



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Sterilizing and Depyrogenation Tunnel	Effective Date:
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1.0 OBJECTIVE:

To lay down a procedure for Operation and Cleaning of Sterilizing and Depyrogenation Tunnel.

2.0 SCOPE:

This SOP is applicable for Operation and Cleaning of Sterilizing and Depyrogenation Tunnel (Make: Klenzaid) in Production area in Dry Powder Line at

3.0 RESPONSIBILITY:

Officer/Executive – Production

4.0 ACCOUNTABILITY:

Head – Production

5.0 DEFINITIONS:

Not Applicable

6.0 PROCEDURE:

6.1 Switch “ON” the main switch control.



6.2 Display on HMI screen will be shows as below:

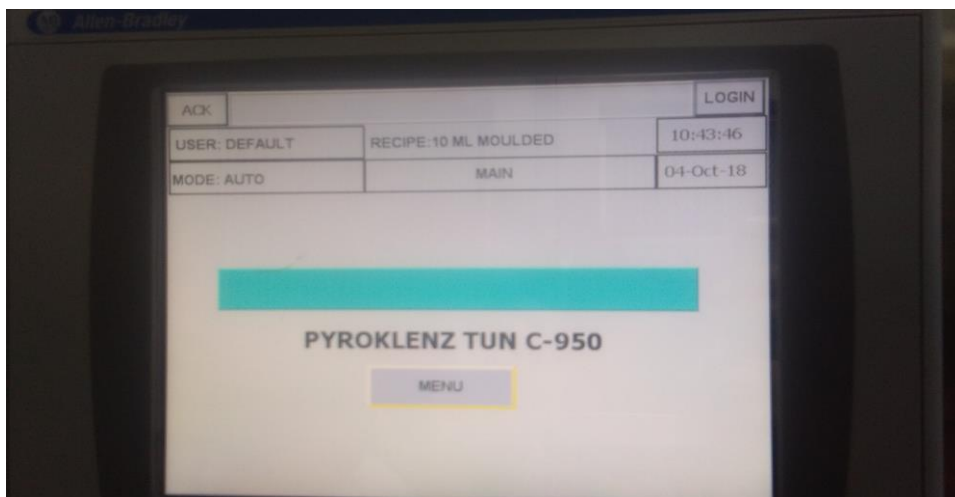


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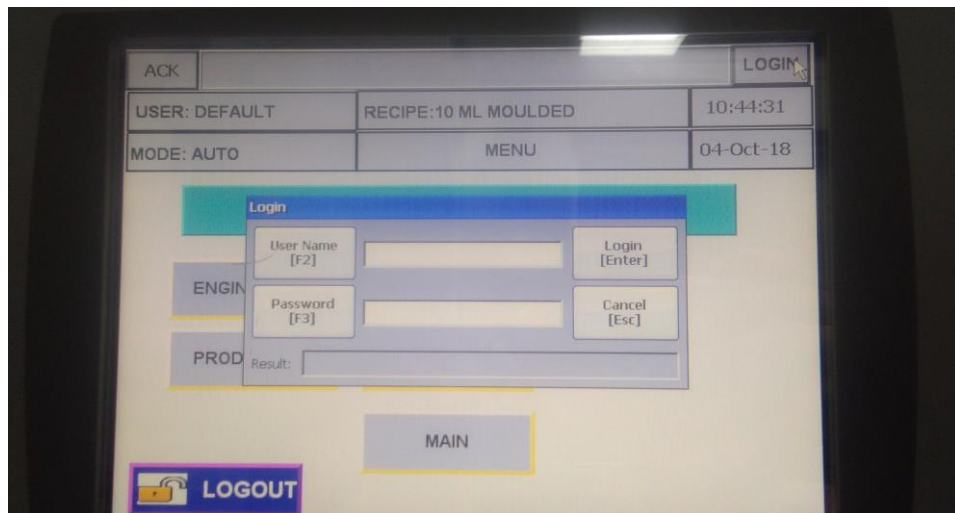
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6.3 Now press “Login ” tab on following screen display, press F2 for User Name and pass word for F3. Press login and enter.



