USER REQUIREMENT SPECIFICATION FOR LYOPHILIZER

PHARMA DEVILS

PRODUCTION DEPARTMENT

USER REQUIREMENT SPECIFICATION FOR LYOPHILIZER

Prepared by		
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Approved by		
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OVERVIEW:

EQUIPMENT DESCRIPTION

The Lyophilizer shall be used to freeze-dry the sterile aqueous solution of the product filled in half-stoppered glass vials or trays. Lyophilizer shall stopper the vial before unloading.

The lyophilizer shall be integrated with semi-automatic loading and unloading system to load and unload thevials in and from lyophilizer respectively.

The lyophiliser shall have facility to directly fill the trays with the product solution

The lyophilizer shall be configured as per the equipment location layout the lyophilizer (the equipmentlayout is attached as Annex 1)

As the product to be dried is sterile, the loading side shall be covered by Laminar air flow system.

This URS is to be complied by the vendor who will be responsible for design, fabrication, installation at siteand qualification of Lyophilizer and loading/unloading system.

REFRENCE STANDARD/GUIDELINE FOR EQUIPMENT

The equipment should comply with the following guidelines/standard:

GMP-Regulations

- Regulation for implementation of the drug administration law of the People's Republic of China EU-GMP-Guideline Part 1, Annexes 1, 15 & 17
- Code of Federal Regulations (CFR) 21, Part 210: cGMP in Manufacturing, Processing, Packing andHolding of Drugs; General
- 21 CFR Part 211: Current Good Manufacturing Practice for finished Pharmaceuticals
- 21 CFR Part 11: Electronic Records; Electronic Signatures

FDA Guidance for Industry

- Sterile Drug Products Produced by Aseptic Processing
- Documentation for Sterilisation Process Validation

GAMP

- The Good Automated Manufacturing Practice (GAMP) Guide for Validation of Automated Systemsin Pharmaceutical Manufacture, Vol. 5

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Vendor shall provide response as Yes or No against each specification for the compliance of theiroffered equipment in the remarks column and send the copy along with the quotation.

	Specifications	Compliance
3.0	**Process Description**	
3.1	**Input & Charging method**	
3.1.1	**Input:** Aqueous solution of the product filled in half stoppered glass vials or intrays. Vial sizes are **ISO 2R, 6R, 10R according to DIN-ISO 8362-1 and 8362-4.** For lyophilization fill volume could be considered as 50% of the total fillcapacity of the vial.	Information
3.1.2	Freezing temperature of product: -55°C	❑ Yes ❑ no
3.1.3	Maximum temperature during secondary drying: +70°C	❑ Yes ❑ no
3.1.4	Condenser temperature minimum : -75°C	❑ Yes ❑ no
3.1.5	600 kg ice condensing capacity	❑ Yes ❑ no
3.1.6	Vendor shall propose a cost effective design of the semi-automatic loading system, which should collect the vials from the upstream filling and stopperingsystem, and load the vials into lyophilizer without or little human intervention maintaining the sterility of the product.	❑ Yes ❑ no
3.1.7	Loading system should consider the upstream filling capacity of 200 vials perminute (based on vial size 10R).	❑ Yes ❑ no
3.1.8	Loading shall be done at room temperature in closed manner within class A under unidirectional air flow.	Information
3.2	**Brief Process Steps**	
3.2.1	The lyophilization shall have the following process steps • Vial lyophilisation ❑ Collection of filled and half stoppered vials from upstream filling &stoppering machine ❑ Semi - automatic loading of vials in lyophilizer ❑ Lyophilization ❑ Pressing of stopper ❑ Semi-Automatic unloading of vials from lyophilizer ❑ Transfer of vials on to crimping machine • Bulk Lyophilisation	❑ Yes ❑ no

