Minutes of the 2nd Technical Specification Committee Meeting for approval of technical specifications of equipment, test kits and drugs under National Viral Hepatitis Control Program (NVHCP) held on 31st January 2019 at room No 439A, Nirman Bhawan, New Delhi

A meeting of the Technical Specification Committee constituted under the DteGHS for approval of the technical specifications of equipment, test kits and drugs was held under the chairmanship of Dr B. D, Athani on 31st January 2019 at room No 439A, Nirman Bhawan, New Delhi. The committee was apprised about the recent approval of Hepatitis B treatment under the NVHCP in addition to Hepatitis C treatment by Dr Sandhya Kabra. It was also informed that the screening of pregnant woman for HBsAg would be carried out in the States having less than 80% institutional deliveries to advocate institutional deliveries and ensuring birth dose vaccination for Hepatitis B and also administration of Hepatitis B immunoglobulin (HBIG) to those newborn born to the positive mothers.Hence the need for approving the rapid serological test kits including whole blood kits for testing at the peripheral health care setup, HBIG and the drugs for treating the HBV infected population. Also those equipment which could not be finalized in the 1st Technical Specification Committee meeting due to paucity of time were also placed before the committee. The technical specifications were also reviewed by the relevant Technical Resource Group under the program earlier.

The following members attended the meeting

1. Dr Sandhya Kabra, Addl. Dircetor, NCDC/MoHFW
2. Dr Shivali Kamal, Consultant, Lab Services, NACO as representative of Dr R.S. Gupta, DDG, NACO
3. Dr S. Anuradha, Director Professor, Medicine, MAMC, Delhi
4. Dr Vaishali, Head of the Dept., Gastroenterology, PGIMER & RML Hospital, New Delhi
5. Dr Aashish Choudhary, Asst. Professor, Virology , AIIMS, New Delhi as representative of Dr Lalit Dar, Professor, Virology, AIIMS, New Delhi
6. Dr Richa Baranwal, Scientist III & Head, Immunodiagnostic kits & Molecular diagnostic lab, NIB, NOIDA
7. Dr Reba Chhabra, Scientist I &incharge DDQC Diagnostic, NIB NOIDA
8. Mr Sella Senthil, Asst Drug Controller (India) – representative Drug Controller General of India
9. Dr Partha Rakshit, Deputy Director NCDC/MoHFW& Member Secretary, Technical Specification Committee for equipment, kits & drugs under NVHCP

Agenda 1

To discuss and finalise the technical specification of the equipment to be used under the NVHCP and other related programs

All annexures with respect to items of the equipment were reviewed and the following decision were taken

1.GEL DOCUMENTATION SYSTEM

Technical specifications

1. Gel imaging system to visualize i) Stained protein gels (coomassie blue, silver, UV light-excited fluorescent stains) and ii) Stained nucleic acid gels (ethidium bromide and other UV light excited fluorescent stains).
2. Compact benchtop instrument
3. Gel doc system should have sensitive, multimode image capture and analysis via an intuitive touchscreen interface.
4. Camera- high speed USB technology for faster image capture and download
5. Auto focus configuration.
6. Auto exposure setting for optimum image exposure time
7. Should have 5 mega pixel or more 16 bit cooled CCD camera with resolution not less than 1200 X 1000.
8. Operating temperature should be 10°C to 28°C (21°C is recommended).
9. There should be at least 5 position motorized filter wheel.
10. System should have pull out transilluminator (UV and white) tray.
11. Illumination/ Excitation source covering wavelengths of 254, 302 and 365nm trans UV, epiwhite. Should have large 10.4 inch touchscreen display with an integrated computer with >200GB hard drive. Wide transillumination area to capture larger gels.
12. Should automatically calculate the exposure time.
13. System should have the capability to automatically capture a series of images using preset or user defined exposure times.
14. Should have Innovative molecular weight overlay feature to allow a colorimetric molecular weight marker to be overlaid onto a chemiluminescent image for molecular weight determination without compromising the underlying chemiluminescent densitometry data
15. At least 3 USB & 1 Network Port
16. Should be an open platform to accept standard image file types (i.e., TIFF, JPEG, PNG, GIF, BMP files).
17. Applications Fluorescence (SYBR Green/GFP/Fluorescein/EtBr/Texas Red/SYBR-Gold/SYBR-Safe/SYBR Orange),Chemiluminescence,colorimetry, densitometry, and gel documentation (Gels, blots, Plates, Microtiter Plates, Microarray)
18. Licensed software for image capturing, data analysis including dendrogram, densitometry
19. Field of View 20 x 24 cm or more.
20. Data station i5 or better processor, 4 GB RAM, 1TB HDD, DVD Read/writer, 1.44 MB FDD, 22" color monitor, Optical mouse, Genuine Window-8 OS, Licensed security

software, Multimedia kit along with 1GB graphics card including all accessories like UPS with at least ½ hour backup.

21. Essential accessories Additional UV illuminator with 20 x 20 cm or more platform size and one set of UV and white lamps for Dark room.

General specifications:

1. Satisfactory working report of the quoted model fromatleast one reputed government institutes/hospitals should be included (within last two years of submission of bid).
2. All equipment should specify Design qualifications, Installation qualifications, Operational Qualifications and Performance qualifications. Validation and calibration reports should have traceability towards applicable national / international standards.
3. Original product catalogue should be provided by the firm.Necessary documents, technical write up in English shall be attached with the offer both in hard and soft copies.Performance, efficiency, other factors such as distortion etc. as applicable be also furnished.
4. Installation: the bidder must arrange for the equipment to be installed by certified or qualified personnel; any prerequisites for installation to be communicated to the laboratory in advance. Onsite, in lab customer training to be provided.The equipment should be supplied with minimum 2 meter cord at input and fitted with plugs of appropriate rating(5/15Amp)
5. 5 years back to back warranty followed by 5 year CMC should be provided by the company and warranty should commence only after delivery of satisfactory working report within 2 weeks of installation.
    a. Complete with comprehensive set of spare parts.
    b. The make, rating, model, description, specifications, quantity of each item shall be furnished separately.
    c. Downtime commitment to be restricted to maximum period of 48 hours in metro cities and 96 hours in hard to reach areas (working days) and punitive actions shall be taken in case of failure to maintain the desirable downtime.
    d. Preventive maintenance plan and technical support to be provided.
6. A suitable voltage stabilizer to be given. A line voltage corrector of appropriate rating should form part of standard configuration. Copper wound single phase automatic line voltage corrector conforming to IS: 9815(5t.l)/94 with latest amendments or equivalent international standards fitted with a voltmeter and switch to indicate output/input voltage as under:
    a. Capacity/rating: 10 KVA: As per the requirement of the equipment.
    b. Output voltage: 220 volts ± 10% volts. Input-out voltmeter and ampere meter. Protection: high-low voltage cut-off, overload and short circuit protection.
7. Certifications:
    a. Product Certification: CE Class II A or US FDA certified
    b. Quality Certification: BIS/ISO certified
    c. Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I)

<u>The committee approved the specification of the Gel Documentation system</u>

2. MICROPIPETTES SINGLE CHANNEL OF VARIABLE VOLUME (0.1-2µl,1-10 µl, 2-20 µl, 20-200 µl and 100-1000 µl).

Technical specifications

1. Extremely light pipetting action by tension free spring mechanism
2. Fully autoclavable(121^{0}C):UV resistant material
3. Volume locking system
4. Increments at least 0.1µl fine adjustment for pipettes expect for 100-1000 µl volume pipette where increments can be read as 0.5 µl
5. Suitable for all brands of tips.
6. Adjustable for variable volume;fixation of adjustable volumes
7. Three defined stops(single button operation preferred)
    a. take up from first stop
    b. dispensing and blow out
    c. tip ejection
8. Slim pipette shaft
9. Cone for standard tips
10. Safe cone filter lock
11. Easy and safe tip ejector mechanism.
12. Made of corrosion proof material.
13. Accuracy ≥98.5%
14. Precision ≥ 99.4%
15. Should be capable of being stored and operable at ambient temperature
16. Provide GLP protocols
17. Provision of onsite/external calibration
18. Stand for micropippetes should be provided.

