



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

FACTORY ACCEPTANCE TEST FOR BECOATER 36”

Department: Quality Assurance

FAT No.:

Title: Factory Acceptance Test for Becoater 36”

Effective Date:

Supersedes: Nil

Review Date:

**FACTORY ACCEPTANCE TEST
FOR
BECOATER – 36”**

Vendor:

	Title	Name	Signature	Date
Prepared by	Project Engineer			
Reviewed by	Quality Engineer			
Approved By	Quality Manager			

Client Approvals:

Title	Name	Signature	Date
Quality Assurance			
Project Engineer			
Project Consultant			



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1 INTRODUCTION:

The objective of this Factory Acceptance Test is to verify that the equipment has been built and engineered according to the design specification and as a result approves the equipment for Shipping to Client site and Handover will be following completion of successful site acceptance test.

This document will be completed as follows:

1. All people who enter data into this report will complete the section of this FAT titled 'FAT Personnel'. See Appendix. A, B, C, D, E, F.
2. Any corrections in handwriting will be made by deleting with a single pen stroke; the correction will be initialed and dated.
3. Entries shall be made in this document using a ballpoint pen or suitable indelible ink in Blue only.
4. Compliance will be indicated by a written YES or NO in the relevant boxes provided. 'Ticks' and 'crosses' must not be used.
5. Correction fluid is not allowed.
6. Each section will be signed and dated by the tester/s when it is complete.
7. Any non-compliance identified during the execution of the test protocols must be documented in a Deviation report. These report sheets must be attached to the appendix of this protocol. The report will describe the deviation in detail and, whenever possible, identifying the cause.



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2 OVERVIEW:

VENDOR has received an order for the material procurement, and manufacture and supply of
1 No. of BECOATER –36" From M/s..... vide their purchase order No:
.....Dated:



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DOCUMENT VERIFICATION

Objective	Ensure that all relevant design documentation is in place and referenced.			
Method	Log the document title, reference number, approval date and revision number. Any discrepancies to be noted on the review form and on the Deviation Report.			
Acceptance Criteria	All columns in the table should be completed. All documents should be identified, approved and referenced.			
Document Expected	Reference Number	Rev	Approval Date	Available Yes/No
Purchase Order				
G A Drawing				
P & I Drawing				
WIP Drawing				
Layout drg				
Utility list				
DQ				
FDS				
PLC FDS				
GA diagram of Control Panel				
IGA diagram of Control Panel				
IGA diagram of Pneumatic Panel				
Power wiring diagram				
PLC Output diagram				
PLC Input diagram				
Analog input wiring Diagram				
Analog output wiring Diagram				
Terminal wiring diagram				
Material Chart List				
Manual				
Operation Manual of BC				
Manual for Bought out components:	AS PER Material Chart			



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Comments

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MAJOR COMPONENT VERIFICATION

Objective	To verify that the Major Components are installed in accordance with the approved GA drawings.
Method	Take a Copy of the Approved GA drawing Highlight the components present on the machine in the drawing then fill the table below. Fill in the drawing number when verified. Attach the Highlighted drawing with this document. Any discrepancies to be noted on the review form and on the Deviation Report. Use Yellow for Accept & Red for discrepancies.
Acceptance Criteria	There should not be any variance with approved GA.

S.No.	COMPONENT DESCRIPTION	MAKE	MODEL / MOC/SIZE.	VERIFIED YES/ NO
1.	Perforated Pan shell (36")	Vendor	SS 316, 2.5Thk	
2.	Pan cone	Vendor	SS 316, 3Thk	
3.	Baffle	Vendor	SS 316, Rabbit Ear Type	
4.	Coater Body	Vendor	SS 304, 3Thk	
5.	Bottom tray	Vendor	SS 304, 3Thk	
6.	Main drive motor	C.G	2HP, 930RPM,V-415,HZ-50,Frame Size 100L ,NFLP	
7.	VFD for main motor	ABB	ACS355 –03E – 04A 1-4	
8.	Main drive gearbox	Elecon	Type SNU, Size 4" , Ratio 60:1	
9.	Driver Sprocket	Vendor	CS, 30Teeth , 1" Pitch	
10.	Driven Sprocket	Vendor	CS, 30Teeth , 1" Pitch	
11.	Supply and Exhaust Plenum	Vendor	SS 304, 1.6Thk	
12.	Supply duct	Vendor	SS 304, 1.6Thk, Ø 300	
13.	Exhaust duct up Dry scrubber	Vendor	SS 304, 1.6Thk, Ø250	
14.	Exhaust duct Dry scrubber to Exhaust blower	Vendor	MS, Epoxy smoke Grey Painted, 1.6Thk, Ø250	
15.	Discharge plate fixed inside the Pan	Vendor	SS 316, 2Thk	
16.	Bearing Housing	Vendor	M.S, Epoxy Grey Painted	
17.	AHU	Damcon	SS 304 , 3 Thk	
18.	Primary Filter (5 Micron) (EU-5)	AAF	Frame – Al, Size: 24" X 24" X 6"-1No, 24" X 12" X 6"-1No.	
19.	Coarse Filter (3 Micron) (EU-8)	AAF	Frame – Al, Size: 24" X 24" X 12"-1No, 24" X 12" X 12"-1No.	