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	Specifications	Compliance
	❑ Filling of sterile bulk in tray ❑ Lyophilisation ❑ Filling in containers (4kg or 8 kg)	
3.3	**Output & Discharging method**	
3.3.1	**Output:** sterile powder of the product. Vendor shall propose a cost effective design options of the semi-automatic unloading system which should collect the vials from the lyophilizer anddischarge the vials on the conveying system of the down stream crimping machine.	❑ Yes ❑ no
3.3.2	Unloading shall be done at room temperature in closed manner within class AIsolator under unidirectional air flow.	Information
4.0	**Productivity Requirement**	
4.1	**Desired/ suggested capacity**	
4.1.1	Capacity of lyophilizer is standardized as 30 sq m shelf area or nearest standardsize	❑ Yes ❑ no
4.2	**Standard batch size**	
4.2.1 4.2.2	Single load should contain 50000 vials of size 10R 600 L bulk volume	❑ Yes ❑ no
4.3	**Change Over Time (if applicable)**	
	Not applicable	
4.4	**Cleaning/sanitization/sterilization Time (if applicable)**	
4.4.1	Vendor shall provide approximate period of cleaning (CIP) and sterilization (SIP). However total time for CIP and SIP of lyophilizer followed by cooling ofthe chamber to 25°C should not be more than 12 Hours.	❑ Yes ❑ no
4.5	**Other Productivity Requirement**	
4.5.1	Vendor shall inform the total water consumption for CIP	❑ Yes ❑ no
5.0	**Safety requirement**	
5.1	**General**	
5.1.1	Following facilities must be provided to protect personnel, article andequipment:	
5.1.1.1	In the event of equipment malfunction or loss of utilities, the unit must contain	❑ Yes ❑ no

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	all necessary protection devices to ensure that the equipment and the articleremain in a safe condition.	
5.1.1.2	Noise level below 80 db at a distance of 1 m from the equipment	❑ Yes ❑ no
5.1.1.3	Emergency stop function on all accessible areas	❑ Yes ❑ no
5.1.1.4	For the safety of the operator the external surfaces should not have temperaturemore than 45°C.	❑ Yes ❑ no
5.1.1.5	Warning stickers on all hot surfaces	❑ Yes ❑ no
5.1.1.6	Appropriate failure detection and alarm notification	❑ Yes ❑ no
5.2	**Power failure and recovery**	
5.2.1	A system has to be defined to guarantee the integrity of the system and the datain case of power failure.	❑ Yes ❑ no
5.2.2	**In case of a power failure the product must be kept in a stable situation:** 1 vacuum pump and 1 cooling compressor must be running and hold temperature and vacuum (power supply of the vacuum pump and the cooling compressor viaseparate emergency power supply). The control section including all necessarydevices like transmitter, PLC and visualization system have to be supplied via the existing UPS system on site. Vendor to specify UPS capacity requirement.	❑ Yes ❑ no
5.2.3	In case of power failure the valve between the drying chamber and icecondenser should remain in previous position before power failure.	❑ Yes ❑ no
5.2.4	A central vacuum valve between the condenser and the vacuum system must beprovided. In case of power failure this valve has to close immediately and automatically.	❑ Yes ❑ no
5.3	**Containment**	
	Not Applicable	❑ Yes ❑ no
6.0	**GMP requirements**	
6.1	**Process control**	
	The lyophilization system should essentially have the necessary provision for thecontrol of following process critical parameters	
6.1.1	Shelf temperature within +/- 1°C	❑ Yes ❑ no
6.1.2	Condenser temperature	❑ Yes ❑ no
6.1.3	Chamber temperature	❑ Yes ❑ no
6.1.4	Product temperature (on each shelf)	❑ Yes ❑ no

