ANNEXURE I

User Requirement Specifications

Machine - Fluid Bed Dryer

Capacity-250 kg

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1.0 Approval signatures

This document has been prepared and reviewed by the technical team of project management and approved by following official of GAPL.

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2.0 INTRODUCTION

This document was generated under the authority of the GOA ANTIBIOTICS AND PHARMACEUTICALS LTD.(A SUBSIDIARY OF HLL LTD)for the purpose of specifying the user requirement for Fluid bed dryer for drying of wet mass/granules. The User Requirements Specification (URS) is provided to aid the user through the important components, variables and options necessary to procure a functional Fluidized bed dryer that meets the users needs in the most cost-effective method possible. The URS shall be provided to the Supplier to provide a price quote for machine supply including the design and manufacture of the equipment.

This URS will be recognized as an integral part of the procurement agreement with the selected equipment vendor. The equipment supplier or vendor will abide by the information and conditions set forth by this document as well as the standard purchasing term and conditions of the Company.

3.0 OVERVIEW

3.1 Project Standard

The facilities, upon completion, shall be in compliance with the CGMP requirement of drugs and cosmetic Act 1940 (Schedule M), WHO, and also the GAPL's internal quality standards.

3.2 Equipment description

The fluid bed drier shall be used for drying of wet mass/granules excipients for the production of tablets. The equipment provides:

a. Mixing: The inherent turbulence in the fluidized bed provides fast, efficient mixing and drying.

b. *Drying:* A fluidized bed is formed when an upward flow of process airlifts small solid particles/granules . As a result, the small particles/granules move rapidly within the fluidized bed and ensure a very efficient heat and material exchange between the bed and the fluidizing air. The temperature in the fluid bed should be constant across the whole height of the bed to ensure gentle drying. The fluid bed drier shall consist of the following:

3.3 Machine Tower with inlet Air Plenum, Product container, Expansion chamber and a Filter housing.

3.4 Exhaust Air Fan.

3.5 Control panel - : Control system is to control critical process parameter and to generate alarms.

3.6 Area of installation .L X B X H i.e.7.5x3x3.75mtrs.

Room designed layout enclosed at annexure – I

3.7Reference standards/guidelines for equipment

The equipment should comply with the following guidelines / standard:

•GMP-Regulations

Equipment meets the Current Good Manufacturing Practice for finished Pharmaceutical products.

Note:

1) This URS has been prepared based on our in-house knowledge & understanding for this equipment. As a vendor we expect manufacturer to go through the documents in depth and give suggestions separately as an option. However, the base offer shall be as per the URS. All suggestions and deviations shall be highlighted and summarized separately.

2) Vendor shall provide response as "Yes" or "No" against each specification for the compliance of their offered equipment in the remarks column.

4.0 PROCESS DESCRIPTION

Input &Charging method (manual)

• Wet granules/semidried powder/ dry powder from the PLM shall be transferred into the FBD bowl manually

Brief Process Steps

•The input material will be charged from the PLM to FBD manually

•The process parameters of the product shall be set and verified.

•Subsequent drying takes place

•Discharge the dry granules into the multimill manually.

Output &Discharging method (manual)

•The dried granules from the FBD bowl are discharged into the multimill.

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5.0 DESIGN REQUIREMENTS

5.1. **Bottom chamber – (MOC SS 304)**

5.1.1 The main function of insulated bottom chamber is to uniformly mix hot air before allowing it to enter in to the product container. Container and bottom chamber shall have suitable flange to fit inflatable silicon seal to achieve leak-proof operation. annual drain port shall be provided suitably with easy excess to the washed water. □Yes □no

5.2 Product container (MOC SS 316)

5.2.1 Perforated Plate: Shall have number of holes of equal diameter for uniform distribution of air through the product. □Yes □no

5.2.2 Bottom sieve: The Dutch weave sieve shall acts as product retaining filter. □Yes □no

5.2.3 Sight glass: To view the movement of product. □Yes □no

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5.2.4 Triclover for sensor: For mounting of product temp. Sensor, which measures product temperature. □Yes □no

5.2.5 Sampling Device: A device for easy withdrawal of sample during process on. □Yes □no

5.2.6 Dutch mesh : Detachable sieve for easy washing and cleaning. □Yes □no

5.2.7 Trolley: Product container shall be mounted on the mobile trolley for easy movement having PU wheels (swirl type) □Yes □no

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5.2.8 Extra two product container with trolley and sampling device shall be provided along with Equipment.(Total 3 nos). □Yes □no