6.4 After entering the correct password on following screen press on Enter tab.

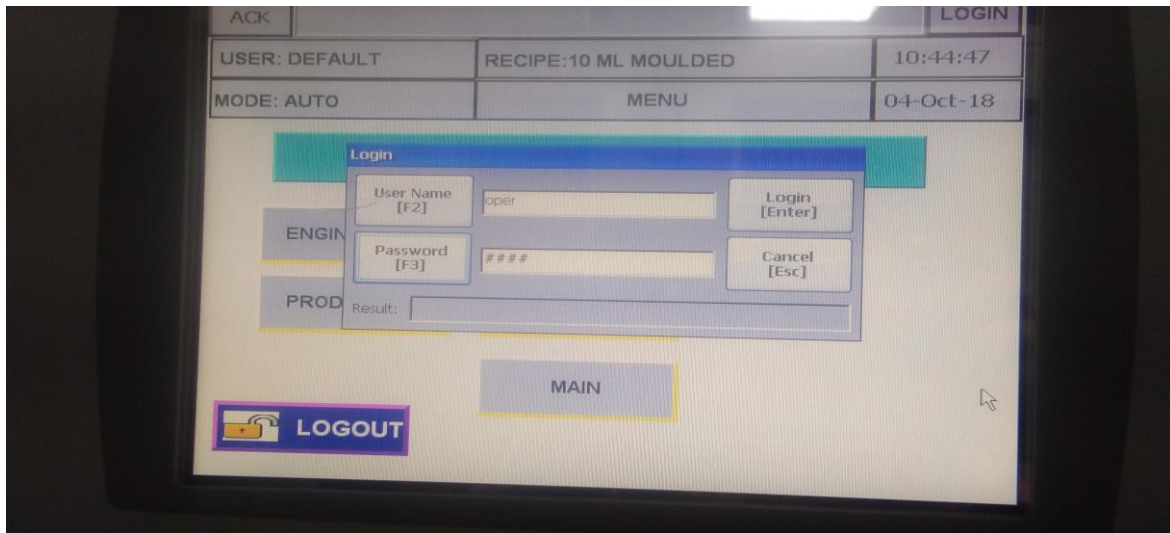


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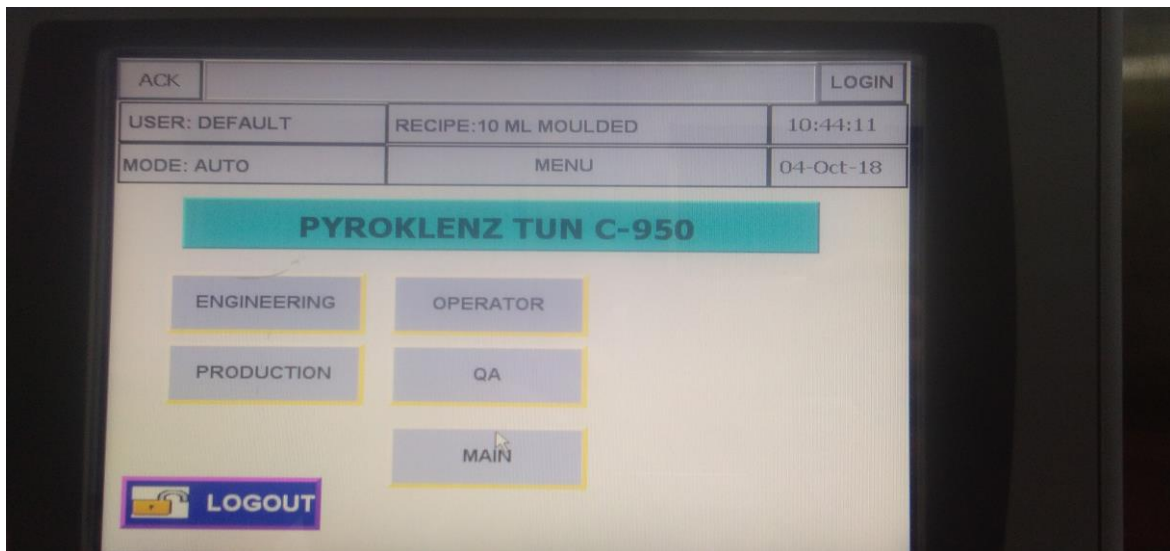
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6.5 Now Press the “Menu” tab on the HMI screen & following screen shall display:



