



PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

FACTORY ACCEPTANCE TEST

Department: Quality Assurance	SOP No.:
Title: Factory Acceptance Test for Autocoater with Interchangeable Drums 12” & 18”	Effective Date:
Supersedes: Nil	Review Date:
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FACTORY ACCEPTANCE TEST
FOR
AUTOCOATER WITH
INTERCHANGEABLE DRUMS 12” & 18”
DOCUMENT:

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1. PRE APPROVAL SHEET:

M/s.					
	Name	Department	Designation	Signature	Date
Prepared by		QA			
Checked by		QA			
Approved by		QA/QC			

M/s.



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	Name	Department	Designation	Signature	Date
Reviewed by					
Reviewed by					
Reviewed by					
Reviewed by					
Approved by					

2. REVISION HISTORY:

S.No.	REVISION	DATE	REVISION SUMMARY

3. SYSTEM INFORMATION:

EQUIPMENT	AUTOCOATER WITH INTERCHANGEABLE DRUMS 12” & 18”
MANUFACTURER	M/s.
CUSTOMER	M/s.
SERIAL NO.	
MODEL NO.	
SITE	



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4. INTRODUCTION & PURPOSE OF DOCUMENTS:

4.1 WE ARE LIFE ENGINEERS:

We are an engineering solutions company working as an essential piece of massive life sciences ecosystem. By bringing together our customers, partners, industry leaders, regulators and governments we effect greater impact and bring our mission to life.

Our purpose is reflected through our strategy, approach and objectives. We consciously evaluate our performance through a broader lens for creating value – economic benefits to our customers, environmental benefits for a greener planet and social benefits to people everywhere.

4.2 LET'S SAVE LIVES TOGETHER:

Our start-to-finish engineering solutions help you accelerate growth and optimize costs. With every project we take on, irrespective of size, complexity, or geography, we commit resources, people, know-how and technology to deliver a successful outcome.

Our purpose is deeply rooted in our belief that all lives have equal value. Together with our customers and partners, we're building pharmaceutical and biotech capability, so everyone, wherever they are in the world has the same access to affordable life-saving medicines.

5. OBJECTIVE:

- Factory acceptance test is a comprehensive document providing all the details required for design and operational point of view. It thus ensures that proposed design of the equipment is suitable for its intended purpose & provides documented evidence that quality is built into the design of the equipment.
- This documentation will define the responsibilities, acceptance criteria, basis of design, technical specifications, list of major bought out parts, utility requirements, safety and c-GMP features.
- Kindly note, this text has been prepared byThe contents include detailed information & No part of it can be changed without our written approval.

6. SUMMARY:

- M/s. has received an order for the manufacture and supplies of M/s.to M/s.Vide their Purchase Order.
- FAT will enable to analyze M/s.it is assembled and trial point of view all accessories are matching with reference Approved drawing.



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- The team from **M/s.**, **M/s.** will jointly ensure execution, review and approval of protocol.

7. VERIFICATION:

- Factory Acceptance Test (FAT), undergo complete checkup of **M/s.** from document verification through DQ, fitment through assembly and trial through utility mentioned in compliance with Approved GA drawing & P&ID.
- **M/s.** assures **M/s.** that the machine is manufactured and tested as per URS and PO.
- **M/s.** assures **M/s.** by undergoing the above said document verification in DQ. Approved GA Drawing, Electrical Drawing, fitment and trial through this Factory Acceptance Test (FAT), will ensure **M/s.** that they are being given what they have offered in Offer Specification (OS) & Purchase Order (PO).

8. RESPONSIBILITIES:

Specific requirements regarding testing of this equipment are:

8.1 MANUFACTURER’S:

- Preparation of the FAT protocol.
- Approval for release of this protocol to **M/s.** For acceptance

8.2 CLIENT’S:

- Supervising and reporting all FAT checks with respect to the **M/s.**
- Approval of the Protocol prior to commencement of the work.
- Final completed report approval.

