers ?

Are you required as small scale unit with the NSIC ? If so, indicate your current Registration number and date and the period up to which the registration will be valid.

Signature of Tenderers

Date \_\_\_\_\_

***Note : Complete items wise tender documents with details and specifications are available in Room No 502-A Nirman Bhawan on payment through bank draft in favour of secretary (FW) Min of Health & Family Welfare Nirman Bhawan, New Delhi-110011***