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	Specifications	Compliance
6.1.5	Rate of cooling (minimum -1 °C /minute)	❑ Yes ❑ no
6.1.6	Rate of heating (minimum 1°C /minute for empty chamber)	❑ Yes ❑ no
6.1.7	Chamber pressure/vacuum (maximum vacuum upto 10 microbar with empty chamber)	❑ Yes ❑ no
6.1.8	Compressed air line pressure for pneumatic control	❑ Yes ❑ no
6.1.9	Differential pressure across the vacuum break filter	❑ Yes ❑ no
6.1.10	Cleaning process parameters	❑ Yes ❑ no
6.1.11	Sterilization process parameters (temperature, pressure and time)	❑ Yes ❑ no
6.2	**Failure mode detection**	
	The equipment should generate audio-visual alarm and print the alarms in case offollowing failure.	
6.2.1	Process critical parameter exceed defined limit	❑ Yes ❑ no
6.2.2	Failure of critical equipment component which can affect the product qualitydirectly or indirectly	❑ Yes ❑ no
6.2.3	Process critical instrument loop disconnected	❑ Yes ❑ no
6.2.4	Failure in utility supply	❑ Yes ❑ no
6.2.5	Failure in data communication	❑ Yes ❑ no
6.2.6	GMP critical test failure i.e. chamber integrity test failure, pressure rise test.	❑ Yes ❑ no
6.2.7	**Vendor shall propose detail list of alarm in functional specification. The alarm list shall be finalized with the final user during discussion detail engineering design of the equipment**	❑ Yes ❑ no
6.3	**In –Process control**	
	Not Applicable	❑ Yes ❑ no

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Specifications	Compliance
6.4 Level of instrumentation	
Sufficient and suitable instrumentation for the process, safety and productivity controlas indicated in the following table:	

Type of control	Purpose	Operation range	Desired Least Count	Extent of Instrumentation				Compliance
				Indication	Alarm	Control	Recording	
Temperature	For controlling/ monitoring the shelf temperature	(- 80)°C to (+ 150°C)	0.1°C	**Y**	**Y**	**Y**	**Y**	❑ Yes ❑ no
Temperature	For controlling/ monitoring the condenser temperature	(- 80)°C to (+ 150°C)	0.1°C	**Y**	**Y**	**Y**	**Y**	❑ Yes ❑ no
Temperature	For controlling/ monitoring the chamber temperature	(- 80)°C to (+ 150°C)	0.1°C	**Y**	**Y**	**Y**	**Y**	❑ Yes ❑ no
Temperature	For controlling/ monitoring the product temperature	(- 80)°C to (+ 150°C)	0.1°C	**Y**	**Y**	**Y**	**Y**	❑ Yes ❑ no
Temperature	For controlling/ monitoring the Chamberdrain temperature during SIP	(- 80)°C to (+ 150°C)	0.1°C	**Y**	**Y**	**Y**	**Y**	❑ Yes ❑ no

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Specifications									Compliance
	Temperature	For controlling/ monitoring the condenser drain temperature during SIP	(- 80)°C to (+ 150°C)	0.1°C	**Y**	**Y**	**Y**	**Y**	❑ Yes ❑ no
	Temperature	For controlling/ monitoring the sterile filter drain temperature during SIP	(- 80)°C to (+ 150°C)	0.1°C	**Y**	**Y**	**Y**	**Y**	❑ Yes ❑ no
	Temperature	For controlling/ monitoring the coolant temperature in shelf heat exchanger and condenser at inlet and outlet	(- 80)°C to (+ 150°C)	0.1°C	**Y**	**Y**	**Y**	**Y**	❑ Yes ❑ no
	Pressure	For controlling/ monitoring the lyophilizer chamber pressure	Full vacuum to 3.0 bar	1 mbar	**Y**	**Y**	**Y**	**Y**	❑ Yes ❑ no
	Pressure	For controlling/ monitoring the lyophilizer condenser pressure	Full vacuum to 3.0 bar	1 mbar	**Y**	**Y**	**Y**	**Y**	❑ Yes ❑ no

