CENTRAL MEDICAL SERVICES SOCIETY

Ministry of Health and Family Welfare (Government of India)
2nd floor, VishwaYuvak Kendra, Pt. Uma Shankar DikshitMarg, Teen Murti Road,
Opposite Police Station ChankayaPuri, New Delhi-110021
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Dated: 01.07.2021

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EoI cum BID INVITATION No.:CMSS/PROC/2021-22/UIP/009
ON EMAIL FOR PROCUREMENT OF
0.5 ml/1.0 ml AD Syringes on immediate basis for COVID-19 vaccination programme

Manual bids shall not be accepted.

CMSS invites bid from manufacturers/ authorised dealers for procurement and supply of 0.5 ml/1.0 ml AD Syringes as per details contained herein.

The Detailed Technical Specifications(Annex-1), main commercial terms (Annex-2), price bid format (Annex-3)and proposed delivery schedule(Annex 4) MAY BE DOWNLOADED FROM

1. CMSS website: http://www.cmss.gov.in/
2. MoHFW WEBSITE:https://www.mohfw.gov.in/
3. CPPP WEBSITE: https://eprocure.gov.in/eprocure/app
4. GeM PORTAL: www.gem.gov.in

Pre bid Meeting and Queries-
Pre Bid Meeting shall be conducted on 3rd July 2021at 11:00 p.m on Zoom Platform. Details of VC link are as follows:
Suresh Puri is inviting you to a scheduled Zoom meeting.

Topic: PRE BID MEETING- 0.5 ML/1 ML AD SYRINGES
Time: Jul 3, 2021 12:00 PM India

Join Zoom Meeting
https://us02web.zoom.us/j/85657638112

Meeting ID: 856 5763 8112
One tap mobile
+13126266799,,85657638112# US (Chicago)
+13462487799,,85657638112# US (Houston)

Dial by your location
+1 312 626 6799 US (Chicago)
+1 346 248 7799 US (Houston)
+1 669 900 6833 US (San Jose)
+1 929 205 6099 US (New York)
+1 253 215 8782 US (Tacoma)
+1 301 715 8592 US (Washington DC)
Meeting ID: 856 5763 8112
Find your local number: https://us02web.zoom.us/u/kbaWzEXpNE

As the procurement is of immediate nature for covid vaccination programme, the bidders can raise any query by 03nd July 2021, 1700 hours, for which CMSS will issue clarification on its website. Queries received after that will not be addressed.

Bid submission time:
The bids are to be submitted on email by 1200 Hours of 6th July 2021.

Bidders who meet the technical specifications and comply the commercial terms, may submit their EoI cum Bid by email on manni.cmss@gmail.com, gmproc.cmss@gmail.com. They would clearly state compliance to technical specifications and commercial terms.

Note: Bidders please note that the last date to submit bids is 6th July 2021(via email), due to CPPP Website mandatory norms the bids submission date published on website is shown as 8th July 2021, bidders are requested to submit their bids on email on or before 6th July 2021 only.

The price bid may be filled as per specified format.

Address for Communication: AGM Procurement or GM Procurement

Central Medical Services Society,
2nd floor, Vishwa Yuvak Kendra,
Pt. Uma Shankar Dikshit Marg,
Teen Murti Road, Opposite Police Station Chankaya Puri, New Delhi-110021

(note –Email mode preferred)

Annexure-1

DESCRIPTION AND SPECIFICATION

0.5 ml AD Syringes

PART A : General Technical Specifications

1. Product and Package Specifications

1.1 The required packing standards and labelling must meet the latest requirements described in ISO 7886-3:2005..

1.2 The Goods should conform to standards specified in the Technical Specifications. The standards will be the latest edition unless otherwise stated by the Purchaser or other if applicable.

1.3 The product and packaging marking should comply with the essential requirements described in ISO 7886-3:2005.

1.4 All labeling and packaging inserts shall be in English.

1.5 Storage instructions must be written on the packages.

1.6 Upon award, the successful Supplier shall, on demand, provide a translated version in the language of the bid of the prescriber's information for any specific Goods the Purchaser may request.

1.7 for Goods supplied from outside India, all wood packaging, including pallet and boxes, utilized in any shipment, should undergo such treatment (heat, impregnation or fumigation), marking and documentation required to meet ISPM 15 specifications and that for each shipment the supplier shall provide a declaration to this effect. Moreover, all shipments that do not use wooden packaging must be accompanied by a declaration to this effect.

2. Labeling Instructions

2.1 The label of the primary container for each products shall meet the ISO 7886 -3:2005 standard and include:

(a) Not applicable

(b) Not applicable

(c) Not applicable

(d) the applicable standard;

(e) the Purchaser's logo and code number and any specific color coding if required;

(f) content per pack;

(g) instructions for use;

(h) special storage requirements;

(i) batch number;

(j) date of manufacture and date of expiry (in clear language, not code);

(k) name and address of manufacture with manufacturing license number.;

(l) any additional cautionary statement.

2.2 The secondary container (shelf box) containing primary packs should also display the above information.

3. Case Identification

3.1 All cases should prominently indicate the following:

(a) Purchaser's line and code numbers;

(b) the name of the product;

(c) date of manufacture and expiry (in clear language not code);

(d) batch number;

(e) quantity per case;

(f) special instructions for storage;

(g) name and address of manufacture with manufacturing license number.;

(h) any additional cautionary statements.

3.2 No case should contain products from more than one batch.

4. Unique Identifiers

4.1 The Purchaser shall have the right to request the Supplier to imprint a logo, if the quantity so justifies it, on thelabels of the containers used for packaging and in certain forms and this will be in the Technical Specifications. The designand detail will be clearly indicated at the time of bidding, and confirmation of the design of such logoshall be provided to the Supplier at the time of Contract award.

5. Standards of Quality Control for Supply

5.1 The successful Supplier will be required to furnish to the Purchaser:

(i) With each consignment, and for each item a certificate of compliance to product standards as per ISO 7886-3:2005 concerning sterility, pyrogen/ Bacterial Endotoxin Test (BET) and other tests, as applicable to the Goods being supplied.

The detailed requirement for the sterility certificate:

The certificate of sterilization shall include:

a) Ministry of Health purchase order and item number;

(b) Manufacturer product reference and short description;

(c) Manufacturing site - Sterilization site;

(d) Batch number (Lot number);

(e) Batch quantity;

(f) Date of sterilization;

(g) Expiry date: month and year;

(h) Sterilization method;

(i) Process (norm) followed for validation and routine control for sterilization of medical devices;

(j) Process (norm) followed for medical devices to be labeled sterile;

(k) Name of the person responsible;

(l) Title;

(m) Date;

(n) Signature

ii) Assay methodology of any or all tests if requested.

(iii) Evidence of basis for expiration dating and other stability data concerning the commercial final package upon request.

5.2 The Supplier will submit the Certificate of conformity

provided by ISO or/and the last inspection report for ISO 13485.

PART B : <u>TECHNICAL SPECIFICATION</u>

<u>Specification for 0.5 ml AD Syringe</u>

General Characteristics	➢ Sterile & Single - use. ➢ Including a mechanism to prevent reuse. ➢ The syringe and needle shall be passively and automatically rendered unusable by the delivery of the intended fixed dose. and / or ➢ The auto-disable feature is automatically activated and remains effective from the time that the injection is commenced. and / or ➢ The auto –disable feature is automatically activated on completion of the delivery of the intended fixed dose.
Type & Application	➢ Non-pre – filled. ➢ To administer DTP, DT, tetanus toxoid and diluted freeze-dried measles for intramuscular or sub – cutaneous injection. ➢ Syringes with permanently fixed needle.
Material	➢ Polypropylene with or without stainless steel.
Syringe size with pre – set volume and single marking	➢ 0.5 ml for immunization (+ 20% to allow for removal of air).
Graduation & Accuracy.	➢ Two markings only: the zero line and the nominal capacity line (ie. The total graduated capacity line). ➢ The difference between the maximum

	graduated volume and the expelled volume of distilled water shall not be greater than +/- 25 microlitres.
Needle Dimensions	➢ Diameter : 23 G ➢ Length : 25 mm
Needle Characteristics	➢ Stainless steel needle tubing suitable for the manufacture of medical devices. ➢ Needle shall confirm to IS 10654: 2002(third revision) equivalents to ISO 7864: 1993.
Needle fixing	➢ Fixed capped needle. The union of the hub and needle tube shall not be broken by the minimum force given in Table 2 of ISO 7864: 1993 applied as push or pull in the direction of needle axis. ➢ If the accidental needle – stick protection devices are included in the design of the syringe or needle, they should not compromise the ease of use or the performance of the syringe.
Leakage	➢ As per ISO 7886 – 3:2005.
Dead space	➢ The maximum dead space shall be as per Table 1 of ISO 7886 – 3:2005.
Self - disable	➢ The syringe shall be automatically rendered unusable when it has delivered a 0.5 ml dose of vaccine or distilled water.
Filling	➢ The syringe is filled by inserting the needle through the septum of a sealed vaccine vial.
Friction	➢ The measured friction values shall be within the following limits during emptying when the piston is moved at 100 mm per minute. As per ISO 7886 – 3 :2005 Table B -1.

