DESIGN QUALIFICATION

NAME OF THE ITEM: ROTOCONE VACUUM DRYER

FUNCTIONAL AREA: PRODUCTION BLOCK

PROTOCOL No. :

CONTENT

1.0 PROTOCOL APPROVAL:

Protocol Prepared By:

Functional area	Name	Signature	Date
Engineering			

DQ Reviewed By:

Functional area	Name	Signature	Date
Engineering			
Production			
Quality Assurance			

DQ Approved By:

Functional area	Name	Signature	Date
Head Engineering			
Head Manufacturing			
Head Quality			

2.0 Objective:

The purpose of this document is to ensure that all the critical aspects of the Equipment, cGMP & Safety features have been considered in designing the equipment/instrument and is properly Documented

3.0 Responsibilities:

In accordance with the document, following functions shall be responsible for initiation and finalization of Equipment user requirement specification. When the work is carried by contract/ consulting staff.

3.1 Preparation of Document

- User department to prepare the DQ
- Ensures that the document is in compliance with current policies and procedures of cGMP regulations.
- Ensures that the content is sufficient, clearly defined, technically sound and accurate.
- It is a Guidance document to prepare the DQ.

3.2 Review of Document

- To be reviewed by Head of the user department and functional department (Engineering & Quality assurance)

3.3 Approval of Document

- Approval of document by Head Manufacturing/Head Engineering/Head Quality.

4.0 Equipment Description & Identification:

4.1 Scope: Rotocone vacuum dryer -1500 LTR

4.2 Purpose: Purpose of Rotocone vacuum dryer to drying the product at low Temperature under vacuum.

4.3 Process Equipment Description:

In this equipment drying take place at even low temperature and under vacuum. It is used economically for drying products temperature sensitive or easily oxidable materials. When the solvent is present in the material its easy recovery is possible. Drying take place when the blender heated from outside jacket and vacuum is applied inside.

5.0 USER REQUIREMENTS

5.1 System Requirements:

S.No.	SYSTEM COMPONENTS	SYSTEM REQUIREMENTS
1	Identification (In case of Equipment /Instrument)	Rotocone vacuum dryer-1500LTR
2	Model/Type	RCVD-1500 ltr with PLC operated.
3	Capacity	1500 ltr.
4	Potential Suppliers	Bectochem
5	Contact parts (In case of Equipment)	SS316L with mirror finish
6	Non contact parts (In case of Equipment)	SS304 with mirror finish
7	Non-metallic contact parts (In case of Equipment /Instrument)	Any material with food grade quality having no Potential impact on the products. Durable. Must be easily cleanable.
8	Motor & Electrical installations (In case of Equipment /Instrument)	Machine should be operated through PLC mounted on separate electrical control panel.
9	Machine assemblies (In case of Equipment /Instrument)	Must be covered with SS 304 with mirror finish.
10	Machine adjustments (In case of Equipment /Instrument)	Setting with Zero clearance with good accuracy.
11	Packaging & Transport	Should be packed and transported in such a way to avoid any damage during transportation.
12	No. of requirements	01
13	Requirements for any power failure backup's (In case of Equipment / Instrument)	To be backed up by installed in-house DG set. After any power failure PLC show continuous counting of Tablets.
14	Gear box specifications(In case of Equipment /Instrument)	As per cGMP model
15	Output Capacity	1500 ltr
16	Material of Construction	▪ All contact parts made of S.S.316L, Nylon & all other non-contact components are of S.S.304 or as per the machine requirements ▪ Exterior easy to clean & non-corrosive.

S.No.	SYSTEM COMPONENTS	SYSTEM REQUIREMENTS
17	Safety features	Adequate safety features for men and material are provided along with the equipment.
18	Qualifications/ Documentations	The manufacturer shall complete and provide the documents pertaining to Design, Installation, and Operation Qualification.
19	Operating System	The equipment shall be operated through PLC system.
20	Control System	▪ The electrical system of the equipment shall be housed as per cGMP and cGEP standards, with adequate safety. ▪ Electrical panel and electro pneumatic panel to be installed on the base structure inside the machine. ▪ Control panel to be housed inside the machine.

