

Drugs Control Laboratory Maharashtra State, Mumbai-400051.
Specifications of the equipments to be purchased for the Year
2010-2011

Specification of equipments to be purchased by Drugs Control Laboratory, Mumbai are given here. Specifications which are given are under consideration .Any suggestion, modification regarding the specifications should be given within 20 days .Suggestion, modification will be consider and then final specifications will be approve.

1. Specifications for Water Purification System:-

The system should provide the following items.

- Feeding Pump
- 5 Micron Cartridge Filter
- Activated Carbon Filter
- High pressure Pump
- RO Modules
- Instruments for the RO
- P. P. Tank
- Feeding Pump
- Mixed Bed unit
- Mixed Bed unit
- Pressurize Tank
- Ultra filtration Unit
- Ultraviolet Unit
- PLC based Electronics device including Instruments
- Flow Rate : 40 lit/hr

QUALITY OF TREATED WATER should be as follows.

- Resistivity : < 18.2 Mohm/cm
- Conductivity : > 0.05 μ S/cm²
- pH : 6.5 – 7.2
- Permanganate Reduction (min) : 60
- Sodium : 0.1 mg/lit
- Silicate : 0.05 mg/lit
- Heavy metals : 0.01 mg/lit
- Bacteria : 10 colonies/ml
- Particles : < 1 no. of >0.1 micron
- TOC : less than 20 ppb
- Water produce should pass as per ASTM Type I and CAP/NCCLS Type I.

SPECIFICATIONS

- RAW WATER FEEDING PUMP
- Flow Rate : 200 lit/hr
- MOC : Plastic
- Pressure : 1.5 kg/cm²
- 5 MICRON CARTRIDGE FILTER
- Flow Rate : 200 lit/hr
- Material of Housing : P.P.
- No. of Cartridges : 1 No.
- Porosity : 5 Micron
- Size : 10"
- Type of Cartridge : P.P. spun depth type
- ACTIVATED CARBON FILTER
- Material of Housing : P.P.
- No. of Cartridges : 1 No.
- Size : 10"

- REVERSE OSMOSIS SYSTEM:
- R. O. Pump
- R. O. Membrane
- Housing
- Instrument
- R. O. PUMP
- Rating : 0.5 H.P.
- Make : Procon
- MOC : S.S.
- Average Flow Rate : 200 lit/hr
- Operating Pr. : 180 – 200 psig
- Inlet/Outlet Connections : ½ "
- Motor : Crompton / Remi
- R. O. MEMBRANE:
- No. of Membrane : 2 Nos.
- Size : 2.5" x 21"
- Type : TFC
- Make : Osmonic
- Feed Flow : 200 lits/hr
- Product Flow Rate : 40 lits/hr
- Pressure : 160 – 180 psig
- Ionic Rejection : 95% - 98% (average)
- HOUSING (Pr. Tube)
- Material of Construction : PVC
- No. of Housing : 2 Nos.
- Size : 2.5" x 21"
- INSTRUMENTS:
- Permeate Rotameter
- Conc. Pressure Gauge
- Pr. Control valve
- Conductivity meter with sensor
- Low Pr. Switch
- High Pr. Switch to protect the pump.
- Complete unit should be mounted on a Powder coated M. S. stand having control panel
- P. P. TANK:
- Capacity : 70 lit
- MOC : P.P.
- Tank should be provided with Inlet, Outlet Recirculation loop connection and drain valve
- RO WATER FEEDING PUMP
- MOC : Plastic
- Flow Rate : 40 lit/hr
- MIXED BED UNIT (2 NOS.)
- Cartridge Size : 10"
- 2 nos. Cartridges are fitted in to get the required quality.
- PRESSURIZE TANK:
- Capacity : 50 lit
- MOC : P.P.
- ULTRAFILTRATION UNIT
- Flow Rate : 40 lit/hr
- Type of UF unit : Hollow Fiber
- Membrane : Polysulphone
- Pore Size : 0.1 absolute
- Extratable : Passes USP Test for oxidizable sub.
- Particle cut off Size : 0.05 micron
- ULTRAVIOLET UNIT

- Housing : S.S. 316
- UV wavelength : 180nm
- INSTRUMENTS:

The Unit should provide with panel consisting of:

- Pr. Gauges
- Rotameter
- Conductivity meter digital Type
- PLC base controller which includes automatic flushing on the set timing,
- Recirculation, Level controller, Conductivity Controller, etc.

