INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR TABLET COATER

Equipment ID	
Equipment Location	
Equipment Make	**Pam Glatt**
Document No.	**IQ/**
Reason For Qualification	**New Equipment**

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR TABLET COATER	PROTOCOL No.:

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TABLE CONTENT

1.0 PRE-APPROVAL

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR TABLET COATER	PROTOCOL No.:

Signing of this Installation Qualification Protocol indicates agreement with the Validation Master Plan approach of the equipment. Further if any changes in this protocol are required, protocol will be revised and duly approved.

PREPARED BY:

Functional area	Name	Signature	Date
Engineering			

CHECKED BY:

Functional area	Name	Signature	Date
Engineering			
Production			
Quality assurance			

APPROVED BY:

Functional area	Name	Signature	Date
Head Engineering			
Head Manufacturing			

2.0 OBJECTIVE

The objectives of this Installation Qualification (IQ) are as follows:

- To verify that the Tablet Coating system in Tablets, Capsules, Dry Syrup and Dry Powder Injection Manufacturing Facility has been installed in accordance with the set acceptance criteria and meets GMP requirements.
- To verify that there is sufficient and accurate information to operate and maintain the system reliably and reproducibly.
- To verify that the requirements specified at the time of purchase are met in the delivered and installed item. Purchase Order and Equipment Specifications have been used to prepare this Protocol. Confirmation of the installed system to pre-determined specifications will verify that user requirements have been met.

3.0 SCOPE

This protocol covers all aspects of Installation Qualification for the Tablet Coating System serving Tablets, Capsules, Dry Syrup, Dry Powder Injection Manufacturing Facility. Scope incorporates qualification of all Oral Dosage Form components from Inlet air Handler with HEPA filter through Tablet Coating System with product filter, up to and including Exhaust blower, spray system including solution tank, pump & spray nozzles.
This protocol will define the methods and documentation used to qualify the Tablet Coating System for IQ. Successful completion of this protocol will verify that the Tablet Coating System meets all acceptance criteria and is ready for Operational Qualification.

4.0 RESPONSIBILITIES

In accordance with protocol, following functions shall be responsible for the qualification of equipment regardless of whether such work is performed by own staff or contract / consulting staff. When the work is carried by contract/ consulting staff, all the work is to be performed.

Department	Responsibilities
Engineering	Prepare, check and approve the Installation Qualification Protocol.
	Distributes the finalized protocol for check, approve and authorization signatures.
	Execution of Installation Qualification Protocol.
	Complied qualification data package, and final report.
Production	Check, approve and execution of Installation qualification protocol.
Quality Assurance	Check the protocol.
	Review and approval of protocol, of equipment.
	Final authorization of protocol.

5.0 SYSTEM DESCRIPTIONS

The Tablet Coating System and its associated equipment are designed to process pharmaceutical products in accordance with cGMP principles. The Tablet Coating System shall be used for coating tablets with aqueous or non-aqueous solvents.
Conditioned Air is drawn through the Tablet Coating System by a Variable speed drive blower. The air is supplied from the Service area and conditioned and filtered by the Inlet air handling Unit (AHU) located within the Service area.
Qualification activities for the Tablet Coating System incorporate the following system components:

- Inlet air handling unit
- Exhaust air blower
- Coating Pan
- Spray system including solution tank, pump & spray nozzles

5.1 Exhaust Air Unit System:
It consists of exhaust blower and an air temperature measuring device. The Exhaust blower draws the process air from the Coater. The exhaust blower is responsible for creating negative pressure in the coating Pan so that there should be no turbulence in the pan & the Process air will be extracted through the tablet bed.

5.2 Coater
It consists of main body, Pan, mixing baffles etc. The tablets are heated up by the inlet air coming from AHU. The tablets are rotated by the Pan and mixing takes place. Meanwhile the spraying is done by the spray guns and the coating of tablets takes place.

5.3 Spraying system
It consists of peristaltic pump, spray guns mounted on the spray gun header & atomizing air control system. Main function of the spraying system is to spray the liquid uniformly over the rotating tablets. For the coating application the spraying is done inside the coating pan at the right angles of the tablet bed.
Associated System components comprise:

- **PLC Description**

The main function of a PLC is to translate the instructions into the digital or analogue codes needed to operate the device or machine. PLC system collects data from field instrumentation & displays the information on the operator station. The instruments are connected to the system Equipment.