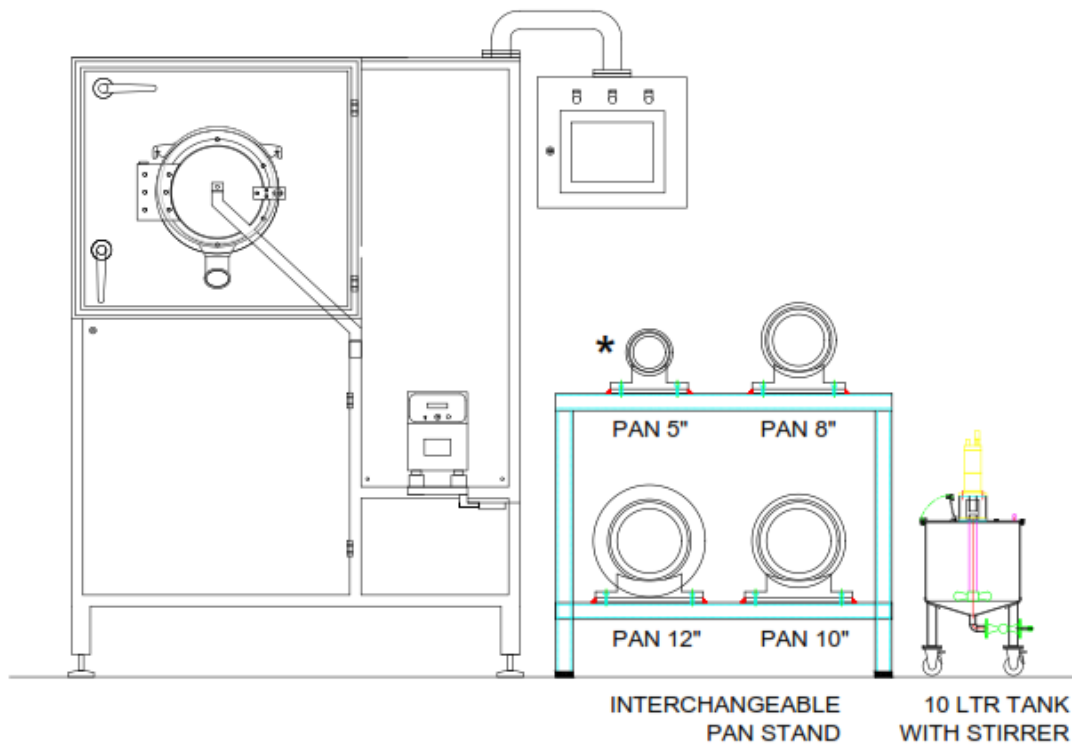


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9. SCHEMATIC DIAGRAM:



(SCHEMATIC DIAGRAM FOR M/s.)



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10.SYSTEM DESCRIPTION:

- Design is cGMP – Current Good Manufacturing Practices compliance.
- All contact parts AISI 316 & non-contact parts AISI 304.
- Fully automatic film coating process by PLC Controls with HMI Touch screen.
- Flexible batch operations.
- Complete separation of production and technical area
- The machine structure made from S.S.304 quality fitted with Closed Drive, Perforated Pan, Washing sink, Inlet air plenum, Exhaust air plenum with Airtight door.
- Perforated pan with 50% opening for better quality finish.
- Excellent mixing and tumbling by special design of removable on each sloping face of the pan and anti-sliding baffles provided on perforated diagonal face.
- Perforated Pan having variable speed through AC frequency Drive.
- Automatic Spraying systems provided with Atomized Spray Gun, Adjustable spray gun arms, High precise flow peristaltic pump, solution holding tank with pneumatic stirrer.
- Front Entry stainless steel arm, with facility to adjust the angle of spray guns is provided.
- Inlet air and outlet air will be controlled by pneumatic operated damper which is provided on top of the machine and at inlet and outlet duck.
- Inlet air and Exhaust air flow controls through AC Frequency drive of both blower.
- Inlet Air handling unit made from stainless steel 304 quality. The Inlet air handling units fitted with Pre filter-EU4 and sandwich of HEPA-EU13 and Fine filters-EU7, Inlet air blower with motor, Electric heater.
- Advance PLC Controls system with HMI- color Touch screen provided of Mitsubishi make for complete automatic coating process and batch data receipt management.



