



**PHARMA DEVILS**

QUALITY ASSURANCE DEPARTMENT

**FAT FOR AUTO COATER**

## **FACTORY ACCEPTANCE TEST PROTOCOL CUM REPORT**

**EQUIPMENT NAME: AUTO COATER**

### **REVISION HISTORY**

<b>Rev.</b>	<b>Date</b>	<b>Authorized By</b>	<b>Revision Summary</b>
00	-----NA-----	-----NA-----	-----NA-----



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### 1.0 Pre-Approval Sheet:

Prepared By (Name & Designation)	Signature	Date
Production		
Quality Assurance		

Checked By (Name & Designation)	Signature	Date
Production		
Maintenance		
Quality Assurance		

Approve By (Name & Designation)	Signature	Date
Quality Assurance		



**FAT FOR AUTO COATER**

**2.0 Objective:** To define the protocol for the Factory Acceptance Test of the Auto coater machine.

**3.0 Scope:** This Factory Acceptance Test Protocol Cum Reportis applicable for Auto coater machine to be installed.

**4.0 Responsibility :**

**4.1 .....Engineers Shall be responsible for**

4.1.1 To provide the desired Qualification document and component certificates.

4.1.2 To provide all related drawings Equipment manual , safety feature.

4.1.3 To carry out installation Qualification , Operation Qualification of equipment at .....

4.1.5 To coordinate in factory acceptance Test (FAT)

**4.2 ..... Shall be responsible for:**

4.2.1 To rise the purchase order after approval and authorization of FAT.

4.2.2 To carry out FAT

**5.0 Equipment Description:** This is automated tablet coating system for efficient film coating/enteric coating of tablet in conical ends in a SS double – walked enclosure. Tablet to be coated are charged in to pan. During the coating process, coating fluids sprayed (film coated/ sugar coating over film coated tablet)through multiple air borne spray gun mounted with in the pan. A peristaltic pump is employed for precise delivery of coating fluids. The tablet beds is gently and efficiently mixed during pan rotation with the aid of mixing baffles attached internally with in pan. The coated tablet cores are dried with heated dehumidified air supplied from an inlet AHU- which contains dehumidification & a heating system as well as sequential better of 10 μ, 5μ,and 0.3μ **filter.**

Pan volume of this equipment is 660 liter, and maximum capacity is 170 kg & minimum capacity is 41 kg.

**The system consistsof:**

Main unit

Air handling equipment

The spraying system

Solution holding system with an agitator assembly

Exhaust system

Automation & control system

Interconnecting air ducts.

**5.1 Function Mechanism:** The Equipment shall be designed to use in production / Batchmanufacturing in sifting of material.



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S.No.	Parameters	Detail
1.	Baffles	Spiral type baffles are welded to the coating drum to ensure rapid and uniform mixing and any dead area.
2.	Spray guns	Highly sophisticated and efficient 6 nos. spray free from chocking problem
3.	Coating application system	It contains 1 no. 75 liters solution holding vessel with a top entry
4.	Peristaltic pump	Peristaltic pump for precise and rapid priming facility for proper and accurate dosing of solution.
5.	Wet scrubber in exhaust system	The scrubber system is design to scrub particulate matter from production area. The system in general shall comprise of ducting, venture scrubber, mono block pump and water re circulation piping etc. the air is scrubbed by using water as the scrubbing media. The scrubbed water is collected in the bottom re circulation tank which has to be drained periodically. The clean air is discharged in to atmosphere through a stack. The scrubbed liquid is collected in the bottom re circulation tank which has to be drained periodically.

### 6.0 Vendor Information:

.....

#### 6.1 Design Specification:

S.No.	Component	Specification	Observation	Checked By
	<b>Auto coater machine</b>			
1.	<b>Air handling unit</b>			
	Make	Damcon		
	MOC	Modular sandwich fabricated panel		
2.	<b>Pre filter</b>			
	Make	Netfil		
	MOC	Synthetic media		
3.	<b>Secondary filter</b>			
	Make	Netfil		
	MOC	Synthetic media		
4.	<b>Super HEPA filter</b>			
	Make	Netfil		
	MOC	Micro fiber glass		
5.	<b>Steam Heater</b>			
	Make	Applo		
	MOC	SS 304 tubing & aluminium fins		
6.	<b>Chilling coil</b>			
	Make	Applo		
	MOC	copper tubing & aluminium fins		
7.	<b>Globe valve on steam inlet</b>			
	Make	bond		
	MOC	40 NB		