The collected data is utilized by the PLC for process control. The user interface, HMI, assists the operator to supervise and control the process. Based on the displayed information, the operator, by means of the user interface, provides commands to the PLC.
The PLC then executes the operator instructions. A Schneider Electric Family

- **M340** PLC is provided as the Central Processing Unit (CPU).
- Safety system: The following Safety systems are incorporated:
    - All motors shall be flameproof.
    - The spray pump system shall not start if atomising air pressure is insufficient for atomising coating suspension.
    - Personnel protection insulation shall be provided in supply air duct.
    - Inlet fan shall not run when exhaust fan is not running.

6.0 DOCUMENTATION REQUIREMENTS

The IQ File should include:

- This IQ Protocol
- All printouts and handouts generated during qualification procedure
- A Signature Sheet where all people, performing the qualification checks, are listed
- Any change control actions that may have occurred during the qualification activities.
- Any deviations, exceptions or investigation reports generated during the qualification activities.

7.0 DATA COLLECTION

All individuals executing this Protocol shall complete the attached *Signature Sheet.* All personnel shall have suitable documented training or experience.

All approvals shall be made in *BLACK* ink.

All data entry shall be made in *BLACK* ink.

When appropriate, Drawings shall be marked up as following:

- System checked and conforms to the Drawing: *YELLOW* highlighter

- System checked and does not conform to the Drawing: *RED* highlighter and notes in *RED* pen.
- Personnel who mark up the drawing shall initial and date it.

All corrections to this Protocol, which are not retyped, are to be made in *BLACK* ink. All written corrections to this Protocol or to data entered in this Protocol should be made by using a single line to delete the error. The person who makes the correction shall initial and date it and add comment to explain reason for correction.
After performing the checks, collect all relevant printouts and certificates and retain for inclusion in the IQ File. If more Data Sheets or Deviation Sheets are required, they are to be attached to this Protocol as *Annexure* and to be listed in *Section 14 List of Annexure*.

8.0 CHANGE CONTROL

Any changes or modifications to the system shall be performed in accordance with the ALL Project Change Control Procedure (SOP No. : …….).
Change Control Forms raised during the execution of this IQ will be filed with the protocol. An assessment will be made to check whether any re-validation is required by ALL before the change request is closed out.

9.0 PRE-QUALIFICATION REQUIREMENTS

The results of any tests should meet the limits and acceptance criteria specified in the test documents. Any deviations or issues should be rectified and documented prior to IQ commencing. Open action items resulting from these tests shall be listed in the Comments section.

Test	Test Date	Documentation [Title, Rev.]	Documentation Location	Complete [Y/N]	Date/ Initials
FAT					
SAT					

Comments:

Reviewed by		Date	

10.0 TESTS AND CHECKS

The following tests and checks are to be completed for IQ of Tablet Coating System. After completion of this section, fill the *Checklist* in *Section 11*.

10.1 Drawing Verification (Ref:)

10.1.1 Objective

To verify that relevant drawings of the equipment are available and current.

10.1.2 Method

Examine whether the specified drawings of equipment are available and current. Ensure Title, Revision No., Originator and Document Location are recorded in *Section 10.1.4 Data*. Record any deviation / non-conformance as described in *Section 12 Deviation Sheet.*

10.1.3 Acceptance Criteria

Drawings must be of the latest version and filed correctly. Drawings must conform to. Where relevant, documents must be approved as per ALL project procedure.

10.1.4 Data

Reference Engineering Drawings	Drawings Rev. No. & Issue Date	Document Location	Acceptable [Y/N]	Date/Initials
P& I Diagram				
P& I Diagram For Air Handling Unit				

Comments:

Reviewed by		Date	

10.2 Documentation Verification (Ref:)

10.2.1 Objective

To verify that sufficient documentation exists to operate and maintain the system reliably and reproducibly.