2.Specifications for Tensile strength Machine [For Sutures and Adhesive Tapes]

Features:-

The equipment should be Two columns, Table top instruments, capable of testing Tensile Strength of sutures and bandages and also adhesive strength of bandages.

Specifications :-

- 1) It should be high precision better than +/-1% of indicated value within 1/1 to 1/500 of the rated force.conforms to EN 10002-2Grade 1,ISO 7500-1 class 1, ASTM E4, JIS B 7721 class 1
- 2) One touch force and displacement zeroing
- 3) One touch crosshead return to the origin
- 4) Automatic detection of specimen breakdown
- 5) Automatic force calibration
- 6) Fine tuning of cross heads
- 7) Direct high precision constant speed strain control method via non back lash ball screw drive
- 8) External analogue output two channels and external analogue input two channels and external digital two inputs two channel

Hardware specification:-

- 1) Machine capacity of maximum loading up to 5 KN
- 2) Cross head speed 0.001 to 1000 mm/minute
- 3) Cross head speed accuracy 0.1 %
- 4) Full speed capability at full load required
- 5) Display resolution 0.001mm
- 6) Positional accuracy +/- 0.1 % of indicated value or +/- 0.01mm
- 7) Sampling speed 1 milli second
- 8) Effective test width 425mm
- 9) Tensile stroke with a typical grip 885mm
- 10)Units system selectable N,Gm,Lbf,mm,inch
- 11)Single phase 220 volts AC
- 12)Weight approx 90 kg maximum

Software Specifications: -

Windows 2000 /XPcompatible data processing software having following features.

- Macros facility to enhance work efficiency.
- Sampling interval can be set by time, test force or displacement.
- Test for Automatic Calibration.
- Re Test., Extra lot test and combine file option required.
- Out put report can be automatically be transmitted to PC/Printer.
- User defined style of report should be generated.
- Output reports as PDF file.
- Report should be compatible with commercial software as word and excel.
- Graph and Report to be monitored by PC.

- Easy visual setting up of test parameters.
- A typical stress strain curve with various results possibility should displayed graphically which could selected by click of mouse by user.
- User defined data processing items can be created by user defined formula.
- Stastical process control function should be available.

Grips and Fixtures:-

- 1) Standard screw type grip along with standard and high intensity rubber coated grip faces required
- 2) Pneumatic grips to test sutures ,with foot valve to control grips.

All necessary documentation such as IQ/OQ/PQ should be given. Vendor should provide comparison chart of their specifications with Laboratory Specifications along with necessary Broachers.

3. Specifications For Telethermometer with 18 Probes

Features.

- The temperature measurement should be in degree Celsius and should be accurate.
- The measurement should be provided with 18 channels.
- These channels should be scanned automatically selecting the proper channel and enables temperature of different points to be read from the location.
- The instrument should be provided with special rectal probes.
- Several rabbits can be tested at a time for pyrogen hyperthermia to detect pyrogen in injectables.

Specification:-

Display	: - 3.5 digit LED display
Range	: - 0 to 50 degree Celsius
Resolution	: - 0.1 degree Celsius
Accuracy	: - ±0.1 degree Celsius
Nos. Of channel	: - 15 channel
Channel selection	: - Automatic scanning type
Nos of temperature rectal probes	: - 15
Power	: - 230 volts AC 50 Hz

All necessary documentation such as IQ/OQ/PQ should be given.

Vendor should provide comparison chart of their specifications with Laboratory Specifications along with necessary Broachers.

4. Specifications for Vacuum Pump [High vacuum]

Oil free for HPLC Solvent.

- Max Flow :- 25-30 LPM (Liter per minute)
- Vaccum :- 22" Hg
- Max Pressure :- 10 psig, 1/8 HP

5. Specifications for Microscope with Digital Camera

Microscope should be with Camera and PC or Inbuilt camera and LCD display.

Microscope:-

- 45° inclined with 360 degree rotatable binocular tube.
- Co-axial built in mechanical stage with fine vernier graduation, designed with convenient coaxial adjustment for Jerk free smooth slide manipulation through 50 x 75mm.
- Dust proof quadruple/quintuple ball bearing revolving nose piece with positive click stops.
- Co-axial coarse and fine focusing adjustment knobs. Fine, motion graduated to 0.002 mm.
- Substage Abbe type N.A. 1.25 condenser with rack and pinion, continuously variable iris diaphragm with built in swing out filter holder.
- Chemical resistant.
- Heavy rectangular sturdy base, with built-in illumination 6V-20W halogen lamp.