Transparency & Resistance to shock	➢ "Excellent" Class 3 on the Standard Opalescence Rating . ➢ Resistance to shock: There shall be no effect on the performance of the syringe after it has been dropped from a height of 1 metre onto a concrete surface. Auto – destruct mechanism shall not activate during transportation. There shall be no effect on the performance of the syringe when vibrated under conditions simulating transport.
Bubble exclusion	➢ Air bubbles introduced during filling can be easily removed by flicking the fingernail against the barrel.
Packaging	➢ Individual sterilized blister or ribbon pack made of paper and plastic wrapping with date of manufacture, date of expiry, method of sterilization used & special print message such as **" Govt. supply for immunization, not for sale".** ➢ Pictorial instructions for usage on a separate sheet. ➢ Needle cap to make syringe into a sterile unit. ➢ 100 /200 syringes in one millboard / greyboard / hard board box indicating date of manufacture, date of expiry, method of sterilization used & special print message such as "Govt. supply for immunization, not for sale".
Shelf -life	➢ The shelf life of syringes shall not be less than three years and not more than 1/6th of the life is consumed while delivering at the consignee's premises.

Essential requirement

- The technical specification of 0.5 ml AD Syringes should conform to ISO 7886 PART 3-product standard and to ISO 13485: 2003 quality system standard.
- The bidders should submit a copy of their ISO 13485 certificate issued by the certifying body. The certificate should be valid on the date of tender opening.
- A certificate from the manufacturer certifying that the product meets the ISO 7886 – PART 3 product standard to be submitted along with the bid documents.

PART C. SPECIAL INSTRUCTIONS

1. Each syringe packing, inner carton and nested cartons to have the following words printed in red ink with bold letters.

   "GOVT. SUPPLY FOR IMMUNUZATION NOT FOR SALE"

2. Life of the product, indicating the date of manufacture and date of expiry should be printed as per Drugs & Cosmetics Act-India.

3. Equivalency of Standards & Codes

   Wherever reference is made in the Technical Specifications to specific standards and codes to be met by the Product to be furnished or tested, the provisions of the latest current edition or revision of the relevant standards or codes in effect shall apply, unless otherwise expressly stated in the Contract. Where such standards and codes are national or authoritative standards that ensure substantial equivalence to the standards and codes specified will be acceptable.

4. Packing (Clause 10 of GCC)
   Add as clause 10.3 of the GCC the following –

   Packing Instruction: The supplier will have to make unit packing for each 0.5 ml A D Syringe. Each unit package will be marked on one side with proper paint/indelible ink, the following ;

   i) Project : Immunization Programme.

ii) Purchase Order No. :
iii) Country of origin of Goods :
iv) Supplier's Name and :
v) Packing list reference number :

Each outer packing containing the unit packing should have the following label printed in bold letters in large size.

i) Purchaser's Name : MINISTRY OF HEALTH & FAMILY WELFARE, Govt. of India.
ii) Project Immunization Programme
ii) Purchase Order No :
i) Country of origin of Goods:
ii) Supplier's Name

SAMPLING PLAN & ACCEPTANCE CRITERIA FOR AUTO-DISABLE SYRINGES FOR FIXED-DOSE IMMUNIZATION									
CHARACTERISTICS	**SPECIFICATION**	**INSPECTION LEVEL**	**AQL**	**SAMPLE SIZE**			**No.Non-Compliers**		
				FOR BATCH SIZE 35001 to 1.50 lakhs	**FOR BATCH SIZE 1.50 lakhs to 5 lakhs**	**FOR BATCH SIZE Over 5 lakhs**	**FOR BATCH SIZE 35001 to 1.50 lakhs**	**FOR BATCH SIZE 1.50 lakhs to 5 lakhs**	**FOR BATCH SIZE Over 5 lakhs**
Description		NA	NA	NA	NA	NA	NA	NA	NA
Definitions									
Nominal Capacity	Capacity of the syringe as designated by the manufacturer with respect to the contract.	S-1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc 0 Rej 1
Auto-disable syringe feature	Feature that automatically activates upon administration of the intended fixed dose to prevent subsequent re-use of the syringe and the needle.	S-1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc 0 Rej 1
Total Graduated Capacity	Capacity of the syringe at the graduation line furthest from the zero graduation line.	S-1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc 0 Rej 1
Maximum Usable Capacity	Capacity of the syringe when the piston is drawn back to its furthest functional position.	S-1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc 0 Rej 1
Fiducial Line	Line circumscribing the end of the piston for determining the capacity corresponding to any scale reading of the syringe.	S-1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc 0 Rej 1
Cleanliness	The surface of the syringe which comes in contact with injection fluids during normal use shall be free from particles and extraneous matter when inspected by normal or corrected to normal vision without magnification under an illumination of 300-700 lux.	S-1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc 0 Rej 1
Limits for acidity or alkalinity	When determined with a laboratory p H meter and using a general purpose electrode, the p H value of an extract prepared in accordance with annexure A of ISO 7886-3 : 2005 shall be with in one unit of p H of that of the control fluid.	NA	NA	8	8	8	p H value of the combined solution from the samples shall be with in one unit p H of that of the control fluid.		
Limit for extractable									

metals									
Total Extractable Heavy metals.	When tested by a recognized microanalytical method, for example by an atomic absorption method, an extract prepared in accordance with annexure A of ISO 7886-3 : 2005, shall when corrected for the metal content of the control fluid, contain not greater than a combined total of 5 ppm.	NA	NA	8	8	8	Combined extract from the samples shall have a value less than 5 ppm.		
Cadmium	When tested by a recognized micro analytical method, for example by an atomic absorption method, an extract prepared in accordance with annexure A of ISO 7886-3 : 2005, the cadmium content of the extract shall, when corrected for the cadmium content of the control fluid, be lower than 0.1 ppm.	NA	NA	8	8	8	Combined extract from the samples shall have a value less than 0.1 ppm.		
Lubricant									
Visual inspection	If the interior surfaces of the syringe, including the piston, are lubricated, the lubricant shall not be visible, under normal or corrected to normal vision as droplets or particles.	S-1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc 0 Rej 1
Tolerence on graduated capacity									
	The tolerance on the graduated capacity shall be as per Table 1 of ISO 7886-3 :2005.	S-1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc 0 Rej 1
Graduated Scale									
Scale - By visual inspection.	The syringe shall have only two markings, the zero line and the nominal capacity line (i.e. the total graduated capacity line). These lines shall be of uniform thickness. They shall lie in planes at right angles to the axis of the barrel.	S-1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc 0 Rej 1
Position of scale	When the plunger is fully inserted, that is as near to the nozzle end of the barrel as it will go, the zero graduation line of the scale shall coincide with the fiducial line on the position to within a quarter of the smallest scale interval.	S-1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc 0 Rej 1

Barrel									
Dimensions	The length of the barrel and the design of the auto-disable feature shall be such that the syringe has a maximum usable capacity of at least 10% more than the nominal capacity and a recommended maximum capacity of 20% more than the nominal capacity.	S-1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc 0 Rej 1
Finger Grips	The open end of the barrel shall be provided with finger grips that shall ensure that the syringe will not roll more than 180° when it is placed on a flat surface at an angle of 10° to the horizontal. The finger grips shall be free from flash and sharp edges. Finger grips should be of adequate size, shape and strength for the intended purpose and should enable the syringe to be held securely during use.	S-1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc 0 Rej 1
Piston / plunger assembly									
Design	The design of the plunger and push button of the syringe shall be such that , when the barrel is held in one hand, the plunger can be depressed by the thumb of that hand. The position shall not become detached from the plunger when tested in accordance with Annex B of ISO 8537 : 1991 for a syringe with integrated needle or in accordance with Annex B of ISO 7886-1 : 1993 for a syringe without needle.	S-1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc 0 Rej 1
	The plunger should be of a length adequate to allow the piston to deliver the designated fixed dose. It should not be possible to defeat the auto-disable feature by removing and re-inserting the plunger.	S-1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc 0 Rej 1

	The projection of the plunger and the configuration of the push button should such as to allow the plunger to be operated without difficulty. When the fiducial line of the piston coincides with the zero graduation line, the preferred minimum length of the plunger from the surface of the finger grips nearer to the push button should be 8 mm.	S-1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc 0 Rej 1
Fit of piston in barrel	When the syringe is filled with water and held vertically with first one end and then the other end uppermost, the plunger shall not move by reason of its own mass.	S-1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc 0 Rej 1
Fiducial Line	There shall be a visible and defined edge serving as the fiducial line at the end of the piston. The fiducial line shall be in contact with the inner surface of the barrel.	S-1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc 0 Rej 1
Needle									
Integrated needle	Syringes with integrated needle shall have a minimum needle union force applied as puch or pull in the direction of the needle axis in accordance with ISO 7864 : 1993.	S-1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc 0 Rej 1
Integrated needle	Needle tubing shall be in accordance with ISO 9626.	S-1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc 0 Rej 1
Non-integrated needle	If a non-integrated needle is used, it shall become an integral part of the syringe and cannot be detached. Both the needle and the syringe shall be rendered incapable of re-use after delivery of the intended fixed dose, under normal conditions of use.	S-1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc 0 Rej 1
Performance									
Dead Space	When a syringe with needle is tested in accordance with Annex E of ISO 8537 : 1991 the dead space shall not exceed the limits given in Table 1 of ISO 7886-3 : 2005.	S -1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc 0 Rej 1