6.6 Fill the Product Name, Batch No, Batch Size and Operator name on following screen:

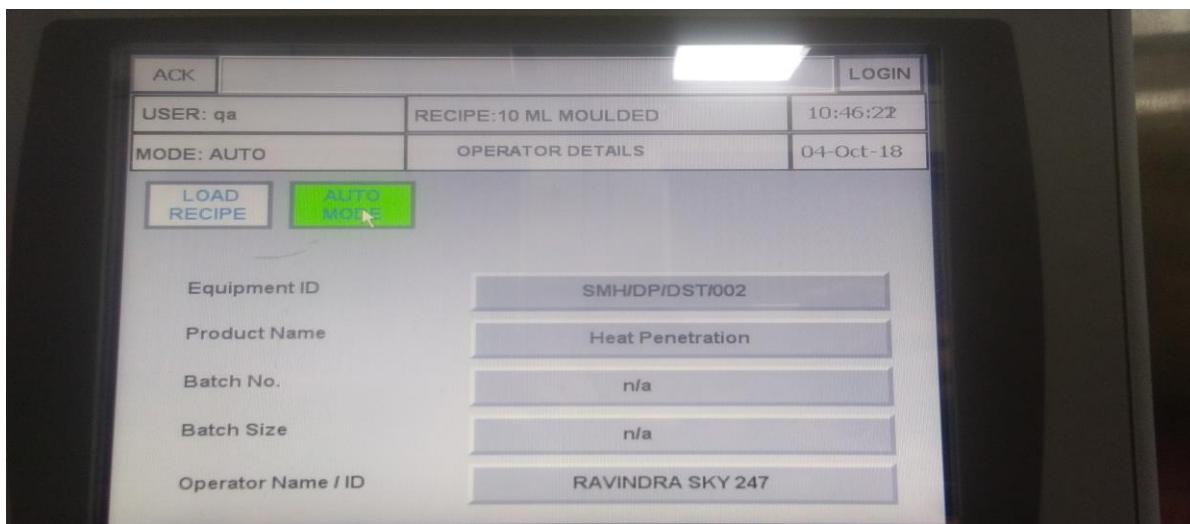


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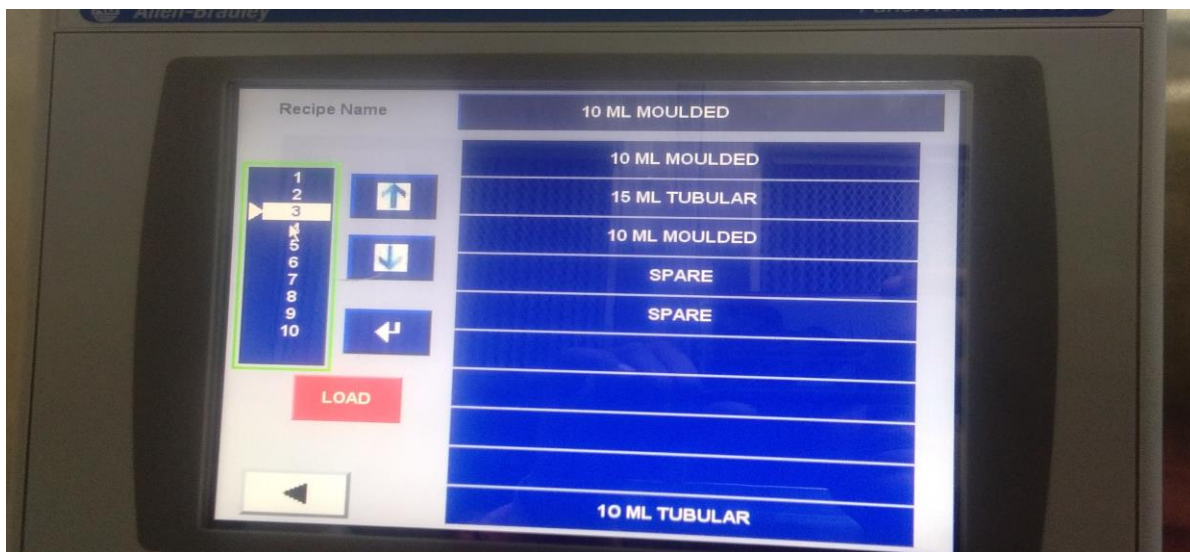
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6.7 Select vial type and load on following display:



6.8 Now following display shown in screen. Set temperature value and conveyor speed as per requirement.

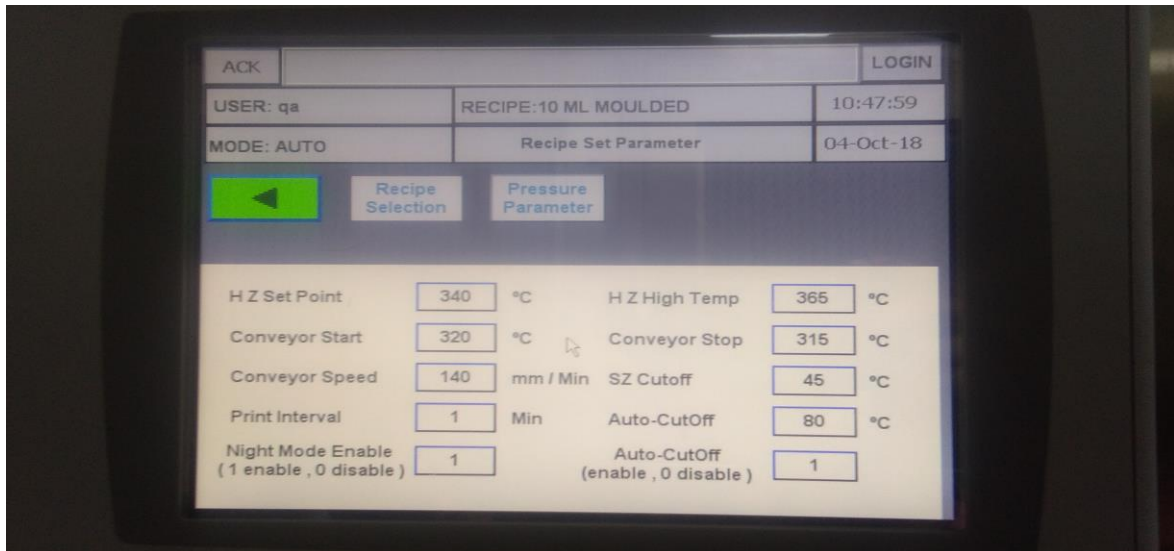


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6.9 Now the tunnel starts by pressing auto mode as shown on following display.



6.10 Now following display show all zone temperature and differential pressure.



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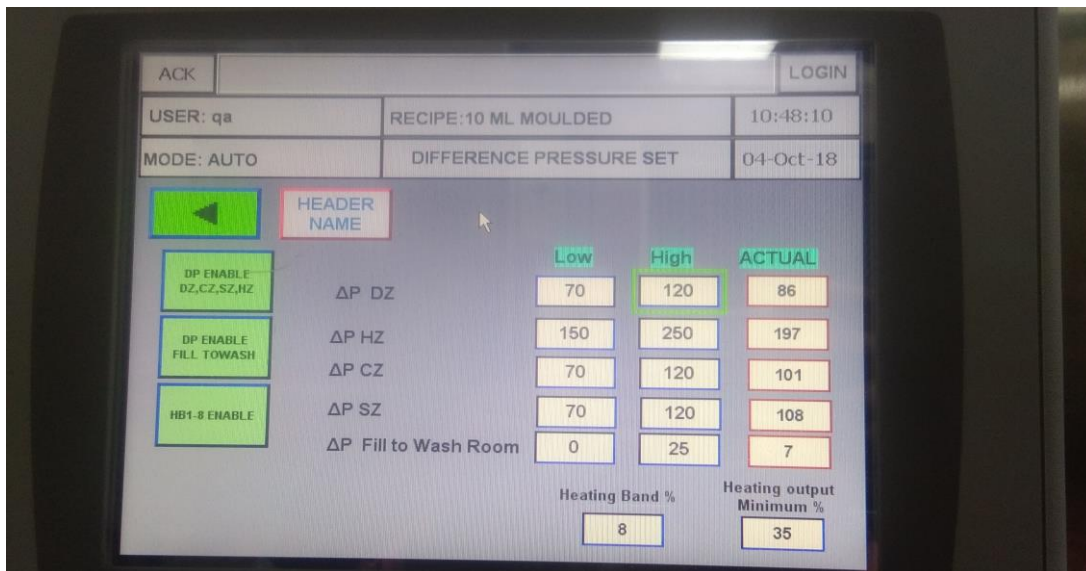
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6.11 Differential pressure of all zone such as Drying, Sterilizing, Cooling and Stabilizing Zone display as below:



6.11.1 Set the Recipe for 7.5ml & 10ml vial and fixed recipe parameter as per Table No.1.

TABLE NO. - 01				
Parameter	Set value			
	10 ml Vials (Tubular) (20mm Dia)	10 ml Vials (Moulded) (24mm Dia)	7.5 ml Vials (Moulded) (24mm Dia)	



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Hot Zone Set Point Temperature	340°C	340°C	340°C
Hot Zone Temperature Overshoot	365°C	365°C	365°C
Conveyor Start Temperature	320°C	320°C	320°C
Conveyor Stop Temperature	315°C	315°C	315°C
Conveyor Speed	140mm/minute	140mm/minute	140mm/minute
Stabilizing Zone Overshoot Temperature	45°C	45°C	45°C
Data Logging in Minute	1 minute	1 minute	1 minute
Night Mode Hot Zone Temperature	80°C	80°C	80°C
Recipe Type	GO	GO	GO