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	Pressure	For monitoring/ controlling the pressure across the sterilizing grade vacuum break filter	Full vacuum to 8.0 bar	0.01bar	**Y**	**Y**	**Y**	**Y**	
	Pressure	For monitoring the main compressed air line pressure for pneumatic control	0 to 8.0 bar	0.1 bar	**Y**	**Y**	**Y**	**N**	
Y *Required,* **N** *Not required*									
6.5	**Cleaning requirement**								
6.5.1	The lyophilizer shall be cleaned by dedicated CIP system. Vendor shall providedetail CIP arrangement and process with requirement of space, load, technicaldetail and control system in the technical offer								❑ Yes ❑ no
6.5.2	The lyophilizer shall be sterilized by dedicated SIP system. Vendor shall provide detail CIP arrangement and process with technical detail and controlsystem in the technical offer. Pure steam supply shall be provided by the user.								❑ Yes ❑ no
6.5.3	Recommended cleaning agents are mild alkaline solution, purified water/ WFI								❑ Yes ❑ no
6.5.4	Design of equipment should enhance cleaning feasibility by providing minimumsharp corners, minimum crevices & smooth finished welds joints.								❑ Yes ❑ no
6.5.5	Parts, which are required for cleaning, should be provided with quick fixingarrangement.								❑ Yes ❑ no
6.5.6	All gaskets provided to avoid leakage should be amenable for easy removed &re- fixing.								❑ Yes ❑ no
6.5.7	All bolts, nuts on the exterior part of equipment will be with cap head or capnut.								❑ Yes ❑ no
6.6	**Qualification requirement**								
6.6.1	All equipments shall be qualified with life cycle approach, i.e. DQ, IQ, OQ &								❑ Yes ❑ no

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	PQ. Vendor shall provide all documentation support including protocol subjectto approval by the user.	
6.6.2	Vendor shall provide execution support to the user to complete all stages of thequalification report.	❑ Yes ❑ no
6.6.3	Steaming in place sterilization process shall be validated by empty chamber heat distribution and bio-challenge study to ensure the temperature uniformitywithin the chamber at 122±1°C during hold time and reduction of bioload bymore than 6 log when challenged by *B. stearothermophillus* spore strips containing 10^6 spores per strips.	❑ Yes ❑ no
6.6.4	Sterility assurance shall be verified by three consecutive and successful processsimulation (media fill) trial	❑ Yes ❑ no
6.7	**Material of construction**	
6.7.1	All following metallic critical contact surfaces should be constructed of 316L grade stainless steel or better with internal mirror surface finish < 0.5µm Ra andexternal surface finish < 1.2µm Ra, matte finish. a) Surfaces coming in direct contact of product b) Surface coming in contact of washing and sterilization media i.e. WFI,purified water, pure steam c) Surface coming in contact of sterile gas	❑ Yes ❑ no
6.7.2	All non product contact metallic surfaces should be constructed of 304 grade stainless steel or better (316 steel for sterile area equipment), external surface finish < 1.2 µm Ra, matte finish.	❑ Yes ❑ no
6.7.3	Gaskets, seals and O-rings coming in direct / indirect contact surfaces should beconstructed of USFDA approved polymeric materials only.	❑ Yes ❑ no
6.7.4	All welds should be ground finished to < 1.2 µm Ra and properly passivated.	❑ Yes ❑ no
6.7.5	Clean media pipes should be orbital welded	❑ Yes ❑ no
6.7.6	Insulation material should be non-fibrous and covered with completely weldedSS 304 or better cladding.	❑ Yes ❑ no
6.8	**Use of lubricants**	
6.8.1	Any lubricant, if used in the equipment must be food grade and non-toxic. Used lubricants must not come in contact of the potential product contact surfaces.	❑ Yes ❑ no
6.8.2	Vendor shall give detail on the coolant and drying media used in the system.	❑ Yes ❑ no

6.9	**21 CFR Part 11 compliance**	
	A criticality assessment is to be made to assess the applicability of the system to Part 11 regulation. Software, if used to generate, process, store the quality critical data must be validated and must comply 21 CFR Part 11 requirements	❑ Yes ❑ no
6.10	**Data integrity**	
	System security access shall consist of the following profiles-:	❑ Yes ❑ no
	a) Operator: Shall provide operator access to allow routine operation of all equipment features	❑ Yes ❑ no
	b) Supervisor: Shall provide access to operator level features in addition tocritical operating parameter configuration	❑ Yes ❑ no
	c) System administrator: Shall provide the access to the Operator andSupervisor level features in addition to system security parameters.	❑ Yes ❑ no
6.11	**Batch record printing**	
	A complete batch record indicating the following important parameters, but notlimited to these:	
6.11.1	Equipment identification number	❑ Yes ❑ no
6.11.2	Process code &/or identification (process program number)	❑ Yes ❑ no
6.11.3	Program information and parameters	❑ Yes ❑ no
6.11.4	Start date and time	❑ Yes ❑ no
6.11.5	End date and time	❑ Yes ❑ no
6.11.6	All failures and alarms.	❑ Yes ❑ no
6.11.7	Process record, preferably a real time graphical representation for importantprocess controls parameters.	❑ Yes ❑ no
6.11.8	Operator code and name	❑ Yes ❑ no
6.11.9	Adequate space for writing remarks / corrective actions if any.	❑ Yes ❑ no
6.11.10	Identified space to sign for operator & supervisor.	❑ Yes ❑ no
6.11.11	There should be a possibility to store and archive the data for future retrievaland analysis.	❑ Yes ❑ no

