


GOA ANTIBIOTICS AND. PHARMACEUTICAL LTD				
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	Effective Date	30.04.2015		
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User Requirement Specifications

Planetary Mixer

Equipment ID: T-PLM01


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1.0 Approval signatures


This document is prepared in line with GMP requirement. Project management of GAPL and same shall be approved by following official of GAPL.

Prepared by		
Name/ Designation	Signature	Date
Mr. Pundalik N. Dhond, Jr. Officer Production		

Checked by		
Name/ Designation	Signature	Date
Mr. B. Demello, Maint. Engineer		

Approved by		
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Mr. Govind R. Tilve, Manager Production		

Authorized by		
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Mr. D.N. Shetty, DGM QC/QA		

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2.0 Overview

2.1 Project Standard

The facilities, upon completion, shall be in compliance with the cGMP requirement of Drugs And Cosmetic Act-1940/ WHO and also the GAPL's internal quality standards.

2.2 Equipment description

Equipment is used for dry mixing and wet mixing of active and non-active bulk material used for tablet formulations.

Area of installation. 6x7.5x2.9 mtr.

Dimensions of equipment should be provided.

Yes no

2.3 Reference standards/guidelines for equipment


The equipment should comply with the following guidelines / standard:

GMP-Regulations

Current Good Manufacturing Practices for finished Pharmaceuticals products.

Note:

- 1) This URS has been prepared based on our in-house knowledge & understanding for this equipment. It is possible that certain points might have been overlooked. As a vendor we expect you to go through the document in depth and give your 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.

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Specifications Remarks

3.0 Process Description

3.1 Input & Charging method

3.1.1 sifted powder/ dry powder is transferred from sifter to the PLM.

3.2 Brief Process Steps

3.2.2 The process parameters of the product will be set and verified.


3.2.3 Subsequent mixing takes place

3.2.4 Discharge the wet granules into the FBD.

3.3 Output & Discharging method

3.3.1 The granules from the PLM bowl are manually discharged into the FBD.

Yes no

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4.0 Productivity Requirement

4.1 Desired/ suggested capacity

250kg

Yes no

4.2 Standard batch size

4.2.1 Variable batch sizes

50kg—250kg

Yes no

The equipment is intended to be utilized for 6-7 hrs per shift (8 hrs Shift).

Yes no

4.3 Change Over Time .

4.3.1 Vendor to give information on change over time from one product to another Product

Yes no

4.4 Cleaning/sanitization/sterilization Time.

4.4.1 The equipment shall be easily accessible for cleaning the non-product contact part at maintenance side of the equipment.


Yes no

4.4.2 Equipments contact parts shall be easily dismantable and cleanable.

Yes no

4.4.3 Cleaning of external/ product non-contact part shall be done manually.

Yes no

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5.0 Safety requirement

5.1 General

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

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

Yes no

5.1.2 Emergency stop function on all accessible areas

Yes no

5.1.3 Automatic switching off PLM blade when set time is achieved with Alarm.

Yes no

5.1.4 Appropriate failure detection and alarm notification

Yes no

5.1.5 Appropriate closure of all the rotating parts.

Yes no

5.1.6 Equipment should be explosion proof.

Yes no

5.1.7 Double blade (beater) with scrapper.

Variable speed (Range 5 RPM-15 RPM) SS316 grade with 320 grit mirror finish

Yes no

5.2 Bowl-

Vertical flat bottom with drain.

Gross volume 520 lts


Maximum blend 250 kgs

Minimum blend 50 kgs

SS316 grade with 320 grit mirror finish

Gaskets if any should be food grade silicone without any joints.

Bowl to be mounted on support frame with wheel assembly.

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5.2.1 Inspection window for visual check.

Yes no

5.2.2 The bowl has to be designed to provide optimum mixing and allow easy access for cleaning and validation. Equipment must meet the requirement of homogeneity of blend/mix for following types of products.

a) Water granulation products.

B) I.P.A. granulation products (inflammable).

Yes no

5.2.3 All trolleys wheels – swirl type

Yes no

5.2.8 Flame proof motors of required capacity.

Yes no

5.2.9 Proper earthing of the equipment.

Yes no

5.3 Power failure and recovery

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


Yes no

5.3.2 Power restart must not be automatic and human intervention must be required.

Yes no

5.3.3 After regain of power the equipment should start from the step it stopped.

Yes no

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6.0 GMP requirements

6.1 Process control

The equipment must operate and control the following process parameters.

6.1.1 RPM as per the products requirement.

Yes no

6.1.2 Process end.

Yes no

6.1.3 Timer with Alaram.

Yes no

6.1.4 All the above settings should be possible to be done from outside without opening
The machine

Yes no

6.2 Failure mode detection

6.2.1 Equipment shall be capable to detect the following failure, notify the operator with alarm and shutdown the process:

6.2.1.1 Emergency stop

Yes no

6.3 In –Process control

6.3.1 A suitable closed sampling port is required for carrying out the manual sampling of granules.

Yes no

6.4 Level of instrumentation


Sufficient and suitable instrumentation for the process, safety and productivity control as indicated in the following table:

Pannel board-
ON/OFF indicator and speed indicator.
Digital timer display, which can be set as per our requirement
Digital RPM display.(blade RPM)
Hooter/Alarm assembly.

6.5 Cleaning requirement

6.5.1 All bolts, nuts on the exterior part of equipment will be with cap head or cap nut.

Yes no

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6.5.2 Design of equipment should enhance cleaning feasibility by providing minimum sharp corners, minimum crevices & smooth finished welds joints.