Magnification Specifications:-

With 10X magnifies to 250 times, 4X to 100 times , 40X 1000 times, 100X to 2500 times.

Output device specifications:-

Screen size: - Through PC or screen size 7 inches digital.

Ratio 15: 9 wide TFT screen.

Resolution:- 800 x 480

Colour Configuration:- RGB stripe (Red, Green and Blue)

Video system:- PAL/NTSC/SECAM(Autoswitching) [Operating System]

VGA input:- USB interface.

Full function OSD [Out Screen Display] control. (Multi language)

High resolution and no radiation.

Computer display/S-video/ DVD/VCD/Security System/ Navigation system.

Compatible

Rear view camera connectable

Power Input:- DC 12V

Video Camera

- Video camera parts:- 1/3 " 1/4" image sensor.
- System PAL/CCIR/NTSC/EIA
- Effective pixel:- PAL 628 x 582 NTSC: 510x 492
- Image area: PAL :5.78 X 4.19 mm NTSC : 4.69 x 3.45 mm
- Scanning Frequency:- PAL/CCIR: 50 Hz NTSC /EIA:60 Hz
- Minimum illumination:- 3 LUX
- Sensitivity:- +18 DB-AGL on off.
- Out put Electrical Level: 50 MW
- Out put frequency:- 1.2 G/2.4G
- Transmission signal :- Video
- Linear Transmission Distance:- 50 to 100 m

Technical Parameters of Receiving unit

- Receiving Signal :-Video
- Reception sensitivity:- 18 DB
- To be connected via USB/Video in.
- Viewing and capturing software.
- IQ,OQ, and PQ.

Vendor should provide comparison chart of their specifications with Laboratory specifications.

6. Specifications for Air Samper.

1	PARTICLE CAPTURE MACHANISM	-	SIEVE IMPACTION
2	SAMPLING VOLUME (MAX)	-	1600 LITERS
3	TIME TO SAMPLE 1000 LITER	-	10 MINUTES
4	VELOCITY	-	0.45 METER/SECOND
5	IMPACTION SPEED	-	11 METER/SECOND
6	FLOW RATE (ADJUSTABLE)	-	30,60,100 LITERES PER MINUTE
7	AIR FLOW BLOCK SYSTEM		
8	WATER LOSS AFTER SAMPLING 1000 LITRES	-	10%
9	PARTICLE DIAMETER CUT OFF SIZE	-	1.3 MICROMETER
10	PERFORATION DIAMETER	-	1 MM
11	NO. OF PERFORATIONS	-	340

REQUIREMENTS:-

- 1 POWDER COATED ALUMINIUM INSTRUMENT WITH CIRCULAR CLAMP WITH BATTERY CHARGER REMOTE CONTROL, RECHARGABLE BATTERY SET, LOW BATTERY INDICATION.
- 2 POWDER COATED MS TALL STAND.
- 3 ADAPTER FOR MOUNTING IN EITHER VERTICLE OR HORIZONTAL POSITION.
- 4 STAINLESS STEEL CONE FOR 90mm PETRIPLATE.
- 5 REMOTE CONTROL OPERATION & DELAY START FUNCTION.
- 6 MICROCONTROLLER BASED SILENT FAN.
- 7 STAINLESS STEEL FEEDER CONE CIRCULAR CLAMP ASSEMBLY HAVING HOLES FOR AIR PASSAGE WITH STAINLESS STEEL FEEDER COVER.HOLES DESIGNED TO OPTIMISE COLONY DISTRIBUTION & REDUCE COLONY OVERLAPPING.
- 8 CALIBRATION CERTIFICATE
- 9 VALIDATION CERTIFICATE
- 10 WARRENTY CARD
- 11 CORRECTION /CONVERSION TABLE

ALL NECESSARY DOCUMENTATION SUCH AS IQ/OQ/PQ SHOULD BE GIVEN.

VENDOR SHOULD PROVIDE COMPARISON CHART OF THEIR SPECIFICATIONS WITH LABORATORY SPECIFICATIONS ALONG WITH NECESSARY BROACHERS.