General specifications:

1. Satisfactory working report of the quoted model from three reputed government institutes/hospitals should be included(within last two years of submission of bid).
2. All equipment should specify Design qualifications, Installation qualifications, Operational Qualifications and Performance qualifications. Validation and calibration reports should have traceability towards applicable national / international standards.
3. Original product catalogue should be provided by the firm.Necessary documents, technical write up in English shall be attached with the offer both in hard and soft copies.Performance, efficiency, other factors such as distortion etc. as applicable be also furnished.
4. Onsite, in - lab customer training to be provided
5. 2 years back to back warranty with preventive maintenance will be provided by the company. Warranty should commence only after delivery of satisfactory working report .
    a. Complete with comprehensive set of spare parts.
    b. The make, rating, model, description, specifications, quantity of each item shall be furnished separately.

3. ADJUSTABLE VOLUME DIGITAL MULTIPLE CHANNEL MICROPIPETTES

Technical Specifications

1. ISO 8655 certified digital multichannel pipettes of variable volume suitable for all brands of tips.
2. Microprocessor controlled motor, rechargeable battery pack with charging adapter
3. Pipetting Modes: Autodispense, Dispense, Pipetting, Pipetting and mixing, Manual pipetting, Sequential pipetting and dispensing
4.

Range	Increment	Precision	Type
5 to 50µL	0.5µL	2.0 to 0.7%	8 channel
			12 channel
30-300 µL	5µL	1.5to 0.3%	8 channel
			12 channel

6. Extremely light pipetting action by tension free spring mechanism
7. Fully autoclavable(121^{0}C):UV resistant material
8. Volume locking system
9. Adjustable for variable volume;fixation of adjustable volumes
10. Safe cone filter lock.
11. With easy and tip ejector mechanism.
12. Made of corrosion proof material.
13. Should be capable of being stored and operable at ambient temperature
14. Provide GLP protocols
15. Provision of onsite and external calibration
16. Stand for micropippetes should be provided.
17. Desirable: a history function, Service interval warning, Sequential tip ejection

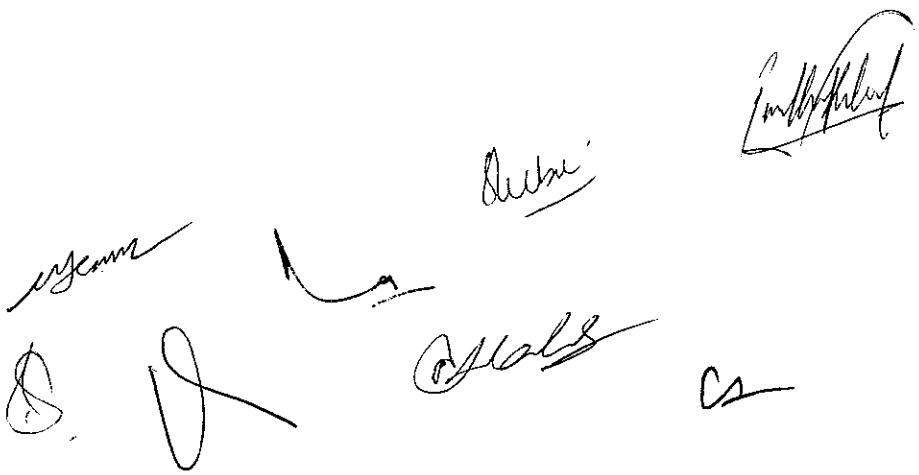
General specifications:

1. Satisfactory working report of the quoted model from three reputed government institutes/hospitals should be included(within two years of submission of bid).
2. All equipment should specify Design qualifications, Installation qualifications, Operational Qualifications and Performance qualifications. Validation and calibration reports should have traceability towards applicable national / international standards.
3. Original product catalogue should be provided by the firm.Necessary documents, technical write up in English shall be attached with the offer both in hard and soft copies.Performance, efficiency, other factors such as distortion etc. as applicable be also furnished.
4. Onsite, in - lab customer training to be provided

c. Downtime commitment to be restricted to maximum period of 48 hours in metro cities and 96 hours in hard to reach areas (working days) and punitive actions shall be taken in case of failure to maintain the desirable downtime.
d. Preventive maintenance plan and technical support to be provided.

6. Certifications:
   a. Product Certification : CE Class II A or US FDA certified
   b. Quality Certification : BIS/ISO certified

The committee approved the specification of the Micropipettes single channel of variable volume (0.1-2µl,1-10 µl, 2-20 µl, 20-200 µl and 100-1000 µl)



5. 2 years back to back warranty followed by 2 year CMC should be provided by the company and warranty should commence only after delivery of satisfactory working report .
    a. Complete with comprehensive set of spare parts.
    b. The make, rating, model, description, specifications, quantity of each item shall be furnished separately.
    c. Downtime commitment to be restricted to maximum period of 48 hours in metro cities and 96 hours in hard to reach areas (working days) and punitive actions shall be taken in case of failure to maintain the desirable downtime.
    d. Preventive maintenance plan and technical support to be provided.

6. Certifications:
    a. Product Certification : CE Class II A or US FDA certified
    b. Quality Certification : ISO 8655 certified

<u>The committee approved the specification of adjustable volume digital multichannel micropipettes</u>

4. BIOLOGICAL SAFETY CABINET (CLASS II TYPE A2)

The committee decided that the technical specifications approved under the NACO program shall be used for the NVHCP (annexed)

5. HOT AIR OVEN

Technical specifications

1. Microprocessor based digitally controlled.
2. Integrated programmable timer
3. programs stored on power failure
4. display of temperature
5. Should have double walled construction, special high quality insulated steel.
6. Enamel painted steel exterior.
7. Facility for adjustable shelves, 3 removable shelves to be provided.
8. Volume of inner chamber approx. 125 - 250litres stainless steel corrosion resistant with internal lighting facility
9. Two doors, insulated door fitted with heavy hinges, mechanical door lock.
10. Temperature range 10-220^{o}C, digitally temperature setting accuracy +/- 1^{0}C
11. Separate PT 100 sensor and display for temperature (LCD).
12. Forced uniform air circulation by air fan
13. Air fan<60dBA at full speed; speed adjustable
14. Adjustable air flap for preheated fresh air intake
15. Vent connection with restrictor flap
16. Alarm; audible ,with display on dysfunction
17. Digitally adjustable electronic temperature controller, TWW protection class 3.1.
18. Mechanical temperature limiter at fixed value 10^{0}C above maximal hot air oven temperature.
19. Switch off function at approximately 10^{0} C above the temperature set
20. High quality heating element. Element to be included in warranty and CMC.
21. Power Supply
    a. Power input to be 220-240V AC, 50Hz,
    b. Resettable over current breaker shall be fitted for protection.

General specifications:

1. Satisfactory working report of the quoted model from three reputed government institutes/hospitals should be included(within two years of submission of bid).
2. All equipment should specify Design qualifications, Installation qualifications, Operational Qualifications and Performance qualifications. Validation and calibration reports should have traceability towards applicable national / international standards.
3. Original product catalogue should be provided by the firm. Necessary documents, technical write up in English shall be attached with the offer both in hard and soft copies. Performance, efficiency, other factors such as distortion etc. as applicable be also furnished.

4. Installation: the bidder must arrange for the equipment to be installed by certified or qualified personnel; any prerequisites for installation to be communicated to the laboratory in advance. Onsite, in lab customer training to be provided.The equipment should be supplied with 2 meter cord at input and fitted with plugs of appropriate rating(5/15Amp)
5. 5 years back to back warranty followed by 5 year CMC should be provided by the company and warranty should commence only after delivery of satisfactory working report.
    a. Complete with comprehensive set of spare parts.
    b. The make, rating, model, description, specifications, quantity of each item shall be furnished separately.
    c. Downtime commitment to be restricted to maximum period of 48 hours in metro cities and 96 hours in hard to reach areas (working days) and punitive actions shall be taken in case of failure to maintain the desirable downtime.
    d. Preventive maintenance plan and technical support to be provided.
6. A suitable in built voltage stabilizer to be given. A line voltage corrector of appropriate rating should form part of standard configuration. Copper wound single phase automatic line voltage corrector conforming to IS: 9815(5t.I)/94 with latest amendments or equivalent international standards fitted with a voltmeter and switch to indicate output/input voltage as under:

a. Capacity/rating: 10 KVA: As per the requirement of the equipment.
b. Output voltage: 220 volts ± 10% volts. Input-out voltmeter and ampere meter. Protection: high-low voltage cut-off, overload and short circuit protection.