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20.	HEPA Filters EU-13 (0.3Micron)	AAF	Frame – Al, Size: 24" X 24" X 12"-1No, 24" X 12" X 12"-1No.	
21.	Steam Heater	Apollo	MOC-SS304,moc of fins-SS 304,3/4" tube , 4rows,10KG/CM ²	
22.	Supply Blower	Swastika	CFM-1250, W.G.-6" CASING-SS304, IMPELLER-AL	
23.	Supply Blower Motor	Crompton Greaves	3HP, 2830 0RPM,V-415,HZ-50,Frame Size ND90 NFLP	
24.	VFD for inlet blower Motor	ABB	ACS550 – 01 – 05A4-4	
25.	Exhaust blower	Swastika	CFM-1500, W.G.-14" CASING-MS, IMPELLER-AL	
26.	Exhaust blower motor	HMM	7.5HP, 2905RPM,V-415,HZ-50,Frame Size 100 NFLP	
27.	VFD for Exhaust Blower Motor	ABB	ACS550 – 01 – 012A-4	
28.	Peristaltic pump	Electro Lab	Model : PP 201NFLP	
29.	Silicon Tubing	Acrosil	Food Grade 11 O/D X 7 I/D	
30.	Solution holding Vessel	Vendor	SS316, 1.6 Thk,50L	
31.	Pneumatic motor for solution preparation vessel	PTM	Air motor Model – AR025 3000, 0.3 H.P,3000 RPM	
32.	Shaft for Impeller	Vendor	SS 316, Ø16 Shaft	
33.	Impeller for Solution preparation vessel	Vendor	SS 316, Ø100 X 2 Thk	
34.	Caster wheel for Solution preparation vessel	Swiss Engg	SS 304 PU Coated swivel type Ø 75 X 38mm W	
35.	Bottom outlet ball valve for Solution preparation vessel	Shakti	SS 316, 1" TC Type	
36.	Needle valve at solution preparation tank	Shakti	SS 316, 3/8"	



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37.	Dry scrubber	Pilani Envirotech	M.S Powder coated , with 5micron filter, dry Scrubber	
38.	Solenoid valve for plunger	Festo	5/2 Way , MFH – 5- 1/4	
39.	Main Air Filter regulator Lubricator	Festo	LFR – D- MINI	
40.	Mini pre regulator for Atomizing	Festo	LR – D- MINI	
41.	Spray gun	Binks	SS 316 – 2Nos	
42.	Wash nozzles	Vendor	Solid cone type SS 316	
43.	Control panel	Vendor	MS powder coated	
44.	HMI	Mitsubishi	E 1032	
45.	PLC	Mitsubishi	FX _{3U} – 32M	
46.	Input module	Mitsubishi	FX _{2N} – 4AD	
47.	Output module	Mitsubishi	FX _{2N} – 4DA/4DA	
48.	Pneumatically Actuated inlet damper with butterfly valve	Rotex	ECF 125, Max. Pre. 8bar , temp - 20 ⁰ C to +80 ⁰ C	
49.	Pneumatically Actuated exhaust damper with butterfly valve	Rotex	ECF 125, Max. Pre. 8bar , temp - 20 ⁰ C to +80 ⁰ C	
50.	Solenoid valve for inlet damper	Festo	5/2 Way , MFH – 5- 1/4	
51.	Solenoid valve for exhaust damper	Festo	5/2 Way , MFH – 5- 1/4	
52.	Butterfly valve for Inlet Duct	Valfit	SS 304,12" ID without handle	
53.	Butterfly valve for Exhaust Duct	Valfit	SS 304,10" ID without handle	
54.	WIP Header	Vendor	SS304 , 2 Thk	
55.	Pneumatic Cylinder for Door Lock	Festo	DSNU-25-40-P-A	
56.	Inlet Filter at canopy	Vendor	EU-13,92 od x149 Long	



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57.	Multistage pump for WIP	CNP	Model : CDLF – 4- 8 , HP -2 , RPM - 2900	
58.	Motor for Multistage pump	CNP	2HP,2850RPM,V-415,HZ-50	
59.	Manual Butterfly Valves for WIP System (Inlet / Exhaust duct wash , pan Internal wash / pan External wash(4 nos)	Valfit	SS 316 , 1.5" TC	
60.	Manual Butterfly Valve for WIP header drain	Valfit	SS 316 , 1" TC	
61.	Needle Valves for WIP System	Shakti	SS 316 , 1/2" BSP	
62.	Lamp	FCG	FLP	
63.	Canopy	Containment service	polyurethane	
64.	RTP LHS in Canopy	Vendor	SS 316	
65.	Bottom Tray for canopy	Vendor	SS 316	
66.	RTP in Base	Vendor	SS316	
67.	Outlet valve at Canopy Tray	Meera	1" TC End,SS 316	
68.	Water Inlet Ball valve for Canopy	Shakti	1" Flange end	
69.	Air inlet Needle valve for Canopy	Shakti	1" Flange end	
70.	Tablet Unloading Tray	Vendor	SS 316,2TH	
71.	Pipe for Spray Gun	Entegris	Silicon Braided	
72.	Breathing Filter	Containment service	EU-13, Polyurethane	

Comments

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INSTRUMENT VERIFICATION

Objective	To ensure that the Instruments Listed in the Instrument List are available, calibrated and fixed on the system, as per the drawings.
Method	Referring to the Instrument List fill out the table below. Verify the ranges, makes, quantities & verify that the calibration certificate are available. Using a yellow Highlighter pen mark out the drawings on verification. Fill in the Drawing number in the column below after confirming installation. Attach the Highlighted drawing or mark on the same drawing as in 6 above. Any discrepancies to be noted on the review form and on the Deviation Report.
Acceptance Criteria	All requirements are listed and referenced in the drawing.

