STANDARD OPERATING PROCEDURE

Title: Handling of Power Failure of Parenteral Blocks

SOP No.:		**Department:**	Production	
		Effective Date:		
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1.0 OBJECTIVE:

To lay down the procedure for Handling of Power failure of parenteral blocks.

2.0 SCOPE:

This SOP is applicable for Handling of Power failure of parenteral block production area.

3.0 RESPONSIBILITY:

Operating Person of Concerned Department: Information given to HOD and execution the process during power failure.

Section Incharge of production & IPQA: Review & assessment the pre & post activity.

Head Production & Manager QA: Approval of assessment & further process accordingly.

4.0 ACCOUNTABILITY:

Head QA

5.0 ABBREVIATIONS:

SOP	Standard Operating Procedure
QA	Quality Assurance
IPA	Iso Propyl Alcohol
LAF	Laminar Air Flow
Sec	Second
RH	Relative Humidity
CIP	Clean In Place
SIP	Sterilization In Place
No.	Number
Ltd.	Limited

6.0 PROCEDURE:

6.1 Precautions:

6.1.1 Immediately inform to HOD / Incharge of Engineering & Production.

6.1.2 Do not carry out any operations during Power Failure.

6.1.3 Do not open any door except in case of emergency.

6.1.4 Avoid unnecessary movement and stand still.

6.1.5 Do not touch any article / object.

6.1.6 Do not use dynamic / static pass box.

6.1.7 Do not intervene in any aseptic process i.e. under LAF activities.

6.2 Conditions of Power Failure:

6.2.1 Unexpected failure of plant or equipment due to loss of power.

6.2.2 Controlled shut down for maintenance work / renovations.

6.2.3 Unspecified damage to rooms or plant.

6.2.4 After power cut, power change over shall be done within one minute as per challenge study.

6.2.5 Any UPS failure.

6.2.1 Due to unexpected malfunctioning of backup system there may be unforeseen delay in power resumption (backup system fails to supply the power within 60 seconds). To handle such circumstances following actions are required to avoid the adverse impact on product quality but not limited to.

6.3 Follow the line of action to handle the power failure event w.r.t. time duration.

6.3.1 If power resumes within backup time i.e. 60 sec.

Action Plan	
During Power Failure	**After Resuming the Power**
➢ Do not intervene or access grade A activity. ➢ Do not access the pass box during the power failure.	➢ Ensure that area DP, temp. , RH and NVPC complies after power resumption. ➢ Ensure grade-A LAF DP is within defined limit i.e. 10-15 mm of water column. ➢ Proceed the aseptic activity after hand sanitization with filtered 70 % IPA solution.

6.3.2 If power not resumes within the defined (backup time) i.e. More than 60 sec. Up to 2 minutes.

Action Plan	
During Power Failure	**After Resuming the Power**
➢ Do not intervene or access grade A activity. ➢ Do not access the pass box during the power failure. ➢ Close the machine door. ➢ Stop the man- material movement. ➢ Do not perform any other activity till power resumption ➢ Verify total duration of power failure from display clock.	➢ Ensure that area DP, temp. , RH and NVPC compliance after power resumption. ➢ Ensure grade-A LAF DP is within defined limit i.e. 10-15 mm of water column. ➢ Sanitize the hands with filtered 70 % IPA solution after resumption of power as well as before filling activity access for Grade A activity. ➢ Proceed the aseptic area activity after 5 minutes.

6.3.3 If power resume after 2 minutes but before recovery period of 15 minutes.

Action Plan	
During Power Failure	**After Resuming the Power**
➢ Do not intervene or access Grade A activity. ➢ Do not access the pass box during the power failure. ➢ Close the machine door. ➢ Stop the man- material movement. ➢ Do not perform any other activity till power restoration. ➢ Verify total duration of power failure from display clock.	➢ Ensure that area DP, temp. , RH and NVPC compliance after resumption of power. ➢ Ensure grade A LAF DP is within defined limit i.e. 10-15 mm of water column. ➢ Sanitize the hands with filtered 70 % IPA after resumption of power as well as before proceeding filling activity/ access for Grade A activity. ➢ Proceed the aseptic area activity after 15 minutes from power resumption.

6.3.4 If power resume after completion of recovery period of 15 minutes (failure of more than 15 minutes).

Action plan	
During Power Failure	**After resuming the power**
➢ Do not intervene or access Grade-A activity. ➢ Do not access the pass box during the power failure. ➢ Close the machine door. ➢ Stop the man- material movement. ➢ Do not perform any other activity till power resumption. ➢ Verify total duration of power failure from display clock.	➢ Ensure that area DP, temp. , RH and NVPC compliance after resumption of power. ➢ Ensure grade-A LAF DP is within defined limit i.e. 10-15 mm of water column. ➢ Vacate the aseptic area after power resumption (failure of more than 15 minutes) followed by personnel monitoring. ➢ Raise the incident/ deviation as per procedure defined in respective SOP. ➢ Proceed further the aseptic area entry after a period of minimum 15 minutes. ➢ Ensure that area DP, temp. , RH and NVPC compliance after resumption of power. ➢ Ensure grade-A LAF, DP is within defined limit i.e. 10-15 mm of water column. ➢ Inform the microbiologist for collection of exposed EM plate at grade B location will subjected for evaluation microbiological status of grade B due to power failure event. ➢ Carry out the further settle plate monitoring for grade B location to proceed the activity. ➢ Sanitize the hands with filtered 70 % IPA to continue the aseptic activity.