7. Certifications:
    a. Product Certification : CE Class II A or US FDA certified
    b. Quality Certification : BIS/ISO certified
    c. Electrical Safety : Equipment meets electrical safety specifications such as that of IEC (Class I)

<u>The committee approved the specification of Hot air oven</u>

6. WATER BATH

Technical specifications:

1. Stainless steel SS304 chamber interior.
2. Benchtop. Capacity: 12-16 Liters
3. Microprocessor controlled.
4. Simultaneous display of set and actual temperature, time and RPM
5. Independent timer with sound signal
6. Temperature range 25 - 100°C
7. Increased temperature stabilization due to built-in magnetic stirrer (regulated speed 300-1000 rpm).
8. Temperature setting via a keypad and digital display; thermostat control knob and on/off switch should be available
9. Adjustable shaking speed.
10. RTD Temperature Sensor.
11. PID Temperature Controller.
12. Accurate temperature control
13. Over Temperature protection.
14. Thermostat equipped with flowing water cooler.
15. High safety level for constant operation
16. The heater for chamber located at outside bottom of water chamber, not inside chamber.
17. Shaking motion-linear.
18. Over Current Protection.
19. Variable fluid level to allow different sample sizes without refilling or overflowing the bath.
20. Proper insulation between outer and inner walls to prevent heat loss.
21. Should provide cover, diffuser tray and drain hose.
22. Water bath should be provided with a drain plug to facilitate easy emptying and cleaning of inner chamber.
23. Should have safety features including audible alarm, adjustable digital over-temperature protection, low-level detection and high-temperature cut-offs
24. Power supply: 220-240V AC,50Hz

General specifications:

1. Satisfactory working report of the quoted model from three reputed government institutes/hospitals should be included(within two years of submission of bid).
2. All equipment should specify Design qualifications, Installation qualifications, Operational Qualifications and Performance qualifications. Validation and calibration reports should have traceability towards applicable national / international standards.
3. Original product catalogue should be provided by the firm.Necessary documents, technical write up in English shall be attached with the offer both in hard and soft copies.

Performance, efficiency, other factors such as distortion etc. as applicable be also furnished.

4. Installation: the bidder must arrange for the equipment to be installed by certified or qualified personnel; any prerequisites for installation to be communicated to the laboratory in advance. Onsite, in lab customer training to be provided. The equipment should be supplied with 2 meter cord at input and fitted with plugs of appropriate rating(5/15Amp)
5. 5 years back to back warranty followed by 5 year CMC should be provided by the company and warranty should commence only after delivery of satisfactory working report.
    a. Complete with comprehensive set of spare parts.
    b. The make, rating, model, description, specifications, quantity of each item shall be furnished separately.
    c. Downtime commitment to be restricted to maximum period of 48 hours in metro cities and 96 hours in hard to reach areas (working days) and punitive actions shall be taken in case of failure to maintain the desirable downtime.
    d. Preventive maintenance plan and technical support to be provided.
6. A suitable voltage stabilizer to be given. A line voltage corrector of appropriate rating should form part of standard configuration. Copper wound single phase automatic line voltage corrector conforming to IS: 9815(5t.I)/94 with latest amendments or equivalent international standards fitted with a voltmeter and switch to indicate output/input voltage as under:
    a. Capacity/rating: 10 KVA: As per the requirement of the equipment.
    b. Output voltage: 220 volts ± 10% volts. Input-out voltmeter and ampere meter. Protection: high-low voltage cut-off, overload and short circuit protection.
7. Certifications:
    a. Product Certification : CE Class II A or US FDA certified
    b. Quality Certification : BIS/ISO certified
    c. Electrical Safety : Equipment meets electrical safety specifications such as that of IEC (Class I)

<u>The committee approved the specification of water bath</u>

7. BOD INCUBATOR

Technical Specifications

1. Double walled construction, inner chamber stain less steel.
2. Inside full length observation glass/ transparent door.
3. Size of inner chamber approximately 50x60x50 cm.
4. Facility for adjustable shelves to convenient heights, 4-5 removable shelves of stainless steel/ anodized aluminum to be supplied.
5. Interior lighting facility,insulated door fitted with heavy hinges handle locking, mechanical door lock.
6. Microprocessor controlled
7. Temperature range:5° to 60°C with accuracy 0.5°C
8. Independent temperature measuring through PT 100 sensor with indicator LCD display
9. Recovery time short, precise regulation of temperature and acoustic alarm.
10. Digital safety thermostat (class 3)
11. Audiovisual alarm and sensor to cut off supply in case of temperature malfunction
12. Adjustable ventilation rate 10 – 100% thin form air circulation.
13. Environmental factors: The unit shall be capable of operating continuously ambient temperature of 10 -45°C and relative humidity of 15-95%.
14. Power Supply:-Power input to be 220-240VAC, 50Hz
15. Resettable over current breaker shall be fitted for protection
16. Suitable UPS with maintenance free batteries for minimum one-hour back-up should be supplied with the system.

General specifications:

1. Satisfactory working report of the quoted model from three reputed government institutes/hospitals should be included(within two years of submission of bid).
2. All equipments should specify Design qualifications, Installation qualifications, Operational Qualifications and Performance qualifications. Validation and calibration reports should have traceability towards applicable national / international standards.
3. Original product catalogue should be provided by the firm.Necessary documents, technical write up in English shall be attached with the offer both in hard and soft copies.Performance, efficiency, other factors such as distortion etc. as applicable be also furnished.
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5. 5 years back to back warranty followed by 5 year CMC should be provided by the company and warranty should commence only after delivery of satisfactory working report.

a. Complete with comprehensive set of spare parts.
b. The make, rating, model, description, specifications, quantity of each item shall be furnished separately.
c. Downtime commitment to be restricted to maximum period of 48 hours in metro cities and 96 hours in hard to reach areas (working days) and punitive actions shall be taken in case of failure to maintain the desirable downtime.
d. Preventive maintenance plan and technical support to be provided.

6. A suitable voltage stabilizer to be given. A line voltage corrector of appropriate rating should form part of standard configuration. Copper wound single phase automatic line voltage corrector conforming to IS: 9815(5t.I)/94 with latest amendments or equivalent international standards fitted with a voltmeter and switch to indicate output/input voltage as under:

a. Capacity/rating: 10 KVA: As per the requirement of the equipment.
b. Output voltage: 220 volts ± 10% volts. Input-out voltmeter and ampere meter. Protection: high-low voltage cut-off, overload and short circuit protection.

7. Certifications:
   a. Product Certification : CE Class II A or US FDA certified
   b. Quality Certification : BIS/ISO certified
   c. Electrical Safety : Equipment meets electrical safety specifications such as that of IEC (Class I)

The committee approved the specificotion of BOD incubotor

8. VORTEX MIXER

1. Sturdy housing ,metal coated,disinfectable
2. Digital display of speed
3. Rotation speed 0-2500rpm, strong orbital movements
4. Standing on four rubber feet design to prevent sliding of the instrument during shaking
5. Two operating modes : continuous and touch function
6. Slip resistant stand
7. Overheating protection
8. Permissible ambient temperature and relative humidity: 5-40^{0}C and $\leq$ 80%
9. Should provide integrated rubber adopter with tube holder and one additional rubber adapter.
10. Adaptor for mixing up to 18 micro tubes (6 x 0.5 ml, 6 x 1.5 ml).
11. Should have speed regulator control system.
12. It should have the interchangeable platform pad with variable for 50 ml tube and micro centrifuge tube.
13. Should have heavy duty AC motor.
14. Must have unique touch feature operate the unit when tube is pressed on the rubber cup.

General specifications:

1. Satisfactory working report of the quoted model from three reputed government institutes/hospitals should be included(within two years of submission of bid).
2. All equipments should specify Design qualifications, Installation qualifications, Operational Qualifications and Performance qualifications. Validation and calibration reports should have traceability towards applicable national / international standards.
3. Original product catalogue should be provided by the firm.Necessary documents, technical write up in English shall be attached with the offer both in hard and soft copies. Performance, efficiency, other factors such as distortion etc. as applicable be also furnished.
4. Installation: the bidder must arrange for the equipment to be installed by certified or qualified personnel; any prerequisites for installation to be communicated to the laboratory in advance. Onsite, in lab customer training to be provided.The equipment should be supplied with 2 meter cord at input and fitted with plugs of appropriate rating(5/15Amp)
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    a. Complete with comprehensive set of spare parts.
    b. The make, rating, model, description, specifications, quantity of each item shall be furnished separately.

c. Downtime commitment to be restricted to maximum period of 48 hours in metro cities and 96 hours in hard to reach areas (working days) and punitive actions shall be taken in case of failure to maintain the desirable downtime.
d. Preventive maintenance plan and technical support to be provided.