S.NO	INSTRUMENT DESCRIPTION	MAKE	MODEL / RANGE / SIZE	VERIFIED YES / NO
1.	PT 100 sensor in inlet duct	Techno	Range 0- 200 ⁰ C, Size 06 X 150mm long	
2.	Differential Pressure Indicator across cabinet	Dwyer	Range 0- 5''WC, Size 4''dial	
3.	Differential Pressure Gauge across HEPA Filter	Dwyer	Range 0-5'' WG	
4.	Differential Pressure Indicator Across 5 micron Filter	Dwyer	0-5'' WG	
5.	PT 100 sensor in exhaust duct	Techno	Range 0- 200 ⁰ C, Size 06 X 150mm long	
6.	PT 100 sensor at tablet bed	Techno	Range 0- 200 ⁰ C, Size 06 X 200mm long	
7.	Proxy sensor for RPM sensing	P & F	M18PNP,10-30VDC	
8.	Proxy sensor for Pan Door sensing	P & F	M18PNP,10-30VDC	
9.	Proxy sensor for Pan RTP sensing	P & F	M18PNP,10-30VDC	
10.	Pressure switch at main air supply	Danfoss	Model : RT-116, Range 0 – 10 kg / cm ²	



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11.	Pressure switch at atomizing air supply	Danfoss	Model : RT-116, Range 0 – 10 kg / cm ²	
12.	Pressure Gauge on WIP Header	Waaree	Range : 0 – 10 kg / cm ² , 4" dial	

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EQUIPMENT MOC VERIFICATION

Objective	To verify that the material of construction of the machine is as per approved documents	
Method	Verify the Material chart (Doc) and that certificates are available with respect to acceptable standards. Use a yellow highlighter pen to mark the components verified & Red for Discrepancies. Note down any discrepancy in the discrepancy report in this document.	
Acceptance Criteria	The MOC and test certificates thereof must comply with the requirement of approved documents.	
Comments		
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EQUIPMENT DIMENSION VERIFICATION

Objective:	To verify that the equipment manufactured is in accordance with approved drawing.
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Procedure:	Refer the approved drawing and compare with the actual dimensions on the equipment. Recheck whether the drawing clearly specifies the manufacturing standards adopted. With a red pen clearly strike off the incorrect dimension and put the correct dimension. Correct the drawing with the proper dimensions name the drawing "AS BUILT". Attach the market drawing with this Document
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Acceptance Criteria	The measured dimensions should be within the acceptable limits.
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Drawing no.:
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Comments:

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EQUIPMENT FINISH VERIFICATION

Objective:	To ensure that the equipment finish is as per the approved drawing/FDS		
Procedure:	<p>Stainless Steel Internal finish:</p> <ul style="list-style-type: none"> ▪ Using an RA meter or comparative plate check the internal finish ▪ There should be no exposed threads. ▪ There should be no crevices or sharp corners, weld splatters. ▪ Edges should be smooth and rounded off. ▪ Using an RA meter or comparative plate check the external finish ▪ No scratches should be present on the surface. <p>Mild Steel.</p> <ul style="list-style-type: none"> ▪ The part should be properly descaled, degreased and painted. <p>Other equipments/Components should be properly cleaned, deburred and should have no sharp edges. Any discrepancies to be noted on the review form and on the Deviation Report.</p>		
Acceptance Criteria	The finish should be as per the approved drawing and as above		
Part	Finish SS Surface	Internal finish as specified in the approved documents	Pass/Fail
Pan	Internal	Ra-0.4(240 Grit Mirror)	
	External	Ra-0.6(180 Grit Matt.)	
Solution Tank	Internal	Ra-0.4(240 Grit Mirror)	
	External	Ra-0.6(180 Grit Matt.)	
Lid	Internal	Ra-0.4(240 Grit Mirror)	
	External	Ra-0.6(180 Grit Matt.)	
Inlet duct			
	External	Ra-0.6(180 Grit Matt.)	
Exhaust duct			
	External	Ra-0.6(180 Grit Matt.)	
Body	External	Ra-0.6(180 Grit Matt.)	
Glove box	Internal	Ra-0.4(240 Grit Mirror)	



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	External	Ra-0.6(180 Grit Matt.)	
Comments:			
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EQUIPMENT NAME PLATE VERIFICATION

Objective:	To ensure that the Nameplate is provided on the machine and is easily visible. It should clearly mention the name, reference no. of the machine and the date of manufacture.
Procedure:	Visually inspect the machine for the Nameplate and check whether it contains the date, reference no. And date of manufacture. Mark /highlight the Location on the drawing. Any discrepancies to be noted on the review form and on the Deviation Report.
Acceptance Criteria	The Nameplate has all the above data inscribed on it.

DESCRIPTIONS	VERIFIED (YES/NO)
Name Plate Location is Acceptable and marked on the drawing?	

Model:	GMP	Capacity:	36"	Pass/Fail
Type:	BECOATER	Date of Mfg.:		
MOC:	SS316	Inspection By:	CLIENT	
Sr. No:				

Comments:		
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CONTROL PANEL BUILD QUALITY

Objective:	To ensure that the electrical equipments are assembled as per electrical GA drawings.	
Procedure:	Check orientations, drawings, and placement of switchgears as per GA. Highlight the components on the GA, so verified yellow for accept & Red for Deviation.. Any discrepancies to be noted on the review form and on the Deviation Report.	
Acceptance Criteria	All the equipments are assembled as per GA.	
	Description	Verified Yes/No
	Electrical Equipments orientations are as per GA Drg no.....	
	Electrical Wiring Diagram Attached?	
	Panel Build Quality Acceptable?	
Comments:		
	Signed	Date
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ELECTRICAL WIRING DIAGRAM

Objective:	To compare the electrical components in the panel and the wiring identification with the electrical drawings.
Procedure:	<p>The tester will compare the installed components with those specified on the drawings and check the wiring identification is as shown on the drawings and will mark with a 'highlighter' pen each of the details on the drawing which are verified. A minimum of 20% of the components fitted will be checked and highlighted. Any correction to the drawing will be written on the drawing by the relevant item in RED ink.</p> <p>When the tester has completed the check they will date and sign the marked-up print and write the words: - 'FACTORY ACCEPTANCE TEST ELECTRICAL COMPONENTS CHECK'</p> <p>The tester will attach the Marked-Up print to this report as an appendix given below. All attachments to this protocol to be marked up with this protocol number including the number of pages and the appendix to which it is attached.</p> <p>Any items on the drawings in non-compliance will be detailed in a deviation report.</p>