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Specifications	Compliance
6.12 Desired documents	
6.12.1 Following documents, but not limited to these, are expected from the vendor as part of the supply package as hard copy and electronic editable version in Englishlanguage	❑ Yes ❑ no
6.12.1.1 Functional design specification containing:	❑ Yes ❑ no
6.12.1.1.1 Equipment descriptions	❑ Yes ❑ no
6.12.1.1.2 Equipment operation steps	❑ Yes ❑ no
6.12.1.1.3 HMI functions with screen shot	❑ Yes ❑ no
6.12.1.1.4 List of failure indications	❑ Yes ❑ no
6.12.1.1.5 List of interlocks and block diagram with their functions and Alarms.	❑ Yes ❑ no
6.12.1.1.6 Critical list of major component, devices and instruments with their specificfunctions, specification data sheet.	❑ Yes ❑ no
6.12.1.1.7 Schematic diagram of the equipment	❑ Yes ❑ no
6.12.1.2 Operation and maintenance manuals, preventive maintenance schedule forequipment major component as well as the operating system	❑ Yes ❑ no
6.12.1.3 Operation and maintenance manuals for the bought out items.	❑ Yes ❑ no
6.12.1.4 Installation instructions/ guideline for equipment	❑ Yes ❑ no
6.12.1.5 Final As-built drawing for equipment	❑ Yes ❑ no
6.12.1.6 Detailed drawing (Plan and minimum one elevation) marking clearly all the necessary dimensions and locations of utilities along with requirement of utilities on the drawing along with the offer.	❑ Yes ❑ no
6.12.1.7 Other drawings (such as PID, electrical, instrumentation etc.)	❑ Yes ❑ no
6.12.1.8 Software ladder logic/ operation and controls flow charts	❑ Yes ❑ no
6.12.1.9 Spare and/ or change parts list with ordering information	❑ Yes ❑ no
6.12.1.10 MOC certificates for all direct/ indirect product contact surfaces.	❑ Yes ❑ no
6.12.1.11 Instrument calibration certificates with respect to the traceable national referencestandard instrument and their calibration procedure.	❑ Yes ❑ no
6.12.1.12 Factory acceptance test specifications and reports with actual test results/ data forequipment	❑ Yes ❑ no
6.12.1.13 Recommended SOP's for operation, cleaning and maintenance of each equipment	❑ Yes ❑ no