10.2.2 Method

Verify that Tablet Coating System contains the following documents where deemed appropriate. Identify the sub-folder index of each available document. Examine whether the available documents are as listed in *Section 10.2.4 Data*. Fill detailed information of the Obligatory documents, such as title, revision number, and location in *Section 10.2.4.1 Document Details*. Report any deviations / non- conformances as described in *Section 12 Deviation Sheet*.

10.2.3 Acceptance Criteria

All obligatory documents must be available in a current status. Where relevant, documents must be approved as per ALL procedure.

10.2.4 Data

When a specified document is located within another document, cross-refer to the main document at the Comment Column.

	Available		
Document	**[Y/N]**	**Comment**	**Initial / Dates**
General Documentation			
Purchase Orders			
Vendor Offer			
URS			
Design Descriptions			
Engineering Drawings List			
Operation Manuals			
Spare Parts			
Mechanical Documentation			
Mechanical Parts List			
Pneumatic Diagrams			
Maintenance Manuals			
Material Specifications			
Product contact material certificate			
Electrical Documentation			
Electrical Parts List			
Electrical Diagrams			
Instrument List			
Instrument calibration certificates			

Comments:

Reviewed by		Date	

10.3 Equipment Verification (Ref:)

10.3.1 Objective

To verify that the equipment components are as specified.

10.3.2 Method

Visually examine all equipment components as listed in the tables below. Confirm that all specified requirements listed in SPECIFIED column [*Section 10.3.4. Data*] have been met. Record any deviations/non-conformances as described in *Section 12 Deviation Sheet*.

10.3.3 Acceptance Criteria

Equipment must be in conformance to specifications as listed in the SPECIFIED column in *Section 10.3.4 Data*.

10.3.4 Data

10.3.4.1 Inlet Air Handling Unit

Parameter	Specified	Actual	Acceptable [Y / N]	Initial / Date
Manufacturer	.			
Location				
Capacity – m^3/hr				
Pre-filter grade/Material	EU-3/HDPE			
Intermediate-filter grade/Material	EU-5/ Non-woven synthetic			
Final-filter grade/Material	EU-13/ Imported submicron glass fiber			

10.3.4.2 Coating Pan

Parameter	Specified	Actual	Acceptable [Y / N]	Initial / Date
Manufacturer	Pam Glatt Pharma Tech.Pvt.Ltd.			
Working Capacity	500 Liters			
Physical construction	SS 316 body			
Baffles	5 Number			

Comments:

Reviewed by		Date	

10.3.4.3 Spray module assembly

Parameter	Specified	Actual	Acceptable [Y / N]	Initial / Date
Spray pump				
Manufacturer	Flowtech			
Type	Single Head			
Capacity - rpm	06 – 100 rpm			
Spray Nozzle assembly				
Make	Glatt GmbH			
Spray nozzle diameter	1.2 mm			
Atomizing air Pressure /Flow rate	4 – 6 Kg/cm^2			
Quantity	5			

10.3.4.4 Exhaust blower

Parameter	Specified	Actual	Acceptable [Y / N]	Initial / Date
Manufacturer	Engicon Airtech Pvt Ltd.			
Type	Flame proof			
Capacity (m^3 /hr)	6000			
Differential pressure across fan - mmWC	900			
Position	Exhaust air Blower			
Power (KW/HP)	30			
Phase	3 phase			

Comments:

Reviewed by		Date	

10.3.4.5 Variable frequency drive for Inlet Blower

Parameter	Specified	Actual	Acceptable [Y / N]	Initial / Date
Manufacturer	Schneider Electric			
Make/Model				
Rating	2.2KW/7.5 HP			
Phase	3 phase input and 3 phase output			

10.3.4.6 Variable frequency Drive for Exhaust Blower

Parameter	Specified	Actual	Acceptable [Y / N]	Initial / Date
Manufacturer	Schneider Electric			
Make/Model				
Rating	30kW/40HP			
Phase	3 phase input and 3 phase output			

10.3.4.7 Variable frequency Drive for Pan Drive Motor

Parameter	Specified	Actual	Acceptable [Y / N]	Initial / Date
Manufacturer	Schneider Electric			
Rating	2.2KW / 3HP			
Phase	3 phase input and 3 phase output			

10.3.4.8 Spray Pump

Parameter	Specified	Actual	Acceptable [Y / N]	Initial / Date
Manufacturer	Solace Engineers. Pvt. Ltd.			
Model				
Rating	0.75KW/1HP			

Comments:

Reviewed by		Date	

10.3.4.9 Auto/Manual/sample Valves/Control Flaps

Check that all valves are identified and listed. Either attach the valve list as Annexure or identify the location of the valve list.

