



STANDARD OPERATING PROCEDURE

Department: Quality Assurance	SOP No.:
Title: Procedure for Handling of Power failure situation	Effective Date:
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1.0 OBJECTIVE:

To lay down a procedure for handling power failure situations.

2.0 SCOPE:

This procedure is applicable to handling power failure situations in production area, Quality Control, Microbiology, Utility and Stores at

3.0 RESPONSIBILITY:

Officer/ Executive – Production, Stores, Quality Control, Quality Control (microbiology) for monitoring and reporting of power failure.

Head-Utility/ Head-Quality Assurance/Head Production, Stores, Quality Control and Microbiology Section - responsible for compliance to the procedure.

4.0 PROCEDURE:

4.1 Action to be taken in granulation area during power failure for more than 10 minutes.

4.1.1 Switch 'off' the power supply to equipment.

4.1.2 Cover the material with lid / fresh poly bag.

4.1.3 After resumption of power, wait for at least 20 minutes and check the following points:

4.1.3.1 Check temperature and relative humidity of the area.

4.1.3.2 Check air differential pressure of the area.

4.1.3.3 If all environmental parameters are within limit, Switch 'on' the mains of the machines.

4.1.3.4 Check the time elapsed and required time for completion activity.

4.1.3.5 Check and record the environmental conditions in the respective formats.

4.2 Action to be taken in compression area during power failure for more than 10 minutes

4.2.1 Switch 'off' the power supply to equipment.

4.2.2 Unload in-process granules from the hopper into containers and close it properly.

4.2.3 Secure the containers to ensure proper storage and integrity of in-process granules and compressed tablets container.



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4.2.4 After resumption of power, wait for at least 20 minutes and check the following points:

- 4.2.4.1 Check the temperature and humidity of the area.
- 4.2.4.2 Check the air differential pressure of the area.
- 4.2.4.3 Remove the upper punches.
- 4.2.4.4 Switch 'on' the power supply to equipment.
- 4.2.4.5 Check the direction of rotation of machine in 'inch' mode.
- 4.2.4.6 Ensure that the physical parameters are within the limit.
- 4.2.4.7 Record the environmental conditions.
- 4.2.4.8 Replace the upper punches and discard initial two rotation tablets.
- 4.2.4.9 Check all the in process parameters as per BMR.
- 4.2.4.10 Record the down time in the equipment usage and cleaning log sheet as per reference SOP No.....

4.3 Action to be taken in coating area during power failure for more than 10 minutes

- 4.3.1 Take out the gun assembly from the coating pan.
- 4.3.2 Switch off the power supply to equipment.
- 4.3.3 Unload the tablets into in-process container and close the containers properly.

4.3.4 After resumption of power, wait for at least 20 minutes and checks the following points:

- 4.3.4.1 Check the temperature and relative humidity of the area.
- 4.3.4.2 Check the air differential pressure of the area.
- 4.3.4.3 Ensure that the parameters are within the limit.
- 4.3.4.4 Switch 'on' the main of the machine.
- 4.3.4.5 After getting all the parameters including coating parameter within the limit, load the tablets into the pan for further processing.
- 4.3.4.6 Record the environmental conditions in the respective formats.
- 4.3.4.7 Load the tablets into coating pan and start coating operation as per BMR.

4.4 Action to be taken in Inspection area during power failure more than 10 minutes:

- 4.4.1 Switch off the Power supply to equipment.