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S.No.	Component	Specification	Observation	Checked By
8.	<b>Globe valve on steam inlet</b>			
	Make	bond		
	MOC	40 NB		
9.	<b>Globe valve on steam inlet</b>			
	Make	bond		
	MOC	40 NB		
10.	<b>PID control valve on steam inlet line</b>			
	Make	Dembla		
	MOC	40 NB, series -1100		
11.	<b>Safety valve on steam inlet line</b>			
	Make	CASA		
	MOC	15 NB		
12.	<b>Solenoid valve</b>			
	Make	Acon		
	MOC	15 NB		
	supply	24 VDC		
13.	<b>Globe valve on steam outlet line</b>			
	Make	bond		
	MOC	40 NB		
	Qty.	1		
14.	<b>Steam trap outlet line</b>			
	Make	SPIRAX		
	MOC	25 NB		
	Qty.	1		
	TC No.	320277/6/105510547		
15.	<b>Gate valve on chilling coil inlet</b>			
	Make	STD		
	MOC	40 NB		
16.	<b>Three way valve on chilling line with electrical actuator</b>			
	Make	Johnson		
	MOC	40 NB		
	S.R. No.	CW617NJCI PN40		
17.	<b>Safety Valve On Chilling Inlet</b>			
	Make	STD		
	MOC	15 NB		
	Qty.	1		
18.	<b>Solenoid valve chilling outlet</b>			
	Make	Avcon		
	MOC	40 NB		
	Qty.	1		
	TC No.	SO/14505060		
19.	<b>Hot And Cold Mixing Damper</b>			
	Make	BLPT		
	MOC	SS304		
	Qty.	01		
20.	<b>Electrical actuator for hot and cold damper</b>			
	Make	Johnson		



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S.No.	Component	Specification	Observation	Checked By
	Model No.	M-9109		
21.	<b>Inlet duct</b>			
	Make	BLPT		
	MOC	SS304		
	Qty.	1		
	TC No.	JSSL-VAD/QC/14-15/DOM/DEC/048		
22.	<b>Inlet Blower</b>			
	Make	Hariudyog		
	MOC	SS 304		
	Qty.	01		
	TC No.	HU-1942		
23.	<b>VFD For Supply Motor</b>			
	Make	ABB		
	supply	7.5 HP		
	Qty.	1		
	TC No.	3ABD00017514S142		
24.	<b>Inlet blower motor</b>			
	Make	Bharat bijalee		
	supply	7.5 hp,2880 rpm,415 volt,3 phase,		
	Qty.	1		
	SR No.	K1501005		
25.	<b>Inlet Shoe</b>			
	Make	BLPT		
	MOC	SS304,16		
	Qty.	1		
	SR No.	JSSL-VAD/QC/14-15/DOM/DEC/048		
26.	<b>Electric Actuator For Inlet Damper</b>			
	Make	BLPT		
	MOC	SS304,16		
	Qty.	1		
	TC NO.	M-9116GGA-2		
27.	<b>Flap Damper For Inlet Damper</b>			
	Make	BLPT		
	MOC	SS304,16		
	Qty.	1		
28.	<b>Exhaust duct</b>			
	Make	BLPT		
	MOC	SS304,16		
	Qty.	1		
	TC. No.	JSSL-VAD/QC/14-15/DOM/DEC/048		
29.	<b>Exhaust shoe</b>			
	Make	BLPT		
	MOC	SS304,16		
	Qty.	1		



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S.No.	Component	Specification	Observation	Checked By
	TC. No.	JSSL-VAD/QC/14-15/DOM/DEC/048		
30.	<b>Exhaust blower</b>			
	Make	Hariudyog		
	MOC	Impeller & stand.-MS		
	Qty.	1		
	TC. No.	HU-1942		
31.	<b>Exhaust blower motor</b>			
	Make	Bharat bijlee		
	Supply	10 HP,2880RPM,415 volt 3 phase		
	Qty.	1		
	Sr. No.	1501957		
32.	<b>VFD for exhaust motor</b>			
	Make	ABB		
	Supply	10HP		
	Qty.	1		
	Sr No.	9142400142		
33.	<b>Electric actuator for inlet damper</b>			
	Make	Johnson		
	Model No.	M-9116GGA-2 % OPENING TYPE		
	Qty.	1		
	Sr No.			
TC NO.	M-9116GGA-2			
34.	<b>Flap Damper For Exhaust Duct</b>			
	Make	BLPT		
	MOC	SS 304		
	Qty.	1		
35.	<b>By pass duct</b>			
	Make	BLPT		
	MOC	SS304X16		
	Qty.	1		
	TC. NO.	JSSL-VAD/QC/14-15/DOM/DEC/048		
36.	<b>Flap Damper For Bypass Duct</b>			
	Make	BLPT		
	MOC	SS304 without handle		
	Qty.	01		
37.	<b>Pneumatic actuator for by pass damper</b>			
	Make	Rotex		
	Model No.	ECF-50		
	Qty.	01		
	TC NO.	QA/13045330		
38.	<b>Wet Scrubber System</b>			
	Make	BLPT		
	Model No.	MS, Venturi type		





