

G: Technical Specifications

P A R T - A

Item No.	NAME OF GOODS, TECHNICAL DESCRIPTION, SPECIFICATIONS, AND STANDARDS	Qty
1A	<p>PRODUCTION FREEZE DRYING (LYOPHILIZED UNIT)</p> <p>Production Specification Number of shelf's = 6+1 Ice capacity 60 kg Capacity freeze drying more than 7300 vials (10ml vial) approx. Shelf Temperature to -55C Condenser Temperature to -75C Hydraulic Stoppering Shelf assembly or Stoppering Configurations Full PC/PLC Control with remote touch screen operation 304 or 316 Stainless Steel Construction GMP and GAMP Compliant, Lyophilization Cycle/recipe support Steam Sterilization (SIP) Clean In Place (CIP) Isolation, Valve Dry Vacuum Pumps ,Cooling Jacket ,Redundant Components Position, Sensors Auto-Locking Doors & Pizza Loading Door, Screw Compressors 21 CFR Part 11 Controls, Capacitance Manometer Allen Bradley PLC, automatic leak testing, alarms, recipe management, data logging graphical display , batch reporting systems, Validation Package and training and backup support.</p>	1 No.
2A	<p>FREEZE DRYER SEMI AUTOMATIC LOADING AND UNLOADING SYSTEMS (integrated/compatibility with production freeze dryer)</p> <ul style="list-style-type: none"> • Simple operation • Reduced manual vial handling • Under Laminar Flow • Product quality improvement through greater repeatability <p>Reduced bio-burden in Class 100 environments, Semi automated vial loading and unloading systems to facilitate the lyophilization, eliminate operator intervention and associated contamination risks.</p>	1 No.
3A	<p>PRODUCTION LINE AUTOMATIC WASHING ULTRA SONIC, STERILIZING DRIER, FILLING, CAPPING , SEALING AND LABELING MACHINE</p> <p>High speed automatic filling the vials (1ml to 20 ml volume), automatic counting, The range of container fills can be adjustable, computer controlled dynamic scan counting for each channel feeder. allows operators to see the individual output of each channel to ensure accurate piece counts and diagnose any troublesome backups self checking sensors that in the event of an operating error identify and help diagnose the problem for minimal downtime computerized recording systems, low noise, options. up gradable, bulk loader, expanded conveyers Vertical Ultrasonic automatic small bottle washer. Unique stand rotor structure, adopting manipulator to continue fix bottle auto rolling to the bottom up and spurt tube to and fro track.</p>	1 No.

Item No.	NAME OF GOODS, TECHNICAL DESCRIPTION, SPECIFICATIONS, AND STANDARDS	Qty
	<p>Ultrasonic coarsely washing auto sand to finely washing, needled into bottle strongly back rinsing and water or gas alternate spurt.</p> <p>Adopting imported electricity elements control, operation parameter can be set, shown and printed. With adjustable running speed, adopting purified 100 class laminar flow protecting while sterilizing and drying and etc.</p> <p>Filling Roll-cap Machine Reeling filling, auto tidy the bottles and capper, auto adding and rolling capper,</p> <p>breakage ratio is low, higher filling precision, airproof is good, no inhale, no trail, the shape is very nice Tolerance of Filling quantity $\leq \pm 2\%$</p> <p>Qualification rate of Roll-cap $\geq 99\%$ Production capacity 60 Bottles/min it satisfies the GMP requirement for drugs production exactly</p>	
4A	<p>PHARMACEUTICAL LIQUID MIXING TANK</p> <p>Pharmaceutical stain less steel body, heating, cooling mixing (Jacketed)</p> <p>GMP compliance</p> <p>Capacity 250 Liters</p> <p>Maximum 400 RPM and variable</p> <p>With Vacuum feeding System</p> <p>Temperature Less than 80° C</p> <p>Mechanical Mixing From Top</p> <p>Sampling required for more than one time from bottom</p> <p>Sterile Filtration of Class A</p> <p>Filter WIT Online testing (Before and After SIP)</p> <p>Online CIP and SIP</p> <p>Piping Standard required ASME BPE-1.6mm</p> <p>Process Valve Brand required GEMU</p>	3 Nos.
5A	<p>PHARMACEUTICAL LIQUID HOMOGENIZING TANK</p> <p>Pharmaceutical stain less steel body, heating, cooling mixing (Jacketed)</p> <p>GMP compliance</p> <p>Capacity 250 Liters</p> <p>Maximum 600 RPM</p> <p>With Vacuum feeding System</p> <p>Temperature Less than 80° C</p> <p>Mechanical Mixing From Top</p> <p>Sampling required for more than one time from bottom</p> <p>Sterile Filtration of Class A</p> <p>Filter WIT Online testing (Before and After SIP)</p> <p>Online CIP and SIP</p> <p>Piping Standard required ASME BPE-1.6mm</p> <p>Process Valve Brand required GEMU</p>	1 No.
6A	<p>TANGENTIAL FLOW FILTRATION SYSTEMS</p> <p>Polyethersulfone Membrane based tangential flow filtration systems which clarifying, concentrated and purifying the antibodies.(IgG, F(ab)2, Fab molecule).</p> <p>Characteristics Broad range of applications that cover ultra filtration and microfiltration especially zoonotic virus filtration, The system can be used with flat sheet cassettes and hollow fibers. Other Systems option such as Pressure,</p>	1 No.