Freedom from air and liquid leakage.	When a syringe with needle is tested in accordance with Annex F of ISO 8537 : 1991 and a syringe without needle is tested in accordance with Annex D of ISO 7886-1 : 1993 there shall be no leakage of water past the piston or seals(s).								
	When a syringe with the intergated needle is tested in accordance with Annex B of ISO 8537 : 1991 and a syringe without needle is tested in accordance with Annex B of ISO 7886-1 : 1993, there shall be no leakage of water past the piston or seal(s) and there shall be no fall in the manometer reading.	S-1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc 0 Rej 1
	For syringes with integrated needle, 14.2 of ISO 8537 : 1991 shall apply.	S-1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc 0 Rej 1
Auto-disable feature	One the auto-disable feature has been activated, (a) it shall no be possible to re-use the syringe and the needle under normal conditions of use (b) it shall not be possible to override the auto-disable feature when tested in accordance with the test method in Annex C of ISO 7886-3 : 2005.	S-1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc 0 Rej 1
Performance after shipping	There shall be no effect on the performance of the syringe when tested in accordance with ASTM D 999-01 and ASTM D 5276-98.	S-1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc 0 Rej 1
Packaging									
Primary & Unit Containers ansd self-contained syringe units.	As per the clause 15.1 of ISO 8537 : 1991								
Secondary Container	One or more primary containers shall be packaged in a secondary container.	S-1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc 0 Rej 1
	The secondary container should be sufficiently robust to protect the contents during handling, transit and storage.								
	One or more secondary containers may be packaged in a storage and								

	/ or transit container.								
Labelling									
Primary & Unit Containers and self-contained syringe units.	The self-contained syringe unit shall bear at least the following information: (a) the words "for single use" or equivalent (such as symbol for single use, reference ISO 7000-1051), the term "disposable" shall not be used. (b) the symbol indicating that the device possesses an auto-disable function for re-use prevention as given in figure 2 or ISO 7886-3 : 2005. (c) the name and/or trade mark of the manufacturer or supplier. (d) the words "sterile interior" or equivalent symbol. (e) the lot number prefixed by the word "LOT" (or equivalent harmonized symbol). (f) the expiry date by year and month, prefixed by the word "EXP" (or equivalent harmonized symbol). (g) external diameter and length of the needle, if included. (h) any other labelling requirement as required by the tender documents, if any. (pls refer).	S -1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc 0 Rej 1
Primary and Unit Containers	The primary and/or unit container shall bear at least the following information: (a) the words "for single use" or equivalent (such as symbol for single use ,reference ISO 7000-1501); the term "disposable" shall not be used. (b) the symbol indicating the device possesses and auto-disable function for re-use prevention as given in figure 2 of ISO 7886-3 : 2005. (c) name and/or trade mark of the manufacturer or supplier. (d) the words "sterile interior" or equivalent symbol. (e) the lot number prefixed by the word "LOT" (or equivalent harmonized symbol) (f) the expiry date by year and month, prefixed by the word "EXP" (or an equivalent harmonized symbol). (g) the	S -1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc 0 Rej 1

	description of contents including the nominal capacity and type of the needle, if included. (h) any other labeling requirement as required by the tender documents, if any. (pls refer).								
Secondary Container	The secondary container shall bear at least the following information: (a) the words "For single use" or equivalent (such as symbol for single use, reference ISO 7000-1051); the term "disposable" shall not be used. (b) the symbol indicating that the device possesses and auto-disable function for re-use prevention as given in figure 2 of ISO 7886-3 : 2005. (c) name and/or trade mark or the manufacturer or supplier. (d) the words "sterile interior" or equivalent symbol. (e) he lot number prefixed by the word "LOT"(or equivalent harmonized symbol) (f) the expiry date by year and month, prefixed by the word "EXP" (or equivalent harmonized symbol) (g) the description of contents including the nominal capacity and type of the needle, if included (h) any other labeling requirement as required by the tender document .if any (plsrefer).								

Secondary Container	(h) a warning to check the integrity of the primary container before use. (i) a warning not to recap the needle, or equivalent symbol. (j) any information for handling, storage and disposal of syringe. (k) the instruction for use, including the instructions appropriate to the auto-disable feature; alternatively, the instructions for use can be indicated on a separate sheet. (l) the number of units per secondary container. (m) any other labeling requirement as required by the tender documents, if any (pls refer).	S -1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc 0 Rej 1
Storage container	The storage container shall bear at least the following information: (a) the description of contents including the nominal capacity and the type of needle, if included. (b) the symbol indicating that the device possessed and auto-disable function for re-use prevention is given ifn Fig 2 of ISO 7886-3 : 2005. (c) the lot number prefixed by the word "LOT" (or equivalent harmonized symbol) (d) the expiry date by year and month, prefixed b the word "EXP" (or an equivalent harmonized symbol) (e) the word "STERILE" or equivalent harmonized symbol. (f) name and/or trade mark and address of the manufacturer or supplier. (g) any information for handling, storage and transportation of the contents (or equivalent symbols as given in ISO 7000 or ISO 780) storage container (h) the number of units per storage container. (i) any other labeling requirement as required by the tender.	S -1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc 0 Rej 1
Transport wrapping	If a storage container is not used but the secondary containers are wrapped for transportation, the information required on the storage containers shall either be marked on the wrapping or shall be visible	S -1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc 0 Rej 1

	through the wrapping.								

SAMPLING PLAN & ACCEPTANCE CRITERIA FOR ATTACHED NEEDLES

ISTICS	SPECIFICATION	INSPECTION LEVEL	AQL	SAMPLE SIZE			No.Non-Compliers		
				FOR BATCH SIZE 35001 to 1.50 lakhs	FOR BATCH SIZE 1.50 lakhs to 5 lakhs	FOR BATCH SIZE Over 5 lakhs	FOR BATCH SIZE 35001 to 1.50 lakhs	FOR BATCH SIZE 1.50 lakhs to 5 lakhs	FO SIZ lak
	When inspected by normal or corrected to normal vision without magnification under an illuminance of 300 lx to 700 lx, the surface of the hypodermic needle tube shall appear free from particles and extraneous matter. When examined under x2.5 magnification, the hub socket shall appear free from particles and extraneous matter.	S - 1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Ac
acidity or	When determined with a laboratory p H meter and using a general purpose electrode, the p H value of an extract prepared in accordance with annexure A of IS 10654 : 2002, shall be within one unit of p H of that of the control fluid.	NA	NA	25	25	25	p H value of the combined soluti samples shall be with in one unit p the control fluid.		
ractable metals									
ctable heavy	When tested by a recognized micro analytical method, for example by an atomic absorption method, an extract prepared in accordance with annexure A of IS 10654 : 2002 shall, when corrected for the metals content of the control fluid contain not greater than a combined total of 5 mg/l of lead, tin, zinc and iron.	NA	NA	25	25	25	Combined extract from the sa have a value less than 5 ppm.		
	When tested by a recognized micro analytical method, for example by an atomic absorption method, an extract prepared in accordance with annexure A of IS 10654 : 2002, the cadmium content of the extract shall, when corrected for the cadmium content of the control fluid be lower than 0.1 mg / l.	NA	NA	25	25	25	Combined extract from the sa have a value less than 0.1 ppm.		

ation	The size of hypodermic needle shall be designated by the following a) the nominal outside diameter of the needle tube expressed in millimeters b) the nominal length of the needle tube, expressed in millimetres. The size shall be referred to as " the designated metric size" and shall be expressed in millimetres. For example 0.8 x 40	S - 1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc
ng	The nominal outside diameter of hypodermic needles shall be identified by colour coding in accordance with ISO 6009 applied to the unit container and / or part of the needle assembly such as the needle hub or the sheath.	S - 1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc
ng	The conical socket of the hypodermic needle hub shall be in accordance with ISO 594 - 1.	S - 1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc
	If the hub has a locking fitting, it shall be in accordance with ISO 594 - 2.	S - 1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc
ub	The hub shall be made either of pigmented or of unpigmented material. If pigmented, the colour shall be in accordance with ISO 6009.	S - 1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc
	If a separate needle sheath is provided, it shall be made either of pigmented or of unpigmented material. If pigmented, the colour shall be in accordance with ISO 6009.	S - 1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc
e									
	The needle shall be made of tubing in accordance with ISO 9626.	S - 1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc
on length	The actual length of the needle tube shall equal the nominal length within the tolerences given table 1 of IS 10654 : 2002.	S - 1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc
om defects	When examined by normal or corrected vision, the needle tube shall appear straight and of regular cross - section and wall thickness.	S - 1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc

	If the hypodermic needle tube is lubricated, the lubricant shall not be visible, under normal or corrected vision, as droplets of fluid on the outside or inside surfaces of the needle tube.	S - 1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc
t	When examined under x 2.5 magnification, the needle point shall appear sharp and free from feather edges, burrs and hooks.	S - 1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc
e									
een hub and e.	The union of the hub and needle tube shall not be broken by the minimum force given in table 2 of IS 10654 : 2002 applied as push or pull in the direction of the needle axis.	S - 1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc
umen	The patency of the lumen shall be such that either a) a stainless steel stylet of the appropriate diameter selected from the diameters given in table 3 of IS 10654 : 2002 shall pass through the needle. OR b) the rate of flow of water through the needle under a hydrostatic pressure not exceeding 1 x 10 Pa shall not be less than 80 % of that of a needle of equivalent outside diameter and length having a minimum inside diameter in accordance with ISO 9626 when tested under the same pressure.	S - 1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc
tainer	Each hypodermic needle shall be sealed in a primary container. The material and design of this container shall be such as to ensure that the colour coding of the contents is visible.	S - 1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc

	The materials of the container should not have detrimental effects on the contents. The materials and the design of this container should be such as to ensure a) the maintenance of sterility of the contents under dry, clean and adequately ventilated storage conditions. b) the minimum risk of contamination of the contents during removal from the container. c) adequate protection of the contents during normal handling, transit and storage. d) that once opened, the container cannot be easily resealed, and it should be obvious that the container has been opened.	S - 1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc
Container	One or more primary containers shall be packaged in a secondary container. The secondary container should be sufficiently robust to protect the contents during transit and storage. One or more secondary containers may be packaged in a storage and / or a transit container.	S – 1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc
tainer	The primary container shall be marked with at least the following information : a) a description of the contents, including the designated metric size in accordance with the details described under " SIZE DESIGNATION" b) the word "STERILE" c) the lot umber, prefixed by the word "LOT" d) the name or trade mark or trade - name or logo of the manufacturer or supplier.	S – 1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc

Container	The secondary container shall be marked with at least the following information : a) a description of the contents, including the designated metric size in accordance with the details described under " SIZE DESIGNATION", the number, the type or angle of bevel and, if appropriate the words "thin walled" or "extra-thin-walled" or equivalent or an abbreviation. b) the word "STERILE" c) the words "FOR SINGLE USE" or equivalent (excepting the term "disposable". d) a warning to check the integrity of each primary container before use. e) the lot number, prefixed by the word "LOT" f) the date of sterilization(year and month expressed as specified in sub clause 5.2.1.1 of ISO 8601 : 1988 g) the name and address of the manufacturer or supplier h) information for handling, storage and transportation.	S – 1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc
ntainer	If secondary containers are packaged in a storage container, the storage container shall be marked with at least the following information a) a description of the contents b) the lot number, prefixed by the word "LOT" c) the word "STERILE" d) the date of sterilization e) the name and address of the manufacturer or supplier f) information for handling, storage and transportation of the contents.	S – 1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc
apping	If a storage container is not used but the secondary containers are wrapped for transportation, the labelling requirements on the storage container shall either be marked on the wrapping or shall be visible through the wrapping.	S – 1	1.5	8	8	8	Acc 0 Rej 1	Acc 0 Rej 1	Acc

S. No.	Parameters (1 ml AD Syringes)	Details
1.	**General Characteristics**	Sterile & Single - use. Including a mechanism to prevent reuse. The syringe and needle shall be passively and automatically rendered unusable by the delivery of the intended fixed does. **and / or** The auto-disable feature is automatically activated and remains effective from the time that the injection is commenced. and / or The auto –disable feature is automatically activated on completion of the delivery of the intended fixed dose.
2.	**Type & Application**	Non-pre – filled. To administer liquid vaccine and diluted freeze-dried vaccine for intramuscular or sub – cutaneous injection. Syringes with permanently fixed needle.
3.	**Material**	Polypropylene with or without stainless steel.
4.	**Syringe size with pre-set volume**	1 ml for immunization (Up to 20% to allow for removal of air).
5.	**Marking, Graduation and accuracy**	Three markings: the zero line, the nominal capacity line (i.e. The total graduated capacity line- 1 ml and a marking at 0.5. The difference between the maximum graduated volume and the expelled volume of distilled water shall confirm from ISO 7886-3:2020(E) (Table-1).
6.	**Needle dimensions**	Diameter: 22-23 G Length: 25 mm
7.	**Needle characteristics**	Stainless steel needle tubing suitable for the manufacture of medical devices. Needle shall confirm to IS 10654 : 2018 (Forth Revision) equivalents to ISO 7864:2016(E) or latest if any
8.	**Needle fixing**	Fixed capped needle. The union of the hub and needle tube shall not be broken by the minimum force given in Table 2 of ISO 7864:2016(E) applied as push or pull in the direction of needle axis. If the accidental needle – stick protection devices are included in the design of the syringe or needle, they should not compromise the ease of use or the performance of the syringe.
9.	**Leakage**	As per ISO 7886-3:2020(E) or latest if any
10.	**Dead space**	The maximum dead space shall be as per Table 1 of ISO 7886-3:2020(E) or latest

		amendments if any
11.	**Self – disable**	The syringe shall be automatically rendered unusable when it has delivered intended (0.5ml or 1ml) dose of vaccine or distilled water.
12.	**Filling**	The syringe is filled by inserting the needle through the septum of a sealed vaccine vial.
13.	**Friction**	The measured friction values shall be within the following limits during emptying when the piston is moved at 100 mm per minute. As per ISO 7886-3:2020(E) Table B - 1.
14.	**Transparency & Resistance to shock**	"Excellent" Class 3 on the Standard Opalescence Rating. Resistance to shock: There shall be no effect on the performance of the syringe after it has been dropped from a height of 1 meter onto a concrete surface. Auto – destruct mechanism shall not activate during transportation. There shall be no effect on the performance of the syringe when vibrated under conditions simulating transport.
15.	**Bubble exclusion**	Air bubbles introduced during filling can be easily removed by flicking the fingernail against the barrel.
16.	**Packaging & Labelling**	Individual sterilized blister or ribbon pack made of paper and plastic wrapping with date of manufacture, date of expiry, method of sterilization used & special print message such as "Govt. supply for immunization, not for sale". Pictorial instructions for usage on a separate sheet. Needle cap to make syringe into a sterile unit. 100 /200 syringes in one millboard / grey board / hard board box indicating date of manufacture, date of expiry, method of sterilization used & special print message such as "Govt. supply for immunization, not for sale".
17.	**Shelf life**	The shelf life of syringes shall not be less than three years and not more than 1/6th of the life is consumed while delivering at the consignee's premises.
18.	**Disposability**	The syringes will be cut from the hub by a hub cutter at the point of use. The separated hub & needle and the cut syringe including plunger will be disposed-

		off as per Biomedical Waste (Management and Handling) rules.
19.	**Essential requirement**	The technical specification of 0.5 ml AD Syringes should conform to ISO 7886-3:2020(E) product standard and to ISO 13485:2016(E) quality system standard. The bidders should submit a copy of their ISO 13485:2016(E) certificate issued by the certifying body. The certificate should be valid on the date of tender opening. A certificate from the manufacturer certifying that the product meets the ISO 7886-3:2020(E) product standard to be submitted along with the bid documents.

We hereby state that the offered goods meet the technical specifications without any deviation

Name ……
Designation……

Signature & Company seal

Annexure-2

Commercial Terms

1. The Items should be delivered strictly as per the specifications attached at Annexure-1.

2. **ELIGIBILITY CRITERIA**

a) Only Class- I and Class-II Local supplier shall be eligible for participation. Bids from supplier (MSE/Non MSE) as defined in DPIIT order no. P-45021/2/2017-PP (BE-II) dt. 04.06.2020 and 16.09.2020.

b) The invitation to bid is open to domestic manufacturers (Indian Manufacturers) or/and their authorized agencies.

c) **For Indian Manufacturers**: Bidder shall be a manufacturer of Syringes having valid own manufacturing license for the offered product. The Manufacturing License should be valid on the date of tender opening packet 1.

d) Non Manufacturer Bidder

The bidder should be duly authorized (as per authorization Form Annexure 13) by the manufacturer of the goods. Information as asked for manufacturer shall be submitted with the bid,

e) For Both Manufacturers and Non-Manufacturers:

Following documents will also be submitted:

i. Average Annual turnover for Tenderers in the last two years .e. 2017-18 and 2018-19 or 2018-19 and 2019-20 shall not be less Rs. 5,00,00,000/-

ii. The turnover benchmark given in (i) above will not apply to Micro and Small Enterprises(MSE).

iii. Traders will not get the benefit of MSE Firm.

Note- For Authorized Agencies (non-manufacturers), the bidders can utilise the financial and past supply credentials of the principal.

f) Tender should not be submitted by the firm/company for the Product(s) for which the firm/ Company has been blacklisted/ banned/ debarred by CMSS/ State Governments/ Central Government/MOH&FW or any of the procurement agencies/Autonomous Bodies under the organisations stated above or if the Firm/Company is debarred as a whole by these organisations or any of its procurement agencies/Autonomous Bodies.

g) Tenderer should have supplied same or similar syringes to any government institutions/ PSUs/ export to foreign government during the last three financial years (Copy of atleast 1 PO of same or similar item is to be submitted).

Note: Similar items here relates to any type of syringes.

h) Tenderer shall have an annual production capacity not less than one and half times the quantity quoted for each schedule.

3. **Technical Bid:**

(a) Bid Security Declaration (as per Annexure 5) in respect of EMD Exemption or in case of MSE, a copy of their valid registration certificate in support of their being an MSE and a Notarised undertaking given in Annexure 9 has to be submitted physically in CMSS Office preferably before the last date and time to submit the bid/EOI. In case of non-submission of the same, physical copy of the above document is to be submitted within 7 days of opening of the bids/EOI. CMSS reserves the right to further extend the date of submission of hard copy of the above documents uniformly for all the bidders.

(b) **For Indian Manufacturers**: Bidder shall be a manufacturer of Syringes having valid own manufacturing license for the offered product. The Manufacturing License should be valid on the date of tender opening.

(c) Non Manufacturer Bidder

The bidder should be duly authorized (as per authorization Form Annexure 13) by

the manufacturer of the goods. Information as asked for manufacturer shall be submitted with the bid,

(d) Capacity certificate issued by the licensing authority or a practicing CA.

(e) Non-Conviction Certificate – in the form of Self undertaking certifying that the firm/company has not been convicted and the products quoted have not been cancelled during last two years i.e.2019-20 and 2020-21.

(f) Conformance to ISO Certification as per technical specifications.

(g) Annual turnover statement for 2 years i.e., 2017-2018 and 2018-19 or 2018-19 and 2019-20 should be furnished in the format given in **Annexure-6** duly certified by the Chartered Accountant.