Verify all valves are tagged.

Supplier	Type	Part No	No. of Valves	Valve/Flap List [Attached or Refer Location]	Tags Available [Y/N]	Initial / Date
	Solenoid Valve		1	At inlet damper		
	Solenoid Valve		1	At outlet damper		
	Solenoid Valve		1	At Bypass damper		
	Solenoid Valve		1	Atomizing valve		
	Solenoid Valve		1	Shutoff Valve		
	Solenoid Valve		1	Drain Valve		
	Puppet type On / Off valve		1	Hot Water Valve		
	Puppet type On / Off valve		1	DM Water Valve		
	Puppet type On / Off valve		1	Shutoff Valve		
	Puppet type On / Off valve		1	Spray Ball valve		
	Puppet type On / Off valve		1	Spray Nozzle valve		
	Solenoid Valve		1	Pneumatic Stirrer		

Comments:

Reviewed by		Date	

10.4 Instrumentation Verification (Ref:)

10.4.1 Objective

To verify the lists of instruments included in the system are as specified. (See *Section 10.5* for *Calibration Verification*)

10.4.2 Method

Visually check whether instruments are installed according to the engineering drawings and system specification. Confirm that all specified requirements have been met. List Tag number, serial number and location for each instrument. Record any deviations / non-conformances as described in *Section 12 Deviation Sheet*.

10.4.3 Acceptance Criteria

All instruments listed must be tagged and in conformance to the specifications listed in the SPECIFIED column in *Section 10.4.4. Data*.

10.4.3 Data

10.4.3.1 Air Flow Sensor

Parameter	Specified	Actual	Acceptable [Y/N]	Initial / Dates
Manufacturer	E+E			
Model	EE 75			
Range (m/sec)	0 - 20			
Location	Inlet air section – Inlet air flow			

10.4.3.2 Differential Pressure Transmitter

Parameter	Specified	Actual	Acceptable [Y/N]	Initial / Dates
Manufacturer/ Supplier	Sensocon			
Quantity	1			
Range	-100 to100 mmWC			
Accuracy	± 1%			

10.4.3.3 Pressure Gauges

Parameter	Specified	Actual	Acceptable [Y / N]	Initial / Date
Manufacturer / Supplier	Baumer			
Quantity	2			
Range (bar)	0 - 10			
Accuracy	±0.5 bar			

10.4.3.4 RH Sensor

Parameter	Specified	Actual	Acceptable [Y/N]	Initial / Dates
Manufacturer/ Supplier	Rotronic AG			
Range (% / °C)	0 to 100% 0 to 120 °C			
Location	At inlet air line			
Transmitter rating	4 – 20 mA			

10.4.3.5 Temperature Sensor / transmitter

Parameter	Specified	Actual	Acceptable [Y/N]	Initial / Dates
Manufacturer	Transmitter: Radix Electro systems			
	Sensor: Radix			
Accuracy (%)	± 0.3 %			
Sensor Model / Type	RTD - PT 100			
Range (°C)	Transmitter: 0 – 150			
	Sensor: 0 – 150			
Quantity	3			

Comments:

Reviewed by		Date	

10.5 Calibration Verification (Ref:)

10.5.1 Objective

To verify that critical instruments have been calibrated as specified.

10.5.2 Method

Verify that all critical instruments have been calibrated on site in accordance with the applicable vendor procedure and that current calibration certificates are available. Indicate the calibration certificate location, if a copy of the certificate is not attached. Record any deviation / non-conformance as described in *Section 12 Deviation Sheet*.

10.5.3 Acceptance Criteria

Critical instruments must be labeled and within the validation calibration period during qualification.