7. Specifications for HPLC column

Sr.No.	Name of Column	Qty
1.	A Stainless steel column 25 cm x 4.6 mm packed with end -capped octadecylsilyl amorphous organosilica polymer for mass spectrometry 5 micron such as waters XTERRA FOR Azithromycin.	01
2.	A stainless steel column 25 cm x 4.6 mm packed with end-capped polar embedded octadecylsilyl amorphous organosilica polymer 5 micron such as waters XTERRA for Azithromycin.	01
3.	A stainless steel column 15 cm x 4.6 mm packed with spherical end capped octadecylsilyl silica gel 5 micron with 10 nm pore size and a carbon loading of about 19 %. For Roxithromycin TABLETS IP. Betasil or equivalent	01
4.	A stainless steel column 30 cm x 4 mm, packed with octadecylsilane bonded to porous silica 5 micron	01
5	A stainless steel column 30 cm x 4 mm, packed with octadecylsilane bonded to porous silica 10 micron	01
6.	Stainless steel column 25 cm x 4.6 mm packed with particles of silica 5 micron. The surface of which has been modified by chemically bonded Trimethylsilyl Groups such as Hypersil SAS for Cefuroxime Axetil For Oral Suspension. Betasil C1 or equivalent	01
6.	L13 as per USP For Cefuroxime Axetil For Oral Suspension USP. Betasil or equivalent.	01
7.	4.6 mm x 15 cm column that contains 5 micron packing L15 (Hexyls lane for Cefuroxime Sodium)	01
8.	4.6 x 25 cm column containing packing L21 For Doxycycline Hyclate USP. 8 micron 100 A ⁰	01
9.	4.6 mm x 25 cm column containing packing L21 (1000 A ⁰) for Erythromycin USP. 8 micron	01
10.	A stainless steel column 20 cm x 4.6 mm packed with stationary phase A (Nucleosil 100-5 is suitable)	01
11	A stainless steel column 25 cm x 4.6 mm packed with Aminopropylmethylsilyl silica gel for Isosorbide dinitrate I.P.	01
12	Chiral column with recognition protein, ovomucoid, chemically bonded to porous silica 15 cm x 4.6 mm x 5 micron for Clopidogrel Tablets IP.	01
13.	Amino and cyano groups chemically bonded to porous silica particles 5 micron.(L 18) 25 cm x 4.6 mm x 5 micron	02

All above mentioned column will be tested in the Laboratory for their performance otherwise rejected.

8. Specifications for:- Water Bath Boiling

- It should have concentric rings.
- It should be fitted with water level indicating device.
- Water bath should have removable flat drop on lid for concentric rings enable the bath to be used for other work also.
- It should be doubled walled insulated, full stainless steel construction.
- Internal chamber, external chamber, drop on lid with holes of 75mm Ø all of stainless steel.
- Concentric rings in steps of 25 and 50 mm ID moulded from industrial grade non-corrosive material.
- A precise digital temperature indicator cum controller having resolution and control accuracy of ± 1 °C in digital model.
- Temperature range should be ambient + 5 to 100°C
- Should have industrial grade long life special heaters for efficient transfer of heat.
- Water bath should be with 12 holes of 75mm Ø with steps of 25 mm having heater 800 W x 2.

Vendor should provide comparison chart of their specifications with Laboratory specifications.

9. Specifications for Unifolls Digital Iodine Value Meter

- Type : Digital
- Measuring Range : 0 to 199.9 Iodine Number
- Accuracy : ± 2 Iodine Number
- Display : 3.5 LCD with auto polarity
- Electrode : Combination Electrode
- Power Battery/ Mains : 9V Battery (4 Number) for Battery operations & 220V A/C 50Hz for mains operations
- Filters : IR Range

10. Specifications for GC Column

Sr. No.	Composition	Polarity	Approximate Temperature limits.	Quantity
1.	6% Cyanopropylphenyl 94% Dimethyl polysiloxane	Mid-polar Capillary 25-30 meter ID 0.18 to 0.35 mm	From -20 to 280/300	01

11. Specifications for S.S Trollys

Size:- 75 x 45 x 81 (l x b x h in cm)

Shelves in between.

Material: - Total Stainless steel of 304 quality.

Joint portion: - All welding joint should be of smoothed and mirror polished.

Polish: - Mirror polished.