(h) Copies of the audited Annual reports including the Balance Sheet and Profit and Loss Account along with all the annexure for the last two years i.e. 2017- 18 and 2018-19 or 2018-19 and 2019-20 duly certified by a practicing Chartered Accountant.

(i) List of items quoted (the name and Item Code of the items quoted) and annual production for the last 2 years as per the **Annexure-7.**

(j) Accelerated Data of atleast 6 months along with available Long Term (Real Time) Stability Data for atleast one batch in support of Shelf Life of the product to be submitted for the quoted tendered item.

(k) A Checklist (**Annexure-8**) indicating the documents submitted with the tender document and their respective page numbers shall be enclosed with the tender document. The documents should be serially arranged.

(l) Each page of submitted bid (along with tender document) be properly page numbered and shall be signed by the authorized signatory of the Tenderer with office seal.

(m) All the documents enclosed with the tender document should also be signed by the authorized signatory of the Tenderer.

(n) No Deviation Certificate as per **Annexure-11**.

(o) Near Relative Certificate as per Annexure –**12.**

(p) Tenderer should submit a certificate from the statutory auditor or cost auditor of the company (in the case of companies) or from a practicing cost accountant or practicing chartered accountant (in respect of suppliers other than

companies) giving the percentage of local content at the time of submission of bid as per Annx- 14.

NOTE: The Price quoted by the technically disqualified bidders will not be considered.

4. **OTHER CONDITIONS:**

a) As follows:

(i) In exceptional situation where the requirement is of an emergent nature and/or it is necessary to ensure continued supplies from the existing vendors, the purchaser reserves the right to place repeat order up to 50% of the quantity of the goods and/or services contained in the running tender/contract up to a period of twelve months from the earliest date of acceptance of letter of acceptance at the same rate or a rate negotiated (downwardly) with the existing vendors considering the reasonability of rates based on prevailing market conditions and the impact of reduction in duties and taxes etc.

(ii) Considering the current scenario of management of COVID-19 Pandemic, in exceptional/ extraordinary/emergency circumstances, additional quantity upto 100% of the contracted (Long Term Agreement) quantity can be ordered on the existing bidders during the validity of the contract (LTA), at the same terms and conditions of the tender. This quantity will include the quantity as per (i) above and acceptance of the same will be on mutual consent.

(iii) The delivery of the additional quantity as stated in clause no. (i) and (ii) above shall be scheduled after the completion of the delivery of the original tendered/ordered/LOA quantity or on mutual consent between the supplier and CMSS.

(iv) Vendors should ensure that delivery commitments against the current tender/bid should not be at the cost of scheduled deliveries against existing POs for 0.5 ml AD Syringes of CMSS and MoHFW.

b) (i) The rates quoted and accepted will be binding on the Tenderer for the full contract period of one year and any increase in the price will not be entertained till the completion of this contract period.

(ii) Any upward/downward revision (only during scheduled delivery period) in statutory taxes, levies will be allowed and benefit will pass on to supplier/purchaser.

(iii) Any increase in taxes and other statutory duties/levies after the expiry of the delivery date shall be to the supplier's accounts. However, the benefit of any decrease in these taxes/duties shall be passed on to the purchaser by the supplier.

c) In accordance to the MSME ACT 2006 notification, the participating Micro and Small Enterprises (MSEs) in a tender, quoting price within the band of L 1 + 15% would be allowed to supply a portion of the requirement by bringing down their price to the L 1 price, in a situation where L 1 price is from someone other than an MSE. In exercising of the powers conferred in Section 11 of the Micro, Small and Medium Enterprises Development (MSMED) Act 2006, the Government has notified a new Public Procurement Policy for Micro & Small Enterprises effective from 9th November 2018. The policy mandates that 25% of procurement of annual requirement of goods and services by all Central Ministries / Public Sector Undertakings will be from the Micro and Small Enterprises. Government has also earmarked a sub target of 4% procurement of goods & services out of 25% from MSEs owned by SC/ST entrepreneurs and 3% to micro and small enterprises owned by women.

d) The DIPP has notified a Public Procurement order-2017 (Preference to Make in India) order 2017- Revision vide Order no P-45021/2/2017-PP (BE-II) - dated 4th June 2020 and 16.09.2020. The provision of said order will apply

in the instant case. Bidders are requested to submit a declaration indicating percentage of local content as per Annex 14.

5. **Quality Control:**

a) Quality Control is an essential part of the current procurement and it is the responsibility of the supplier to ensure quality assurance as per specifications/bid document. The products should conform to the standards as specified in Annexure-I of the Tender document.

b) The bidder/ supplier understand that the tendered item/items is/are critical health goods and the quality parameters of supplied goods are to be ensured during complete specified shelf life as indicated in technical specification/bid document/ official compendium. Bidder/Supplier also appreciate that failure in quality checks is serious default as it may derail entire programme and can also risk the life of users of supplied health goods.

c) CMSS will embark on stringent quality checks to ensure that tendered goods meet required standards throughout specified shelf life. For this purpose, CMSS reserves the right to carry necessary inspections/tests at any of, or any combination of or/ all of following stages:

(i) At Pre-Dispatch stage.

(ii) At Delivery Stage: inspection done once the goods reach at consignee location and before taking over supplied goods in inventory.

(iii) Post Delivery Surveillance: The Drugs/goods shall have the active ingredients and all other parameters at the prescribed level as indicated in official compendiums or technical specifications throughout the shelf life period of the drugs/ goods. Quality Monitoring Activities may also be organized by CMSS post-delivery.

d) CMSS may engage the services of a Quality Control Agent & Quality Control Testing Laboratories for the purpose of Inspection & Quality

Control. The Sampling quantities shall be borne by the supplier. As per applicable Pharmacopeia, the samples/batches are to be sent for QA/QC tests. This qty. will be supplied additionally by bidder at its cost and above the tendered quantity.

e) Inspection Methodology: At pre-dispatch and/or delivery stage, samples of supplies in each batch will be chosen for testing. The samples will be collected and sent to designated laboratories (Government/ Private Drugs Testing Laboratories) for testing as decided by the CMSS. Handling and testing charges will be borne by CMSS.

At post-delivery surveillance - The samples will be collected from the warehouse of CMSS/or final consignee in States/UTS and sent to designated Quality Control Labs in respect of supplied goods at any point during specified shelf life as per decision of CMSS.

In case of failure of batches during or at any stage (indicated at 16.3), the testing charges would be claimed for the defaulting vendor.

f) The supplies will be deemed to be completed only upon receipt of the quality certificates from the laboratories.
"Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches will be deemed to be rejected goods.

g) **At any of testing stage,** samples which do not meet quality requirement shall render the relevant batches liable to be rejected. If the sample is declared to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches will be deemed to be rejected goods and the cost of entire batch paid will be recovered whether consumed fully/ partially. Besides action may also be initiated for debarring/blacklisting against supplier for suitable period.

h) In the event of the samples of Drugs/goods supplied fails in quality tests or found to be not as per specifications at any of testing stages, depending upon the type, nature and seriousness of failure, consequences resulting from such default, availability of alternate sources, the CMSS is at liberty to either :

(i) Ask the supplier to replace entire quantity of the relevant batches, in addition to imposition of penalty @ 25% of batch supply cost or

(ii) to make alternative purchase of the items from other approved suppliers or in the open market or from any other Tenderer who might have quoted higher rates, at the risk and the cost of the supplier.

(iii) In addition to (i) or (ii) above, action to debar/blacklist the supplier for suitable period, as decided by CMSS may also be initiated. In addition forfeiture of PSD.

(iv) In addition, the FDA/ Drugs Control Authority of concerned State will be informed for initiating necessary action on the Tenderer in their state. Security deposit will also be forfeited without any intimation.

(v) The decision of the CMSS or any officer authorized by CMSS, as to the quality of the supplied drugs, medicines, vaccines etc., shall be final and binding.

i) If the product is non-Pharmacopoeial then the supplier must provide the in house test method along with the required reference standards if asked for. The Master Formula of the products shall be provided whenever asked for.

j) **Note: In the current tender- Pre-Dispatch Inspection shall be carried out and Inspection will be carried out within 5 days of intimation.**

Release/Dispatch Instructions pending QC Test reports with Supplier's undertaking -

The supplies are allowed after samples are drawn to save the transit time however; supplier must give an undertaking that if by chance samples fail in testing, the supplier will call back entire quantity on their own cost and replace the entire quantity.

6. **Security Deposit:**

On being intimated about the acceptance of the bid the tenderer shall pay a Security Deposit at the rate of 3% of the total value of purchase order being awarded. The Security Deposit amount to be deposited in the form of Account Payee Demand Draft, FD receipt, Bank Guarantee or NEFT/RTGS in favor of Central Medical Service Society within 15 days from the date of receipt of LOA or can be deducted from running bills. The validity of the Security deposit should be at least 500+365 (Shelf Life) days from the date of its commencement.

Order submission-	15 days
Rate Validity-	365 days
Delivery Period-	60 days
Shelf Life-	365x(Shelf Life) days
B.G. Extension-	60 days
	500+365 (Shelf Life)

For NEFT/RTGS:

Beneficiary Name: Central Medical Services Society
A/C No. : 32719062216
Bank Name : SBI Bank
Branch : Nirman Bhawan, Maulana Azad Road, New Delhi
IFSCCode : SBIN0000583

Format of Bank Guarantee is attached for reference (Annexure 15).