Item No.	NAME OF GOODS, TECHNICAL DESCRIPTION, SPECIFICATIONS, AND STANDARDS	Qty
	temperature, air sensors ,adjustability, compatibility, systems easy cleaning , clean in place and the valves and the fittings are specially developed for hygienic, leak-free operation. Electrically actuated diaphragm valves diminish hold up volumes and prevent dead volumes. resistant to a wide range of chemicals ,Silicone encapsulant, Volume handling capacity 200 liters clarifying within two to three hours	
7A	<p>AUTOMATED LIQUID CHROMATOGRAPHY SYSTEMS FOR PROCESS SCALE-UP, AND LARGE-SCALE MANUFACTURING.</p> <p>Three Flow rates up to 2000 l/h for large-volume manufacturing Versatile configuration with UNICORN control and different op Post-purchase configuration increases usability and lifespan Traceable USP Class VI, Intelligent packing of Axi Chrom columns Full regulatory documentation and service and etc.</p>	1 No.
8A	<p>CLEAN ROOMS FOR PRODUCTION LINE</p> <p>Clean rooms meet ISO standard 1 and WHO standards, sterile quality index, and controlled level of contamination of biological products/ pharmaceuticals production line, air lock, air shower and etc.</p> <p>Wall Panel for internal Partition (50mm Thickness) with all Accessories View Panel for internal Partition (50mm Thickness) with all Accessories Ceiling Panels (50mm Thickness) with All Accessories Covings Clean Room Doors & Windows Clean Room Light Fixture Cutouts for sockets & switches Embedded Electrical Pipes for Internal Wall Panel Switches and Sockets Flooring</p>	1 No.
9A	<p>DRYING AND STERILIZATION OVEN</p> <p>Performance Features Inner chamber volume in Liters: 500 Temperature range, 5⁰ C above ambient up to 280⁰ C With different digital timer functions, Timer 0-99.59 h, and continues operation. Exhaust duct with ventilation slide and ventilation flap Fast and temperature-accurate heating. Lockable castors (4 pieces) Calibrations and validations possible. RS 422 communication interface for the standard software Equipment: Microprocessor temperature controller with LED-display One ramp function 2 SS shelves Safety device (TWB) class 2. Ventilation slide and exhaust duct 0 50mm</p>	1 No.