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11.SYSTEM VERIFICATION:

11.1 PHYSICAL VERIFICATION:

METHOD	DESCRIPTION	ACCEPTANCE CRITERIA	OBSERVATION
Internal Surface finish Verification	Check internal surface of machine	-Mirror finish -Curved corner	Yes <input type="checkbox"/> No <input type="checkbox"/>
External Surface finish Verification	Check outer surface of machine	-Matt finish -Curved corner	Yes <input type="checkbox"/> No <input type="checkbox"/>
Document Verification	Verification of Wiring diagram	-As per wiring diagram attached in Documentation file.	Yes <input type="checkbox"/> No <input type="checkbox"/>
Document Verification	Verification of Input / Output connection	-As per Input/ Output List are Mention in PLC FDS.	Yes <input type="checkbox"/> No <input type="checkbox"/>
Document Verification	Verification of MOC certificate	-Verification of MOC Contact and Non-Contact parts as per test certificate.	Yes <input type="checkbox"/> No <input type="checkbox"/>
Machine Dimension	Verification with machine	As per attached GA drawing in Documentation file.	Yes <input type="checkbox"/> No <input type="checkbox"/>



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11.2 DRAWING VERIFICATION:

Following documents are required for execution of the FAT protocol: -

S.No.	DOCUMENTS	REFERENCE No.	CHECK (YES/NO)
1.	Approved G.A Drawing		Yes <input type="checkbox"/> No <input type="checkbox"/>
2.	Electrical Drawing		Yes <input type="checkbox"/> No <input type="checkbox"/>
3.	P & ID Drawing		Yes <input type="checkbox"/> No <input type="checkbox"/>

Comments:

Reviewed By: _____

Signature & Date: _____



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11.3 ELECTRICAL COMPONENTS VERIFICATION:

Verification

Major Components in GA Drawing to be covered in Component List Any discrepancies and deviations are to be noted in deviations report.

Compliance

Major components mentioned below should comply in accordance with the approved GA Drawing.

HMI	
Make	Mitsubishi
Model No.
Serial No.
Quantity	01 No.
Location	At operating panel
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remark	
PLC	
Make	Mitsubishi
Model No.
Serial No.
Quantity	01 No.
Location	Inside the control panel
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remark	
VFD FOR PAN MOTOR	
Make	Mitsubishi
Model No.
Serial No.
Quantity	01 No.
Location	Inside the control panel
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remark	
VFD FOR INLET BLOWER	
Make	Mitsubishi
Model No.
Serial No.
Quantity	01 No.
Location	Inside the control panel



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Verification	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Remark		
VFD FOR EXHAUST BLOWER		
Make	Mitsubishi	
Model No.	
Serial No.	
Quantity	01 No.	
Location	Inside the control panel	
Verification	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Remark		

11.4 PNEUMATIC COMPONENTS VERIFICATION:

MAGNEHELIC PRESSURE GAUGE		
Make	Dwyer	
Range	0-250 Pascal	
Quantity	01 Nos. (For chamber pressure)	
Location	At structure	
Verification	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Remark		
AIR FILTER REGULATOR		
Make	Festo	
Model	
Quantity	01 No.	
Location	Pneumatic Panel	
Verification	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Remark		
PRESSURE REGULATOR		
Make	Festo	
Model	
Location	Pneumatic Panel	
Quantity	03 Nos.	
Verification	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Remark		
PRESSURE SWITCH		
Make	Festo	
Model	
Quantity	03 Nos.	



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Location	Pneumatic Panel
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remark	

11.5 BOUGHT OUT COMPONENTS VERIFICATION:

PAN MOTOR	
Make	Hindustan
Serial No.
Description	FLP
Voltage	415±10% V
HP	1.5
Speed	1415 RPM
Quantity	01 No.
Location	Table Housing
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remark	
GEAR BOX	
Make	Bonfiglioli
Type
Serial No.
Ratio	56:1
Quantity	01 No.
Location	Table Housing
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remark	
PNEUMATIC BUTTERFLY VALVE ON/OFF TYPE	
Make	Aira
Serial No.	Inlet- A-751017147 , Exhaust- A-751017142
Size	6"
Quantity	02 Nos.
Location	At Inlet and exhaust Duct
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remark	
RH SENSOR	
Make	Radix
Serial No.
Type	NONFLP
Description	0-100 % Rh



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Quantity	01 No.
Location	Inlet Duct
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remark	

TEMPERATURE SENSOR

Make	Radix
Serial No.	Inlet – Exhaust-
Type	NONFLP
Range	0-150°C
Description	PT 100 3 wire
Quantity	02 No's.
Location	Inlet duct & Exhaust duct
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remark	

PRODUCT SENSOR

Make	Radix
Serial No.
Type	NONFLP
Description	0-100°C
Quantity	01 No.
Location	Inside the pan
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remark	

VESSEL LAMP

Make	Neptune
Model No.
Serial No.
Quantity	01 No.
Location	Top side of the chamber
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remark	

SPRAY GUN

Make	Spraying System
Description	For Film Coating
Serial No.
Orifice	1.0 mm
Quantity	01 No.