7. **PAYMENT PROVISIONS**

a) The payment towards supply of items to CMSS will be made either by means of Cheque or through RTGS (Real Time Gross Settlement System)/ Core Banking/ NEFT. The Tenderer shall furnish the relevant details in original **(Annexure-10)** to make the payment through RTGS/Core Banking/NEFT.

b) All bills/ Invoices should be raised in duplicate and the bills should be drawn in the name of Central Medical Services Society, 2nd Floor, Vishwa Yuvak Kendra, Pandit Uma Shankar Dikshit Road, Chanakyapuri, New Delhi-110021or in the name of any other authority as may be designated.

c) Payments for supply will be made only after completion of supply of Items ordered in the individual Purchase Order PROVIDED quality reports are acceptable. The CMSS shall endeavour to make payment within 30 days from the date of submission of invoice or from the date of receipt of material, whichever is later along with all the relevant documents of tender.

d) Lot/Tranche/PO vise Part payments for supply will be considered only after completion of supply of atleast 50% quantity ordered in the individual Purchase Order/Lot/Tranche, with original CRC produced/submitted and the quality pass reports of Standard Quality on samples testing are received from approved laboratories of CMSS.

e) (i) Variations in prices will be admitted on account of increase or decrease in the Statutory taxes levies, such as customs duty, GST etc., on production of relevant government notification, but during scheduled delivery period only.

(ii) Any increase in taxes and other statutory duties/levies after the expiry of the delivery date shall be to the supplier's accounts. However, the benefit of any decrease in these taxes/duties shall be passed on to the purchaser by the supplier.

f) The supplier shall submit the following documents while claiming payments for supplies:

(i) Delivery challan along with the supplies (POD)

(ii) Packing list

(iii) Certificate of analysis along with the supplies (for each batch supplied).

(iv) Itemized Invoice/ Bill in duplicate to CMSS Head Office.

(v) Such other documents as required by CMSS.

(vi) Bidders are requested to submit their Original Invoice along with copies of Lorry Receipt/ Delivery challans and original Consignee Receipt Certificate (CRC) as per format given in the tender document Annexure duly signed & stamped with other necessary documents for smooth processing of payment.

g) Supplier will integrate with e- aushdhi system of CMSS and Supplier Interface Module in which selected bidders shall be required to enter/upload batch no, qty, mfg& expiry date, tranche no, invoice/challan copy etc. against PO no.

8. **LIQUIDATED DAMAGES AND OTHER PENALTIES:**

8.1 DELAYS IN SUPPLIER'S PERFORMANCE:

(a) Delivery of the goods and performance of services shall be made by the supplier in accordance with the time schedule specified by the purchaser in its LOA/purchase order. In case the supply is not completed in the stipulated delivery period, as indicated in the LOA/purchase order or in case of non-submission of Security Deposit within the stipulated time, purchaser reserves the right either to short-close/cancel this LOA/purchase order and/or recover liquidated damage charges. The cancellation/short-closing of the LOA/Purchase order shall be at the risk and responsibility of the supplier and purchaser reserves the right to purchase balance-unsupplied quantity at the risk and cost of the defaulting vendor. This purchase at the risk and cost of the defaulting vendor can be at the same L1 cost of the tender or at higher cost and can be met through other vendors available in the present tender/contract or through any vendor from the open market. Any additional cost towards this risk purchase will be entirely borne/adjusted from running bills/demanded from the defaulting vendor. Since the tendered item is for COVID management, hence this risk purchase action as explained above may not require any fresh tendering attempt.

(b) Repeated/habitual delays by the supplier in the performance of its delivery obligations shall render the supplier liable to any or all of the following sanctions;

imposition of liquidated damages, forfeiture of its performance security, and/or termination of the contract for default and purchaser reserves the right to purchase balance-unsupplied quantity at the risk and cost of the defaulting vendor.

(c) If the suppliers are not completed in the extended delivery period, the purchase order may be short closed without any compensation to supplier and the performance security shall be forfeited.

(d) Quantum of liquidated damages assessed and levied by the purchaser shall be final and not challengeable by the supplier.

(e) Purchaser reserves the right to debar/blacklist the supplier for a suitable period who habitually failed to supply the goods/services in time. The decision of purchaser will be final and binding.

8.2 If the supply reaches the designated consignee places or CMSS Warehouse after the 60th day or after scheduled delivery date mentioned in P.O., a liquidated damages will be levied at 2.5% per week for delayed supply up to a maximum of 10% of P.O. Cost, irrespective of the fact that whether the CMSS has suffered any damage/ loss or not, on account of delay in effecting supply. If the 60th day happens to be a holiday the supply will be accepted on the next working day without any penalty.

8.3 If the supply is received in damaged condition it shall not be accepted. In case of damage in the packing only, the supply may be accepted subject to purchaser's decision and after levying a penalty which may be upto 5% of cost of package received with damaged packing.

8.4 Timely supply is the essence of contract/ Purchase order. The drugs/medicines/items ordered are meant for key National programmes & delay in supply can have the adverse impact on patients can derail the critical National level Disease Control Programme.

In continuation top provisions of liquidated damages clause no. 18, it may be noted that:

a) Any lot delayed beyond LD period may be short closed by CMSS if delivered qty. is <75%and CMSS reserves the rights/options to procure the undelivered quantity from other approved supplier available in the contract or from open market at the risk & cost of the defaulting supplier.

b) If any lot where delivered qty. is ≥75% and <95% is delayed beyond LD period a final Show Cause Notice will be issued intimating the supplier to deliver the balance qty. within one month time else CMSS reserves the rights/options to procure the undelivered quantity from other approved supplier available in the contract or from open market at the risk & cost of the defaulting supplier. The same lot shall be short closed after the given time of one month.

Supplier/s will submit proposal/ request for each such case &CMSS reserves the right to decide each case taking all the circumstances &situations into view. CMSS's decision will be final & binding.

If 2 or more lots are short closed with delivered qty. is <75% in maximum LD period in same PO, proportionate deductions from the security deposit submitted by the supplier or from running bills/invoices will be forfeited. However, in case where deliveries were to be made in a single lot, the same shall be applicable on single lot.

Note:- In event of Force majeure reasons/ situations as explained herein at clause no. 18, this clause would not be operated.

9. **Allocation of quantity:**

a) While distribution of the ordered quantity, efforts would be made to align it in accordance with the above clause, MSME, DPIIT and MOF guidelines. However, in view of the COVID pandemic situation, Purchaser reserves the right to place

Purchase orders and distribute quantities among any number of bidders after assessing the capacities, quoted quantities, quoted rates, early delivery, etc. in the interest to meet the requirement of Programme Division.

b) Micro and Small Enterprises as per classification given in MSME Notification dtd. 26.06.2020 registered under "Udyam Registration" w.e.f 01.07.2020 -In accordance to the Public Procurement Policy for Micro & Small Enterprises effective from 9th November 2018, the participating Micro and Small Enterprises (MSEs) in a tender, quoting price within the band of L 1 + 15% would be allowed to supply a portion of the requirement by bringing down their price to the L 1 price, in a situation where L 1 price is from someone other than an MSE. The policy mandates that 25% of procurement of annual requirement of goods and services by all Central Ministries / Public Sector Undertakings will be from the Micro and Small Enterprises. Government has also earmarked a sub target of 4% procurement of goods & services out of 25% from MSEs owned by SC/ST entrepreneurs and 3% to micro and small enterprises owned by women. Udyam Registration Certificate has to be produced in support of above.

c) The existing Micro and Small Enterprises as per classification given in MSME Act 2006 , registered till 30.06.2020 and holding Permanent Registration Certificate from the District Industries Centers or Khadi and Village Industries Commission or Khadi and Village Industries Board or Coir Board or National Small Industries Corporation or any other body specified by Ministry of Micro Small and Medium Enterprises will be granted exemption from payment of Earnest Money Deposit till 31.12.2021. Registration Certificate has to be produced in support of above.

d) The DIPP has notified a Public Procurement order-2017 (Preference to Make in India) order 2017- Revision vide Order no P-45021/2/2017-PP (BE-II) - dated 16th September 2020. The provision of said order including any subsequent orders issued from time to time will apply in the instant case. Bidders are

requested to submit a certificate from the statutory auditor or cost auditor of the company (in the case of companies) or from a practicing cost accountant of practicing chartered accountant (in respect of suppliers other than companies) giving the percentage of local content as per Order no P-45021/2/2017-PP (BE-II) - dated 16th September 2020

10. **FORFEITURE OF EMD:**

(i) The Earnest Money Deposit (EMD) will be forfeited/vendor would be required to deposit the equivalent EMD amount as per Bid Security Declaration, if the Tenderer withdraws or amends, impairs or derogates from the tender in any respect within the period of validity of his Tender.

(ii) The Earnest Money Deposit (EMD) will be forfeited/ vendor would be required to deposit the equivalent EMD amount as per Bid Security Declaration, in case of the lowest/ matched bidder, fails to execute the contract agreement and / or deposit the Security Deposit within the stipulated time. Additionally, actions as stipulated in clause no. 8.1 will also be taken.

(iii) In both the above cases, the bidder will not be eligible to participate in the tender for same item for two years from the date of issue of letter of acceptance. The bidder will not approach the court against the decision of the CMSS in this regard.