Item No.	NAME OF GOODS, TECHNICAL DESCRIPTION, SPECIFICATIONS, AND STANDARDS	Qty
10A	<p>WATER FOR INJECTION PRODUCTION PLANT(500 liters/hour) Comprises of: 1 Multicolumn Distillation Plant 2 WFI Storage System (Including Storage Tank, Recirculation Tank and Buffer Tanks) 3 WFI Distribution Loop System 4 Pure Steam Generator The pre-treatment system comprises of: Pressure Filters, Activated Carbon Filters D.M. Plant or Reverse Osmosis system (with Softener)Ultra-Filtration system) UV Sterilizer Storage and Distribution loop system The tank is designed to withstand pressure as well as vacuum. No stagnant points which will promote bacterial growth All surfaces are creviceless and having high degree of finish Insulation with SS welded sheeting and jacket provided on the tank will minimize heat loss. All the surfaces coming in contact with WFI are made of SS 316/316L quality. And all other accessories Electropolished interiors are provided as optional. Spray Ball for SIP / CIP Temperature Indicator cum Control Arrangement. Level Indicator cum Controller. 0.2 Micron Vent Filter. Pressure Gauge and Safety Valve. Diaphragm Valve.</p> <p>SS FI Distribution Loop System has the following special features: Material of construction - SS 316L. Internals electro polished to Ra < 0.8. Externals Mechanically polished to 180 grit finish. Welding technique - Automatic Orbital Welding. All interconnections through triclovers. All valves are of self draining type. All gaskets are of Teflon. Dead leg not more than 6d for d < 30mm. Dead leg not more than 3d for d >=30mm. Entire installation will be completely drainable. Slope of the low point must be 1: 100 minimum. Following accessories are supplied as a part of the loop system WFI circulation pump. Saunders diaphragm valves. Temperature Indicator cum Controller. Flow Indicator cum Totalizer. Conductivity Indicator cum Controller. Sanitary Diverting Valve. Back Pressure Valve. Panel board with Data Logger, printer and alarm system panel.</p>	1 No.
11A	<p>PULSE VACUUM STERILIZER 1.2 ³m Inner Chamber loading Capacity 1200 Liters Inner Chamber S.S. 316L Two separate pipe lines (One for Chamber and Second for Jacket) Pipeline to chamber S.S.316L Door teeth S.S. 316L Pipe Line to Jacket S.S. 304 Two Inner Trolleys S.S. 316L Two Out Side Cart S.S. 304</p>	1 No.

P A R T - B

Item No.	NAME OF GOODS, TECHNICAL DESCRIPTION, SPECIFICATIONS, AND STANDARDS	Qty
1B	<p>SPECTROPHOTOMETER True double beam UV/Visible spectrophotometer with parallel sample and reference beams and is supplied with two x 10mm precision cell holders as standard. Basic Mode - Absorbance, %T, Concentration Quantitative Mode - Concentration calibration curves Wavelength Scanning Mode Kinetics Mode - Including time/drive DNA/Protein Analysis Mode Multi-wavelength Mode Performance Validation Mode Measurement of DNA, RNA and protein concentration (UV and colorimetric Incorporation rate of fluorescent molecules e. g., for microarray experiments) Enzymatic assays (e.g., peroxides, alkaline phosphates, β-glycosidase) Optical density of cells Including data transfer software to all measurement and calibration data to a PC.</p>	1 No.
2B	<p>DENSITY METER Measure in units of Kg/m³, g/cm³, g/ml, pounds/gallon, specific gravity, Baumé and more. Determine concentration in: %, molarity, normality, mole fraction, ppm, and more Check batch consistency and ensure proper blending rations Wetted materials compatible with the most aggressive chemicals. Capable of 3, 5 or more multiple measurements with standard deviation, mean, min and max reading for true cGLP / GMP compliance Complete IQ / OQ / PQ documentation Checking of raw materials and product release Electronic Signature and Secure Data Storage.</p>	2 Nos.
3B	<p>CHROMATOGRAPHY DETECTORS UV /Visible detectors includes UV optics module and conductivity monitors, analytical cell flow systems</p>	2 Nos.
4B	<p>CHROMATOGRAPHY FRACTION COLLECTORS SYSTEMS UV/VIS detectors, Degaser, pda detector, fluoresce, EC detector, sample injector kit, Dell controller, F40 workstation, mixer, rack, flow cell and filters, AVR7-3 valve.</p>	2 Nos.
5B	<p>CHROMATOGRAPHY GLASS COLUMNS 1) 40 centimeter length 2.5 cm dia 2) 20 centimeter length 2.5 cm dia 3) 1.5. x 50 cm, glass chromatography column, max. vol. 40 ml, cross-sectional area 0.79 cm², for use in low-pressure chromatography</p>	5 Sets
6B	<p>CHROMATOGRAPHY PERISTALTIC PUMPS Peristaltic pump for low-pressure chromatography or pumping liquids, compatible with biological Flow system ,two-channel, bidirectional, variable-speed, for use capable of isocratic and gradient elution applications.</p>	2 Nos.
7B	<p>WESTERN AND NORTHERN BLOAT COMPLETE SET UP Includes gel casting system, transfer equipment Protein Blotting Membranes, Detection, Reagents ,gel drying systems ,electrophoresis systems ,Protein Blotting Standards</p>	1 No.