10.5.4 Data

Instrument	Tag No.	Cal'n Date	Maximum Calibration Interval	Calibration Due Date	Calibration Certificate Available [Y/N; Attached or Location]	Acceptable [Y/N]	Initial / Date
Temperature sensor (Dehumidification Temp.)							
Temperature sensor (Inlet Temp)							
Temperature sensor (Exhaust Temp)							
Differential Pressure Transmitter (Coating Pan)							
Pressure Transmitter (Atomisation Air)							

Comments:

Reviewed by		Date	

10.6 Materials in Product Contact (Ref:)

10.6.1 Objective

To verify that all materials in product contact meet the specified requirements.

10.6.2 Method

Examine there is documented evidence that all materials that come into product contact meet the required specifications for

material type and surface finish as applicable. Attach documents/identify the location. Utilities (such as air, steam, water) that subsequently come into contact with the pharmaceutical products shall be deemed as "product". Report any deviation / non-conformances as described in *Section 12 Deviation Sheet*.

10.6.3 Acceptance Criteria

All materials in product contact must be in conformance with the specifications listed in the SPECIFIED column in *Section 10.6.4 Data*.
Documented evidence attached/location checked.

10.6.4 Data

System Component	Reference Document	Specified	Actual	Material Certificate Available [Y/N, Location]	Acceptable [Y/N]	Initial / Date
Coating Pan	Installation Qualification of Tablet Coater	AISI 316L				
Baffles		AISI 316L				
Spray nozzle		AISI 316L				
Spray pump		SS316L				
Solution vessel		SS 316L				
Inlet Air handling unit (Inside)		AISI 304				
Coating Housing		AISI 304				

Comments:

Reviewed by		Date	

10.6.4 Data

System	Reference Document	Specified	Actual	Material	Acceptable	Initial /

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR TABLET COATER	PROTOCOL No.:

Component	[Title, No., Rev. No., Date]			Certificate Available [Y/N, Location]	[Y/N]	Date
WIP facility (WIP pump)		SS316 L				
Sight glass /Inspection window						
Sealing/ Gasket material		Silicon				
Atomising air line						
Pipe and fittings		PU Tube				
Sealing / Gasket material		Silicon				
Spray liquid line						
Pipe and fittings		PU Tube				
Sealing /Gasket material		Silicon				

Comments:

Reviewed by		Date	

10.7 Services Verification (Ref:)

10.7.1 Objective

To verify that all services required for the operation of the system are available and connected to the system and that these utilities conform to the system requirement.

10.7.2 Method

Visually examine that all services are available and connected in accordance with the engineering drawings and system specifications. Complete the list of services installed in *Section 10.7.4 Data*. Record any deviation / non-conformances as described in *Section 12 Deviation Sheet*.

10.7.3 Acceptance Criteria

All services are available and connected in conformance to specifications listed in the SPECIFIED column in *Section 10.7.4 Data*.

10.7.4 Data

Services	Specified	Actual	Acceptable [Y/N]	Initial / Dates
Compressed air	• Pressure: Minimum 6 kg/cm^2(g) • Pipe Material:SS	• Pressure: • Pipe Material:		
Steam supply	• Pressure: Min 3.5 bar and max 4.5 bar • Pipe Material: MS	• Pressure: • Pipe Material:		
Chilled water	• Pressure: 3.0 kg/cm^2(g) • Pipe Material: MS	• Pressure: • Pipe Material:		
Electricity	• Voltage: 415 V • Phases: 3 • Frequency: 50Hz	• Voltage: • Phases: • Frequency:		

Comments:

Reviewed by		Date	

10.8 Automation and Control Systems Hardware Installation Verification (Ref:)

10.8.1 Objective

To verify that the control and monitoring devices are installed as specified.

10.8.2 Method

Visually examine the hardware components as listed in the SPECIFIED column in *Section 10.8.4Data*.
Report any deviation / non-conformances as described in *Section 12 Deviation Sheet*.

10.8.3 Acceptance Criteria

The hardware components must be in conformance to the specifications listed in the SPECIFIED column.