6. Certifications:
   a. Product Certification : CE Class II A or US FDA certified
   b. Quality Certification : BIS/ISO certified
   c. Electrical Safety : Equipment meets electrical safety specifications such as that of IEC (Class I)

<u>The committee approved the specification of Vortex mixer</u>

9. VERTICAL AUTOCLAVE

1) Sterilization chamber volume of ≥70 liters
2) Sterilization chamber dimensions (width 30-40 cm, height 70-80cm)
3) Microcomputer controlled system
4) The sterilization chamber – triple walled unit constructed of corrosion resistant stainless steel (SS 304).
5) Heating device (steam generator) horizontally mounted,preferably separated from the chamber with minimal water volume(4-7 litres)
6) Air removed by upward displacement
7) Automatic water feed, connection to a demineralized water supply
8) Integrated pump to equalize pressure variations in external supply lines
9) Automatic level control before, during and after the sterilization cycle
10) Low water level cut out device
11) LCD/LED Display for temperature, steam pressure, sterilization time, stage of cycle and warning/alarm alert checks along with control panel
12) Automatic sterilization system for unattended operation
13) Maximum operating tempaerature:134^{0}C
14) Maximum operating pressure: 2.5 bar
15) Sterilization timer 1/250 minutes
16) The pressure gauge attached to the front side for easy check
17) A control panel with
    a. Temperature setting keys to increase/ decrease temperature
    b. Real time temperature display
    c. Graphical display which shows the progress of sterilization cycle throughout the process
    d. Time display and keys to set time
18) The instrument should have Mechanical Safety Devices :-
    a. Over current protection
    b. Over temperature protection by automatic power cutoff
    c. Over pressure protection by automatic and manual safety valve
19) The instrument should have Safety Warning System/ alarm
    a. Over temperature warning
    b. Sterilization fail warning
    c. Low water level
20) Supplied with two suitable stackable perforated stainless steel bucket with handle for sterilization
21) Supplied with an Extra silicone or suitable gasket.
22) Lid made of SS304 with insulation cover to prevent hot burns to user
23) Top opening lid, should have foot mediated opening facility also. Fast safety lid lock.
24) Control lock-out switch that prevents starting a cycle if the door is not locked safely
25) Control that prevents opening the door until chamber is depressurized.
26) Temperature dependent door locking system according to international standards.
27) Exhaust valve knob and air release knob should be present
28) An exhaust bottle to recover and cool down the steam exhausted from the chamber. The steam should not be exhausted openly in the room

29) Drain port for draining water inside the chamber
30) Water level sensor to detect & display warning if water level is below acceptable range
31) Element heater to heat the sterilizing water inside the chamber
32) Piping diagram demonstrating the flow of water and steam should be there in the accompanying manual
33) **Power Supply:** 220/230 volts AC-50 Hz 3 phase

General specifications:

1. Satisfactory working report of the quoted model from any reputed government institutes/hospitals should be included(within two years of submission of bid).
2. All equipments should specify Design qualifications, Installation qualifications, Operational Qualifications and Performance qualifications. Validation and calibration reports should have traceability towards applicable national / international standards.
3. Original product catalogue should be provided by the firm.Necessary documents, technical write up in English shall be attached with the offer both in hard and soft copies.Performance, efficiency, other factors such as distortion etc. as applicable be also furnished.
4. Installation : the bidder must arrange for the equipment to be installed by certified or qualified personnel; any prerequisites for installation to be communicated to the laboratory in advance. Onsite, in lab customer training to be provided.The equipment should be supplied with 2 meter cord at input and fitted with plugs of appropriate rating(5/15Amp)
5. 5 years back to back warranty followed by 5 year CMC should be provided by the company and warranty should commence only after delivery of satisfactory working report.
    a. Complete with comprehensive set of spare parts.
    b. The make, rating, model, description, specifications, quantity of each item shall be furnished separately.
    c. Downtime commitment to be restricted to maximum period of 48 hours in metro cities and 96 hours in hard to reach areas (working days) and punitive actions shall be taken in case of failure to maintain the desirable downtime.
    d. Preventive maintenance plan and technical support to be provided.
6. A suitable voltage stabilizer to be given. A line voltage corrector of appropriate rating should form part of standard configuration. Copper wound single phase automatic line voltage corrector conforming to IS: 9815(5t.I)/94 with latest amendments or equivalent international standards fitted with a voltmeter and switch to indicate output/input voltage as under:

a. Capacity/rating: 10 KVA: As per the requirement of the equipment.
b. Output voltage: 220 volts ± 10% volts. Input-out voltmeter and ampere meter. Protection: high-low voltage cut-off, overload and short circuit protection.

7. Certifications:
    a. Product Certification : CE Class II A or US FDA certified
    b. Quality Certification : BIS/ISO certified
    c. Electrical Safety : Equipment meets electrical safety specifications such as that of IEC (Class I)

The committee approved the specification of verticle autoclave

10.WATER PURIFICATION SYSTEM

Technical:

1. A compact water purification system with ISO 9001 certification and designed to be fed directly by potable tap water. Should have visual display for quality parameter, filter condition etc. Reservoir capacity of minimum 30 ltr. All necessary pre-filters should be provided.
2. The system should meet ASTM Type I, ISO 3696 andCLSI-CLRW specifications.
3. The system should have recirculation of the purified water to maintain consistent peak quality.
4. Cartridge identification technology provides full traceability and history of each cartridge for full validation and other GLP requirements.
5. Microprocessor controller complete water purification system, should comprise primary continuous electro-de-ionization attached to a tank followed by secondary ultrapure polishing system.
6. Additional one set of consumables should be provided.
7. Water softener at all the inlets
8. **Power Supply:** 210-240V/50-60 Hz
9. Final filtration provided by online UV and Ultra filtration cartridge to produce Dnase&Rnase free water.
10. Suitability of water for Mass spectrometry, HPLC, GLC, Molecular biology, proteomics, cell culture work and crystallization etc

11. Quality of ultra pure water provided by system should fulfill following criteria:–

a) Pretreatment system:

Three stage pretreatment system with 10, 5 & 1 micron spun filters 10" long for removal of suspended particles and to take care of F.I. and Chlorine in feed water.

b) Analytical grade water system:

The system should respond favourably to feed water having Fouling Index (FI) approx 10, total Free Chlorine <0.5 ppm and Feed Water Conductivity upto 2000 µs/cm; maximum silica 30 ppm.

Second stage purification process; primary purification by a pre-filter, secondary purification through RO membrane, final purification step should involve a self-regenerating Electro-deionization module to avoid cartridge replacement. System should be microprocessor controlled with continuous water purity monitoring. System should have photo-oxidation technology (with UV lamp) ensuring that bacteria counts are low.

System should have integral recirculation ensures optimum water quality at point of dispense.

Product Water Quality of Type 2 water:

Resistivity	:	10 to >15 mΩ at 25 deg. C (megaohm C).
TOC	:	<20 ppb
Bacteria	:	<1CFU/10ml
Flow rate	:	10 liters / Hr at 25 deg. C.
pH	:	Effectively neutral.

12. System should have 30 - 40 liters HDPE reservoir with level sensors and switches from Original Manufacturer.
13. Third Stage system should have facility to remove Ionic and organic impurities by the polishing purification pack. Product water resistivity and temperature are measured before dispense and indicate when the purification pack needs to be replaced.
14. System should have auto volume dispense for drop by drop facility like a pipette (50ml to 7500ml).
15. System should have on-line monitoring for Resistivity or Conductivity and TOC.
16. System should have height adjustable dispenses point which glides easily up and down to accommodate any size of container.
17. System should have one time sanitization for 1 year.
18. The water within the unit should be recirculated through the purification technologies to maintain purity. To reduce heat buildup the recirculation is at reduced flow rate and is set to be intermittent (10 minus every hour).
19. The system should have the safety feature includes –Low feed Shut-Off, Audio-Visual Alarms, PIN coded system settings, Dispense shut-off during disinfection Auto-restart.