Yes no

6.5.3 Parts, which are required for cleaning out of place, should be provided with quick fixing arrangement.

Yes no

6.5.4 The equipment shall be compatible to different cleaning agents.

Yes no

6.6 Qualification requirement

6.6.1 General

6.6.1.1 Equipment shall be qualified for design phase (DQ), installation phase (IQ), Operational phase (OQ) and the performance phase (PQ).

Yes no

Specifications Remarks

6.6.1.2 Vendor shall support client in execution of all the qualification phases.

Yes no

6.7 Material of construction

6.7.1 All following metallic critical contact surfaces should be constructed of 316L grade stainless steel with internal mirror surface finish < 0.5µm Ra .

Yes no

6.7.2 All non-product contact metallic surfaces should be constructed of 304 grade stainless steel., external surface finish as matte finish< 1.2µm Ra.

Yes no

6.7.3 Gaskets, seals and O-rings coming in direct / indirect contact surfaces should be constructed of FDA approved polymeric materials(food grade only).


Yes no

6.7.4 All welds should be ground finished to < 1.2µm Ra and properly passivated.

Yes no

6.7.5 Insulation material should be non-fibrous and covered with completely welded SS 304 or better cladding

Yes no

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6.8 Use of lubricants

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

Yes no

6.9 Desired documents

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

6.9.1 Vendor shall supply the document package in phases throughout the life cycle of the project as follows:

Yes no

6.9.2 Phase 1: Preordering of the equipment

6.9.2.1 Filled in URS

Yes no

6.9.2.2 Equipment layout drawing fitted in the room layout block

Yes no

6.9.2.3 Detail technical offer that support the compliance of the URS

Yes no

6.9.3 Phase 2: Post ordering and prefabrication stage of the equipment

6.9.3.1 Functional design specification and technical specification, that should contain the following:

Yes no

- Equipment descriptions and its function

Yes no

- Equipment operation steps

Yes no

- List of failure indications


Yes no

- List of interlocks

Yes no

- List of input/outputs and its functions

Yes no

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• Critical list of major component, devices and instruments with their specific functions, specifications data sheet

Yes no

• Schematic diagram of the equipment.

Yes no

Based on the above documents, equipment design shall be evaluated and approved by the user for the fabrication.

6.9.4 Phase 3: Fabrication stage of the equipment

6.9.4.1 Vendor shall provide the FAT protocol at least 1 month in advance of the date of FAT, for the approval by the user.

Yes no

6.9.5 Phase 4: Delivery of the equipment

Vendor shall provide the following documents in the delivery package in minimum 2 sets. The delivery package shall reach the site of user atleast 15 days before the delivery equipments for the engineering check of the documents.

Yes no

6.9.5.1 Operation and maintenance manuals, preventive maintenance schedule for equipment major component as well as the operating system

Yes no

6.9.5.2 Installation instructions/ guideline for equipment

Yes no

6.9.5.3 Final as-built drawing for equipment.

Yes no

6.9.5.4 Detailed drawing marking clearly all the necessary dimensions and locations of utilities along with requirement of utilities on the drawing along with the offer.

Yes no

6.9.5.5 Spare and/ or change parts list with ordering information


Yes no

6.9.5.6 certificates for MOC of all direct/ indirect product contact surfaces.

Yes no

6.9.5.7 Weld verification reports.

Yes no

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6.9.5.8 Instrument calibration certificates.

Yes no

6.9.5.9 Guaranty/ warranty certificates for each equipment and major bought-out items, instrumentation etc.

Yes no

6.9.5.10 IQ and OQ protocols

Yes no


6.9.5.11 Types of Lubricant and Lubrication instructions. Food grade Certificate

Yes no

6.10 Training

6.10.1 Training for operators and technical has to be included in the offer

Yes no

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7.0 Technical requirement

7.1 Basic technical requirement

7.1.1 A proposal of a possible installation layout should be added to the documentation.

Yes no

7.1.2 The manufacturer has to give the clear details on the total weight and the capacity of the equipment.

Yes no

7.1.3 The heat given off by the unit must be stated (inside the room and through exhaust).

Yes no

7.1.4 The construction of the complete system should be described in the documentation in detail.

Yes no

7.1.5 All revolving parts should be mounted on antifriction thrust bearings.

Yes no

7.1.6 Cables, air tubes, etc required from the point (single utility point) to equipment is in scope of vendor.

Yes no

7.1.7 Vendor shall provide special tools for maintenance of the equipment

Yes no

7.1.8 Technical requirement for foundation / installation to be provided by the party at list one month in advance of the dispatch date.

Yes no

7.2 Specific requirements

7.2.1 Preferred makes for Motor: Kirloskar / Compton Greaves/ Siemens


Yes no

7.2.2 Preferred make of Pneumatics: Festo

Yes no

7.2.3 One extra bowl with trolley in the supply scope

Yes no

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7.3 Utility Requirement

7.3.1 Electricity: Consumption details to be provided by Vendor

Yes no

7.3.2 Compressed air: Consumption details to be provided by Vendor.

Yes no

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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 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 .

Yes no

c. All sensors, controllers, transmitters, indicators and will have to be calibrated, 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 of software used in the equipment control and/or monitoring system.

Yes no

8.1 Inspection and testing

a) System shall be inspected and tested (FAT) at the Vendor's site in the presence of user's representative before delivery.


Yes no

b)Vendor shall prepare FAT and SAT protocol and get approved from GAPL.

Yes no

c) Minimum 3 days shall be reserved for FAT and SAT each and vendor shall ensure the availability of relevant personnel test material and measurement devices.

Yes no

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9.0 Constraints

9.1 Equipment location and available space

This equipment will be installed in the existing available area-

Floor: Ground Floor

Department: Tablet

Area : Granulation.

Site visit preferred for the confirmation of exact location for new installation.