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6.4 Follow the line of action to handle the power failure event w.r.t. Equipment/Instrument, but not limited to.

S.No.	Equipment /Instrument	Recommendation
1.	LAF	a. Raise the incident/ deviation as per QMS. b. Raise the work order. c. Terminate the grade-A activity. d. Remove the impacted material i.e. filling machine parts, filling assembly and send the machine parts for re-cleaning and re-sterilization as per SOP. e. Keep the remaining bulk solution in the respective tank and fate of this solution will be proceed after QA approval. f. Proceed the recommendation if the sterile bulk solution is within the hold time and if it exceeds the hold time then discard.
2.	MLAF	a. Raise the work order to rectify the machine. b. Impacted material has to be removed to provide the machine to engineering team for rectification. c. After rectification, clean the machine take one trial to ensure the satisfactory working of the machine. Record the same in the respective logbook. d. Mobile LAF backup working up to 1 hrs. o **Non-operational** (If No power backup) - Clean the MLAF as per cleaning procedure. o **Operational condition** (If No power backup) - Send the material/Items/Parts outside again for Cleaning sterilization purpose and clean the MLAF. g. Raise the incident/ deviation as per QMS.
3.	Vial/ Ampoule washing machine	a. When power resumes, ensure that the differential pressure of the area is within limit. b. Sanitize the hands with 70% IPA solution. c. Ensure that availability of required pressure. d. Restart the machine and run to empty in progress Vials / Ampoules.
4.	Depyrogenation tunnel	a. If power resume within time (Validation study to be performed) no action shall be taken. b. If power not resume within defined time following action to be taken: i. Suspend the activity. ii. Inform to engineering department through work order.

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S.No.	Equipment /Instrument	Recommendation
		iii. Raise the work order to rectify the machine. iv. Impacted material has to be removed to provide the machine to engineering team for rectification. v. After rectification, clean the machine take one trial to ensure the satisfactory working of the machine. Record the same in the respective logbook. vi. Raise the incident/ deviation as per QMS. vii. Remove the all ampoules/Vials from tunnel via filling in feed turn table. viii. Perform the machine/area cleaning as per procedure. ix. Take the Reline-clearance. x. Check the Area/machine DP, Temperature, RH & Proceed the activity
5.	Autoclave / Bung processor	a. Raise the work order to rectify the machine. b. Impacted material has to be removed to provide the machine to engineering team for rectification. c. After rectification, clean the machine take one trial to ensure the satisfactory working of the machine. Record the same in the respective logbook. d. After Power failure wait for resuming the power supply then re-start the activity.
6.	Terminal sterilizer	a. Raise the incident/ deviation as per QMS. b. Raise the work order to rectify the machine. c. Impacted material has to be removed to provide the machine to engineering team for rectification. d. After rectification, clean the machine take one trial to ensure the satisfactory working of the machine. Record the same in the respective logbook. e. Segregate the particular load & after QA approval proceed for further.
7.	Filling machine	If power not resume within 3 minutes, follow the below steps: a. Raise the incident/ deviation as per QMS b. Raise the work order. c. Raise the work order to rectify the machine. d. Impacted material has to be removed to provide the machine to engineering team for rectification. e. After rectification, clean the machine take one trial to ensure the satisfactory working of the machine. Record the same in the respective logbook. f. Terminate the grade “A” activity

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S.No.	Equipment /Instrument	Recommendation
		g. Remove the impacted material i.e. filling machine parts, Remove the exposed ampoules/Vials, filling assembly and send the machine parts for re-cleaning and re-sterilization as per SOP h. Keep the remaining bulk solution in the respective tank and fate of this solution will be proceed after QA approval. i. Proceed the recommendation if the sterile bulk solution is within the hold time and if it exceeds the hold time then discard. j. If power resume within 3 minutes(As per validation study)follow the below steps: ➢ Remove the exposed ampoules/vials (unsealed/ unstoppered). ➢ Inform to engineering department. ➢ Terminate the grade "A" activity. ➢ Before start of activity check the DP. ➢ After QA approval continue the activity.
8.	Integrity machine	a. Raise the work order to rectify the machine. b. Impacted material has to be removed to provide the machine to engineering team for rectification. c. After rectification, clean the machine take one trial to ensure the satisfactory working of the machine. Record the same in the respective logbook. d. Check all the parameters. e. Restart the activity.
9.	Mfg. / Holding tank	a. Raise the work order to rectify the machine. b. Impacted material has to be removed to provide the machine to engineering team for rectification. c. After rectification, clean the machine take one trial to ensure the satisfactory working of the machine. Record the same in the respective logbook. d. Check the all parameter & Restart the activity.
10.	Bottle filling machine	a. Raise the work order to rectify the machine. b. Impacted material has to be removed to provide the machine to engineering team for rectification. c. After rectification, clean the machine take one trial to ensure the satisfactory working of the machine. Record the same in the respective logbook.
11.	Vial filling machine	a. Raise the work order to rectify the machine. b. Impacted material has to be removed to provide the machine to engineering team for rectification. c. After rectification, clean the machine take one trial to ensure the satisfactory working of the machine. Record the same in the respective