11. Defaulting bidder/vendor may be blacklisted/debarred for a period of 2 years from participation in tenders

We hereby state that the offered goods meet the above commercial conditions without any deviation

Name ……
Designation……

Signature & Company seal

Annexure-3

The price and quantity (item wise) to be quoted in the following table:

Sch. No.	Item Description	Qty. In tender	Qty. quoted	Ex-Works Price per Unit (Rs)	GST on Ex-Works Price (%)	GST on Ex-Works Price (Rs)	Transportation Charges and other charges (all inclusive, fixed and firm) (Rs.)	Rate Per Unit (including GST) (Rs)
A	B	C	D	E	F	G	H	E+G+H
I	0.5 ml AD Syringes	125,00,00,000						
II	1 ml AD Syringes							

Name ……
Designation……

Signature & Company seal

Annexure-4

Delivery period and Consignee Wise Allocation:

Consignee list of 125 cr pieces of 0.5ml/ 1 ml AD Syringes						
SL	**State/ GMSD**	**1st Lot 25 cr in Aug 2021**	**2nd Lot 25 cr in Sept 2021**	**3rd Lot 25 cr in Oct 2021**	**4th Lot 25 cr in Nov 2021**	**5th Lot 25 cr in Dec 2021**
1	Andhra Pradesh	78,92,000	78,92,000	78,92,000	78,92,000	78,92,000
2	Assam	47,24,000	47,24,000	47,24,000	47,24,000	47,26,000
3	Bihar	1,46,66,000	1,46,66,000	1,46,66,000	1,46,66,000	1,46,70,000
4	Chhattisgarh	39,24,000	39,24,000	39,24,000	39,24,000	39,22,000
5	Haryana	41,10,000	41,10,000	41,10,000	41,10,000	41,08,000
6	Karnataka	97,68,000	97,68,000	97,68,000	97,68,000	97,68,000
Madhya Pradesh						
7	Bhopal	21,94,000	21,94,000	21,94,000	21,94,000	21,98,000
8	Gwalior	16,46,000	16,46,000	16,46,000	16,46,000	16,46,000
9	Indore	16,46,000	16,46,000	16,46,000	16,46,000	16,46,000
10	Jabalpur	21,94,000	21,94,000	21,94,000	21,94,000	21,98,000
11	Riwa	10,98,000	10,98,000	10,98,000	10,98,000	10,94,000
12	Sagar	10,98,000	10,98,000	10,98,000	10,98,000	10,94,000
13	Ujjain	10,98,000	10,98,000	10,98,000	10,98,000	10,94,000
14	Odisha	64,96,000	64,96,000	64,96,000	64,96,000	64,94,000
Rajasthan						
15	Jaipur	36,00,000	36,00,000	36,00,000	36,00,000	36,00,000
16	Jodhpur	30,86,000	30,86,000	30,86,000	30,86,000	30,84,000
17	Udaypur	36,00,000	36,00,000	36,00,000	36,00,000	36,00,000
Uttar Pradesh						
18	Agra	26,50,000	26,50,000	26,50,000	26,50,000	26,48,000
19	Bareily	38,28,000	38,28,000	38,28,000	38,28,000	38,24,000
20	Faizbad	38,28,000	38,28,000	38,28,000	38,28,000	38,24,000
21	Gorakhpur	32,38,000	32,38,000	32,38,000	32,38,000	32,40,000
22	Jhansi	14,72,000	14,72,000	14,72,000	14,72,000	14,72,000
23	Kanpur	17,66,000	17,66,000	17,66,000	17,66,000	17,68,000
24	Lucknow	38,28,000	38,28,000	38,28,000	38,28,000	38,24,000
25	Meerut	29,44,000	29,44,000	29,44,000	29,44,000	29,44,000
26	Varanasi	58,86,000	58,86,000	58,86,000	58,86,000	58,90,000
27	GMSD, Chennai	3,60,86,000	3,60,86,000	3,60,86,000	3,60,86,000	3,60,84,000
28	GMSD, Karnal	3,11,48,000	3,11,48,000	3,11,48,000	3,11,48,000	3,11,50,000
29	GMSD, Kolkata	3,77,10,000	3,77,10,000	3,77,10,000	3,77,10,000	3,77,10,000
30	GMSD, Mumbai	4,27,76,000	4,27,76,000	4,27,76,000	4,27,76,000	4,27,88,000
Total:	**25,00,00,000**	**25,00,00,000**	**25,00,00,000**	**25,00,00,000**	**25,00,00,000**	**25,00,00,000**

The bidders are required to propose per month quantities that can be delivered by them starting from August 2021 till December 2021 in the following format:

Sch. No.	Item	Total quoted qty.	Qty. offered to be delivered in August 2021	Qty. offered to be delivered in September 2021	Qty. offered to be delivered in October 2021	Qty. offered to be delivered in November 2021	Qty. offered to be delivered in December 2021
I	0.5 ml AD Syringes						
II	1 ml AD Syringes						

Due to current prevailing COVID wave, early deliveries are preferred. CMSS reserves the right to accept any combination offered by the technically and commercially qualified bidders, aiming fastest procurement.

Additional quantity- As per clause no. 4 (a) (i).

We hereby state that the offered goods meet above conditions without any deviation

Name ……
Designation……

Signature & Company seal

Annexure 5

"Bid Security Declaration"

NOTARISED UNDERTAKING

(In 100- Rupees stamp paper)

We, …… (name of bidder), having offices at

……..are participating in Bid No.

…… Dated ……..

In reference to tender clause no. 9, and in accordance with MoF circular No. F.9/4/2020-PPD dt. 12.11.2020

We equivocally and irrevocably undertake that,

i) If we withdraw or modify our bids during period of validity etc. or
ii) If we fail to execute the Contract Agreement and/or deposit the Security Deposit within the stipulated time or
iii) Indulge in any action which is deemed fit for forfeiture of EMD as mentioned in the tender document and subsequent amendments,

We will be liable to pay penalty as stated in the order and actions as per the tender terms and condition including suspension/debarment from any bidding in CMSS/MoHFW tenders for two years shall be taken against us.

M/s_____

Witness

1.

2.

For Self and Firm/Company Limited

Signature & Seal of company

Annexure 6

ANNUAL TURN OVER STATEMENT

The Annual Turnover (Sales) of M/s._____ for the past two years are given below and certified that the statement is true and correct.

Sl. No.	Financial Year	Turnover in Lakhs (Rs)
1.	2018-2019	-
2.	2019-2020	-

Total - Rs. _____ Lakhs.

Average Turnover Per Annum in the last two years mentioned above -

Rs._____ Lakhs.

Date:

Signature of Auditor/

Seal: Chartered Accountant

(Name in Capital)

Annexure 7

LIST OF ITEMS QUOTED & THEIR PRODUCTION CAPACITY

1. Name of the firm :

2. Address of the firm as given in Drug license :

3. Details of Endorsement for all products quoted :

Sch No	Item Code	Item Name	UOM	Quantity Tendered	Quantity quoted	Manufacturing Capacity	Quantity Manufactured		Average Quantity Manufactured
							2019-20	2020-21	
1	**2**	**3**	**4**	**5**	**6**	**7**	**8A**	**8B**	**9**
				TOTAL					

Date:

Authorized Signatory:

Annexure 8

CHECK LIST

1.	Checklist		Yes		No		
2.	Bid Security Declaration/Notarised Undertaking for MSE Firm		Yes		No		
3.	Certificate by MSME/ SSI units in support of being a MSE/ SSI unit.		Yes		No		
4.	Duly attested photocopy of License for the product duly approved by the Licensing Authority for each and every product quoted		Yes		No		
5.	Authorization letter nominating a responsible person of the tenderer to transact the business with the Tender inviting Authority.		Yes		No		
6.	Notarized Undertaking by MSE (Annex – 9)		Yes		No		
7.	Non Conviction Certificate –Self undertaking		Yes		No		
8.	Compliance to ISO Certificate as per Tech Specs		Yes		No		
9.	Manufacturer's Authorization Form (Annexure 13)		Yes		No		
10.	Annual Turnover Statement for 2 Years (Annex-6)		Yes		No		
11.	Copies of Balance Sheet & Profit & Loss Account for last TWO YEARS		Yes		No		

12.	Capacity Certificate issued by the Licensing Authority/ CA		Yes		No	
13.	List of items quoted and their production capacity – Annex-7		Yes		No	
14.	Mandate Form for RTGS Annex-10		Yes		No	
15.	The Tender document signed by the tenderer in all pages with office seal.		Yes		No	
16.	Accelerated Stability Data along with available Long Term Stability Data of the quoted products (at least for 1 batch) to support shelf life)		Yes		No	
17.	Undertaking that Firm is not being blacklisted or debarred from any Govt. Agency		Yes		No	
18.	No Deviation Certificate		Yes		No	
19.	Near Relative Certificate (Annexure 12)		Yes		No	

Annexure 9

NOTARISED UNDERTAKING BY MSE COMPANIES

(In 20- Rupees stamp paper)

I _____, S/o _____, Proprietor / Partner / Managing Director of _____ (Proprietary Concern / Firm / Company Ltd.) execute this Undertaking for myself and on behalf of _____ (Proprietary Concern / Firm / Company Ltd.).

2. Whereas, CMSS (Tender Inviting Authority) has invited Tender for supply of items for the year 2019-2020 and in pursuant to the conditions in the tender documents. M/s _____ (Proprietary Concern/ Firm / Company Ltd.), having its Office at _____ _____ is exempted from payment of Earnest Money Deposit as indicated in the Clause 9.2 of tender document.

3. And whereas, in pursuant to the conditions in Clause Nos. 9.3& 9.4 of the tender, the Earnest Money Deposit can be forfeited by the Tender Inviting Authority in case of violation of any of the conditions and for non-performance of the obligation under tender document.