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5.2 Technical Description

5.2.1 Specification of components/MOC

S.No.	Components	Descriptions
1	Working Capacity	1500 LTR
3	Contact Parts	SS 316 L with Mirror finish
4	Non Contact Parts	SS 304 & Mirror Finish
5	Structural Supporting & Brackets	Mild Steel Powder Coated Frame
6	Main Gear Box	Make: Elecon Model -5” SNU-U, Ratio 60:1,Shaft handling-SNU-UR
7	Drive motor	▪ Make: HMM ▪ Model-7.5 HP, 1440 RPM,NFLP,Footmounted,Frame-132M
8	Charging port	▪ Make:BCEPL ▪ Size-Dia 400 mm manhole
9	Discharge butterfly valve	Make: Valfit Engg Size-Dia 300 mm
10	Shell	▪ Make: BCEPL ▪ Size -8 mm thk
11	Jacket	▪ Make : BCEPL ▪ 6 mm thk

S.No.	Components	Descriptions
12	Insulation	▪ Make: BCEPL ▪ 14 SWG
13	Shaft	▪ Make: BCEPL ▪ Size -Dia 12 mm
14	Mechanical seal for steam side	▪ Make: Hi- Fab ▪ Single dry Seal for 45mm thk shaft. Carbon vs. T. carbide, SS304
15	Mechanical seal for Vacuum side	▪ Make : Hi- Fab ▪ Single dry Seal for 45mm thk shaft. Carbon vs. T. carbide, SS304
16	Cyclone separator (100ltrs.)	▪ Make : BCEPL ▪ Size 5mm thk
17	Vacuum pump	▪ Make: New Genere ▪ 2 HP, 1440 RPM, NFLP
18	Operating panel HMI	▪ Make : BCEPL ▪ SNYDER
19	PLC	▪ Make: BCEPL ▪ SNYDER

5.3 MACHINE DESCRIPTION

It consist following major components:

1) Shell
2) Charging/discharge
3) Baffle
4) Drive
5) Mounting
6) Control panel
7) Jacket

5.3.1 Shell: Consists of cylindrical central portion and the top and bottom conical frustum. The shell is provided with a circular opening at one end for cleaning/ discharge and a circular opening for charging/discharge at the other end.

The shell is welded with the hollow driving shafts, which are mounted, on Plumber block at both ends.

The complete body is jacketed suitable for steam/hot water system for heating the material inside the drier. Both steam/ hot water for heating and vacuum system are provided through the hollow driving shafts. Both the steam and vacuum system inlet are provided with suitable mechanical seal to suit the material to be drier. Vacuum is facilitated through a filter assembly which remains in upright condition while the drier is rotating to avoid any carryover of the material through a vacuum system.

5.3.2 Charging/discharge: The smaller circular opening is provided with a butterfly valve to facilitate discharging of the drier. The valve is operated by a lever arrangement designed to avoid accidently opening. A bigger cylindrical opening at the other end is provided with circular lid with fixing handle & eye bolt for clamping. This opening is for cleaning the inside for drier & at the time can be used for charging.

5.3.3 Baffle: Suitable designed baffle is fixed on central shaft bolted inside the drier.

5.3.4 Drive: Drive mechanism consist of 7.5 HP motor connected to 60:1 ratio gearbox through a belt/coupling drive. The gearbox in turn is coupled with driving hollow shaft to give final RPM.

5.3.5 Mounting: The hollow driving /driver shafts of the shell are mounted on suitable plumber blocks and entire assembly along with the drive mounted on a robust A shaped frame. Motor is mounted on a rigid steel frame /adjustable plate with bolt and nuts assembly which facilitates belt fixing/adjustment. The gearbox is mounted on steel frame. Entire assembly is suitable protected by cover for easy maintenance.

5.3.6 Control panel: The unit is provided with control panel. This consists of PLC and MMI for operation and panel is also provided with temperature controller/indicator for controlling the temperature.

5.3.7 Jacket: The unit provided for the continuous Circulation of hot air or stream in the Dryer for the drying.

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5.4 Utility Details:

S.No.	Utility	Supply
1	Power supply	▪ HP: 7.5 HP ▪ Power Supply:415 V AC, 3 Phase, 50 Hz

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5.4 Material of Construction

5.4.1 Contact and Non-contact surfaces

S.No.	Component Description	MOC
1	Machine frame structure	SS 304
2	External cladding	SS 304
3	Shell	SS 316 L
4	Charging/Discharge	SS 316 L
5	Baffle	SS 316 L
6	Mounting	SS 304
7	Jacket	SS 304

