


### Corrigendum Details

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<b>Tender ID :</b>	2018_CSIR_19362_1
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<b>Tender Title :</b>	Tender for Lyophilizer
<b>Corrigendum Type :</b>	Technical Bid

Corr.No.	Corrigendum Title	Corrigendum Description	Published Date	Complete specification sheet
1	Complete Technical Specifications	Due to oversight, 2nd page of technical specifications (Points 17 to 22) was not uploaded. Hence complete specifications sheet is being uploaded again	21-Dec-2018 03:49 PM	Complete Specification as per Annexure-II 

## ANNEXURE - II

### Specifications for Lyophilizer

**Lyophilizer for protein concentration is required with following specifications: -**

1. Vessel capacity
  - a. System should handle maximum sample loading capacity of 10.0 kg (Its) or better.
  - b. Capacity of ice removing drying rate/ performance: 10 kg or Its in 24 hours or better.
2. Vessel design
  - a. Product chamber with at least 3 temperature controlled shelve (-45°C to +50°C) or better for petri dish/vials applications and minimum shelf surface area  $\geq 0.40 \text{ m}^2$
  - b. Distance between shelves:  $\geq 100 \text{ mm}$  enough to accommodate 50 ml and 100ml vials along with rubber cap.
  - c. Vial sealing/stoppering device.
3. Material of construction: The chamber/ice condenser, shelves and other product related parts must be made up of SS 316L/Teflon coated SS316.
4. Controller
  - a. Microprocessor controller for system operation and parameter settings such as ice condenser temperature, vacuum pressure with proper units.
  - b. Graphical user interface with process control software for visualization, operation and recording.
  - c. Capability to input a minimum of 10 user-defined individual freeze drying programs.
5. System should be able to reach ice condenser temperature: minimum - 80°C or better.
6. Should have vacuum control option vacuum sensor to maintain set point of vacuum level.
7. Pressure control through control valve between pump and ice condenser.
8. The machine should be equipped with air injection precision needle valve for pressure control through regulated gas admission.
9. Hot gas rapid defrosting (heating of the ice condenser).
10. System should be supplied with 2 stage rotary vein chemical resistant vacuum pump with capacity at least 100 liters/min or better with an exhaust filter or equivalent (chemical solvent compatible).
11. Any failure during cycle should trigger the alarm & show detail message of error.
12. With facility for product phase monitoring including necessary measuring sensor for temperature and resistance and automatic end-point determination of drying cycle.
13. System build in-high capacity double cascade based refrigerator systems, with CFC-free refrigerant.
14. Facility for arrangement and record of process data in the freeze dryer flow sheet such as product temperature, ice condenser temperature, shelf-temperature vacuum etc. for process validation and compatible to export data from the system in the form of MS EXCEL and PDF.
15. It should meet ISO, GMP guidelines.
16. Spare parts kit and preventive maintenance kit for trouble free and maintenance free operation. Must include one copy of all O rings, gasket, freeze dryer door gasket.

17. The company should also supply below mentioned items along with
  - a. Oil for vacuum pump: 50 liters.
  - b. Oil mist trap/eliminator: 10 nos.
  - c. Vacuum tester for checking vacuum in vials.
  - d. Following vials along with rubber cap, aluminum seal and seal crimper
    - i. 1000 nos. of 50ml vials.
    - ii. 500 nos. of 100ml vials.
18. A set of operating and maintenance manuals complete with parts list and assembly drawings to be provided.
19. Warranty: 02 years from the date of installation.
20. AMC for 03 years after expiry of warranty must be quoted.
21. Compliance certificate: A compliance table in addition to marking in technical brochure (quoted models) as per the specifications point by point must be submitted by the vendor.
22. List of users (at least two industrial users) in India should be provided.