10.8.4 Data

10.8.4.1 PLC Controller

Parameter	Specified	Actual	Acceptable [Y / N]	Initial / Date
CPU				
Manufacturer	Schneider Electric			
Model	M340 series			
IPC				
Manufacturer	Contec			
Model	PT1561E			
Resolution	15” TFT touch screen display,1024 x 768			
Degree of Protection	IP65 front			
Wide DC Supply	9-36VDC			
RAM	1GB , 160GB Shock proof HDD			
Analog/Digital Input/output cards				
Digital input	DDI 1602			
Digital output	DRA 1605			
Analog input				
Manufacturer	Schneider Electric			
Model	BMX AMI 0800 & BMX AMI0410			
No. of Channels	8 & 4 Nos			
Analog output				
Manufacturer	Schneider Electric			
Model	BMX AMO 0410			
No. of Channels	4 No.			

Comments:

Reviewed by		Date	

10.9 Spare Parts List (Ref:)

10.9.1 Objective

To verify the availability of specified spare part lists.

10.9.2 Method

Examine for the availability of spare part lists and attach either as *Annexures* or indicate location of the actual spare part lists. Record any deviations / non-conformances as described in *Section 12 Deviation Sheet*.

10.9.3 Acceptance Criteria

Approved spare part lists must be available.

10.9.4 Data

Spare Parts List	Confirm Attached or Refer to Location	Initial / Date
General Spare Parts List		
Mechanical Spare Parts List		
Electrical Spare Parts List		

Comments:

Reviewed by		Date	

10.10 Lubricants List (Ref:)

10.10.1 Objective

To verify all fluids used in the system are as specified.

10.10.2 Method

Examine whether all fluids used in the system are as listed in the SPECIFIED column in *Section 10.10.4. Data*. Classify whether each fluid may be in product contact or not. Record the quantity and location of the fluids inventory. Confirm that all specified requirements have been met. Record any deviations / non-conformances as described in *Section 12 Deviation Sheet*.

10.10.3 Acceptance Criteria

Fluids used must be in conformance with the specifications listed in the SPECIFIED column.

10.10.4 Data

Lubricant	Product Contact [Y/N]	Specified	Actual	Quantity & Location of Inventory	Acceptable [Y / N]	Initial / Date

Comments:

Reviewed by		Date	

10.11 Filter List (Ref:)

10.11.1 Objective

To verify all filters used in the system are as specified.

10.11.2 Method

Visually examine the filters used in the system are as listed in the SPECIFIED column in *Section 10.11.4 Data*. Relevant certificates and test reports must be available and attached as an *Annexure*. Confirm that all filters are installed in the correct orientation and that all specified requirements have been met. Record any deviations / non-conformances as described in *Section 12 Deviation Sheet*.

10.11.3 Acceptance Criteria

Filters must be in conformance with specifications listed in the SPECIFIED column.

10.11.4 Data

10.11.4.1 HEPA Filter

Parameter		Specified	Actual	Acceptable [Y / N]	Initial / Date
Location		Inlet Air handler			
Manufacturer		Airtech India			
Filter class		EU 13 (HEPA)			
No of filter elements		2			
Capacity (cfm)		2000			
Material	Frame/Housing	Aluminium			
	Element	Imported submicronic glass fibre			
Efficiency		99.97% down to 0.3 µ			

10.11.4.2 Compressed air filter

Parameter	Specified	Actual	Acceptable [Y / N]	Initial / Date
Location	At compressed air line			
Manufacturer	AGS			
Filter class/Quality	0.2 micron			
No of filter elements	01			
Capacity (m^3/hr)	235			
Maximum temperature (°C)	100°C			

Comments:

Reviewed by		Date	

10.12 Visual Inspection (Ref:)

10.12.1 Objective

To verify that the Tablet Coating System is ready for operation.

10.12.2 Method

Visually examine that the installation of Tablet Coating System is completed and that all instrument / component packaging is removed. Visually examine the cleanliness of the Tablet Coating System and verify that all connections to instrument/components (electrical wire, hoses, pipes, clamps, etc) are firmly affixed. Confirm that the Tablet Coating System is ready for operation.

10.12.3 Acceptance Criteria

The specifications listed in the SPECIFIED column are met.

10.12.4 Data

S.No.	Specified	Acceptable [Y/N]	Initial / Date
1.	Installation of Tablet Coating System is completed.		
2.	Tablet Coating System is clean.		
3.	All instrument/component packaging is removed.		
4.	All instrument/ component hoses, piping, clamps, wire etc firmly affixed.		
5.	All accessories are available.		