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6.0 COMPLEMENTARY ASPECTS

6.1 Training

S.No.	Specification	SYSTEM REQUIREMENTS
1	The vendor Shall supply all available information for the adequate exploitation of equipment. For the Compliance of this purpose at the Job site and/ or at the Vendors Shop. Vendor's technical staff shall train customer's personnel. The scope of the Training will be agreed during the contract signature.	YES
2	The supplier is to include the personnel training activities. The Supplier is to specify the foreseen time for: • Operator/Supervisor training • Manager Training • Electrical maintenance training • Mechanical Maintenance training	YES
3	The Supplier is to specify the personnel background needed for each of the operators maintenance.	YES

6.2 Pre Delivery Qualifications (FAT)

S.No.	Specification	SYSTEM REQUIREMENTS
1	The System or its parts as provided for in the scope of supply shall be pre-installed at the vendors shop prior to delivery to customer site. Installation will be completed and documented including mechanical parts as well as electrical connections of all parts to facilitate taking over tests at Vendors shop prior to delivery.	YES

6.3 Supplier Technical Documentation Requirements:

S.No.	COMPONENTS	REQUIREMENTS
1.	Technical Documents	FAT,IQ,OQ Electrical Drawing P & ID diagram GA diagram Operation manual Bought out components certificates. MOC certificates

6.4 Technical Manuals

S.No.	Specification	Requirements
1.	Operation manual	2 copies each

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7.0 SAFETY AND ENVIRONMENTAL PROTECTION

S.No.	Specification	Requirements
1.	Environment	NA
7.1 Safety and Interlocking		
1	Safety guard open	Machine Stop
2	Air pressure low	Machine Stop
3	Low level	Machine Stop
4	High temperature	Machine Stop
5	Vacuum sov not start	Machine Stop

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8.0 CLEANING MAINTENANCE AND SERVICE

S.No.	Specification
1.	In accordance with cGMP guidelines the units must be easy to clean.
2.	The Supplier should guarantee that, if required, a service team can be on site within one working day.
3	The design should be such as to allow mechanical cleaning of the surface and that the cleanliness of the surface can be checked easily.
4	All machine parts, in particular instrumentation, should be constructed so that they can be easily removed and calibrated.
5	All special tools required for running and maintenance should be best.
6	A spare parts delivery guarantee with in time.

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9.0 RULES AND REGULATION:

These standards, recommendation and requirements are considered the minimum. Specifications that are more stringent or expansive take the precedence. In case of conflict between published requirements, final determination is the responsibility of the Owners Representative.

10. SCOPE OF DELIVERY

S.No.	Specification	Requirements
1	Units described in the specific system requirements including all necessary controls and instrumentation.	YES
2	The complete mechanical and electrical installation.	YES
3	The Connections to all the necessary utilities, exhaust, and waste lines necessary for its operation.	YES
4	All piping and cabling of the units itself.	YES

S.No.	Specification	Requirements
5	Wiring and cable run: all wiring and cable run is part of the supply. Site will supply the main power switches to be located in correspondence to the electrical and control cabinets delivered by the equipment supplier.	YES
6	All internal contacts of the supplied equipment for the required utilities.	YES
7	Unload on site of the equipment: the supplier is required to define all the necessary handling devices required to the unloading operation. The supplier will inform at least 4 weeks in advance the day of delivery and the list of required handling devices.	YES
8	Assembling operation: the required consumable, the internal transportation, the assembling tools and the required personal are part of the supply.	YES
9	A complete set of commissioning spare parts.	YES
10	All special tools necessary for use and maintenance of the supplied equipment.	YES
11	A complete set of two years spare parts should be listed quoted and offered as option.	YES
12	All test activities as specified in this document.	YES
13	Training in the use and maintenance of the equipment.	YES
14	A complete set of documentation as specified in this document.	YES

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11.0 INSTALLATION, COMMISSIONING AND TESTS

11.1 General

S.No.	Specification	Requirements
1.	The Supplier must specify for each piece of equipment the Guaranteed performance and the guaranteed system performance. These values will be tested during the acceptance tests.	YES
2	In addition the functionality described in the user requirements and detailed in the system specifications will be tested.	YES

11.2 INSTALLATION, COMMISSION

S.No.	Specification	Requirements
1	The commissioning tests will be carried out in accordance with a written test plan developed by the supplier with clearly stated test procedures and acceptance criteria.	YES
2	The Supplier will approve successfully completed tests and will specify items requiring additional work. Representatives from site will attend and participate in the commissioning tests as required.	YES
3	The installation and commissioning of the system will be performed at the site facility by the Supplier.	YES