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S.No.	Component	Specification	Observation	Checked By
	Qty.	01		
39.	<b>Wet Scrubber PUMP and motor</b>			
	Make	crompton		
	type	DMB10DG ,1 HP,HEAD- 18-45 M		
	Qty.	01		
40.	<b>Bellow</b>			
	Make	Acrosil ( 200x300 long )		
	Type	Neoprene rubber		
	Qty.	01		
41.	<b>Gasket for ducting</b>			
	Make	Acrosil ( 230x200 long )		
	Type	Neoprene rubber		
	Qty.	08		
42.	<b>Perforated drum</b>			
	Make	BLPT		
	Type	Triangular Pitch , With Spiral Baffle		
	Qty.	01		
43.	<b>Bottom tray</b>			
	Make	BLPT		
	MOC	SS304 L		
	Qty.	01		
44.	<b>Main drive motor</b>			
	Make	HMM		
	Type	FLP, 3 HP, 1430 RPM		
	Qty.	01		
	SR No.	427391		
45.	<b>VFD for main motor</b>			
	Make	ABB		
	SUPPLY	3 HP		
	Qty.	01		
	SR No.	3ABD00017513S144594368		
46.	<b>Main drive gear box</b>			
	Make	Elecon		
	SUPPLY	Horizontal hollow Shaft SNU-U Size-5		
	Qty.	01		
	SR No.	1034645		
47.	<b>Light fixture with lamp</b>			
	Make	STD		
	Type	FLP,LED LIGHT		
	Qty.	02		
48.	<b>Bearing housing wit Bearing</b>			
	Make	STD		
	Type	M.S,SPH- Roller		
	Qty.	01		
49.	<b>Front door glass</b>			



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S.No.	Component	Specification	Observation	Checked By
	Make	STD		
	Type	Toughened glass		
	Qty.	01		
<b>50.</b>	<b>Square gasket for door</b>			
	Make	Acrosil		
	Type	Food grade silicon,10x10 mm		
	Qty.	01		
	TC No.	1691		
<b>51.</b>	<b>Spray Gum</b>			
	Make	Spraying system		
	Type	SS316		
	Qty.	06		
<b>52.</b>	<b>Spray Pump</b>			
	Make	Flow tech		
	Type	FLP,SIHGLE		
	Qty.	01		
	Sr. No.	FP-130101-4		
<b>53.</b>	<b>Motor For Spray Pump</b>			
	Make	HMM		
	Type	FLP,0.5 HP,1380 RPM		
	Qty.	01		
	Sr NO.	569764		
<b>54.</b>	<b>Pneumatic Motor</b>			
	Make	PTM		
	Type	0.3 HP,2000RPM		
	Qty.	01		
	Sr NO.	141914		
<b>55.</b>	<b>Shaft for impeller</b>			
	Make	BLPT		
	Type	SS316		
	Qty.	01		
	Sr NO.	X/16174		
<b>56.</b>	<b>Impeller</b>			
	Make	BLPT		
	Type	SS316, 100 MM		
	Qty.	01		
	Sr NO.	F/8071		
<b>57.</b>	<b>Castor Wheel</b>			
	Make	Swiss		
	Type	SS316		
	Qty.	03		
	TC NO.	2438		
<b>58.</b>	<b>Manual ball bottom valve at drain</b>			
	Make	Swiss		
	Type	SS316		
	Qty.	03		
	Sr NO.	2438		



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S.No.	Component	Specification	Observation	Checked By
59.	<b>Silicon tube for liquid inlet</b>			
	Make	Acrocil		
	Type	Food grade silicon white 29 mm		
	Qty.	01		
	TC NO.	1691		
60.	<b>Spray gum</b>			
	Make	Cris		
	Type	SS316 water saver gun with ½ house connector		
	Qty.	1		
61.	<b>Spray ball for inner wash</b>			
	Make	Spraytech		
	Type	SS316		
	Qty.	5		
	TC No.	D3713		
62.	<b>Spray nozzle for external wash</b>			
	Make	Spraytech		
	Type	SS316		
	Qty.	4		
	TC No.	X/1732/R		
63.	<b>Spray nozzle for Inlet &amp; Exhaust</b>			
	Make	Spraytech		
	Type	SS316		
	Qty.	4		
	TC No.	G/5646/T		
64.	<b>Spray nozzle for DUCT WASH</b>			
	Make	Lechler		
	Type	SS316		
	Qty.	2		
	TC No.	X/1732/R		
65.	<b>Manual operated butterfly valve for inlet duct</b>			
	Make	valfit		
	Type	SS316		
	Qty.	01		
	TC No.	485		
66.	<b>Manual operated butterfly valve for exhaust</b>			
	Make	valfit		
	Type	SS316		
	Qty.	01		
	TC No.	485		
67.	<b>Manual operated butterfly valve for drum internal wash &amp; hand gun</b>			
	Make	valfit		
	Type	SS316		
	Qty.	01		
	TC No.	485		
68.	<b>Manual operated butterfly valve for drain</b>			
	Make	valfit		