5.3. Retarding chamber (MOC SS-316)

5.3.1 Shall consists of explosion flap fitted on upper portion of the filter housing where filter bag assembly is placed. □Yes □no

5.4 Manufacturer shall provide

5.4.1 Light source for better visibility. ☐Yes ☐no

5.4.2 Main chamber & product container shall have flange to fit Inflatable seal to achieve leak proof operation. ☐Yes ☐no

5.4.3 Explosion duct: It works as a safety valve for the unit. When pressure increases above 2 bars, disc shall opens and pressure shall be released to atmosphere. ☐Yes ☐no

5.4.4 In the event of explosion, a limit switch shall be activated upon opening of explosion disc which shuts down the machine operation. ☐Yes ☐no

5.5 Filter bag Unit

5.5.1 Top filter ring: shall hold the top end of the filter bag. This ring shall attached to the shaking assembly. (MOC SS-304) ☐Yes ☐no

5.5.2 Bottom filter ring: The other end of the filter bag shall attached to this ring through a clamping assembly. (MOC SS-316) ☐Yes ☐no

5.5.3 Filter Bag: A filter bag with antistatic non leachable material shall be use to retain the fines. (PC Satin 20/5 Micron). ☐Yes ☐no

5.5.4 P C satin finger bags 10 nos (additional) to be supplied by manufacturer. ☐Yes ☐no

5.6 Filter Bag Shaking assembly•

5.6.1 This assembly is to shake the filter bag at predetermined intervals manually to bring back the fines in to product container which are deposited in the bag during the process.

☐Yes ☐no

5.7. Solid flow monitor

5.7.1 solid flow monitor will monitor the flow of particles during fluidization.

☐Yes ☐no

5.8. Damper OR Control Flap

5.8.1 Damper at inlet/outlet: This shall be located on the bottom chamber flange and prevents water from entering in the inlet duct during washing and also shall prevents suction of air from inlet air handler during suction charging. ON / OFF TYPE (MOC SS-304) ☐Yes ☐no

5.9 Blower

5.9.1 The airflow through the machine shall be produced by the blower by creating suction and same shall be located at the outlet end. ☐Yes ☐no

5.9.2 MOC- MS/AL. with epoxy painted. ☐Yes ☐no

5.10. Inlet Air Handling Unit

5.10.1 AHU Double skin 50mm PUF insulated inside SS304 sheet & Outside MS Powder coated sheet, Steam radiator with counter flange, 10 micron, 5 micron and HEPA Filter Steam Valve ON/OFF type. □Yes □no

5.10.2 Support Column frame: It supports the Operating control panel, pneumatic control panel,Main Body housing and also the bottom chamber.(MS WITH SS-304 CLADING) □Yes □no

5.11. Inlet / Outlet Temperature Measurement

5.11.1 Inlet temperature measurement: Provision is made at inlet duct for measuring inlet temperature of the air. As the temperature reaches the set temperature the face portion close gradually. □Yes □no

5.11.2 Outlet temperature measurement: Provision is made at outlet for measuring outlet temperature of the air required . As the inlet air passes through the product heat is transferred to the product and the process air leaves through the finger bag which is then routed through exhaust system. □Yes □no

5.12 <u>Exhaust system</u>

5.12.1 Exhausted material shall pass through a series of filters like 10, 5, 3 and (HEPA) 0.3 micron and material/particles shall rest in a water carbouys of suitable capacity with simple mechanism without hampering the process / operation of FBD to avoid the environmental contamination.

□Yes □no

5.13. Operating Control Panel

5.13.1 Control panel (mounted on the lateral support) shall be made of SS 304 for manual Operations. Control panel shall be with touch screen / HMI and shall be flame proof.

□Yes □no

5.13.2 One emergency push button shall be given for shutting the machine off for any unlikely event. □Yes □no

5.13.3 One pressure gauge for monitoring pneumatic pressure for machine operation. □Yes □no

5.13.4 Pressure gauges to monitor sealing pressures.
□Yes □no

5.13.5 Gauges to monitor differential pressure across product / bottom screen. □Yes □no

5.13.6 Pneumatic switch and indicator for filter bag locking and other need base control. □Yes □no

5.14 The following functions will be operated through the PLC

5.14.1 Inflate / Deflate filter sealing

5.14.2 Inflate / Deflate container sealing

5.14.3 Exhaust air temperature – set, actual, min & max

5.14.4 Product air temperature – set, actual, min & max

5.14.5 Inlet air temperature – set and actual with PID control

5.14.6 Pneumatic filter Bag shaking device- Manual mode.

5.14.7 Air Pressure .

5.14.8 Process on/off

5.14.9 Steam radiator control on/off

5.14.10 Safety alarms & safety interlock

5.14.11Solid flow monitor.

☐Yes ☐no

5.15. Electric panel

5.15.1 All the electrical control components like contactor, relay & transformer etc. shall be mounted inside the M.S. Power Coated panel which is placed in the service area.

☐Yes ☐no

5.1.2 All electrical hardware and bought out components shall be of standard material.

☐Yes ☐no

5.16. Pneumatic panel

5.16.1 All pneumatic components are mounted inside the S.S.304 panel and fitted on support column of the machine. ☐Yes ☐no

5.17 Cleaning/maintenance

5.17.1 The equipment shall be easily accessible for cleaning the non-product contact part at Maintenance side of the equipment. ☐Yes ☐no

5.17.2 Product contact parts shall be easily dismantle and cleanable. ☐Yes ☐no

5.17.3 Vendor to give information on the cleaning procedure for the machine. ☐Yes ☐no

5.17.4 Vendor shall provide tool all relevant kit for maintenance of the equipment.

☐Yes ☐no

5.17.5 Vendor shall give recommended spare parts list. Yes no

6.0 SAFETY REQUIREMENT

6.1 General

Following facilities must be provided to protect personnel, article, equipment and surrounding.

6.1.1 In the event of equipment malfunction the unit must contain all necessary protection devices to ensure that the equipment and the article remain in a safe condition.

☐Yes ☐no

6.1.2 Noise level below 75 db at a distance of 1 m from the equipment

☐Yes ☐no

6.1.3 Emergency stop function

. ☐Yes ☐no

6.1.4 Appropriate closure of all the rotating parts.

☐Yes ☐no

6.1.5 Proper earthing of the equipment.

☐Yes ☐no

6.1.7 All electrical/ wirings properly insulated and concealed

☐Yes ☐no

6.2 Power failure and recovery

6.2.1 On power failure equipment shall come to rest, to protect operator, equipment itself and the product .

☐Yes ☐no

. 6.2.2 The FBD will stop automatically upon loss of electricity, air, or other major utility and will require operator intervention to re-start.

☐Yes ☐no

6.3 Use of lubricants

6.3.1 Any lubricant, used in the equipment must be of food grade and non-toxic.

☐Yes ☐no

6.3.2 Vendor to state the specification of lubricants to be used on the machine

☐ Yes ☐no

7.0 TESTING AND DELIVERY

7.1 In order to verify the machine performance, GAPL shall allowed to witness the execution of the Factory Acceptance Test (FAT) procedures. ☐Yes ☐no

7.2 Vendor shall prepare FAT and get approved from GAPL. ☐Yes ☐no

7.3 Delivery

a) The FBD, with all ,accessories and auxiliary equipments, shall be delivered to the GAPL "s factory site. ☐Yes ☐no

b) The equipment shall comply user specification. ☐Yes ☐no

7.4 Documentation

Installation, operation, and maintenance instruction documentation for the fluidized bed dryer shall be submitted along with delivery. ☐Yes ☐no

8.0 QUALIFICATION REQUIREMENT

8.1. **General**

8.1.1 Equipment shall be qualified for design phase (DQ), installation phase (IQ), Operational phase (OQ) and the performance phase (PQ). Yes no

8.1.2 Vendor shall support client in execution of all the qualification phases. Yes no

8.1.3 **Desired documents**

Following documents, but not limited to these, are expected from the vendor as part of the supply package along with technical bid.

- Filled in URS ☐Yes ☐no
- Equipment layout drawing fitted in the room layout block ☐Yes ☐no
- Detail technical offer that support the compliance of the URS ☐Yes ☐no

8.2 Specifications for critical components:

- Critical list of major component, devices and instruments with their specific functions, specifications data sheet ☐Yes ☐no
- Schematic diagram of the equipment/components ☐Yes ☐no

8.3: Required Documents

Vendor shall provide the following documents in the delivery package

- Operation and maintenance manuals, preventive maintenance schedule for equipment major component as well as the operating system. □Yes □no
- Installation instructions/ guideline for equipment . □Yes □no
- Final as-built drawing for equipment. □Yes □no
- Detailed drawing marking clearly all the necessary dimensions and locations of utilities along with requirement of utilities on the drawing. □Yes □no
- Spare and/ or change parts list with ordering information. □Yes □no
- Types of Lubricant and Lubrication instructions. Food grade Certificate . □Yes □no
- Instrument calibration certificates. □Yes □no
- Guaranty/ warranty certificates for each equipment. □Yes □no