S.No.	Specification	Requirements
4	The commissioning can only start once all the foreseen documents have been delivered by the supplier to site.	YES
5	All equipment should be properly installed, adjusted, leveled, tagged, and connected with utilities.	YES
6	Point to point checks on wiring and pneumatic should be performed.	YES
7	All instruments should be properly calibrated.	YES
8	An equipment (Instrument) used for qualification must be listed and approved by site.	YES
9	The calibration equipment must have all the necessary documents to demonstrate their maintenance & use.	YES
10	The last calibration of all this equipment must be less than 6 months old, and evidenced by certificate.	YES
11	Verification that the interior surfaces of equipment are free of practices and dirt and all points of product contact meet the specified material requirements.	YES
12	All the clearances and tolerances specified in the drawing or recommended by component manufacturers are correct.	YES
13	On site verification that valves and other equipment with moving parts are in their normal position if in a power down condition and move in the correct direction with the correct speed and precision.	YES
14	Verification that all the Input and Output points are connected and labeled according to the documentation and that all the along the input values have been scaled in accordance with the system specification and process requirements. That all equipment components requiring configuration	
15	The commissioning should demonstrate that the system supplied by the Supplier has been properly installed and that the functions are in accordance with ……..User Requirements specifications, Vendors System specifications Manuals and other Documentation.	YES

11.3 Site Acceptance Test (SAT)

S.No.	Specification	Requirements
1.	This test will be carried out once the commissioning will be completed. The scope will be to verify the performance and the functionality of the system integrated with the other factory systems.	YES
2.	The test will be carried out to verify the system response with the expected productivity of the system.	YES
3.	Details on the test realization will be defined during the project Phase. The supplier is asked to specify the proposed duration for SAT and the standard procedure proposed.	YES
4.	During SAT the required functionality, performances and system reliability are met.	YES
5.	The Functionality described in the User Requirements Specification and in the System Specifications are verified and met.	YES
6.	All the documentation agreed has been delivered.	YES

12.0 QUALIFICATION / VALIDATION

S.No.	Specification	Requirements
1.	The maintenance Qualification is responsibility of the customer. However, the supplier is responsible for delivering the basic documents for maintenance qualification.	YES
2.	This includes all side costs such as: calibration measuring equipment and instruments: manpower (IQ and OQ will take place completely on site)	YES
3	Time Schedule for IQ/OQ execution will be developed by site. With the supplier.	YES
4	Suppliers personnel used for IQ/OQ must be well trained and experienced. This should be documented.	YES
5	The onsite test run performed by the supplier might become part of the IQ.	YES
6	Main IQ/OQ steps such as calibration must be performed and documented in accordance to a SOP approved by site.	YES
7	All equipment used for qualification must be listed and approved by site. The calibration equipment should be well documented.	YES
8	The last Recalibration of all this equipment should be less than 06 month old. Proofed by Certificate.	YES
9	OQ can only start after IQ approved by site.	YES
10	IQ will be carried out by site. During Installation phase. IQ will include the tests performed by the Supplier.	YES
11	Part of the OQ will be carried out by site. During commissioning and SAT phase. OQ will include the tests performed by the Supplier.	YES
12	After installation of the equipment at customers site. Complementary IQ & OQ tests will be performed by the Customer and may be supervised by a member of Technical staff.	YES
13	Qualification documents (In case of equipments/Instruments)	IQ, OQ, MOC & test certificates

13.0 GAURANTEE/WARRANTEE

S.No.	Specification	Requirements
1.	The System must be guaranteed including all the sub- system and components for a period of 12 months from the date of the system acceptance for a 03- shift operation.	YES
2	The servicing companies involved for the Sub- systems maintenance must be declared and the maintenance group organization described. Furthermore, the Supplier will be directly responsible of the system assistance and the required operation will be co- ordinate by him.	YES
3	In case of failures, the intervention will be guaranteed by the Supplier within a maximum time limit. The Supplier is asked to specify the maximum time limit.	YES
4	The supplier is asked to propose as option maintenance and assistance contract after the guarantee expiration.	YES

Verified By & Date:

14.0 Deviation

15.0 Annexure

16.0 Summary and Conclusion

17.0 Approval of Design Qualification.

Functional area	Name	Signature	Date
Head Engineering			
Head Manufacturing			
Head Quality			

18. Acceptance By vendor

Name of Vendor:

Sign/Date: