SPECIFICATIONS FOR CRYO-BATH

Purpose:

The Cryo Bath is designed for rapid and uniform thawing of fresh frozen plasma bags at 4 °C +/- 0.2 °C such that the cryoprecipitate remains solid, and a cry supernatant liquid is formed that can be transferred out of the bag in order to manufacture cryoprecipitate units.

Operational Requirements:

1. Floor standing system, mounted on lockable castors.
2. Should be able to thaw ten to twelve plasma units (FFP ~200-300 ml) at a time.
3. Should have a Stainless Steel Tank of 22G, and an insulated lid covered with 20G Stainless Steel.
4. Should be fitted with compartments that have a removable rack/tray system for securely holding the plasma bags and ensuring that entry ports are not contaminated with water.
5. Should be microprocessor-controlled water bath-based system operating at a temperature of 4 °C +/- 0.2 °C or an alternative can also be safely set at 37 °C +/- 0.2 °C.
6. Digital, an electronic system with provision for programmable temperature adjustment setting with LED display with a temperature resolution of 0.1 °C
7. Programmable temperature range covers 3-50 °C.
8. Should not take more than 2 hours at full loads to thaw the plasma into cry supernatant.
9. Should have a deep thawing chamber with a stirrer for water circulation & gentle rocking for uniform heating
10. Should have a system to drain the chamber without lifting or tilting, and should be fitted with a shut-off valve.
11. The unit shall be capable of being stored continuously in the ambient temperature of 0 - 50deg C and relative humidity of 15-90% without getting rusted.
12. Compatible with Input voltage: 240V 50 Hz Single phase Ac
13. Should have an integrated voltage stabilizer or external servo stabilizer of appropriate ratings meeting ISI Specifications (Input 160-260 V and output 220-240 V and 50 Hz)
14. Resettable over the current breaker shall be fitted for protection. Quality standards
15. Manufacturing should be compliant with ISO 13485 and ISO 9001:2008.
16. Should be compliant with European CE Class IIA and/or US FDA
17. Equipment must meet electrical safety specifications of IEC 61010-1

Additional requirements:

1. All equipment should specify qualifications for design, installation, operation and performance.
2. Validation and calibration reports should have traceability to applicable national and international standards.
3. Complete with a comprehensive set of spare parts, a suitable capacity voltage stabilizer and Suitable UPS with maintenance-free batteries for a minimum one-hour back-up for each piece of equipment should be supplied with the system.
4. The make, rating, model, description, specifications, and price quantity of each item should be furnished separately.
5. Necessary catalogues, and technical write-up in English, should be attached with the offer both in hard and electronic copies.
6. Performance, efficiency, and other factors as applicable should be furnished.
7. Demonstration and continued comprehensive training for lab staff and support services till familiarity with the system.
8. Should provide electronic and hard copies of User Manual (English), Service manual (English) and Complete construction details with respect to material specification, thickness, finish etc.
9. Should provide a set of equipment for providing calibration (eg thermometer) and routine Preventive Maintenance as per manufacturer documentation in service/technical manual.
10. Should provide a Log book with instructions for daily, weekly, monthly and quarterly maintenance checklists. The job description of the hospital technician and company service engineer should be clearly spelt out.

Conditions for tenderer:

1. All accessories should be from the same Original Equipment Manufacturer for the main unit.
2. Instruments must be ISO certified and a copy should be enclosed. (The ISO Certificate must be issued by any organization accredited by the Bureau of Indian Standard or accredited by the international accrediting forum "IAF" (Certificate to be attached).
3. Should be USA FDA and/ or European CE be approved by 4 digits notified body.
4. Other necessary certifications, if any, will be provided by the bidder for the smooth functioning of the machine.