9.0 TRAINING AND TECHNICAL SUPPORTS

9.1 User training shall consist of minimum 2 days of Operator training or till the fluency of the operator on the machine and 1 day for Maintenance training. □Yes □no

9.2 Technical support shall be provided by personnel visit telephone/ electronic media for a period of one years following the completion of validation activities. Yes no

9.3 A recommended period for replacement of critical change parts list including normal lead times for supply shall be provided in machine manual. □Yes □no

10.0 GOOD ENGINEERING PRACTICES

10.1 Equipment must be fabricated following all Good Engineering Practices. The vendor's Quality System must follow applicable national standards. ☐Yes ☐no

10.2 For all sensors, controllers, indicators original calibration certificate to be submitted by the vendor. ☐Yes ☐no

11.0 CONSTRAINTS

11.1 Equipment location and available space

This equipment will be installed in the existing available area-

Floor: Ground Floor

Department: Tablets

Area : Granulation

Area Available for installation: L X B X H i.e.7.5x3x3.75mtrs.

(Site visit preferred for the confirmation of exact location for installation.)

11.2 Additional Spares

1) Extra two product container with trolley and sampling device shall be provided along with Equipment. ☐Yes ☐no

2) 10 number P.C. Satin filter bags. ☐Yes ☐no

12.0 <u>UTILITY REQUIRMENTS</u>

12.1 General

- Batch Size (kg) 250 kg
- Steam Pressure (kg/cm sq.) 3.0-3.5
- Steam Consumption (kg/hr) as applicable
- Compressed air Pressure(bar) NMT 5
- Drying Temp. (°C) 27-90 °C
- Electrical supply 3 Ph. AC

12.2 Exhaust air unit :

Exhaust air volume sufficient to carry out fluidization of 200 kg wet mass .

Type of Blower	SISW high-pressure blower
Fan Construction	FRP/Metallic Lining
Motor	3 Phase Non FLP suitable for fluidization of 200 kg mass
MOC	Fan casing, Impeller, Inlet cones, Hub, etc of GI/ MS with powder coating.
	Bearing base, common base & support with powder coating.
	Blower casing must be FRP Lined
	Blower must be mounted on Anti-vibration mount.
Filters Series	HDPE, 5ply washable filters with appropriate dimension and filter frame with powder coating. Size - 10µ,5µ and 3 µ
HEPA filter	0.3 micron efficiency 99.97%

12.3 Air Handling Unit

AHU construction	Double skin skid mounted with hollow section.
AHU panel	Double skin with PUF insulation
Inner skin construction	From inlet air to micro vee filter – inner skin GI 24SWG From micro vee filter to air outlet – inner skin SS 304 SWG
Outer skin construction	24SWG power coated blue colour.
Air flow	Desire level of air flow to dry and fluidize wet mass more than 200 kg
Steam coil	Air inlet – ambient Air outlet temperature =-around 90°**c** MOC tube –SS 304 MOC fins Aluminum MOC header – SS304 Test Pressure 10-bar Steam control valve solenoid (auto steam control valve through PID temperature controller PLC base)
Filters Series	HDPE, 5ply washable filters with appropriate dimension and filter frame of SS 304. Size - 10µ,5µ and 3 µ.
HEPA filter	0.3 micron efficiency 99.97%

13 SCOPE OF WORK

1. The supply, installation, commissioning and validation has to be done by the supplier at 'Goa Antibiotics & Pharmaceuticals Ltd. Tuem -pernem Goa. However FAT will be perform by GAPL team at manufacture site.

2. Vender shall depute their technical person for installation, commissioning and validation of FBD.

3. Inlet and outlet ducting shall be designed, installed and commission as per space available at site.

4. The cost of ducting from AHU to FBD and FBD to discharge/ exhaust shall be in the scope of vendor

5. All utility points such as electrical, steam line, compressed air line shall be provided by GAPL.

6. All cable, pneumatic tubes, steam line, etc., required from the functional point (single utility point) to installation point is in scope of vendor. All the cabling etc., up to the control panel is in the scope of GAPL and from control panel to the respective machine shall be in the scope of manufacturer.

7. Vendor shall prepare qualification document protocol and get approved from GAPL

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8. Validation of air filter and calibration of instruments is in the scope of vendor.

9. Vendor shall provide necessary test certificates at the time of installation.

10. Warrantee - 12 months from the date of commissioning.

11. All the electrical motors / connective / filters shall be flame proof and party shall provide the CMIR / certificate in this regards for these flame proof items.