Acceptance Criteria	The connections are as per the wiring diagrams.
----------------------------	---

Electrical Drawing No.....	Rev. No.	Pass/Fail

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ELECTRICAL COMPONENT/WIRING TAG VERIFICATION

Objective	Confirm that all the electrical Components/Wires are as per given Tag in the drawings.					
Method	Verify that the tags on the Components and wires are as per the wiring diagrams. Fill in the table below. Any discrepancies to be noted on the review form and on the Deviation Report.					
Acceptance Criteria	The tag Numbers should tally.					
S. No.	Description Of components	Type / Specification	Qty.	Make	Actual	Verified Yes/No
1	MCB-1	MCB 6A 3P	1	Hager		
2	MCB-2	MCB 25A 3P	1	Hager		
3	MCB-3	MCB 10A 3P	1	Hager		
4	MCB-4,5	MCB 6A 3P	2	Hager		
5	MCB-6,7	MCB 6A 2P	2	Hager		
6	VFD1	VFD 2HP	1	ABB		
7	VFD2	VFD 7.5HP	1	ABB		
8	VFD3	VFD 3HP	1	ABB		
9	EM-1	MODULE FX 2N-4ADMModule	1	mitsubishi		
10	EM-2,3	MODULE FX 2N-4DAModule	2	mitsubishi		
11	PLC	PLC-FX3U-32M	1	mitsubishi		

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WIRING TUG TEST

Objective	Confirm that all the wires are connected to the electrical components tightly.
Method	Lightly Pull all the wires connected to the electrical components one by one testing any loose connections. Redo the connection if any is found loose. Any discrepancies to be noted on the review form and on the Deviation Report.
Acceptance Criteria	Ensure all wires connected tightly to the electrical components.

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TEST INSTRUMENTS

Objective	To identify the equipment and instruments used for testing during the Factory Acceptance Test phase and to verify that they were calibrated.
Method	List all test or reference instruments used during the Factory Acceptance Test of the system. Include the description, serial number, manufacturer, and calibration for each item, as applicable. Cert-attachment 3 Verify that all such instruments are calibrated. Document the results in the table below. Any discrepancies to be noted on the review form and on the Deviation Report.
Acceptance Criteria	All instruments used to qualify the system during Factory Acceptance Test shall be listed along with their description, serial number, Certificate number, calibration dates, as applicable. For each instrument, a copy of the calibration certification is to be included with this protocol or its location referenced.

Instrument	Serial Number	Certificate Number	Available Yes / No
RA METER			
Anemometer			
Temperature Gauge			
Noise Gauge			
Tachometer			
Manometer			

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I/O CHECK

Objective:	To check the I/O with respect to the PLC FDS
Procedure:	<p>To verify actual I/O listing with that mentioned in PLC FDS, by performing each operation required for respective FUNCTIONS given.</p> <p>When the operation is performed, digital inputs are shown on PLC on LED Indicator. Other I/Os can be checked using Multimeter and tester</p> <p>The following points for I/O checks mentioned as drawn from PLC FDS.</p>
PLC FDS Reference Number	
Acceptance Criteria	All the I/Os listed in the PLC FDS should be included in the PLC.

Digital Input List

S.No.	Address	Description	Verified Yes/No
1.	X 0	Pan RPM Proxy Sensor	
2.	X 1	Wash/Production Key Switch	
3.	X 2	Spare	
4.	X 3	Exhaust Blower ON Feedback	
5.	X 4	Inlet Blower ON Feedback	
6.	X 5	Pan Motor Feedback	
7.	X 6	Main Air Pressure Switch	
8.	X 7	Spare	
9.	X 10	Spare	
10.	X 11	Emergency Stop Push Button	
11.	X 12	Pan Door Close Proxy Sensor	
12.	X 13	RTP Close Proxy Sensor	
13.	X 14	Atomizing Air Pressure Switch	
14.	X 15	Scrubber Pump ON Feedback	
15.	X 16	Wash Pump ON Feedback	
16.	X 17	Spare	



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Digital Output List

S.No.	Address	Description	Verified Yes/no
1.	Y 0	Pan Motor ON	
2.	Y 1	Inlet Damper SOV	
3.	Y 2	Exhaust Blower ON	
4.	Y 3	Inlet Blower ON	
5.	Y 4	Steam Condensate SOV	
6.	Y 5	Exhaust Damper SOV	
7.	Y 6	Wash Pump ON	
8.	Y 7	Peristaltic Pump	
9.	Y 10	Plunger SOV	
10.	Y 11	Hooter	
11.	Y12	Spare	
12.	Y13	Pan Door Close SOV	
13.	Y14	Pan Reverse ON	
14.	Y15	Scrubber Pump ON	
15.	Y16	Dust Collector SOV	
16.	Y17	Lamp ON	

Analogue Input List

S.No.	Address	Description	Verified Yes/no
1	AI-01	Inlet Temp. : 0-200 Degree C (4-20 mA)	
2	AI-02	Exhaust Temp. : 0-200 Degree C (4-20 mA)	
3	AI-03	Bed Temp. : 0-200 Degree C (4-20mA)	
4	AI-04	DPT across HEPA Filter : 0-20" w/c (4-20mA)	



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Analogue Output List

S.No.	Address	Description	Verified Yes/no
1	AO-01	Pan Speed : 0-16 RPM (0-10V)	
2	AO-02	Inlet Blower Speed : 0-2880 RPM (0-10V)	
3	AO-03	Exhaust Blower Speed : 0-2880 RPM (0-10V)	
4	AO-04	Peristaltic Pump Speed : 0-200 RPM (0-10V)	
5	AO-05	Steam PID Valve: 0-100% (4-20mA)	
6	AO-06	Spare	
7	AO-07	Spare	
8	AO-08	Spare	

Comments:

	Signed	Date
Executed By:		
Reviewed By:		



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EQUIPMENT OPERATION VERIFICATION

Objective	To verify the operation of the Machine is as per manual.
Method	Check the Operation of the unit as per start sequence detailed in the manual. fill out the table as per attachment, a discrepancies to be noted on the review form and on the deviation report.
Acceptance Criteria	The operation sequence should be as per attached Manual.