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S.No.	Equipment /Instrument	Recommendation
		logbook.
12.	Vial sealing machine	a. Raise the work order to rectify the machine. b. Impacted material has to be removed to provide the machine to engineering team for rectification. c. After rectification, clean the machine take one trial to ensure the satisfactory working of the machine. Record the same in the respective logbook.
13.	Leak tester	a. Raise the work order to rectify the machine. b. Impacted material has to be removed to provide the machine to engineering team for rectification. c. After rectification, clean the machine take one trial to ensure the satisfactory working of the machine. Record the same in the respective logbook. d. Check the all parameters. e. Restart the activity.
14.	Garment washing machine	a. Raise the work order to rectify the machine. b. Impacted material has to be removed to provide the machine to engineering team for rectification. c. After rectification, clean the machine take one trial to ensure the satisfactory working of the machine. Record the same in the respective logbook. d. Check the all parameters. e. Restart the activity.
15.	FFS machine	a. Raise the work order to rectify the machine. b. Impacted material has to be removed to provide the machine to engineering team for rectification. c. After rectification, clean the machine take one trial to ensure the satisfactory working of the machine. Record the same in the respective logbook. d. Proceed as per ampoule filling machine.
16.	Dynamic pass box	a. Remove the material from pass box. b. Raise the work order to rectify the machine. c. Impacted material has to be removed to provide the machine to engineering team for rectification. d. After rectification, clean the machine take one trial to ensure the satisfactory working of the machine. Record the same in the respective logbook. e. Clean the pass box as per procedure. f. Retransfer the material as per procedure.
17.	Static pass box	a. Remove the material from pass box. b. Raise the work order to rectify the machine. c. Impacted material has to be removed to provide the machine to

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S.No.	Equipment /Instrument	Recommendation
		engineering team for rectification. d. After rectification, clean the machine take one trial to ensure the satisfactory working of the machine. Record the same in the respective logbook. e. Clean the pass box as per procedure. f. Retransfer the material as per procedure.
18.	BFS machine	a. Raise the work order to rectify the machine. b. Impacted material has to be removed to provide the machine to engineering team for rectification. c. After rectification, clean the machine take one trial to ensure the satisfactory working of the machine. Record the same in the respective logbook.
19.	Torque machine	a. Raise the work order to rectify the machine. b. Impacted material has to be removed to provide the machine to engineering team for rectification. c. After rectification, clean the machine take one trial to ensure the satisfactory working of the machine. Record the same in the respective logbook.
20.	Hi cart machine	a. Raise the work order to rectify the machine. b. Impacted material has to be removed to provide the machine to engineering team for rectification. c. After rectification, clean the machine take one trial to ensure the satisfactory working of the machine. Record the same in the respective logbook.
21.	Labelling machine	a. Raise the work order to rectify the machine. b. Impacted material has to be removed to provide the machine to engineering team for rectification. c. After rectification, clean the machine take one trial to ensure the satisfactory working of the machine. Record the same in the respective logbook. d. Check the all parameters. e. Restart the activity.
22.	Blister / autocartonator	a. Raise the work order to rectify the machine. b. Impacted material has to be removed to provide the machine to engineering team for rectification. c. After rectification, clean the machine take one trial to ensure the satisfactory working of the machine. Record the same in the respective logbook.

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S.No.	Equipment /Instrument	Recommendation
		d. Check the all parameters e. Restart the activity.
23.	Shrink Wrapping Machine	a. In case of power failure discard the product shrink pack after resumption of power supply and write the detail in the respective BPR. b. Check the all parameters c. Restart the activity.
24.	pH meter	d. Raise the work order to rectify the issue. e. Provide the pH meter to engineering team for rectification. f. After rectification, clean pH meter take one trial to ensure the satisfactory working of the machine. Record the same in the respective logbook. g. Perform the recalibration of pH meter h. Restart the activity.
25.	Cool Chamber	a. Raise the work order to rectify the cool chamber. b. Impacted material has to be removed to provide the machine to engineering team for rectification. c. After rectification, clean the cool chamber, take one trial to ensure the satisfactory working of the machine. Record the same in the respective logbook.
26.	Storage area	a. Raise the work order to rectify issue. b. Impacted material has to be removed to provide the area to engineering team for rectification. c. After rectification, clean the storage area take one trial to ensure its satisfactory. Record the same in the respective logbook.

7.0 REFERENCES:
Not Applicable.

8.0 ANNEXURES:
Not Applicable.
ENCLOSURES: SOP Training Record

9.0 DISTRIBUTION:

- Controlled Copy No.01 Quality Assurance
- Controlled Copy No.02 Production DPI
- Controlled Copy No.03 Production Ampoule
- Controlled Copy No.06 Engineering
- Master Copy Quality Assurance

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10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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