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6.12.1.14	Guaranty/ warranty certificates for each equipment and major bought-out items,such as PLC, printer, recorders, instrumentation etc.	❑ Yes ❑ no
6.12.1.15	21 CFR part 11 compliance report/ certificates for the software(s). (if applicable)	❑ Yes ❑ no
6.12.1.16	Software installation CD/ floppy with 2 back-ups, wherever applicable.	❑ Yes ❑ no
6.12.1.17	Software recovery procedures in case of computer system breakdown, forequipment control system	❑ Yes ❑ no
6.12.1.18	Shipping checklist.	❑ Yes ❑ no
6.12.1.19	DQ, IQ and OQ protocols	❑ Yes ❑ no
6.12.1.20	Control System input / output verification data & report	❑ Yes ❑ no
6.12.1.21	Types of Lubricant and Lubrication instructions. Food grade certificate.	❑ Yes ❑ no
6.13	**Training**	
	a) A special training for operators has to be included in the offer. b) A special training for technical staff has to be included in the offer	❑ Yes ❑ no
6.14	**GMP requirement (others)**	
6.14.1	A clear separation between clean and technical area must be realized.	❑ Yes ❑ no
6.14.2	Required leakage rate for chamber/condenser should be less than 0.01 mbar/l/s	❑ Yes ❑ no
6.14.3	All utility pipes specifically pure steam/ water for injection/ condensate shouldhave sufficient slope towards drain for complete emptying of the pipes	❑ Yes ❑ no
6.14.4	All drives, filters, pumps, valves (specially chamber drain) should have easyaccess	❑ Yes ❑ no
6.14.5	The chamber safety valve should be of aseptic type with a sanitary flange connection. If vacuum tightness of safety valve could not be assured, a rupturedisk can be a solution	❑ Yes ❑ no
6.14.6	For all clean media a sampling valve should be provided at supply and in drain	❑ Yes ❑ no
6.14.7	All drains must be equipped with an air-gap before connected to the drainsystem on site	❑ Yes ❑ no
6.14.8	All drains should be at the lowest point of the chamber / condenser for completedrainage.	❑ Yes ❑ no
6.14.9	All valve in contact of the clean media should be of sanitary type and suitable	❑ Yes ❑ no

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	for aseptic use (e.g. deadleg free, diaphragm type with PTFE or EPDMdiaphragm)	
6.14.10	The validation ports should be provided for inserting temperature probe fortemperature mapping	❑ Yes ❑ no
6.14.11	The chamber should have sufficient slope for complete drainage	❑ Yes ❑ no
6.14.12	The stoppering system of the lyophilizer should not create any particle or affectthe sterility of the system	❑ Yes ❑ no
6.14.13	The sterile filters must be testable for integrity. An online integrity systemshould be proposed as optional	❑ Yes ❑ no
6.14.14	An appropriate seal must be used for connecting the panelling to the suspendedceiling, clean room walls and floor.	❑ Yes ❑ no
6.14.15	The front panelling on both sides must be gas tight to the technical area of thefreeze dryer.	❑ Yes ❑ no
6.14.16	Vendor to give code numbers for each component	❑ Yes ❑ no
7.0	**Technical requirement**	
7.1	**Basic technical requirement**	
7.1.1	The layout must be taken into account when determining the layouts of theunits.	❑ Yes ❑ no
7.1.2	A proposal of a possible installation layout should be added to thedocumentation.	❑ Yes ❑ no
7.1.3	The manufacture has to give the clear details on the total weight, dimensionsand the capacity of the equipment.	❑ Yes ❑ no
7.1.4	The heat given off by the unit must be stated.	❑ Yes ❑ no
7.1.5	The construction of the complete system should be described in thedocumentation in detail.	❑ Yes ❑ no
7.1.6	Vendor shall provide special tools for assembling, disassembling andmaintenance	❑ Yes ❑ no
7.2	**Level of automation**	
7.2.1	The equipment should operate with minimum operator involvement.	❑ Yes ❑ no
7.2.2	The equipment should control automatically all critical parameter and detectfailure mode automatically.	❑ Yes ❑ no