5. Installation process should be performed by O.E.M trained service engineers/ service representatives on OEM letterhead or Service Report within 15 days of supply, with the mandatory provision of providing preventive services visit of OEM trained Service Engineer/ Service Representative quarterly per year till the completion of warranty period (i.e., 20 visits for the first 05 years) & further quarterly visits (04 visits/year) year till the completion of CMC period.
6. The equipment should have a Brand name/ Model Number embossed/etched on the equipment.
7. All the technical specifications in the compliance statement must be supported by Original Literature from the firm/ O.E.M with highlighting Numbering & flagging of all technical certificates.
8. Offered Equipment should have a strong Government Installation base.
9. Offered Equipment should have a Regional Sales Service Centre of the Original Equipment Manufacturer in the region for a 95 % uptime guarantee.
10. For the offered main unit, the essential, optional required consumables'/accessories' shelf life should be declared on the Original Equipment Manufacturer's letterhead.
11. In case of technical snag/failure/breakdown the response time for the inspection should be within 24 hours and repair within 05 days otherwise provide a service machine/ alternate arrangement to be made till the period of recovery of the breakdown of the unit, failing which attracts penal action as per the decision of institute/ hospital.
12. For offered equipment the Training of technical staff and users should be performed by Original Equipment Manufacturer trained Service Engineers at the proper designated place- at bidders' cost.
13. Company should quote their latest model and need to provide an affidavit for the same.
14. As a tendering process the Demonstration of the offered Equipment is Mandatory at hospital/institute premises or other designated places at the bidder's cost.
15. The bidder must comply with the General Financial Rules and their modifications if any issued by the Government of India- 2017.
16. Any bidder from a country that shares a land border with India will be eligible to bid in the tender only if the bidder is registered with the Competent Authority (i.e., Registration certificate issued by the Ministry of Commerce and Industry (Department for Promotion of Industry and Internal Trade- DPIIT after October 2020). If any such bidder is not registered with DPIIT they will be liable for technical disqualification.

17. Principal (OEM) must authorize only one agent to be quoted in the bid otherwise multiple quotes through different agents in the same bid will be cancelled.
18. The Bidder and its OEM both have to submit a notarized affidavit on the Indian Non-Judicial Stamp Paper of Rs.100/- that the bidder has not quoted the price higher than the current financial year and last financial year supplied to any government Institute/ Organization/ reputed Private Organization. OEM also has to submit that the price quoted by the bidder in the bid is on its behalf and the lowest in the current and last financial year in the country. Therefore, if at any stage it has been found that the supplier and its OEM have quoted lower rates than those quoted in this bid; the Institute (the purchaser) would be given the benefit of lower rates by the Supplier and any excess payment if any, will become immediately payable to the Institute (the purchaser). The bid will be outright rejected if such an affidavit is not submitted. (Part of technical bid).
19. Guarantee / Warranty Period: Separate offers of Comprehensive Maintenance Contract (CMC on main equipment) and Annual Maintenance Contract (AMC on main equipment) for further 5 years after expiry of 5 years of warranty (i.e., 6th, 7th, 8th, 9th and 10th years) in rupees only (and on basis of percentage of price) should be included in a financial bid in the absence of which the offer is liable to be rejected. Payment for CMC/AMC shall be made only after the warranty expiry of 5 years, in case the Institute (the purchaser) decides to avail of CMC/AMC services. Contract for CMC/AMC shall be decided on expiry of warranty but rates (not more than 5% inclusive of all taxes for 6th to 10th year) will be frozen at the price of an issued purchase order before the release of payment by the Institute (the purchaser). However, the Institute (the purchaser) may decide not to enter into any CMC/AMC contract without assigning any reason for the same, which shall be binding upon the bid.
20. Should provide 5-year CMC. CMC cannot be more than 5% of the contract value.
21. System configured application-specific educational video tutorials shall be provided as standard with the system.
22. Details of service outlet in India to render services during 5 years warranty period.
23. The principals must give a certificate if the supplier/vendor is changed during the course of the guarantee/warranty period, the principals would be responsible for the upkeep/maintenance of the quote/supplied equipment, besides honouring all the terms and conditions of CMC/AMC in letter and spirit.