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S.No.	Component	Specification	Observation	Checked By
	Type	SS316		
	Qty.	01		
	TC No.	485		
69.	Gas spring cylinder			
	Model	UES 500 N-2A2NO		
<b>CONTROL AND AUTOMATION</b>				
70.	Main control panel			
	Make	BLPT		
	Type	MS powder coated		
	Qty.	01		
71.	<b>HMI</b>			
	Make	Bijers		
	Model	E-1101		
	Qty.	1		
	TC no.	M-3521		
72.	<b>PLC</b>			
	Make	Mitsubhi		
	Model	FX3GE40M		
	Qty.	01		
	TC no.	M-3521		
73.	<b>Input Module</b>			
	Make	Mitsubhi		
	Model	FX2N-8AD		
	Qty.	01		
	TC no.	M-3521		
74.	<b>Output Module</b>			
	Make	Mitsubhi		
	Model	FX2N-4DA		
	Qty.	02		
	TC no.	M-3521		
75.	<b>Communication On Module</b>			
	Make	Mitsubhi		
	Model	FX2N-16EYR-ES		
	Qty.	01		
	TC no.	M-3521		



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### 6.2 Material of Construction:

#### 6.2.1 Product Contact Part:

S.No.	Component	MOC	Observation	Checked By
1.	Cylindrical Pan	SS 316		
2.	Baffle	SS 316		
3.	Door cover	Poly carbonate		
4.	Solution tank	SS 316		
5.	Agitator	SS 316		
6.	Heator	SS 316		
7.	Gun ,Nozzle, Cap, needle.	SS 316/ SS 304		

#### 6.2.2 Non-ContactParts:

S.No.	Component	MOC	Observation	Checked By
1.	In let AHU ( skin , inner skin, After HEPA)	GI powder coated SS 304		
2.	Plenums ( inlet exhaust )	SS 304		
3.	Damper	SS 304		
4.	Main unit	SS 304/MS		
5.	Wip spray nozzles	SS 304		
6.	Operating panels	SS 304		
7.	Power panels	MS powder coated		
8.	Tubing s	Silicon PU		
9.	Heating coils with fins	SS 304/ Aluminium		
10.	Cooling coil	Copper / Aluminium		
11.	Fip light	Aluminium		
12.	Spraying ARM	SS 304		
13.	Ducting interconnecting	SS 304		
14.	Blower impeller	MS		

### 6.3 Factory Acceptance Test:

S.No.	Specification	Observation	Checked By Sign./date
1.	Equipment shall be fabricated in accordance with approved drawing		
2.	Arrangement /connection of required utilities		
3.	Test certificate of MOC		
4.	Equipment shall be finished smoothly		
5.	G. A. Drawing shall be available		
6.	P & I Drawing shall be available		
7.	Purchase order		
8.	System Specification		
9.	Installation, Operation and Maintenance manuals		
10.	Spare part list		
11.	Drawings		



## Certificate of Factory Acceptance Test

This to certified that Auto Coater has completed Factory Acceptance test successfully.

This Factory Acceptance test has been performed by;

S.No.	Name	Department	Designation	Sign/ Date

### 7.0 Change Control :

.....  
 .....  
 .....  
 .....

### 8.0 Abbreviation:

S.No.	Abbreviation	Expanded Form
1.	DQ	Design Qualification
2.	MOC	Material of construction
3.	RPM	Revolution per Minute
4.	GA	General Arrangement
5.	P& I	Piping & Instrumentation

### 9.0 Equipment/ system Drawing & Documentation Requirement:

- GA Drawing
- Electrical circuit Diagram
- Control Panel Layout
- Pneumatic circuit Diagram
- P & I Diagram
- Installation operation & maintenance manuals
- MOC Certificates

### 10.0 Summary and Conclusion

#### Summary:

.....  
 .....  
 .....



**FAT FOR AUTO COATER**

**Conclusion:**

.....  
.....  
.....

**11.0 List of Reference Document/ Records:**

- URS
- Equipment Drawing
- Layouts



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**12.0 Post-Approval:** Based on the data collection and combination of the data, draw the conclusion of complete study. A Protocol cum report shall be prepared for the complete activity. All the raw data generated during the study shall be documented for future reference.

Prepared By (Name & Designation)	Signature	Date
Production		
Quality Assurance		

Checked By (Name & Designation)	Signature	Date
Production		
Maintenance		
Quality Assurance		

Approve By (Name & Designation)	Signature	Date
Quality Assurance		