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7.2.3	Critical process parameters and failure modes are listed in the precedingsections.	❑ Yes ❑ no
7.2.4	Human - machine interface (PC) must be used to enter the process details (minimum 20 recipe), which should appear in the print out in English. Print out must provide results of all critical process parameter andfailure alarms.	❑ Yes ❑ no
7.3	**Specific requirements**	
7.3.1	All main technical installations (i.e. condenser, refrigeration unit etc) of the lyophilizer should be on the basement. Exact dimensions must be given be thesupplier. Vendor shall also make proposal of a possible installation layout	❑ Yes ❑ no
7.3.2	A pressure test according to EU regulations is required for at least the chamberand condenser	❑ Yes ❑ no
7.3.3	The panelling of the equipment should reach the suspended ceiling. The cladding panel should be constructed to allow easy removal for inspection andmaintenance	❑ Yes ❑ no
7.3.4	The vendor shall provide the detail nozzle schedule of the chamber andcondenser in the documentation	❑ Yes ❑ no
7.3.5	It has to be assured that fallen vials cannot reach the condensers under allconditions. The used precaution should be described	❑ Yes ❑ no
7.3.6	The door operation should be mechanized or automatic with an automaticlocking system	❑ Yes ❑ no
7.3.7	For loading and unloading slot door shall be provided and hinge type maindoor shall be used for maintenance	❑ Yes ❑ no
7.3.8	The slot door opening vertically should operate automatically. The bid mustinclude a description of both opening/closing and locking mechanisms.	❑ Yes ❑ no
7.3.9	The drive system for the slot door movement must be located within the technical area. Any movement of rods e.g. between the technical area and the clean room areas is not permitted. The separation between the areas should bedescribed in the bid.	❑ Yes ❑ no
7.3.10	The slot door must be designed for semi-automatic loading and unloading of thefreeze dryer.	❑ Yes ❑ no
7.3.11	An illuminated sight class within class A/B is required to allow visual control of stoppering by the operator.	❑ Yes ❑ no
7.3.12	All doors must be interlocked if the pressure in the chamber goes aboveatmospheric pressure.	❑ Yes ❑ no

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7.3.13	If any door is incorrectly closed the CIP and the SIP processes cannot bestarted.	❑ Yes ❑ no
7.3.14	The sealing mechanism for all doors should be described in the offer – staticsealing will be preferred.	❑ Yes ❑ no
7.3.15	If dynamic sealings (or combined solutions of static and dynamic sealings) areused it has to be assured that only sterile compressed air is used for sealing operation.	❑ Yes ❑ no
7.3.16	All door sealings must operate without any additional lubricant.	❑ Yes ❑ no
7.3.17	It has to be assured that during CIP/SIP no liquids remain between door, sealingand chamber.	❑ Yes ❑ no
7.3.18	The replacement of any door sealing must be possible without disassembling ofany other parts or components.	❑ Yes ❑ no
7.3.19	A hydraulic pressure test of the shelves with at least 4 bar (abs) shall beperformed and documented.	❑ Yes ❑ no
7.3.20	The operating temperature of the shelves should be between -55° to +70°C.	❑ Yes ❑ no
7.3.21	It has to be sure, that no vials will fall from the sides of the shelves. Thereforethe shelves shall be executed with a border system on the sides to ensure coherent lyo conditions even on the shelf edges. If a different system will beused to ensure this, it has to be described in the documentation.	❑ Yes ❑ no
7.3.22	The shelf clearance should be suitable for all sizes of the vials with a system ofchanging the shelf clearance	❑ Yes ❑ no
7.3.23	The collapsing (and levelling after CIP/SIP) of shelves should be performedautomatically. The construction should be described in the documentation.	❑ Yes ❑ no
7.3.24	The shelves must be levelled and constructed to a tolerance of at least +/- 0.5mm/m or less.	❑ Yes ❑ no
7.3.25	A constant loading level (for the loading and unloading system) is required. Therefore a defined position (approx. 1000 mm above floor) must be reachablewith each shelf during loading and unloading.	❑ Yes ❑ no
7.3.26	It must be possible to define the constant level infinitely variable via software for each shelf separately (no hardware based solution like limit switch permitted). A description of the used system shall be added to the bid (optional).	❑ Yes ❑ no
7.3.27	The accuracy of the positioning system should be at least +/-0.5 mm or better.	❑ Yes ❑ no
7.3.28	In addition the position of each shelf must be mechanically adjustable (to ensureminimum tolerances concerning constant loading level for each shelf).	❑ Yes ❑ no