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- 4.4.2 Unload the tablets/capsules from hopper/ inspection belt into double lined poly bag/ in-process container with proper status label. Secure the polybag/ in-process container.
- 4.4.3 After resumption of power, wait for at least 20 minutes and checks the following points:**
- 4.4.3.1 Check the temperature and humidity of the area.
- 4.4.3.2 Check the air differential pressure of the area.
- 4.4.3.3 Ensure that all the parameters are within the specified limit.
- 4.4.3.4 Switch 'on' the main of the machine.
- 4.4.3.5 Discard the left over tablet between two belts.
- 4.4.3.6 Check and record the environmental conditions in the respective formats.
- 4.4.3.7 Load the tablets into hopper and start the inspection activity as per BMR.
- 4.5 Action to be taken in Capsule filling area during power failure more than 10 minutes:**
- 4.5.1 Switch off the Power supply to equipment.
- 4.5.2 Unload the powder / granules from hopper in the double lined poly bag with proper status label.
- 4.5.3 Remove empty capsule from empty capsule hopper and sorter elevator and put into double polybag lined container or in-process containers and tie the poly bags with status label. Secure the polybag.
- 4.5.4 Remove filled capsule from capsule polishing machine and put in polybag and tie it. Label it and secure it.
- 4.5.5 After resumption of power, wait for at least 20 minutes and checks the following points:**
- 4.5.5.1 Check the temperature and humidity of the area.
- 4.5.5.2 Check the air differential pressure of the area.
- 4.5.5.3 Ensure that all the parameters are within the specified limit.
- 4.5.5.4 Switch 'on' the main of the machine.
- 4.5.5.5 After getting the set parameter within the limit, load the powder / granules in to hopper and start further activity and record the activity in the respective BMR.
- 4.6 Action to be taken in Packing area during power failure for more than 10 minutes**
- 4.6.1 Switch off the power supply 'main' of the machine (strip / blister/ (tablet/capsule)/Sachet Packing).
- 4.6.2 Unload the contents from the hopper into the double poly bag lined container or in-process container with proper status label.



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4.6.3 Remove the contents from the feeding box, feeding channel, guide track and store properly as per step 4.6.2.

4.6.4 After resumption of power, wait for at least 20 minutes and checks the following points:

4.6.4.1 Check the temperature and humidity of the area.

4.6.4.2 Check the air differential pressure of the area.

4.6.4.3 Switch 'on' the main of the machine.

4.6.4.4 Discard the strips/blisters/sachets under sealing roller

4.6.4.5 Check the temperature of sealing

4.6.4.6 After getting the set parameter within the specified limit

4.7 Action to be taken in Sampling & dispensing area during power failure for more than 10 minutes:

4.7.1 Switch off the "main" of the machine (RLAF).

4.7.2 Stop the sampling & dispensing activities, closed the open container with lid & double lined poly bag.

4.7.3 After resumption of power, wait for at least 20 minutes and checks the following points:

4.7.3.1 Check the temperature and humidity of the area.

4.7.3.2 Check the air differential pressure of the area.

4.7.3.3 Switch 'on' the main of the machine (RLAF) and wait for 10 minutes.

4.7.3.4 Restart the sampling and dispensing activities.

4.7.3.5 Make appropriate entries in logs and BMR, as and where applicable

4.8 Action to be taken in stability chamber during power failure for more than 2 minutes.
Refer SOP No.....

4.9 Action to be taken in Sterility and MLT room during power failure for more than 10 minutes:

4.9.1 All LAF in MLT and sterility area have UPS connectivity. Activity can be continued during power failure.

4.10 Action to be taken in Oral Dry powder filling area during power failure for more than 10 minutes:

4.10.1 Switch off the Power supply to equipment.



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4.10.2 Unload the in powder from hopper.

4.10.3 Tie the poly bags containing oral dry powder and label it as per procedure

4.10.4 After resumption of power, wait for 20 minutes and checks the following points:

4.10.4.1 Check the temperature and humidity of the area.

4.10.4.2 Check the air differential pressure of the area.

4.10.4.3 Switch on the power supply to equipment.

4.10.4.4 Ensure that physical parameters are within the limit.

4.10.4.5 Record the environmental conditions.

4.10.4.6 Check all the in process parameters as per BMR.

4.10.4.7 Record the down time in the equipment usage and cleaning log sheet.

4.11 Action to be taken in Dry powder injection area during power failure for more than 5 minutes:

Refer SOP No.....

4.12 Action to be taken in External preparation area during power failure

Refer SOP No.....