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Location	Spray Gun header	
Verification	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Remark		
INLET AHU		
Make	Damcon	
Capacity	250CFM	
Quantity	01 No.	
Location	Inside structure	
Verification	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Remark		
INLET BLOWER MOTOR		
Make	Hindustan electric motor	
Serial No.	
Voltage	415±10% V	
Description	NON FLP	
HP	0.5	
Speed	2810 RPM	
Quantity	01 No.	
Location	Inside AHU	
Verification	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Remark		
INLET BLOWER		
Make	Hari Udyog	
Capacity	250 CFM	
Job No.	122/0.5	
Static pressure	5”	
Quantity	01 No.	
Location	At Inlet AHU	
Verification	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Remark		
EXHAUST BLOWER MOTOR		
Make	Hindustan electric motor	
Serial No.	
Voltage	415±10% V	
Description	NONFLP	
HP	1	
Speed	2845 RPM	



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Quantity	01 No.
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remark	

EXHAUST BLOWER

Make	Universal Air Technologies
Capacity	400 CFM
Static pressure	6”
Quantity	01 No.
Location	At scrubber unit
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remark	

PRE FILTER

Make	Fine Airsys
Serial No.
Description	10 micron
Quantity	01 No.
Location	Inside AHU
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remark	

FINE FILTER

Make	Fine Airsys
Serial No.
Description	3 micron
Quantity	01 No.
Location	Inside AHU
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remark	

HEPA FILTER

Make	Fine Airsys
Serial No.
Description	0.3 micron
Quantity	01 No.
Location	Inside AHU
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remark	

PROXY SENSOR

Make	Pepperl+Fuchs
Description	NBB4-12GM50-E2



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Quantity	01 No.
Location	At Pan drive
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remark	
PERISTALTIC PUMP	
Make	Flowtech
Model No.
Serial No.
Type	NONFLP
Description	2 Head
Quantity	01 No.
Location	At structure
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remark	
SOLUTION TANK	
Make	Fablife
MOC	SS 316
Capacity	05 L
Quantity	01 No.
Location	Near pan chamber
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remark	
PNEUMATIC STIRRER	
Make	PMT
Description	Pneumatically operated
Quantity	01 No.
Location	At solution tank
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remark	
SCRUBBER	
Make	Universal Air Technologies
Type	Wet Scrubber (Venturi type)
Capacity	400 CFM
Quantity	01 No.
Location	Service Floor
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remark	
MOTOR FOR PUMP	



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Make	Hindustan electric Motors
Serial No.
HP	1
Voltage/Frequency	415/50Hz
Quantity	02 No's.
Location	Service Floor
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remark	

RECIRCULATION PUMP – 1 & RECIRCULATION PUMP – 2

Make	Leakless
Model No.
Serial No.
Quantity	02 No's.
Location	Service Floor
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remark	

pH SENSOR WITH TRANSMITTER

Make	Aster
Range	0-14 ph
Serial No
Quantity	01 No.
Location	Service Floor
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remark	

PRESSURE SWITCH

Make	Danfoss
Model No
Quantity	01 No.
Location	Service Floor
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remark	

PRESSURE GAUGE

Make	Fiebig
Range	0-2.1 kg/cm ²
Quantity	01 No.
Location	Service Floor
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remark	



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Comments:

Reviewed By: _____

Signature & Date: _____

12. MATERIAL OF CONSTRUCTION CERTIFICATE VERIFICATION:

S.No.	COMPONENTS	SPECIFIED	FINISH	PASS/ FAIL
1.	Coating pan cabinet	SS 316 L, 3 mm thick sheet		
2.	Structure cladding	SS 304, 1.5 mm thick sheet		

Comments:

Reviewed By: _____

Signature & Date: _____



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13. TEST VERIFICATIONS:

13.1 EQUIPMENT DIMENSION VERIFICATION:

Verification

Refer the approved drawing and compare with the actual dimensions on the equipment. Re-check whether the drawing clearly specifies the manufacturing standards adopted.

Compliance

Deviations in the measured dimensions, if any, should be within acceptable limits.