4. In consideration of exempting M/s._____ (Proprietary Concern/ Firm / Company Ltd.) from payment of Earnest Money Deposit as indicated in the Clause 9.2of tender document, I undertake to pay the said sum without any demur on receipt of demand issued by the tender inviting authority.

M/s _____

For Self and Firm / Company Ltd.

Signature and Seal

Witness:-

(1)

(2)

Annexure 10

MANDATE FORM

01	Company Name	
02	Postal Address of the company with Telephone No., Fax No. and Mail ID.	
03	Name of the Managing Director / Director / Manager Mobile No. / Phone No. E-mail ID.	
04	Name and Designation of the authorized company official Mobile No. E-mail ID	

Date: Company Seal

Signature

Place: (Name of the person signing & designation)

Mandate Form contd..

01	Name of the Bank. Branch Name& address. Branch Code No. Branch Manager Mobile No. Branch Telephone no. Branch E-mail ID	
02	9 digit MICR code number of the bank and branch appearing on the MICR cheque issued by the bank.	
03	IFSC code of the Branch	
04	Type of Account (Current / Savings)	
05	Account Number (as appear in Cheque book)	

(in lieu of the bank certificate to be obtained , please **attach the original cancelled cheque** issued by your bank for verification of the above particulars).

I /We hereby declare that the particulars given above are correct and complete. If the transaction is delayed or not effected at all for reasons of incomplete or incorrect information, I would not hold M/s. Central Medical Services Society (CMSS) responsible. I have read the conditions of the tender/agreement entered and agree to discharge the responsibility expected of me / from the company as a tenderer /successful tenderer.

Date: Company Seal Signature
Place: (Name of the person
Signing& designation)

CERTIFIED THAT THE PARTICULARS FURNISHED ABOVE BY THE COMPANY ARE CORRECT AS PER OUR RECORDS.

Bank Seal with address. Signature of the authorized
official of the bank.

Annexure 11

No Deviation Certificate

This is to certify that the quoted SYRINGES by our firm, M/s ……is as per the given technical specifications in the tender document and there is no deviation in relation to any conditions/requirements specified in the tender document.

Annexure 12

Near Relative Certificate

(In case of Proprietorship firm certificate will be given by the proprietor. For partnership firm certificate will be given by all the partners and in case of limited company by all the Directors of the company excluding Govt. of India/Financial Institutions nominees and independent non-official part time directors appointed by Govt. of India or the Governor of the state. Authorised signatory of bid may also sign this bid on behalf of the entire directors/ partners/ proprietor).

This is to certify that none of my/our Company Directors' near relative as defined below currently works in CMSS where I am/we are going to apply for the tender. I/We also agree to the condition that due to any breach of conditions by the company or firm or any other related person the bid submitted on behalf of the company or firm will be cancelled and bid security will be forfeited at any stage whenever it is noticed and CMSS will not pay any damage to the company or firm or the concerned person. The company or firm will also be debarred for further participation for the quoted item in CMSS for a period of one year.

The near relatives for this purpose are defined as:

(a) Members of a Hindu undivided family.

(b) They are husband and wife.

(c) The one is related to the other in the manner as father, mother, son(s) & son's wife (Daughter in law), daughter(s) and daughter's husband (son in law), brothers(s) and brother's wife, sister(s) and sister's husband (brother in law).

Signature/Signatures (with Stamp)

Annexure 13

Manufacturer's Authorization

[The Tenderer shall require the Manufacturer to fill in this Form in accordance with the instructions indicated. This letter of authorization should be on the letterhead of the Manufacturer and should be signed by a person with the proper authority to sign documents that are binding on the Manufacturer.]

Date: *[insert:* ***date*** *(as day, month and year)* ***of Bid Submission****]*
Tender No.: *[insert:* ***number of bidding process****]*
Alternative No.: *[insert:* ***identification No if this is a Bid for an alternative****]*

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

WHEREAS

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

We hereby extend our full guarantee and warranty in accordance with Tender Terms and Conditions, with respect to the Goods offered by the above firm.

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

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

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

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

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

Annexure 14

FORMAT FOR LOCAL CONTENT DECLARATION

Tender Reference No: Date:

I _____, S/o, D/o, W/o _____,

Resident of _____do hereby solemnly affirms and declares as under:-

The local content is _____% (for the Equipment part) _____ (quoted item of M/s _____.

That I on behalf of M/s _____will agree to abide by the terms and conditions of the Ministry of Chemicals & Fertilizers, DOP, Government of India issued vide notification no. 31026/4/2018- policy dated 01.01.2019 and DPIIT order no. P-45021/2/2017-PP (BE-II) dt. 16.09.2020 and I hereby undertake that calculations for local content have been done in accordance with the referred order.

That the information furnished hereinafter is correct to best of my knowledge and belief and I on behalf of M/s _____ undertake to produce relevant records (whenever demanded) before the procuring entity or any authority so nominated by the Department of Pharmaceuticals/any other relevant Ministry, Government of India for the purpose of assessing the local content.

(Name of Firm/ Entity)

Authorized Signatory/ Statutory Auditor/ Chartered Accountant
(with Company Seal/Stamp)

Annexure 15

Security Bank Guarantee (Format)

_____ *[insert: **Bank's Name, and Address of Issuing Branch or Office**]*

Beneficiary: _____ *[insert: **Name and Address of Purchaser**]*
Date: _____

PERFORMANCE GUARANTEE No.: _____

We have been informed that *[insert: **name of Supplier**]* (hereinafter called "the Supplier") has received a Letter of Acceptance No. *[insert: **reference number of the Letter of Acceptance**]* dated _____ for entering into a Rate Agreement with you, for the supply of *[insert: **description of goods**]*

Furthermore, we understand that, according to the conditions of the Tender, a performance guarantee is required post acceptance of letter of Acceptance.

At the request of the Supplier, we *[insert: **name of Bank**]* hereby irrevocably undertake to pay you any sum or sums not exceeding in total an amount of *[insert: **amount in figures**]* (___) *[insert: **amount in words**]*[1] upon receipt by us of your first demand in writing accompanied by a written statement stating that the Supplier is in breach of its obligation(s) under the Tender , without your needing to prove or to show grounds for your demand or the sum specified therein.

This guarantee shall expire no later than the ____ day of _____, 2_____,[2] and any demand for payment under it must be received by us at this office on or before that date.

This guarantee is subject to the Uniform Rules for Demand Guarantees, ICC Publication No. 758, except that subparagraph (ii) of Sub-article 20(a) is hereby excluded.

_____
[signature(s)]

The Guarantor shall insert an amount representing the percentage of the Price specified in the letter of Acceptance and denominated in the currency of the Contract.

Established in accordance with tender conditions taking into account any warranty obligations of the Supplier as per tender conditions The Purchaser should note that in the event of an extension of the time to perform the Contract, the Purchaser would need to request an extension of this guarantee from the Guarantor. Such request must be in writing and must be made prior to the expiration date established in the guarantee. In preparing this guarantee, the Purchaser might consider adding the following text to the form, at the end of the penultimate paragraph: "The Guarantor agrees to a one-time extension of this guarantee for a period not to exceed [six months] [one year], in response to the Purchaser's written request for such extension, such request to be presented to the Guarantor before the expiry of the guarantee."

Annexure 16

CONSIGNEE RECEIPT CERTIFICATE

(To be given by consignee's authorized representative)

The following store(s) has/have been received in good condition:

1) P.O No. & date:_____
2) Supplier's Name:_____
3) Consignee's Name & Address with telephone No. & Fax No. : _____

   _____

   _____
4) Name of the items/equipment supplied:_____
5) Quantity of items/equipment Supplied:_____
6) Date of Receipt of items/equipment by the Consignee:_____
7) Name and designation of Authorized Representative of Consignee :_____
8) Signature of Authorized Representative of Consignee with date:_____
9) Counter Signed by Director/MS/Dean of the concerned Hospital/Institute:_____
10) Seal of the Consignee:_____

Annexure 17

Performa of Final Acceptance Certificate

No_____ **Date**_____

To
M/s _____

_____

_____

Subject: Certificate of commissioning of equipment/plant.

This is to certify that the equipment(s)/plant(s) as detailed below has/have been received in good conditions along with all the standard and special accessories and a set of spares (subject to remarks in Para no.02) in accordance with the tender/order/Purchase order/technical specifications. The same has been installed and commissioned.

(a) PONo_____ dated_____

(b) Description of the equipment(s)/plants: _____

(c) Equipment(s)/ plant(s) nos.:_____

(d) Quantity: _____

(e)

(h) Date of Installation/ commissioning
and Quality checktest date:_____

Details of accessories/spares not yet supplied.

Sl. No.	Description of Item	Quantity	Amount to be recovered

The proving test has been done to our entire satisfaction and operators have been trained to operate the equipment(s)/plant(s).

The supplier has fulfilled its contractual obligations satisfactorily or

The supplier has failed to fulfil its contractual obligations with regard to the following:

a) He has not supplied/provided the documents/ drawings pursuant to 'Technical Specifications'/tender.
b) He has not commissioned the equipment(s)/plant(s) in time, i.e. within the period specified in the contract and there is delay of ….days
c) The supplier has not done training of personnelas specified in the contract.

(Signature)
(Name)
(Designation with stamp)

(Counter Signed by Director/MS/Dean of the concerned Hospital/Institute)

Explanatory notes for filling up the certificate:

i) In the event of documents/drawings having not been supplied or installation and commissioning of the equipment(s)/plant(s) having been delayed on account of the supplier, the extent of delay should always be mentioned in clear terms.