Product water quality of Type 1 water or Ultra- pure water:

- Resistivity : >18.2M Ω -cm @ 25oC
- Conductivity :<0.056microsec/cm
- TOC : <5 ppb
- Bacteria : < 0.1 CFU/ml
- RNase : <0.002 ng/ml
- Bacteria endotoxin: :<0.001EU/ml
- Flow Rate : 2 Ltr./min.
- Particles : Ultrafilteration

General specifications:

1. Satisfactory working report of the quoted model from three reputed government institutes/hospitals should be included (within two years of submission of bid).
2. All equipments should specify Design qualifications, Installation qualifications, Operational Qualifications and Performance qualifications. Validation and calibration reports should have traceability towards applicable national / international standards.
3. Original product catalogue should be provided by the firm. Necessary documents, technical write up in English shall be attached with the offer both in hard and soft copies. Performance, efficiency, other factors such as distortion etc. as applicable be also furnished.
4. Installation : the bidder must arrange for the equipment to be installed by certified or qualified personnel; any prerequisites for installation to be communicated to the laboratory in advance. Onsite, in lab customer training to be provided.The equipment should be supplied with 2 meter cord at input and fitted with plugs of appropriate rating(5/15Amp)
5. 5 years back to back warranty followed by 5 year CMC should be provided by the company and warranty should commence only after delivery of satisfactory working report.

a. Complete with comprehensive set of spare parts.
b. The make, rating, model, description, specifications, quantity of each item shall be furnished separately.
c. Downtime commitment to be restricted to maximum period of 48 hours in metro cities and 96 hours in hard to reach areas (working days) and punitive actions shall be taken in case of failure to maintain the desirable downtime.
d. Preventive maintenance plan and technical support to be provided.

6. A suitable voltage stabilizer to be given. A line voltage corrector of appropriate rating should form part of standard configuration. Copper wound single phase automatic line voltage corrector conforming to IS: 9815(5t.l)/94 with latest amendments or equivalent international standards fitted with a voltmeter and switch to indicate output/input voltage as under:
   a. Capacity/rating: 10 KVA: As per the requirement of the equipment.
   b. Output voltage: 220 volts ± 10% volts. Input-out voltmeter and ampere meter. Protection: high-low voltage cut-off, overload and short circuit protection.

7. Certifications:
   a. Product Certification : CE Class II A or US FDA certified
   b. Quality Certification : BIS/ISO certified
   c. Electrical Safety : Equipment meets electrical safety specifications such as that of IEC (Class I)

The committee approved the specification of water purification system

11. Thermal Cycler

Technical Specifications:

1. 96 well, with 6 separate peltier blocks to provide independent temperature zones to run user defined gradient PCR to run six different temperature in the same run.
2. *PCR Volume Range*: 0.2ml or microplates; to accommodate PCR volumes ranging from 10- 80ul.
3. Block for 96 × 0.2 ml tubes; possibility to use block with 48 × 0.5 ml tubes and 96-well PCR plates.
4. Blocks must be resistant to oxidation.
5. **Run Mode:** Standard and fast run.
6. **Temperature:** Range +4-99°C; Accuracy +/-0.25°C from 35-99°C;Uniformity<0.5°C (20sec after reaching 95°C)
7. **Ramp rate:** Maximum should be 5°C / sec and adjustable between 3 -5°C /sec
8. Heatable lid with automatic height adaptation.
9. Electromechanical lid blocking to prevent accidental opening during a run.
10. Temperature range for lid: 80°C to103°C.
11. Optional: Interface for remote control via PC; activated RS 232 serial port.
12. **Program:** Around 800 typical programs; with USB flash drive expansion
13. **Power Supply:** Should include 210-240V/50-60 Hz Should have auto restart on power failure.
14. *Display Interface* : at least16.51 cm (6.5 in) VGA 32k color with touch screen.
15. *Tm Calculator*: Menu driven through touch screen.
16. Should be provided with UPS as per requirement.
17. Comprehensive warranty for 5 years.

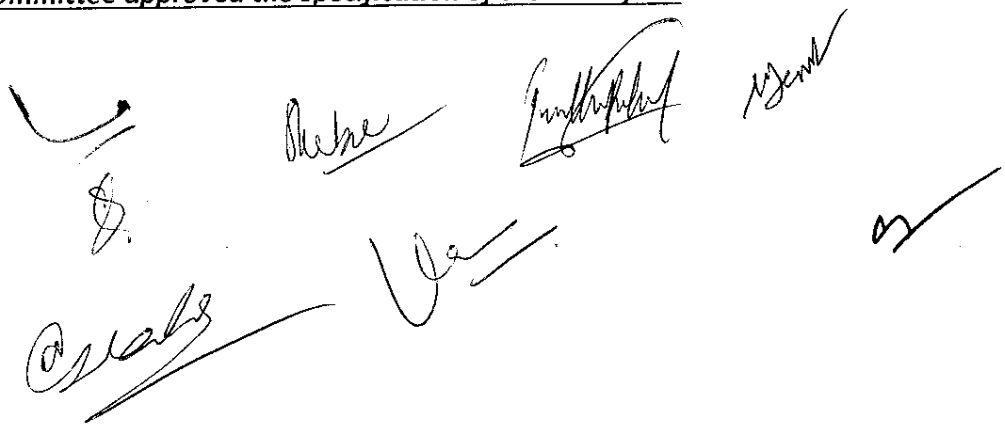
General Specifications:

1. Documentation- Manufacturer's certificate: The manufacturer must have a management system certified to ISO 9001.One certificate to state that the thermocycler has been calibrated at the factory and certified according to ISO 13485 quality regulations. Quality and safety standards met by the product must be listed.
2. Operation and maintenance manual: At least one set of operation, maintenance and service manuals written in English.
3. Installation and maintenance: The bidder must arrange for the equipment to be installed by certified or qualified personnel; any prerequisites for installation to be communicated to the purchaser in advance, in detail. The bidder to also provide user training (including how to use and maintain the equipment) and a comprehensive maintenance plan. The cost of the maintenance plan to be defined and guaranteed over the period of warranty. The supplier to provide an after-sale service that covers the whole country. The service to have competent staff, adequate infrastructure and

sufficient spare parts to be able to respond to any complaints and to repair or replace the thermocycler within 14 days.

4. Standard maintenance tools: All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer. Bidders to specify the quantity of every item included in their offer (including items not specified above).
5. Spare parts: Each thermocycler to be accompanied by an authorized list of accessories and spare parts. Set of fuses, if used separately in the instrument.

The committee approved the specification of thermal cycler



12. Next Generation Sequencing Setup

Technical Specifications

1) The sequencer should be capable of automated paired end sequencing and analysis without additional steps.
2) The system should be able to generate data output up to 120GB per run.
3) Sequence output should generate accurate base calls and high error free reads with greater than 75% bases with high quality Q30 Score at 2x150bp read length.
4) System should be able to generate upto 800 million paired-end reads from a single run enable robust counting applications like human whole genome and transcriptome sequencing, Exomeseq, RNA-seq and Chip seq.
5) The Sequencer should be able to read through at least 15 bases homo-polymer stretches in the genome accurately.
6) The system should offer the option of seamless integration with cloud computing environment to avoid manual data transfer and analysis.
7) System should occupy minimal lab foot print and should be offered as a single, integrated instrument capable of performing template DNA amplification and sequencing onboard on machine.
8) The sequencing chemistry should be robust and globally proven as demonstrated with more than 4500 peer reviewed publications.
9) The setup should include a server with following minimum specifications:
10) Manufactured by - HP/DELL/TOSHIBA/IBM/APPLE/LENOVO or other reputed brand.
11) Processor – Intel Xeon Processor, Minimum 2 processors with 12-18 Cores (thus a total of minimum 24-36 Cores), Clock Speed of minimum 2.5 GHz
12) Power Supply – Redundant – Double
13) Memory – 512 GB, DDR4 2133MHz (16*32GB) @ 2133 MHz or more (Motherboard must support memory of upto 1 TB)
14) Hard Disk – SSD =1TB x 1&DVD Writer x 1
15) SATA=3TB x 6 = 18TB 3.5' SATA 3.6 GBPS 7.2K RPM HDD
16) SAS = 1.2 TB x 2= 2.4TB, 10K RPM
17) Nvidia GT Graphics Card x 1
18) Latest Intel Chipset
19) Inter 1217 & 1210 Gigabit Ethernet controllers with Intel Remote Wake Up, PXE and Jumbo frames support.
20) The Setup should be fully functional when installed including ancillary equipment (e.g. temperature and humidity maintenance)
21) Power input 220-240VAC, 50 Hz
22) Compatible UPS- microprocessor controlled, line interactive, compatible pure sinewave online continuous transducer of ≥4 hours backup and maintenance battery

General specifications:

1. Satisfactory working report of the quoted model from any one reputed government institutes/hospitals should be included(within two years of submission of bid).
2. All equipments should specify Design qualifications, Installation qualifications, Operational Qualifications and Performance qualifications. Validation and calibration reports should have traceability towards applicable national / international standards.