DRAWING No.:			REV:
S.No.	DESCRIPTION	DIMENSION OBSERVED	COMPLIES (YES/NO)
1.	Overall Dimension		

Comments:

Reviewed By: _____

Signature & Date: _____

14. FUNCTIONAL KEY VERIFICATION OF AUTO COATER:

S.No.	FUNCTION	VERIFICATION	COMPLIES (YES/NO)
1.	Inlet blower working	Check the performance of blower	
2.	Exhaust blower working	Check the performance of blower	
3.	Inlet and Exhaust Valve Operation	Check pneumatic operation On/OFF	
4.	Product temperature sensor	Product temperature sensor working	
5.	Inlet & exhaust temperature sensors	Check the working of temperature	



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	working	sensor	
6.	Spray gun working	Check the Spray gun working	
7.	Alarms & interlocks	Verify the alarm & interlock as per PLC FDS	

14.1 FUNCTIONAL VERIFICATION OF AUTO COATER:

S.No.	DESCRIPTION	NO LOAD	CURRENT (AMP)			SPEED (RPM)
			R	Y	B	
1.	Pan motor	N.A.				
2.	Inlet blower motor	N.A.				
3.	Exhaust blower motor	N.A.				

14.2 AUTO COATER PAN SPEED VERIFICATION:

S.No.	FUNCTION	VERIFICATION	COMPLIES (Y/N)
1.	Pan speed	Pan max speed 20 RPM	

14.3 FUNCTIONAL VERIFICATION OF SOLUTION TANK 10 L:

FUNCTION	WORKING (SATISFACTORY/ NOT SATISFACTORY)
Solution tank working	

Comments:

Reviewed By: _____

Signature & Date: _____



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14.4 SAFETY VERIFICATION:

S.No.	SAFETY FEATURE	Complies (Yes/No)
1.	After pressing emergency stop button machine operation should be stopped	

Comments:

Reviewed By: _____

Signature & Date: _____

15.EQUIPMENTFINISH VERIFICATION:

15.1 AUTO COATER 12” & 18”:

Description of Item	Finish Required as per DQ Protocol.		Finish Achieved as per DQ Protocol		Pass/Fail
	Area	Finish	Area	Finish	
Main body	Internal	RA≤0.4μm	Mirror		
	External	RA≤0.6μm	Matt		
Coating Pan12”	Internal	RA≤0.4μm	Mirror		
	External	RA≤0.4μm	Mirror		
Coating Pan 18”	Internal	RA≤0.4μm	Mirror		
	External	RA≤0.4μm	Mirror		

Comments:

Reviewed By: _____

Signature & Date: _____



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16. WATER DRAINABILITY TEST:

For cleaning verification;

- Put water inside the chamber (where the work is actually going to process)
- Ensure that there is no resistance/obstruction from the test point to drain port.
- Ensure that no water remains inside the chamber.

ACTION	DRAINABILITY (SATISFACTORY/ NOT SATISFACTORY)
Put water inside the chamber	

Comments:

Reviewed By: _____

Signature & Date: _____

17. POST-APPROVAL SHEET:

S.No.	ACCEPTANCE CRITERIA	REMARKS (YES/NO)
1.	Visual Inspection and Fitment check carried out and found satisfactory.	Yes <input type="checkbox"/> No <input type="checkbox"/>
2.	MOC & Bought Out Item Verified and found satisfactory.	Yes <input type="checkbox"/> No <input type="checkbox"/>
3.	Deviations (If any) compiled and M/s.can be dispatched.	Yes <input type="checkbox"/> No <input type="checkbox"/>

Comments:



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QUALITY ASSURANCE DEPARTMENT

FACTORY ACCEPTANCE TEST

Department: Quality Assurance	SOP No.:
Title: Factory Acceptance Test for Autocoater with Interchangeable Drums 12” & 18”	Effective Date:
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M/s.

	Name	Department	Designation	Signature	Date
Reviewed by					
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18.ABBREVIATIONS:

ABBREVIATIONS	FULL FORM
AISI	American Iron & Steel Institute
CFM	Cubic Feet Per Minute
cGMP	Current Good Manufacturing Practices
DQ	Design Qualification
FAT	Factory Acceptance test
FLP	Flame Proof
FS	Full Scale
GA	General Assembly
GEP	Good Engineering Practices
HMI	Human Machine Interface
MCB	Miniature Circuit Breaker
MOC	Material of Construction
NFLP	Non-Flame Proof
OQ	Operational Qualification
P & ID	Process & Instrumentation Diagram
PLC	Programmable Logic Controller
RH	Relative Humidity
SS	Stainless Steel
VFD	Variable Frequency Drive