6.12 After achieving the set temperature conveyor will be started.

6.13 After completion of tunnel operation press “Stop” tab on the HMI screen and press “Night Mode” and display as below:



6.14 Night Mode will stop at 80°C and switch off to stop the machine.

6.15 Record the operation details in Format No. SOP/PD/084/F01-00 Titled “Equipment Log” of SOP.

6.16 CLEANING:

6.16.1 Cleaning Procedure (Before & End of Operation) Daily:



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6.16.2 Clean the tunnel conveyor by lint free cloth followed by 70% IPA in running mode of conveyor to clean entire surface with operation machine.

6.16.3 Open the bolt of dry zone cover plate with the help of the key

6.16.4 Remove the SS cover plate for cleaning of conveyor belt.

6.16.5 Start the conveyor with PLC to select the “Maintenance” tab on PLC.

6.16.6 Select tab “ON” for DZ Blower, HZ Blower, CZ/SZ Blower, and Extractors & Conveyor indicated as “Green & Yellow” colour.



6.16.7 Set the conveyor speed in manual mode at 200mm/minute for cleaning purpose

6.16.8 Damped the lint free moping pad with 70% IPA solution for cleaning of conveyor belt shown in fig. as under.





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6.16.9 Conveyor belt shall be clean to cover entire surface of conveyor in operation mode.



6.16.10 Outer surface of tunnel to be cleaning with help of lint free duster.

6.16.11 Production Officer / Executive shall check the conveyor cleaning by using High Beam Torch & verified by IPQA Officer / Executive and cleanness should be pass as per visual clean criteria. Shown in fig.



6.16.12 Cleaning Frequency: Weekly

6.16.12.1 Open the Dry Zone & Cooling Zone both side cover and clean the Tunnel by using vacuum cleaner.

6.16.12.2 Clean the pre-filters of Tunnel with Purified water as well as with air jet weekly followed by air drying.

6.17 Product Change Over:

6.17.1 Open the both side cover of the sterilizing and Depyrogenation tunnel.

6.17.2 Adjust the height of the both dampers (hot zone cover and tunnel out feed) and adjust the height by measurement with scale as per **Annexure-III** by rotating the knob of the tunnel.



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6.17.3 After adjustment of damper height according to vial size, lock the damper rotating knob.

6.18 Record the daily & weekly cleaning details in Format Titled “**Equipment Log**” of SOP.

7.0 ABBREVIATIONS:

°C	Degree Celsius
IPA	Isopropyl Alcohol
Ltd.	Limited
Min	minutes
ml	milliliter
Mm	millimeter
HMI	Human Machine Interface
PLC	Programmable Logical Controller
QA	Quality Assurance
SOP	Standard Operating Procedure
Temp.	Temperature
WFI	Water for Injection
IPQA	In process Quality Assurance
Pa	Pascal

8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	List of Conveyor Speed	
Annexure-II	Set Parameter List of Differential Pressure Limit and Temperature	
Annexure-III	List of Damper Height for Glass Vial (DPI Line)	

9.0 DISTRIBUTION:

- Master Copy Quality Assurance
- Controlled Copy No.1 Production Department



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10.0 REFERENCES:

- SOP Titled “ **Equipment Log book**”

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		



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ANNEXURE – I

	PRODUCTION
	LIST OF CONVEYOR SPEED

S.No.	Vials Size	Conveyor Speed (in mm/min)
1.	7.5 ml Vials (24mm Outer Dia)	140
2.	10 ml Vials (Moulded) (24mm Outer Dia)	140
3.	10 ml Vials (Tubular) (20 mm Outer Dia)	140



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ANNEXURE – II

	PRODUCTION
	SET PARAMETER LIST OF DIFFERENTIAL PRESSURE LIMIT AND TEMPERATURE

PARAMETERS	DIFFERENTIAL PRESSURE LIMIT	TEMPERATURE LIMIT
Pressure Differentials (Drying Zone)	70-120 Pa	70°C - 110°C
Pressure Differentials (Sterilization Zone)	150-250 Pa	320°C - 340°C
Pressure Differentials (Cooling Zone)	70-120 Pa	25°C - 50°C



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ANNEXURE – III

	PRODUCTION
	LIST OF DAMPER HEIGHT FOR GLASS VIAL

S.No.	Vial Size	Vial Height (in mm)	Damper Height (in mm)
1.	7.5 ml	35	40
2.	10 ml	51	55