Motor

Operations	Speed (rpm)	Time interval	Temp <80 ^{0c}	Motor current <3 AMPS)
Main Motor Performance at min, Speed(2 RPM)	(2 RPM)	10-Min		
Main Motor Performance at Avg, Speed(8 RPM)	(8 RPM)	10-Min		
Main Motor Performance at Maxi, Speed(16 RPM)	(16 RPM)	10-Min		

Gear Box

Operations	Speed (rpm)	Oil level	Alignment to motor	Temp. <80 ^{0c}
Gear box Performance at min, Speed(2 RPM)	(2 RPM)			
Gear box Performance at Avg, Speed(8 RPM)	(8 RPM)			
Gear box Performance at Maxi, Speed(16 RPM)	(16 RPM)			



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Spray Gun

Operations	Peristaltic pump Speed	Actual speed	Acceptance Criteria	Pass/Fail
Spray gun Performance at min, Speed	RPM-15		Conical Spray Form	
Spray gun Performance at Avg, Speed	RPM-50		Conical Spray Form	
Spray gun Performance at Maxi, Speed	RPM-200		Conical Spray Form	

Solution Tank

Operations	Speed (rpm)	Sound <80db	Temp<80 ^{0c}	Pass/Fail
Solution tank Motor Performance				

Inlet Blower & Motor Performance Checks:

S.No.	Time	Motor RPM	Motor Temp. <80 ^{0c}	Motor Current. <11amp	AIR Velocity (CFM-1250)	Pass/Fail
1.	5 Min.	2880				
2.	5 Min.	2880				
3.	5 Min.	2880				
4.	5 Min.	2880				

Blower CFM: Area of Blower Exhaust X Blower Max.Velocity X 2118.



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Exhaust Blower & Motor Performance Checks:						
S.No.	Time	Motor RPM	Motor Temp. <80 ^{0c}	Motor Current. <11amp	AIR Velocity (CFM-1500)	Pass /Fail
5.	20 Min	2900				

Blower CFM: Area of Blower Exhaust X Blower Max.Velocity X 2118.

Dry Scrubber Performance Checks:		
<p>Procedure for Safe change – Fixed Poly Bag with liner & tie with O-ring, Removed the filter, & double tie Bag, cut Bag in between Both Tie. Then Insert new filter in new poly Bag, Fixed Filter at liner & tie with O-ring, Remove previous small poly Bag, then Place filter at its Own Location, Double tie New poly bag Remove Old Poly Bag.</p>		
Filter safe change check	Acceptance criteria	Safe change Yes / No
1 st	There should no leakage from Dry Scrubber /Poly Bag at safe change Time.	
2 nd		
3 rd		
4 th		

Pulsation check procedure	Acceptance criteria	Verified Yes / No
Switch ON power to Electronic Timer	Pulsation SOV-1 will come ON for two no.s of filters for set interval. Then after Pulsation SOV-2 will come ON for next two no.s of filters. Process repeats till the supply to electronic timer gets off.	



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Comments:

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	Signed	Date
Executed By:		
Reviewed By:		



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EQUIPMENT CONTROL FUNCTIONS AND INTERLOCKS VERIFICATION

Objective	To verify that the equipment controls and interlocks function.
Method	Run the machine. By operating verify and check whether the controls and interlocks are in place by simulating the conditions. Any discrepancies to be noted on the review form and on the Deviation Report.
Acceptance Criteria	The Controls and interlocks should function as specified.

INTERLOCKS LIST:

S. No	Interlock	Acceptance criteria	Pass/Fail
1.	Exhaust air blower motor overload relay is in tripped condition.	Supply air blower will not come ON	
2.	Main air pressure is below set value		
3.	Atomizing air pressure is below the set value.		
4.	Pan motor overload relay is in tripped condition.		
5.	Emergency stop is pressed.		
6.	Scrubber pump on feedback is not received.		
7.	Wash/Prod. Key switch is not in prod. Mode.		
8.	Supply air blower motor overload relay is in tripped condition.	Steam PID will not come ON	
9.	Main air pressure is below set value		
10.	Atomizing air pressure is below the set value.		
11.	Pan motor overload relay is in tripped condition.		
12.	Emergency stop is pressed.		
13.	Scrubber pump on feedback is not received.		
14.	Exhaust air blower motor overload relay is in tripped condition.		
15.	Set inlet temp. is achieved.		



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16.	Wash/Prod. Key switch is not in prod. Mode.	Peristaltic pump will not come on if any of the following is present.	
17.	Pan Door Close Proxy Feedback is not received.		
18.	Pan motor overload relay is in tripped condition.		
19.	Atomizing air pressure is below the set value.		
20.	Main air pressure is below set value.		
21.	Supply air blower motor overload relay is in tripped condition.		
22.	Exhaust air blower motor overload relay is in tripped condition.		
23.	If the exhaust air temperature is above/below the high/low set value.		
24.	Emergency stop is pressed.		
25.	Scrubber pump on feedback is not received.		
26.	Heating is not ON.		
27.	Wash/Prod. Key switch is not in prod. Mode.		Exhaust air blower will not come on if any of these conditions are present.
28.	Pan Door Close Proxy Feedback is not received.		
29.	Main air pressure is below set value.		
30.	Atomizing air pressure is below the set value.		
31.	Emergency stop is pressed.		
32.	Wash/Prod. Key switch is not in prod. Mode.		
33.	Pan motor overload relay is in tripped condition.	Plunger air solenoid valve will not open if any of these conditions are present	
34.	Main air pressure is below set value.		
35.	Atomizing air pressure is below the set value.		
36.	Supply air blower motor overload relay is in tripped condition.		
37.	Exhaust air blower motor overload relay is in tripped condition.		
38.	If the exhaust air temperature is above/below the high/low set value.		
39.	Emergency stop is pressed.		



