



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Operation and Cleaning of Vertical Autoclave in FFS Section

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 vertical autoclave in FFS section.

2.0 SCOPE:

This SOP is applicable for Operation and cleaning of vertical autoclave of FFS section.

3.0 RESPONSIBILITY:

Officer / Executive Production

4.0 ACCOUNTABILITY:

Head-Production

5.0 ABBREVIATIONS:

AR No.	Analytical Report Number
LDPE	Low Density Polyethylene
Ltd.	Limited
No.	Number
NLT	Not Less Than
QA	Quality Assurance
SOP	Standard Operating Procedure

6.0 PROCEDURE:

6.1 OPERATION:

6.1.1 Pre checks to be done at before starting the autoclave (main power supply/ purified water / WFI feeding up to given level as per floating valve then close the main hole lid and tighten the bolt.

6.1.2 Switch ON the display shows the following screen for 5 seconds.

OSWORLD AUTOCLAVE LOGGER & CONTROLLER
--

6.1.3 All the connections are proper; the process screen is displayed as follows.

SP; 121.4 C	030	min.
PV: 30.5 C	000	min.

6.1.4 Unless the logged data is printed, the process cannot be started. This ensures that the last cycles data is not inadvertently lost. Press the PASSWORD key to print. Ensure that the printer is on and the baud is set properly after the data is printed, the process screen shows as follows.

A : 00 psi	B : 32.0
C : 32.0	D : 32.0



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Operation and Cleaning of Vertical Autoclave in FFS Section

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	2 of 5	

6.1.5 Zone-A is used as reference for control. The system is in idle state now .air purging relay is ON and is indicated on the LED.

6.1.6 To start the batch, press START/STOP key (to terminate the batch, press this key again) the process screen alternatively toggles between the above screen and the following one.

SV :121.4	PV: 82.0
HEATING	

6.1.7 The HEAT LED glows and shows the status of the heater .meanwhile, when the factory set air exhaust relay is put OFF once the control set point (set1) is reached, the following screen is displayed.

SV: 121.4	B: 124.0
STERILIZING 30	

6.1.8 The proportion action ensures that the process temperature is controlled at or above the set value. The value on the right corner of the second line is the remaining sterilizing time in minutes. Once the sterilization time has elapsed, the heater is put OFF and the air exhaust relay and the buzzer comes ON indicating that the sterilizing time is over.

EXAUST

6.1.9 To acknowledge the buzzer, press the P/ALM ACK key.

6.1.10 Air exhaust is ON till the temperature reaches 99.98 C after which the buzzer (if not acknowledged) and the air exhaust relay is OFF .the display shows:

SV : 121.4	PV : 99.9
END OF CYCLE	

6.1.11 The batch process is over .audio and visual indications are also provided for the following:-

- Water level LOW
- Sensor open/polarity
- Cycle over.

6.1.12 To acknowledge the audio alarm, press the ACK button.

6.1.13 Before start the operation and end operation of the day, switch OFF the main supply and clean the outer surface with 70% v/v IPA solution , drain the chamber water and collect fresh water for the cycle (also can make up the water level at intermediate whenever required).



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Operation and Cleaning of Vertical Autoclave in FFS Section

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	3 of 5	

6.1.14 Setting and control set point for 121.4 to 124 deg. For 30 minutes.

6.1.15 Press PROG key. The display shows.

STER TEMP (deg C)

6.1.16 Press UP or DOWN key to increment or decrement this set point.

6.1.17 Press ENTER key to save the new set point, then display shows.

STER TIME (min.)
30

6.1.18 Press UP or DOWN key to increment or decrement this set point or go to step 5.1.19.

6.1.19 Press ENTER key to save the new set point the display now shows.

Date (MM:DD)
05:28

6.1.20 Press UP or DOWN key to increment or decrement this set point.

6.1.21 Press ENTER key to save the new set point.

Time (HH:MM)
21:10

6.1.22 Press UP or DOWN key to increment or decrement this set point.

6.1.23 Press ENTER key to save the new set point.

Year (YYYY) 2016

6.1.24 Press UP or DOWN key to increment or decrement this set point.

6.1.25 Press ENTER key to save the new set point.

Baurd rate
19200



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Operation and Cleaning of Vertical Autoclave in FFS Section

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	4 of 5	

6.1.26 This is the rate at which data is sent to the serial printer.

6.1.27 Press ENTER key to save the new set point. The display now shows the process screen.

7.0 ANNEXURES:

ANNEXURE NO.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Operation And Cleaning Record Of Vertical Autoclave In FFS Section.	

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:

User manual of OSWORLD.

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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