3. Original product catalogue should be provided by the firm. Necessary documents, technical write up in English shall be attached with the offer both in hard and soft copies. Performance, efficiency, other factors such as distortion etc. as applicable be also furnished.
4. Installation: the bidder must arrange for the equipment to be installed by certified or qualified personnel; any prerequisites for installation to be communicated to the laboratory in advance. Onsite, in lab customer training to be provided. The equipment should be supplied with 2 meter cord at input and fitted with plugs of appropriate rating(5/15Amp)
5. 5 years back to back warranty followed by 5 year CMC should be provided by the company and warranty should commence only after delivery of satisfactory working report.
    a. Complete with comprehensive set of spare parts.
    b. The make, rating, model, description, specifications, quantity of each item shall be furnished separately.
    c. Downtime commitment to be restricted to maximum period of 48 hours in metro cities and 96 hours in hard to reach areas (working days) and punitive actions shall be taken in case of failure to maintain the desirable downtime.
    d. Preventive maintenance plan and technical support to be provided.
6. A suitable voltage stabilizer to be given. A line voltage corrector of appropriate rating should form part of standard configuration. Copper wound single phase automatic line voltage corrector conforming to IS: 9815(5t.l)/94 with latest amendments or equivalent international standards fitted with a voltmeter and switch to indicate output/input voltage as under:

a. Capacity/rating: 10 KVA: As per the requirement of the equipment.
b. Output voltage: 220 volts ± 10% volts. Input-out voltmeter and ampere meter. Protection: high-low voltage cut-off, overload and short circuit protection.

Certifications:

    a. Product Certification : CE Class II A or US FDA certified
    b. Quality Certification : ISO certified
    c. Electrical Safety : Equipment meets electrical safety specifications such as that of IEC (Class I)

7. Additional requirements
    a. Bidder to be responsible for site preparation (minor works), installation, commissioning, trial run etc of the system in laboratory. All reagents to make the machine functional along with trial runs to user satisfaction should be provided free of cost.
    b. Lab staff should be comprehensively trained on all the operational function of equipment. Satisfactory working report of machine will only be provided once the lab staff is trained to our satisfaction
    c. The supplier should be authorized dealer for the principal firm & should produce original certificate for the same
    d. The principal firm should provide certificate stating the machine is brand new.

<u>The committee approved the specification of next generation sequencer</u>

Annexure 4 The committee deliberated on the technical specification of the drugs/ immunoglobulin to be used under the NVHCP and finalized the following specifications

1) Tenofovir 300 mg (TDF)
2) Entecavir 0.5 mg
3) Entecavir 1mg
4) Hepatitis B Immunoglobulin (HBIG)

1) **Tenofovir 300 mg (TDF)**

Technical specifications:

1. Each tablet contains TenofovirDisoproxilFumarate 300mg
2. Number of tablets /capsules per container: 30 tablets/package
3. Should be licensed under the provisions of Drugs and Cosmetics Act and Rules
4. The product insert must indicate dosage form (tablet/capsule) and the drug content. The product should conform to standards of IP or any other pharmacopeia
5. The label must indicate clearly the manufacturing and the expiry dates

General specifications:

1. Standard Shelf Life: at least 18 months at the place of dispatch to the consignee
2. Primary Container: Suitable , Opaque Plastic Bottle to contain 30 tablets. It should be sealed with plastic plug/diaphragm and should contain silicon packs, and should have a tightly fitting suitable screw cap**OR** any other packaging subject to the approvals of the concerned authority based on which the license has been granted under the provisions of Drug and Cosmetic Act & Rules
3. Label: It should be glazed label in accordance with the statutory requirements as per drug and cosmetic Act. The standard color of the label as approved by NVHCP should be used. Each label should have clearly marked as "Government of India Supply, Not for sale" on primary packaging. The packaging and labelling requirements must meet the GMP practices
4. Each lot shall be tested in compliance with thepharmacopeia specifications by a designated laboratory before supply.

The committee approved the specification of Tenofovir 300 mg (TDF)

2) Entecavir 0.5 mg

1) Each tablet contains : Entecavir 0.5mg
2) Number of tablets per container: 30 tablets/package
3) Should be licensed under the provisions of Drugs and Cosmetics Act and Rules
4) The product insert must indicate dosage form (tablet) and the drug content. The product should conform to standards of IP or any other pharmacopeia
5) The label must indicate clearly the manufacturing and the expiry dates

General specifications

1. Standard Shelf Life: atleast 18 months at the place of dispatch to the consignee
2. Primary Container: Suitable , Opaque Plastic Bottle to contain 30 tablets. It should be sealed with plastic plug/diaphragm and should contain silicon packs, and should have a tightly fitting suitable screw cap**OR** any other packaging subject to the approvals of the concerned authority based on which the license has been granted under the provisions of Drug and Cosmetic Act & Rules
3. Label: It should be glazed label in accordance with the statutory requirements as per Drug and Cosmetic Act. The standard color of the label as approved by NVHCP should be used. Each label should have clearly marked as " Government of India Supply, Not for sale" on primary packaging. The packaging and labelling requirements must meet the GMP practices
4. Each lot shall be tested in compliance with the pharmacopeia specifications by a designated laboratory before supply.

The committee approved the specification of Entecavir 0.5 mg

3) Entecavir 1 mg

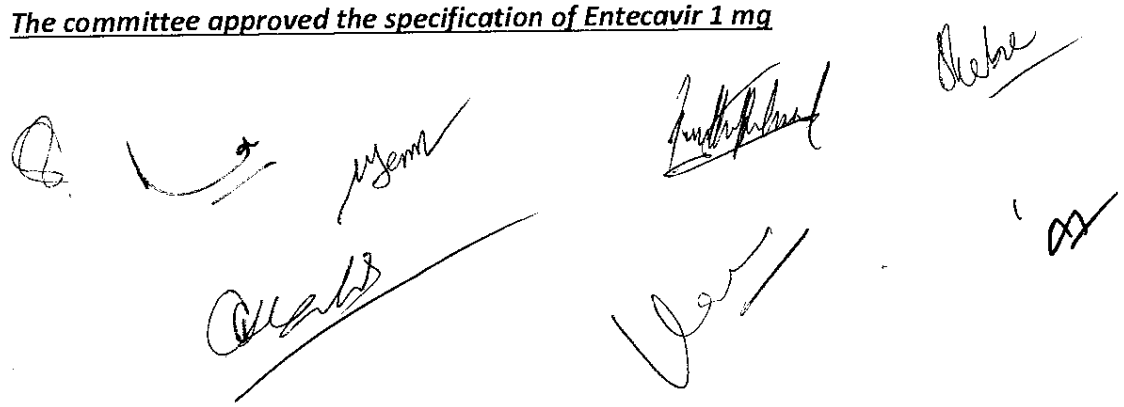
Technical specifications

1. Each tablet contains : Entecavir1mg
2. Number of tablets per container: 30 tablets/package
3. Should be licensed under the provisions of Drugs and Cosmetics Act and Rules
4. The product insert must indicate dosage form (tablet) and the drug content. The product should conform to standards of IP or any other pharmacopeia
5. The label must indicate clearly the manufacturing and the expiry dates

General specifications

1. Standard Shelf Life: atleast 18 months at the place of dispatch to the consignee
2. Primary Container: Suitable , Opaque Plastic Bottle to contain 30 tablets. It should be sealed with plastic plug/diaphragm and should contain silicon packs, and should have a tightly fitting suitable screw cap**OR** any other packaging subject to the approvals of the concerned authority based on which the license has been granted under the provisions of Drug and Cosmetic Act & Rules
3. Label: It should be glazed label in accordance with the statutory requirements as per drug and cosmetic Act. The standard color of the label as approved by NVHCP should be used. Each label should have clearly marked as " Government of India Supply, Not for sale" on primary packaging. The packaging and labelling requirements must meet the GMP practices
4. Each lot shall be tested in compliance with the pharmacopeia specifications by a designated laboratory before supply.