12. Proper earthing is in the scope of the manufacturer

13. DQ/IQ/OQ is in the scope of manufacturer

14. One set of a filter bags along with the supply is in the scope of manufacturer.

15. Extra two product containers in the scope of supply of manufacturer.

16. Air handling unit to FBD shall be in the scope of manufacturer.

17. Scrubber (non inclusive in the commercial bid) shall be optional and may be decided depending upon the technical aspects.

18. Specific requirement for motor : Kirloskar / Compton Greaves/ Remi / Bharat Bijlee

19. Preferred makes for PLC: Siemens / Allen Bradley

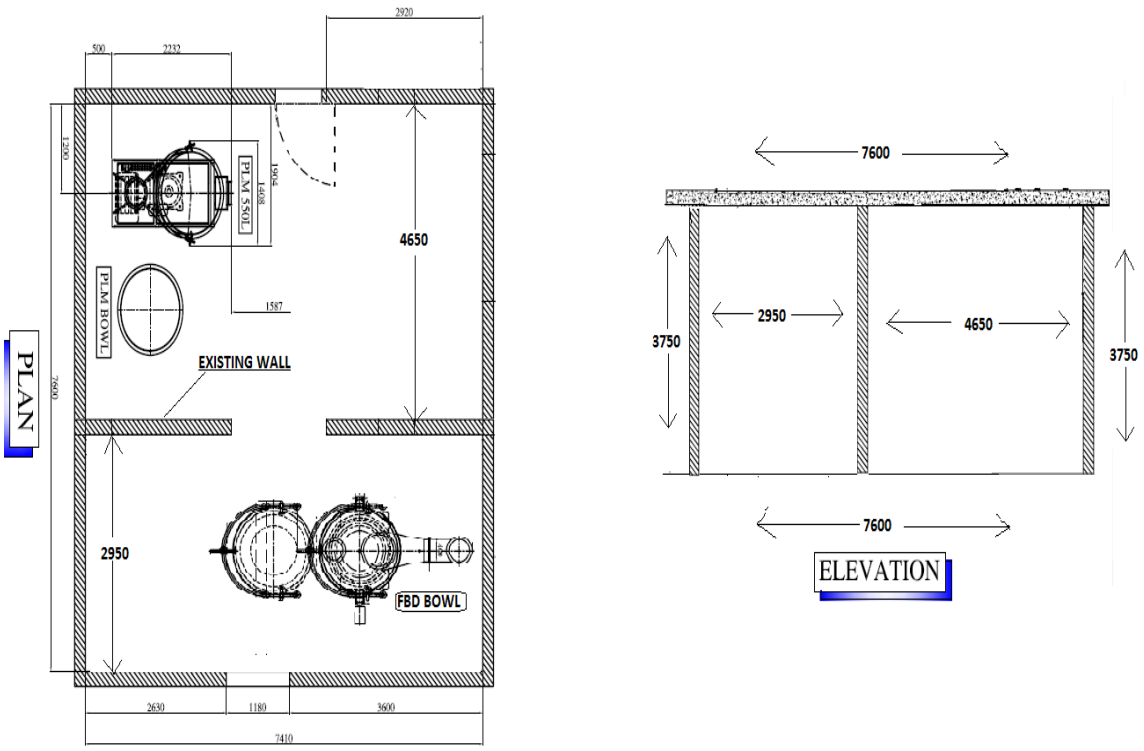
20. Preferred makes for PLC: Siemens / Allen Bradley

21. Preferred make of Pneumatics: Festo

14.0 ABBRIVATIONS

01.	GAPL	-	Goa Antibiotics & Pharmaceuticals Ltd.,
02.	HLL	-	Hindustan Life Care Limited
03.	URS	-	User Requirements Specification
04.	WHO	-	World Health Organization
05.	GMP	-	Good manufacturing practices
06.	PLM	-	Planetary mixer
07.	FBD	-	Fluid Bed dryer
08.	MOC	-	Material of construction
09.	SS	-	Stainless steel
10.	AHU	-	Air Handling unit
11.	HEPA	-	High efficiency particulate air
12.	HMI	-	Human machine interface
13.	PLC	-	Programmable logic controller
14.	FAT	-	Factory Acceptance Test
15.	DQ	-	Design qualification
16.	IO	-	Installation qualification
17.	OQ	-	Operational qualification
18.	PQ	-	Performance qualification
19.	SAT	-	Site Acceptance Test
20.	PU	-	Polyurethrene
21.	PC	-	Poly cotton
22.	MS	-	Mild steel
23.	PID	-	proportional–integral–derivative
24.	GI	-	Galvanised Iron

ANNEXURE - I



ALL DIMENSIONS ARE IN MILLIMETER