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40.	Scrubber pump on feedback is not received.		
41.	Heating is not ON.		
42.	Wash/Prod. Key switch is not in prod. Mode.		
43.	Pan Door Close Proxy Feedback is not received.		
44.	Main air pressure is below set value.	Pan Door Close SOV will not come ON if any of these conditions are present	
45.	Atomizing air pressure is below the set value.		
46.	Emergency stop is pressed.		
47.	Pan Door Close Proxy Feedback is not received.		
48.	Wash/Prod. Key switch is not in wash Mode.	Wash mode will not come ON if any of these conditions are present	
49.	Pan motor overload relay is in tripped condition.	Charging cycle will not come ON if any of these conditions are present	
50.	Main air pressure is below set value.		
51.	Atomizing air pressure is below the set value.		
52.	Supply air blower motor overload relay is in tripped condition.		
53.	Exhaust air blower motor overload relay is in tripped condition.		
54.	Emergency stop is pressed.		
55.	Wash/Prod. Key switch is not in prod. Mode.		
56.	Pan Door Close Proxy Feedback is received.		
57.	RTP Close Proxy Feedback is received.		



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ALARMS LIST:

S.No.	Test Procedure	When	Acceptance Criteria	Result	Alarms on HMI	Pass / Fail
1.	Decrease the main air pressure by filter regulator so that it gets lower than main air pressure switch set air pressure.	Occurs if main air pressure is less than the set value.	Alarm displayed on HMI. Alarm will be visual & audible.	Abort the cycle.	Main air pressure low	
2.	Switch ON Pan Motor & remove the digital input X5 from Pan VFD.	Occurs if pan motor VFD is ON and VFD on feedback is not received within 5 sec.	Alarm displayed on HMI. Alarm will be visual & audible.	Abort the cycle.	Pan VFD fault	
3.	Switch ON Exhaust Blower Motor & remove the digital input X3 from Ex. blower VFD.	Occurs if exhaust air blower VFD is ON and VFD on feedback is not received within 5 sec.	Alarm displayed on HMI. Alarm will be visual & audible.	Abort the cycle.	Exhaust blower fault	
4.	Switch ON Inlet Blower Motor & remove the digital input X4 from Inlet blower VFD.	Occurs if Inlet blower VFD is ON and VFD on feedback is not received within 5 sec.	Alarm displayed on HMI. Alarm will be visual & audible.	Abort the cycle.	Inlet blower fault	
5.	Switch ON Scrubber motor & remove the digital input X15 from Scrubber motor start contactor	Occurs if the scrubber pump on feedback is not achieved within 5 sec.	Alarm displayed on HMI. Alarm will be visual & audible.	Abort the cycle.	Scrubber pump not on	
6.	Set the inlet temp. high set point lower than the actual inlet temp.	Occurs if inlet temperature equals/exceeds the inlet temperature high set-point.	Alarm displayed on HMI. Alarm will be visual & audible.	Abort the cycle.	Inlet temp. high	
7.	Set the exhaust temp. high set point lower than the actual	Occurs if exhaust temperature	Alarm displayed on HMI. Alarm	Stop the spray cycle	Exhaust temp. high	



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	exhaust temp.	equals/exceeds the exhaust temperature high set-point.	will be visual & audible.	only.		
8.	Press Emergency stop mounted on operating panel.	Occurs if emergency stop push button is pressed.	Alarm displayed on HMI. Alarm will be visual & audible.	Abort the cycle.	Emergency pressed	
9.	Set the exhaust temp. low set point higher than the actual exhaust temp.	Occurs if exhaust temp. less than the exhaust temp. low set point..	Alarm displayed on HMI. Alarm will be visual & audible.	Stop the spray cycle only.	Exhaust temp. low	
10.	Decrease the atomizing air pressure by filter regulator so that it gets lower than the atomizing air pressure switch set air pressure.	Occurs if atomization air pressure is less than the set value.	Alarm displayed on HMI. Alarm will be visual & audible.	Abort the cycle.	Atomizing air pressure low	
11.	Set the bed temp. high set point lower than the actual bed temp.	Occurs if bed temperature equals/exceeds the bed temperature high set-point.	Alarm displayed on HMI.	No interruption to cycle.	Bed temperature high	
12.	Set the bed temp. low set point higher than the actual bed temp.	Occurs if bed temperature less than the bed temperature low set-point.	Alarm displayed on HMI.	No interruption to cycle.	Bed temperature low	
13.	Set the DP across Hepa high set point lower than the actual DP.	If the DP equals/exceeds the DP set point.	Alarm displayed on HMI. Alarm will be visual & audible.	No interruption to cycle.	DP across Hepa Filter high	
14.	Switch ON Wash pump & remove the digital input X16 from Wash pump start contactor.	If the wash pump is on & its on feedback is not received in 5 sec.	Alarm displayed on HMI. Alarm will be visual & audible.	Abort the cycle.	Wash pump not ON	



