



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Operation and Cleaning of Compounding/Holding/Filling Vessel

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	1 of 5	

1.0 OBJECTIVE:

To lay down a Procedure for Operation and Cleaning of Compounding / Holding / Filling Vessel.

2.0 SCOPE:

This SOP is applicable for Operation and Cleaning and Sterilization In Process of Compounding / Holding / Filling Vessel (Make: **Pharma Tech** and **Bright Pharma**) for batch Manufacturing / filtration / Filling in Production Department.

3.0 RESPONSIBILITY:

Officer / Executive - Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

CIP	Cleaning In Process
ID No.	Identification Number
Ltd.	Limited
No.	Number
PLC	Programmable Logic Controller
Pvt.	Private
QA	Quality Assurance
SOP	Standard Operating Procedure
SIP	Sterilization In Process

6.0 PROCEDURE:

6.1 CHECKS & PRECAUTIONS:

6.1.1 Check and ensure that availability of Utilities for Operation of Compounding/holding/filling vessel along with product line (Nitrogen, Compressed Air and Electricity).

6.2 OPERATION OF COPOUNDING/HOLDING/FILLINGVESSEL:

6.2.1 Switch "ON" the main switch of the Compounding/holding/filling vessel along with product line.

6.2.2 Open the Compressed Air Inlet Valve and check the Pressure of Compressed Air. (It should be between 6.0 to 7.0 Kg /cm²).

6.2.3 Check and ensure all the Pneumatic Valve Connection and Operation is OK.

6.2.4 The PLC of Pharmatech Vessels will display as:



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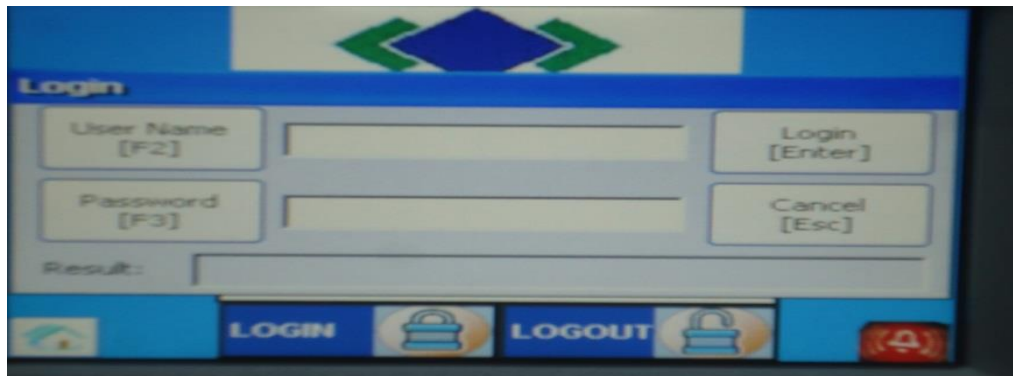
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6.2.5 To go to the Login Menu, press “NEXT” on the Main Menu and the PLC display the Login Menu as: (It is compulsory that the Operator / Supervisor / Manager should Login before start any operation on the Compounding/Holding vessel with their Name and Password provided).



6.2.6 To enter at the Supervisor Level, press the “NAME” button in the Login Menu and enter the Supervisor level. The following are the operator levels:

- A - Operator Level
- B - Supervisor Level
- C - Manager Level

6.2.7 To enter the Password, press the “PASSWORD” screen in the Login Menu and enter the Password provided for the Supervisor level. It is confidential.

6.2.8 To complete the Login Option, press “LOGIN” button & “HOME” button The PLC will display as:



6.2.9 Press “MANUAL” button, the PLC will display as :



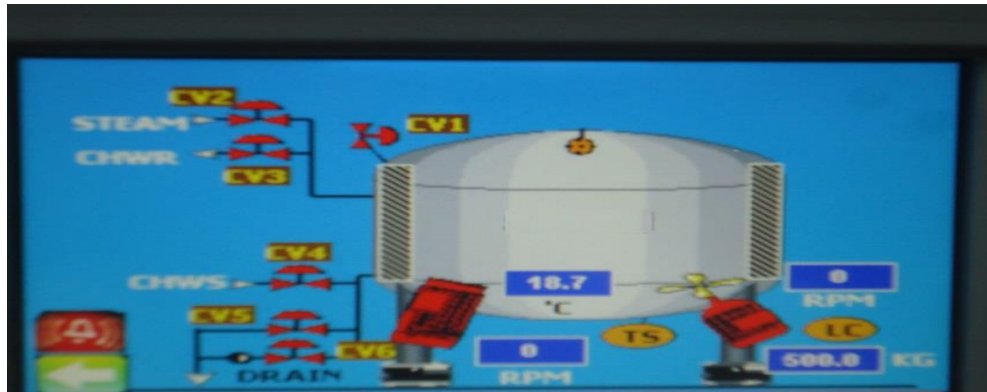
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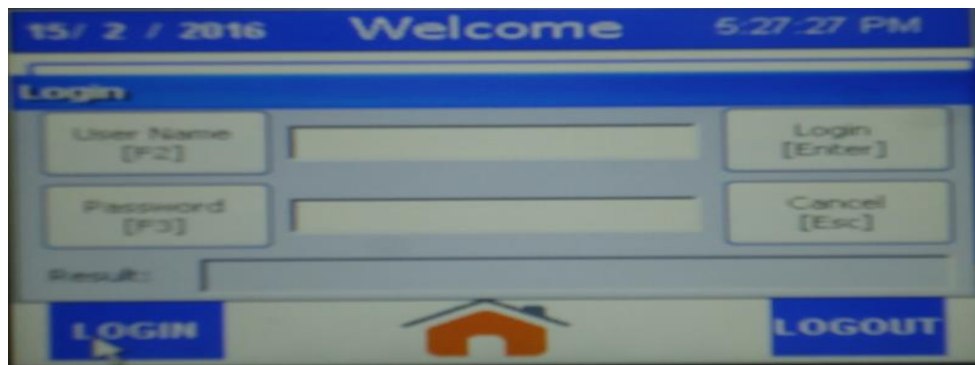
6.2.10 Press the valve display in screen according to the process requirement.

6.2.11 Switch “OFF” the PLC after completion of operation.

6.2.12 Record the operation details in “**Machine Utilization record**” as per Format.

6.2.13 The **PLC** of Bright Pharma Vessels will display as:

6.2.14 To go to the Login Menu, press “**NEXT**” on the Main Menu and the **PLC** display the Login Menu as: (It is compulsory that the Operator / Supervisor / Manager should Login before start any operation on the Compounding/Holding vessel with their Name and Password provided).



6.2.15 To enter at the Supervisor Level, press the “**NAME**” button in the Login Menu and enter the Supervisor level. The following are the operator levels:

- A - Operator Level
- B - Supervisor Level
- C - Manager Level

6.2.16 To enter the Password, press the “**PASSWORD**” screen in the Login Menu and enter the Password provided for the Supervisor level. It is confidential.

6.2.17 To complete the Login Option, press “**LOGIN**” button & “**HOME**” button The **PLC** will display as:



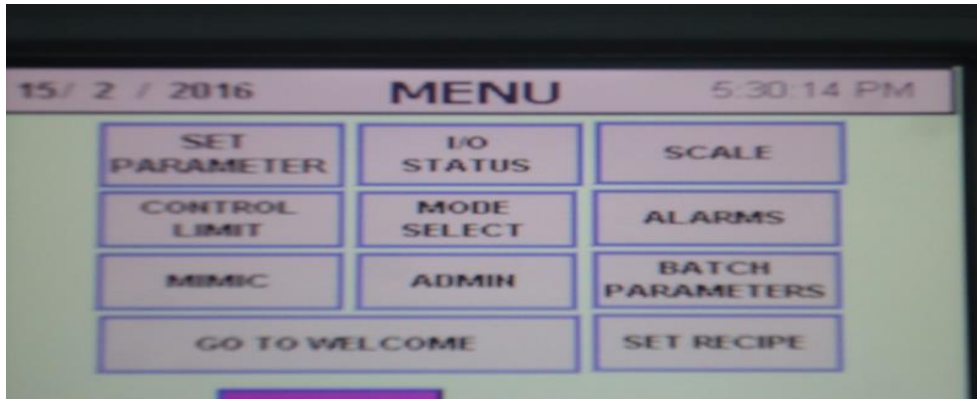
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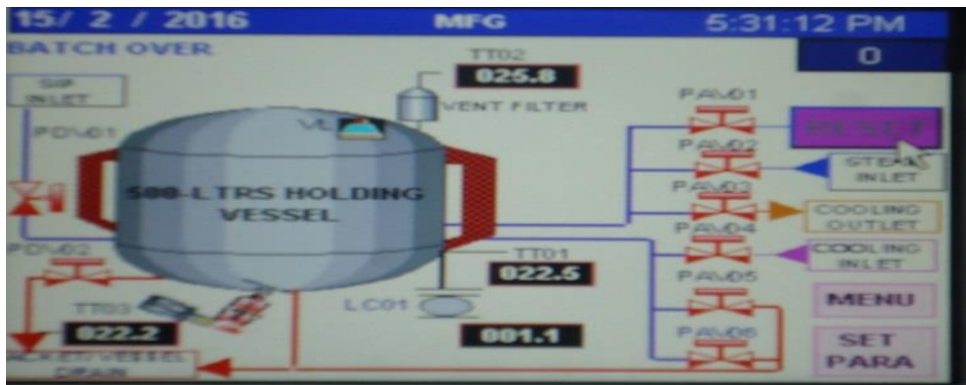
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6.2.18 Press “MANUAL” button. the PLC will display as :



6.2.19 Press the valve display in screen according to the process requirement.

6.2.20 Switch “OFF” the PLC after completion of operation.

6.2.21 Record the operation details as per “Machine Utilization Record” in SOP Titled “Machine Utilization Record”.

6.3 CLEANING OF COMPOUNDING / HOLDING / FILLING VESSEL:

6.3.1 Before starting cleaning of the Compounding/holding/filling vessel along with product line ensure that all the Pneumatic Valve are closed.

6.3.2 Switch “OFF” the PLC before Start up of Cleaning Activity.

6.3.3 Clean the external surface of the Tank, PLC Panel & SS Pipelines with Clean Lint Free Mopping Pad dipped in Water for Injection.

6.3.4 While Cleaning Do Not Open / Touch the Electrical Parts.

6.3.5 Dry Mop all the Electrical Parts and PLC Screen with Clean Lint Free Mopping Pad.

6.3.6 Dry the Tank (Panel & Pipelines) with Dry & Clean Lint Free Mopping Pad to ensure complete cleaning of the Tank.



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6.3.7 After Cleaning write the Status Label on the Compounding/holding/filling vessel along with product line.

6.4 STERLIZATION IN PROCESS OF COMPOUNDING / HOLDING / FILLING VESSEL:

6.4.1 After completion of CIP cycle of Compounding/holding/filling vessel along with product line change connection.

6.4.2 In this all tank of Q-Block three piece have SIP inbuilt with every tank.

6.4.3 Select SIP icon and start SIP.

6.4.4 After completion of sip cycle print should be checked by production and verified by QA.

6.4.5 Attached print out in concerned BMR.

7.0 ANNEXURES:

Not Applicable

ENCLOSURES: SOP Training Record.

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance
- Controlled Copy No. 02 Production
- Master Copy Quality Assurance

9.0 REFERENCES:

Not Applicable.

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By