The committee approved the specification of Entecavir 1 mg



The meeting ended with a vote of thanks to the chair

Dr Sandhya Kabra, Addl. Dircetor, NCDC/MoHFW	
Dr Shivali Kamal, Consultant, Lab Services, NACO	
Dr S. Anuradha, Director Professor, Medicine, MAMC, Delhi	
Dr Vaishali, Head of the Dept., Gastroenterology, PGIMER & RML Hospital, New Delhi	
Dr Aashish Choudhary, Asst. Professor, Virology , AIIMS, New Delhi	
Dr Richa Baranwal, Scientist III & Head, Immunodiagnostic kits & Molecular diagnostic lab, NIB, NOIDA	
Dr Reba Chhabra, Scientist I &incharge DDQC Diagnostic, NIB NOIDA	
Mr Sella Senthil, Asst Drug Controller (India)	
Dr Partha Rakshit, Deputy Director NCDC/MoHFW& Member Secretary	

DR B.D. ATHANI
CHAIRMAN

Annexure.

Minutes of the meeting of Technical Specifications Committee held on 27th Nov 2018 to review the specification of Ancillary Equipments required for setting up Viral Load Labs.

- A meeting of Technical Specifications Committee to review the specifications of Viral Load Equipments was held on 27th Nov 2018 at 4:00 PM at Room No. 342 B, A Wing, Nirman Bhawan, New Delhi under the Chairmanship of Dr. AK Gadpayle (Addl DGHS).

- The following member attended the meeting:

1. Dr. AK Gadpayle (Addl DGHS). (Chairperson)
2. Dr. Naresh Goel, DDG(LS), NACO (Member)
3. Mr Sella Senthil. DCGI Representative (Member)
4. Dr Anoop Kumar, Junior Scientist, NIB Representative (Member)
5. Dr. Sumit Agrawal, Scientist-C,ICMR Representative (Member)
6. Dr Sunil K Arora, Prof of Immunopathology, PGIMER, Chandigarh (Member Expert)
7. Dr. Vandana Saxena, Scientist , NARI, Pune (Member Expert)
8. Dr. Luke Elizabeth Hanna, Scientist D,NIRT, Chennai (Member Expert)
9. Dr Sanjeev Verma (Member Expert)
10. Dr Anu George (Member Expert)

- The agenda of the meeting was to review technical specifications of equipments required to set up Viral Load lab.
- The committee approved the technical specification of following equipments:

1. **Table top laboratory centrifuge**

Compact table top laboratory centrifuge with

1. Speed Regulator: Maximum speed required at least 4000 rpm with increment of at least 100 rpm
2. Safety Lid Lock
3. Digital Speed Meter
4. Timer for setting time between 0 to 60 with increment of at least 5 min
5. Rotor: Angled head with capacity for at least 3-8ml blood tubes fit
   - Adaptors Each With Capacity of 6 ml tube
   - Adaptors Each With Capacity of 8 ml tube.
6. Facility for level adjustment and firm base to prevent walking and provide assure stability while equipment is in use.
7. Electrical compatibility:
   i. Must be compatible at 220 V, 50/60 Hz.
   ii. Power plug should fit on Indian system of electrical supply.
8. Should be able to accommodate minimum 12 tubes at one time.
9. The product must be CE (European)/ BIS approved

Other conditions:

1. The supplier will provide 6 years warranty that will include Comprehensive Annual Maintenance Contract (CAMC) including all spare parts and repairs
2. The manufacturer should be able to provide service of equipment across India within 24 hrs after receipt of breakdown report for the metro location and within 3 days for the non metro located instruments.
3. Purchase reserves the right to subject the equipments for independent evaluation of performance.
4. The company will provide installation qualification, operational qualification and performance qualification with log book for maintenance of the equipments at no extra cost
5. Company will be responsible for Training of lab staff on operation of equipments.
6. Manuals: Operation, maintenance & part list with detailed specifications must be provided in original

2. Vortex mixer with digital display

1. Adjustable to 100 to 2500 rpm
2. Continuous and intermittent "touch-control" modes
3. Heavy cast-metal base and suction cup to assure stability prevent "walking"
4. 220-230 Volts, AC, 50HZ.
5. Digital Display :LED
6. Capacity of 2-3 kg and orbit of 35mm required.
7. The product must be CE (European)/ BIS approved

Other conditions:

1. The supplier will provide 6 years warranty that will include Comprehensive Annual Maintenance Contract (CAMC) including all spare parts and repairs
2. The manufacturer should be able to provide service of equipment across India within 24 hrs after receipt of breakdown report for the metro location and within 3 days for the non metro located instruments.
3. Purchase reserves the right to subject the equipments for independent evaluation of performance.
4. The company will provided installation qualification, operational qualification and performance qualification with log book for maintenance of the equipments at no extra cost.
5. Company will be responsible for Training of lab staff on operation of equipments
6. Manuals: Operation, maintenance & part list with detailed specifications must be provided in original

3. **Pipettes**

Single channel (20-200ul)

1. Single channel with variable volume
2. Volume Range: 20-200 ul
3. Dispensing Increment- 1 ul
4. Volume adjustment facility
5. Ejector
6. Volume display
7. Compatible for universal tips available in India.
8. Calibrated pipette to be supplied along with calibration certificate
9. Fully autoclavable
10. The product must be CE (European)/ BIS approved

4. Pipette

Single channel (100-1000ul)

1. Single channel with variable volume
2. Volume Range: 100-1000 ul
3. Dispensing Increment- 1 ul
4. Volume adjustment facility
5. Ejector
6. Volume display
7. Compatible for universal tips available in India.
8. Calibrated pipette to be supplied along with calibration certificate
9. Fully autoclavable
10. The product must be CE (European)/ BIS approved

Other conditions:

1. Manuals: Operation and maintenance with detailed specifications must be provided in original
2. The supplier will provide 2 years warranty that will include Comprehensive Annual Maintenance Contract (CAMC) including all spare parts and repairs

5. Biological safety cabinets (BSCs): Bio safety cabinets Class II, Type A2

- **Certification**: It must be
    1. NSF (National Sanitation Foundation)/ANSI 49 certified/EN12469/BIS standard

- **Design and dimensions cabinet**:
    1. The exterior dimensions must be at least WxHxD (in mm) 1300 x 1500 x 750.
    2. The Interior dimensions must be at least WxHxD (in mm) 1200 x 630 x 600.
    3. The working height of front window must be at 8 to 10 inches and be made of laminated safety glass to ensure containment of potentially hazardous samples in the case of accidental glass breakage.
    4. The maximum height of front window opening must be between 500 to 600mm.
    5. The front of the cabinet must be angled 10° to help minimize glare on the window to the user.
    6. Must be provided with comfortable armrest or V shaped air vent grill which should sit just above the intake grill to enable farther reach inside the cabinet without hampering safe airflows inside the cabinet working area.
    7. Must be one piece 304 stainless steel interior or better or equivalent.
    8. Must have flat, single-piece stainless steel removable work tray preferably with seamless lift out knobs.
    9. Must be having epoxy-coated steel exterior
    10. Must be with door- fully closing, clear ¼" tempered safety glass sash.
    11. Must be supplied with Counter balanced adjustable (Preferably Electrical or manual if electrical not available) base stand of standard height for laboratory work.
    12. Must be supplied with Combustible gas valve.
    13. Must be supplied with Non-combustible gas valve.
- **Electrical compatibility**:
    1. Must be compatible at 220 V. 50/60 Hz.
    2. Power plug should fit on Indian system of electrical supply.
    3. A 3 KVA online UPS and 3 KVA voltage stabilizer must be supplied with the instrument which can withstand a continuous and stable voltage of at least 30 minutes in case of electrical breakdown of main supply.
- **Filters specifications**:
    1. H14 HEPA EN 1822, 99.995% MPPS (Most Penetrating Particle Size) or better.
    2. Must have Supply and exhaust HEPA filters.
    3. Guage for monitoring the condition of all HEPA filters as well as work space
- **Air Circulation**:
    1. Airflow is drawn into the front grille of the cabinet, providing personnel protection.
    2. Inflow face velocity (open front) of at least 100 fpm.
    3. Down flow velocity of minimum 55 fpm (0.3 m/sec)
    4. Air flow pattern: 70% recirculation of air to the cabinet work area through HEPA file, 30% balance can be exhausted through HEPA filter into the canopy unit. Must have supply and exhaust air through HEPA filters.
    5. All the positive pressure contaminated plenums within the cabinet are surrounded by a negative air pressure plenum thus ensuring that any leakage from a contaminated plenum will be drawn into the cabinet and not released to the environment. Also the plenum to be under negative pressure to the room.