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15.	Switch ON Auto or Manual mode, put the Wash/Prod. selector switch in Wash position	If the auto/manual mode started & sel. Switch is not in production position.	Alarm displayed on HMI. Alarm will be visual & audible.	Abort the cycle.	Wash/Prod. Sel. Switch not in production position	
16.	Switch ON Wash mode, put the Wash/Prod. selector switch in Production position.	If the wash mode started & sel. Switch is not in wash position.	Alarm displayed on HMI. Alarm will be visual & audible.	Abort the cycle.	Wash/Prod. Sel. Switch not in wash position	
17.	Run the Auto or Manual cycle & remove Pan door close proxy or remove X12 input from terminal.	If Auto Cycle or Manual Cycle is started i.e. charging mode is not switched ON & Pan door close proxy sensor feedback is not received.	Alarm displayed on HMI. Alarm will be visual & audible.	Abort the cycle.	Pan Door opened	
18.	Run the Charging cycle & close Pan door manually or connect X12 input to 24VDC on terminal.	If Charging cycle is started & Pan door close proxy sensor feedback is received (After acknowledging the Pop Up Message "Open Pan Door & RTP active").	Alarm displayed on HMI. Alarm will be visual & audible.	Abort the cycle.	Pan Door closed	
19.	Run the Charging cycle & close RTP manually or connect X13 input to 24VDC on terminal.	If Charging cycle is started & RTP close proxy sensor feedback is received (After	Alarm displayed on HMI. Alarm will be visual & audible.	Abort the cycle.	RTP closed	



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		acknowledging the Pop Up Message "Open Pan Door & RTP active").				
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Comments

	Signed	Date
Executed By:		
Reviewed By:		



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TRIAL VERIFICATION

Objective	To verify the functionality of the BECOATER – 36"		
Method	Fill the pan with sample Tablets & then turn the main supply ON, press start button. Document the results on the attachment.		
Acceptance Criteria	Tablets should be coated properly.		
DESCRIPTIONS	ACCEPTANCE		VERIFIED (YES/NO)
Put the pan on maximum RPM.	Pan Rotates smoothly. No abnormal sound. No overheating of parts. Check the current drawn. Current Drawn: _____ Current drawn by motor should not exceed 3 amps.		
Pan RPM verification.	Set RPM	Actual RPM	
	2		
	8		

HOMOGENIETY OF MIXING

Time	Test Method	Quantity of Colored Tablet in Kg	Quantity of White Tablet in Kg's	RPM	Acceptance Criteria	Pass/Fail



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	Signed	Date
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PRESSURE HOLD TEST

Objective	To find out the leak rate of Glove box
Method	<ol style="list-style-type: none">1 This test requires minimal temperature fluctuations minimal external influences from drafts ie open doors, windows etc2 Ensure all valves on service entries are closed and any non-valve service entries are blanked off with suitable blanking plates and gaskets.3 Ensure all gloves are fitted to the glove ports with no sign of damage to gauntlets4 Connect the Manometer and the Compressed air supply to the Isolator as shown in the diagram above5 Open the Isolation valve slowly until a pressure of +200Pa is recorded on the Manometer then close the valve.6 Open the needle valve until the pressure in the Isolator has reduced to +150pa and note the time. Record the starting pressure in the table below.7 Record the pressure within the Isolator every minute for a period of 10 minutes and record the pressure and the temperature in the table below.8 After 10 minutes calculate the Leakage Rate from the Chamber using the formula below.9 If the acceptance criteria are not achieved locate the leak and re test.
Acceptance Criteria	Hourly leakage rate should be $\leq 2.5 \times 10^{-3}$ Per Hour



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Formula

Tf = Leakage Rate (Per Hour)

$$Tf = \frac{60}{t} \left(\frac{P_2}{P_1} \frac{T_1}{T_2} - 1 \right)$$

t = Duration of test Minutes

P₁ = Start Test pressure

P₂ = End Test Pressure

T₁ = Start test Temperature (Kelvin)

T₂ = End test Temperature (Kelvin)

Time Minutes	Start Pressure Absolute Pa	Measured Pressure Pa	Measured Temperature Kelvin (°C +273)
0			
10			
20			
30			
40			
50			
60			

Calculation :

Space for Calculation of leakage rate Tf

$$Tf = \frac{60}{t} \left(\frac{P_2}{P_1} \frac{T_1}{T_2} - 1 \right)$$



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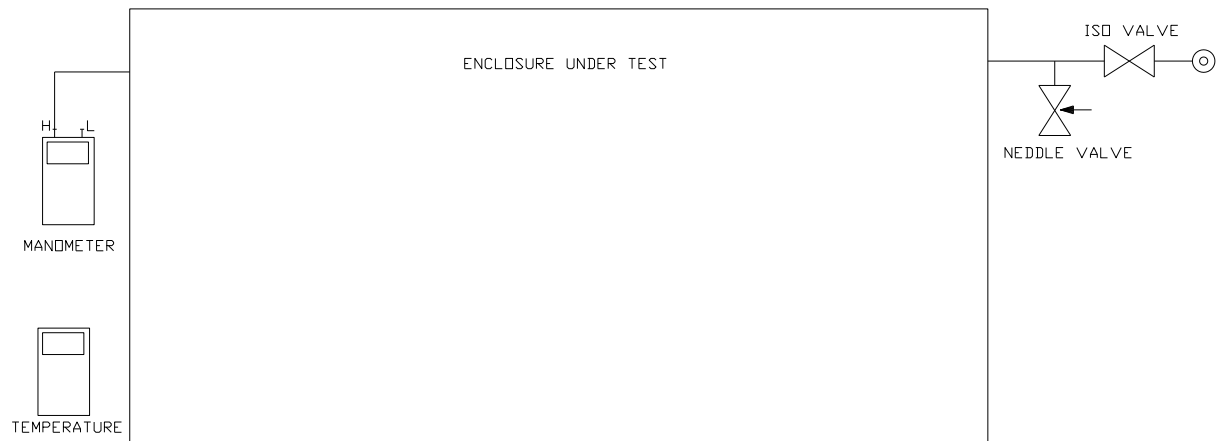
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Pressure Hold Test-

Calibrated Manometer	6mm Nylon Pneumatic Tube	Needle Valve
Stop Watch	Isolation Valve	Compressed Air Supply