Comments:

Reviewed by		Date	

11.0 CHECKLIST OF ALL TESTS AND CHECKS

This checklist is provided to ensure that all tests or checks required for this IQ have been executed.

Reference No.	Tests or Checks	Executed [Y/N]	Comment
10.1	Drawing Verification		
10.2	Documentation Verification		
10.3	Equipment Verification		
10.4	Instrumentation Verification		
10.5	Calibration Verification		
10.6	Materials in Product Contact		
10.7	Services Verification		
10.8	Control systems se-point and software parameter verification		
10.9	Spare Parts List		
10.10	Lubricants List		
10.11	Filter List		
10.12	Visual Inspection		

Comments:

Reviewed by		Date	

12.0 DEVIATION SHEET

Report any deviations from the acceptance criteria or exceptions from protocol instructions in the Record Sheet as described in SOP No: ……-" Handling Of Deviations" Record the total number of exceptions / deviations reported during the qualification activities of this Protocol. Record the Deviation Number and Title in the Table below. Include all Deviation Record Sheets in the IQ File.

TOTAL NO. OF EXCEPTIONS / DEVIATIONS = _____

Exception / Deviation No.	Exception / Deviation Title	Status

Comments:

Reviewed by		Date	

12.1 DEVIATION AND CORRECTIVE ACTION REPORT FORM

This Deviation and Corrective Action Report Form shall be completed for each result that does not meet the expected or as designed condition encountered during the execution of the protocol. Each form shall be numbered sequentially and tracked on the Deviation Sheet within the protocol.

Deviation Report Number:		
PROTOCOL SECTION NO.:	**DATE OF TEST:**	
Description Of Test Result:		
IMMEDIATE ACTION TAKEN:		
Corrective Action Taken / Planned:		
Deviation Reported By:		
Name:	Signature:	Date:
Corrective action must be taken prior to approval of IQ or OQ? :		
HEAD - ENGG. SIGNATURE		**DATE:**
Head-User dept. signature		Date
QA Signature:		Date:
<u>Corrective Action Implemented:</u>		
Corrective Action Implemented By:		
Name:	Signature:	Date:
(Attach comments and supporting documentation as necessary)		
Was a re-test or amendment necessary due to the Deviation?		Date of re-test:
Is Deviation Closed (Yes/No):		
QA Signature:		Date:

13.0 REFERENCES

The Principle Reference is the following

- Master Validation Plan for.
- Schedule – M – "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol 2 – Good Manufacturing Practices and Inspection.

The following references are used to give addition guidance

- FDA/ISPE Baseline Pharmaceutical Engineering Guide-Volume 5:- Commissioning and Qualification Guide, First Edition / March 2001.
- Code of Federal Regulations (CFR), Title 21, Part 210, Current Good Manufacturing Practice (cGMP) in Manufacturing, Processing, Packing, or Holding of Drugs, General. April 1, 1998.
- Code of Federal Regulations (CFR), Title 21, Part 211, Current Good Manufacturing Practice (cGMP) for Finished Pharmaceuticals, April 1, 1998.
- EU Guide to Good Manufacturing Practice, Part 4, 1997.
- European Commission's working party on control of medicines and inspections document, Validation Master Plan, Design Qualification, Installation & Operational Qualification, Non Sterile Process Validation, Cleaning Validation, October 1999.
- GAMP Guide, Validation of Automated Systems in Pharmaceutical Manufacture, Version 4.0, December 2001.
- SOP No. -"Handling of Deviations".
- SOP No. -"Change Control Procedure".

14.0 LIST OF ANNEXURES

Annexure No.	Document Title

15.0 SUMMARY

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16.0 POST- APPROVALS

The following approvals signify that the IQ is complete and acceptable and that the system is ready for OQ Execution.

PREPARED BY:

Functional area	Name	Signature	Date
Engineering			

CHECKED BY:

Functional area	Name	Signature	Date
Engineering			
Production			
Quality assurance			

APPROVED BY:

Functional area	Name	Signature	Date
Head Engineering			
Head Manufacturing			

AUTHORISED BY:

Functional area	Name	Signature	Date
Head Quality			