USER REQUIREMENT SPECIFICATION FOR LYOPHILIZER

Specifications		Compliance
7.3.29	The bottom part of the shelves should be specially treated to avoid the stickingof stoppers (glass-pearl blasted e.g.).	❑ Yes ❑ no
7.3.30	The connection of heating/cooling media to the shelves should be completelywelded; flanging is not permitted.	❑ Yes ❑ no
7.3.31	Even under vacuum conditions no silicon oil (gas) is permitted to be detectablewithin the chamber.	❑ Yes ❑ no
7.3.32	The tightness of the tubes and the whole system must be checked via He-leak-test (and documented) before and after installation within the chamber.	❑ Yes ❑ no
7.3.33	All the shelves shall be pressure tested at 20% higher than the design pressure. X-ray test: One sample self shall be X-ray tested only for checking. Incase offailure 100% shelves shall be X-ray tested.	❑ Yes ❑ no
7.3.34	The vendor shall provide detail information of all critical technical componentswhich are Aeration system, Ice condenser, vacuum generation system, primary cooling system, heating/cooling system for shelves	❑ Yes ❑ no
8.0	**Good Engineering Practices Requirements**	
	a) Equipment must be fabricated following all Good Engineering Practices. The vendor's Quality System must follow applicable national orinternational standards.	❑ Yes ❑ no
	b) Vendor must generate all applicable documents during all phases of equipment fabrication i.e. design, fabrication, testing and shipment as per applicable standards e.g. GAMP.	❑ Yes ❑ no
	c) All sensors, controllers, PLC, transmitters, indicators and any other controller or indicators to read, print or control any of the parameter, will have to be calibrated, traceable to National or international standards. Original calibration certificate along with traceability to be submitted by vendor in their IQ file.	❑ Yes ❑ no
	d) All material of construction should have test certificate	❑ Yes ❑ no
	e) Vendor must generate and provide all specifications and test certificates ofsoftware used in the equipment control and/or monitoring system.	❑ Yes ❑ no
8.1	**Inspection and testing**	
	➢ System shall be inspected and tested (FAT) at the supplier's site in thepresence of user's representative before delivery.	❑ Yes ❑ no

PHARMA DEVILS

PRODUCTION DEPARTMENT

USER REQUIREMENT SPECIFICATION FOR LYOPHILIZER

Specifications	Compliance
9.0 Constraints	
9.0 Equipment location and available space	
This equipment will be installed in the Sterile bulk and formulations Facility. The equipment location is indicated in the relevant block of the layout enclosed	❑ Yes ❑ no
9.1 Available utility	
➢ Electricity:_____(Report Requirement) ➢ Purified Water_____(Report Requirement) ➢ Water for injection_____(Report Requirement) ➢ Pure steam_____(Report Requirement) ➢ Compressed air / nitrogen pressure_____(Report Requirement)Note: Vacuum system to be supplied by the Vendor	❑ Yes ❑ no
9.2 Timelines	
a) Response to URS: Within 2 weeks of receipt of URS	❑ Yes ❑ no
b) Quotation Submission: Within four weeks of receipt of URS	❑ Yes ❑ no
c) Submission of detail functional design specification, Design Qualification(DQ) and schematic drawings: Four weeks after order finalization	❑ Yes ❑ no
d) Submission of FAT/SAT Specification-: Four weeks after order finalization	❑ Yes ❑ no
e) Submission of Installation Qualification (IQ) and Operational Qualification(OQ) protocols: Two months after order finalization	❑ Yes ❑ no
f) Mechanical and electrical drawings: Two weeks before FAT.	❑ Yes ❑ no
g) Submission of control system details and control system verificationprotocol: 2 weeks before FAT	❑ Yes ❑ no

10.0 Abbreviation:

Terms	Abbrevation
CD	Compact Disc
CFR	Code of Federal Regulation
DQ	Design Qualification
EU-GMP	European –Good Manufacturing Practice
FAT	Factory Acceptance Test
GAMP	Good Automated Manufacturing Practices
GMP	Good Manufacturing Practices
HMI	Human Machine Interface
IQ	Installation Qualification
ISO	International Standards Organization
MOC	Material Of Construction
OQ	Operational Qualification
Ph	Phase
PID	Proportional Integral Derivative.
PLC	Programmable Logic Controller
PQ	Performance Qualification
RTD	Resistance Temperature Device
RTP	Rapid Transfer Port
SAT	Site Acceptance Test
SOP	Standard Operating Procedures
SS	Stainless steel
TGA	Theraupeatic Goods Authority
UPS	Uniterrupted Power Supply
US FDA	United State Food and Drugs Administration
WFI	Water For Injection
WHO	World Health Organisation