Procedure



	Signed	Date
Executed By:		
Reviewed By:		



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RTP OPERATIONAL CHECK

Objective:	To check the operation of RTP Rotate type
Procedure:	Using the passive RTP, Dock to active several times to prove the interlock and ease of use. Ensure that faces are cleaned before docking and no damage is visible on contact surfaces. Record results in tables provided
Acceptance Criteria	Passive port docks to active without excessive force. Valve opens and closes without excessive force

Active RTP	No	Dock	Valve Opens	Valve closes	De Dock	Complies Yes/No
Passive	2					

Comments:

	Signed	Date
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Post approval

Acceptance of the successful completion of the FAT, including satisfactory resolution of all discrepancies noted during execution, will be documented below, signed by the person with overall review responsibility for the protocol and by the client's authorized signatories who approved the protocol.

The FAT data for this equipment has been reviewed and found to be acceptable as per acceptance criteria.

Agreed criteria	Agreement YES / NO
1. Approval subjected to shipment as is	
2. Machine is approved with correction of all Deviation noted during FAT	
3. Machine is not approved & will require repeat FAT following correction of all deviation.	

VENDOR

Reviewed By	Print Name	Signature	

Client

	Print Name	Signature	Date
Consultant			
Engineering			
Quality Assurance			



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APPENDIX C - DEVIATION REPORTS PROCEDURE

During FAT testing, a Deviation Report must be raised when there is a failure to meet acceptance criteria.

The aim is to:

- Clearly describe the deviation.
- To document and approve the evaluation of the impact of the deviation.
- To document and approve the corrective action required to resolve it.
- To document the closing out of the deviation with the appropriate approvals.

Procedure

- a. If a test step fails to meet test acceptance criteria/method then a Deviation Report must be raised. See Appendix.
- b. All Deviation Reports must be logged by completing the Deviation Report Register. See Appendix
- c. Each Deviation Report must reference the following identification numbers: -
 - a. Protocol document reference number.
 - b. The applicable test reference number (XX) as defined in the protocol.
 - c. A unique deviation reference number, which comprises the specific test number and a sequential deviation number (YY) for that test in the format XX/YY. Subsequent deviations on the same
- d. The person raising the deviation must clearly describe the exact nature of the deviation (why acceptance criteria/method has not been met) using the ‘details of deviation noted’ box provided.
- e. The deviation must be fully evaluated and the necessary corrective action formulated and must be pre-approved by Vendor & the Client. The findings of this evaluation together with details of corrective action required to resolve the deviation should be clearly documented by completing the ‘evaluation of deviation/corrective actions to be taken’ box.
- f. Once the proposed corrective action has been pre-approved, the tester will execute the corrective work and verify implementation of corrective action by completing the ‘Results of Corrective Action’ box. The tester will then sign and date the Deviation report.
- g. The completed Deviation Report will require approval by the appropriate personnel on the Deviation Report.
- h. Completed Deviation Reports must be attached to the Appendix of this FAT protocol.



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APPENDIX E - DEVIATION REPORT SHEET

Deviation No:		Test Reference:		
Details Of Deviation Noted:				
Completed By:			Date:	
Evaluation Of Deviation / Corrective Actions To Be Taken:				
Completed By:		Date:		
PRE-APPROVALS - EVALUATION / CORRECTIVE ACTIONS				
The following signatures pre-approve the content of the evaluation and the necessary corrective actions to be taken.				
Function	Pre-Approval Required (Yes / No)	Name (Print)	Signature	Date
VENDOR				
Client				
Results Of Corrective Action:				



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Completed By:	Date:
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APPROVALS - RESULTS OF CORRECTIVE ACTIONS/ DEVIATION CLOSE OUT

The following signatures approve the results corrective actions taken and the closure of the deviation.

Approvals	Name (Print)	Signature	Date
VENDOR			
Client			



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

FACTORY ACCEPTANCE TEST FOR BECOATER 36"

Department: Quality Assurance	FAT No.:
Title: Factory Acceptance Test for Becoater 36"	Effective Date:
Supersedes: Nil	Review Date:

CLEANLINESS AND APPEARANCE (VENDOR ONLY)

Objective	Equipment and parts thereof properly cleaned after the Factory acceptance tests	
Method	Physically examine the internal wetted part of equipment. Ensure there is no material retention, all surfaces are properly washed and fit for client use fill out the table below. External Surface: All surfaces should be cleaned for stains or marks if any. Visually inspect the cleaning after it is complete. Any discrepancies to be noted on the review form and on the Deviation Report.	
Acceptance Criteria	Machine should be thoroughly cleaned	
Part	Part Cleaned Yes/No	
Pan	Internal	
	External	
Solution tank	Internal	
	External	
Control Panel	External	
Motor cover	External	
Gear box cover	External	
Inlet duct	Internal	
	External	
Exhaust duct	Internal	
	External	
Panel	Internal	
	External	
Stand	External	
Comments:		
	Signed	Date
Executed By:		
Reviewed By:		



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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Department: Quality Assurance	FAT No.:
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POST FAT DOCUMENT (VENDOR ONLY)

Objective	The machine has been dismantled and packed in accordance with PO and site conditions	
Method	Machine should be dismantled, marked and matched to facilitate ease of Installation. Individual Sub-assemblies/components so dismantled should be wrapped in plastic and packed in accordance with the Shipment protocol. In case of over seas assignments painted parts should be greased and labeled" DE-GREASE BEFORE USE". Sub-assemblies/components should be properly secured to packing to prevent transit damage A detailed packing list will be filled as per format and signed out.	
Acceptance Criteria	Packing list should be complete and no. of components must tally with list. Packing sizes should be in accordance with commercial documentation.	
Comments:		
	Signed	Date
Executed By:		
Reviewed By:		