6. Motor for air circulation should be Dual DC & must automatically adjust the airflow speed (balancing inflow and down flow) without the use of a damper to ensure continuous safe working conditions.
7. Cabinet must be capable of automatically handling more 150% or more increase in pressure drop across the filter without reducing total air delivery >10%.
8. The cabinet must automatically reduce fan/blower motor speed to 30% when the front window sash is in closed position to ensure reduced energy consumption when the cabinet is not in use.
9. Canopy (Thimble) unit as per the NSF 49/ ANSI 49 certified/EN12469/CE/BIS guidelines for the Bio safety cabinets Class II, Type A2 must be provided. All the material, labour technical manpower etc. required is to be provided by the installation agency. The site may be inspected if needed after taking permission from head of department microbiology of the institute.
10. LED/LCD display:
    a) The microprocessor must display the inflow and down flow air velocities in real-time on an LED/LCD display
    b) Display showing hours of operation.
    c) Visual and audible alarm for showing front window working position safety.
    d) Visual and audible alarm for showing airflow safety.

- **Ergonomics**:
    1. Lighting power at least ≥ 1100lx
    2. Smart ports: Two 3 "plugged cable ports ,one on each side wall
    3. Service valves up to 6 (three on each side wall)
    4. Receptacles of 220V: two standard single receptacles located on rear wall, right and left sides.
    5. Should include a germicidal UV lamp. This UV lamp must be programmable to allow for specific exposure times from 0 to 24 hours.
    6. The cabinet noise level must be less than 65 dBA
    7. Cabinet must be installed at a working surface height of approximately 30 inch from ground with the adjustable channel stands which has adjustable legs and leg levelers. The legs should provide approximately 6 inch of height adjustment and the leg leveler should provide an additional 2.5 inch of height adjustment.
    8. Must be supplied with two adjustable saddle stools.
    9. One footrest must be provided.

- **Installation, onsite validation and certification** to be provided with testing as per "Field Certified in accordance with NSF/ANSI / BIS 49" and must meet the criteria as prescribed by NSF/ ANSI 49 certified/EN12469/CE/BIS for Bio safety cabinets Class II, Type A2. The certificate of successful installation will only be given after departmental technical committee satisfy with the for performance of onsite validation and certification tests as per standards mentioned in NSF/ANSI 49 document for the following parameters:
    1. HEPA filer leak test
    2. Down flow face velocity
    3. Inflow velocity
    4. Air flow smoke pattern test
    5. cabinet integrity test (positive pressure plenum cabinets only)
    6. site installation assessment tests which includes [alarm functions as required by NSF/ANSI 49 Standard, blower interlock and exhaust system performance (proper exhaust duct negative pressure and canopy and performance)

Other conditions:

1. The supplier will provide 6 years warranty that will include Comprehensive Annual Maintenance Contract (CAMC) including all spare parts and repairs
2. The manufacturer should be able to provide service of equipment across India within 24 hrs after receipt of breakdown report for the metro location and within 3 days for the non metro located instruments.
3. Purchase reserves the right to subject the equipments for independent evaluation of performance.
4. The company will provide installation qualification, operational qualification and performance qualification with log book for maintenance of the equipments at no extra cost
5. Company will be responsible for Training of lab staff on operation of equipments
6. Manuals: Operation, maintenance & part list with detailed specifications must be provided in original

6. Deep Freezer -20 ° C along with Voltage Stabilizer

1. Capacity 370-400 Lts or better
2. Microprocessor controlled vertical (upright) deep freeze (-20^{0}C) with adjustable 3-4 interior compartments/ adjustable shelves with preferably two internal doors
3. Digital display of temp with facility to set temp between -10 to -40^{0}C with 1^{0}C increment
4. CFC/HCFC free non-inflammable refrigerant
5. Polyurethane vacuum insulation with silicon gasket on doors for tight sealing
6. Double door with lockable outer door
7. Audio-visual alarm for temp. deviation, power failure, door open etc.
8. Low noise level: ≤60 decibel 50Hz/230V
9. Minimum 3 star 2.0 ton split AC for optimal operation during the summer season with voltage stabilizer
10. Suitable voltage stabilizer
11. The product must be CE (European)/ BIS approved

Other conditions:

1. The supplier will provide 6 years warranty that will include Comprehensive Annual Maintenance Contract (CAMC) including all spare parts and repairs
2. The manufacturer should be able to provide service of equipment across India within 24 hrs. after receipt of breakdown report for the metro location and within 3 days for the non metro located instruments.
3. Purchase reserves the right to subject the equipments for independent evaluation of performance.
4. The company will provide installation qualification, operational qualification and performance qualification with log book for maintenance of the equipments at no extra cost
5. Company will be responsible for Training of lab staff on operation of equipments
6. Manuals: Operation, maintenance & part list with detailed specifications must be provided in original.

7. Deep Freezer -80 ° C along with Voltage Stabilizer

1. One - 80 degree deep freezer system with temperature control/display,
2. Temperature range: -50 to – 86 ^{0} C,
3. Capacity cu ft/liters: 350 or more,
4. Cryobox Capacity 2":230 or more,
5. Max. shelf weight: 120lbs/65 kg or more,
6. CFC/HCFC free non-inflammable refrigerant
7. Refrigeration Compressor HP: Two of minimum 1.0 HP each
8. Voltage: 230V, 50/60 Hz.
9. Heavy gauge, cold rolled steel cabinets with a powder coat paint finish for a uniform exterior that resists chipping and rust,
10. 5" (12.7 cm) foamed-in-place polyurethane insulation/ VIP insulation technology
11. Vacuum relief port/ pressure equalization port for easy access after door openings,
12. Easy to remove washable filter for protection from dust on the condenser and increasing refrigeration performance,
13. Single hand operation with an easy-to-use padlock-compatible, ergonomic door handle with integrated key lock,
14. Simplified installation with our new easy –roll 2" locking casters,
15. Four inner doors to reduce cold air loss and improve temperature recovery after door openings.
16. Microprocessor control and monitoring system to ensure that all controls and displays are easy to reach and read, power management system with low voltage surge protection and buck/boost.
17. Safety-backup systems for additional sample protection in the event of power or mechanical failure.
18. Suitable voltage stabilizer to be supplied to support the instrument
19. Minimum 3 star 2.0 ton split AC for optimal operation during the summer season with voltage stabilizer
20. The product must be CE (European)/ BIS approved

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8. Refrigerator

Type	:	Single Door
Refrigerator Type	:	Top Freezer Refrigerator
Defrosting Type	:	Direct Cool
Refrigerant	:	CFC/HCFC free non-inflammable
Compressor Type	:	Reciprocatory Compressor
Capacity	:	230±10 L
Number of Doors	:	1
Star Rating	:	5
Coolpad	:	Yes
Toughened Glass	:	Yes
Built-in Stabilizer	:	Yes
Express Freezing	:	Yes
Moisture Control	:	Yes
Other Performance Features	:	12 hrs Cooling Retention During Power Cuts, Advanced Moisture Control
Clock	:	No
Door Lock	:	Yes
Removable Gasket	:	Yes
Warranty Summary	:	1 Year on Refrigerator & 10 Years on Compressor

Other conditions:

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6. Manuals: Operation, maintenance & part list with detailed specifications must be provided in original
7. The product must be CE (European)/ BIS approved

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