Item No.	NAME OF GOODS, TECHNICAL DESCRIPTION, SPECIFICATIONS, AND STANDARDS	Qty
8B	BLOOD BAG SEALER Portable and table top	1 No.
9B	PLASMA EXTRACTOR For 1000 cc to 5000 cc bag extractor including digital sensor	1 No.
10B	AGGLUTINATION VIEWER Antigen, Blood agglutination test	1 No.
11B	PLATE FORM ROCKER Medium size, Variable Speed and including timer	1 No.
12B	BLOOD COLLECTION BAGS FOR HORSE 4000 to 5000ml	100 Nos.
13B	FPLC (VERSTILE PURIFICATIONS OF PROTEINS AND PEPETIDES) Fast and efficient purification, reproducible results, multiple wave detectors, easy programming, measurement pH, conductivity, temperature, tion sample application, purification of proteins in milligrams, micrograms, flexible fractionate, automatic column selection, automatic buffer ,reagent selection, reversed flow evaluation, compatibility and integrated with fraction collectors printer, scanner, monitor and security for programmed events .all accessories and documents and fraction collector include and equipments training.	1 No.
14B	FLOOR STANDING REFRIGERATED CENTRIFUGE Capacity 12 Triple Bags Max. Speed : 4900 RPM. Max. RCF : 7300 xg. Temperature Range: -8 ° C to + 40° C. Microprocessor Control. Quite Brushless Induction Motor. Video Set Intuitive Graphic Control System. Programmable Parameters. Speed, RCF, Radius, Time, 10 Acceleration / Braking Rates, Temperature, Temp. compensation, Integral of Centrifugation (Auto Calculated) 24 Memories + Test Program + Password. Upgradeable with BB-CQCS Software for QC. Safety Feature: Imbalance, Lid Interlock, Guard Ring, Current, Temperature, TFT Cooling System / CRF FREE. Air cooled Condenser. Accessories a) Lid Free Wind Shielded Swing Out Rotor b) 06 Transfusion Buckets. c) Liner for Quin/ Quad/Triple Bags	

SPECIAL NOTE FOR PART – A AND PART - B:

- **The Purchaser will evaluate and compare bids on Package Basis for the equipment required in Part – A. Whereas, equipment of Part – B will be evaluate and compared on Itemized Basis or on the basis of a group or a combination of groups or as total of groups.**
- **Equipment must be quoted with all the standard accessories.**
- **UPS/Power protection for the equipment shall be incorporated in the systems or must be quoted separately.**
- **All the civil works will be carried-out by the Dow University of Health Sciences, Karachi with the consultation of the responsive bidder.**
- **Responsive bidder will provide the consultancy regarding the installation of the Equipment according to the GMP / WHO standards.**
- **All site specific work to be incorporated in the system viz. Lead Glass/special antistatic flooring, environment control/radiation protection etc. must be quoted separately.**
- **The bidder shall separately quote the price of service contract inclusive of parts as well as excluding the parts for 5 years (minimum) in term of %age for total contract value.**
- **Goods must be conform to the GMP, FDA, WHO, European Union validation / qualification. Bidder must provide procedures and services for IQ and OQ.**