4.13 Action to be taken in Soft gelatin area (Medicament and Gelatin Preparation) Area during power failure more than 10 minutes

4.13.1 Switch off the Power supply to equipment.

4.13.2 Immediately stop all manufacturing process.

4.13.3 All raw materials poly bag to close tightly with cabal tie.

4.13.4 Close all valves of medicament mixing tank, lobe pump and In line homogenizer.

4.13.5 Close lid of all liquid containers and placed a side.

4.13.6 Switched of main power supply of all equipment.

4.13.7 Remove all manpower from area.

4.13.8 After resumption of power, wait for at least 20 minutes and checks the following points:

4.13.8.1 Check the temperature and humidity of the area.

4.13.8.2 Check the air differential pressure of the area.

4.13.8.3 Switch on the power supply to equipment.

4.13.8.4 Ensure that the parameters are within the limit.



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4.13.8.5 Record the environmental conditions.

4.13.8.6 Check all the in process parameters as per BMR.

4.13.8.7 Record the down time in the equipment usage and cleaning log sheet.

4.14 Action to be taken in Soft gelatin area (Encapsulation Area) during power failure more than 10 minutes

4.14.1 Switch off the Power supply to equipment.

4.14.2 Immediately close valve of medicament and Gelatin supply tank in feeding area.

4.14.3 Close shut off valve of encapsulation area

4.14.4 Remove capsules from tumbler dryer and polishing pan. Spread capsules in drying tray.

4.14.5 Transfer drying trolley into drying area.

4.14.6 Switched of main power supply of all equipment.

4.14.7 Remove all manpower from area.

4.14.8 After resumption of power, wait for at least 20 minutes and checks the following points:

4.14.8.1 Check the temperature and humidity of the area.

4.14.8.2 Check the air differential pressure of the area.

4.14.8.3 Switch on the power supply to equipment.

4.14.8.4 Ensure that the parameters are within the limit.

4.14.8.5 Record the environmental conditions.

4.14.8.6 Check all the in process parameters as per BMR.

4.14.8.7 Record the down time in the equipment usage and cleaning log sheet.

4.15 Action to be taken in Oral Liquid Manufacturing during power failure more than 10 minutes

4.15.1 Switch off the panel board.

4.15.2 Tie lock the remaining material to be used in the manufacturing with proper status label on the poly bags.

4.15.3 After power resuming switch on the panel board wait for at least 20 min.

4.15.4 Ensure the environmental condition within the specified limit as per BMR.

4.15.5 Action to be taken in Oral Liquid filling and sealing during power failure more than 10 minutes

4.15.5.1 Switch off the machine



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- 4.15.5.2 Remove all the filled and partial filled bottles from the line discard them.
- 4.15.5.3 Filled and sealed bottles are left for further processing
- 4.15.5.4 After resuming the power switch on the machine and wait for the at least 20 minutes.
- 4.15.5.5 Ensure the environmental condition within the specified limit as per BPR.
- 4.15.5.6 Then proceed for further processing.

4.16 Action to be taken in Oral Liquid Empty Bottle Washing during power failure more than 10 minutes

- 4.16.1 Switch off the machine.
- 4.16.2 Remove all the online bottles meant for washing and keep in poly bags with proper tie lock
- 4.16.3 After resuming the power switch on the machine, wait at least for 20 minutes.
- 4.16.4 Ensure the environmental monitoring within specified limit.
- 4.16.5 Rewash the all previously removed bottle and carry for further processing.

4.17 Action to be taken in water system during power failure for more than 05 minutes:

- 4.17.1 Switch off the "main" of the system.
- 4.17.2 Avoid the use of water during power failure condition.
- 4.17.3 After resumption of power, following activities shall be done.
- 4.17.4 Sanitize /Sterilize the water/ WFI distribution system as per SOP.
- 4.17.5 After sanitization/Sterilization, water sampling shall be done from all user points of the distribution loop.
- 4.17.6 Based on pH and conductivity, allow to use of water for production purposes.

5.0 ANNEXURE (S):

NIL

6.0 REFERENCE (S):

- SOP: Preparation, approval, distribution control, revision and destruction of Standard Operating Procedure.
- SOP: Procedure of filling of equipment log book.
- SOP: Procedure for Stability Programme.



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SOP: Hot Water Sanitization of Purified Water Distribution Loop.

SOP: Sterilization of Water For Injection System.

SOP: Hot Water Sanitization of Purified Water Distribution Loop.

SOP: Procedure for restart /resume the production area activity after power failure/major break down /incidence.

SOP: Procedure of handling product during power failure in production area.

7.0 ABBREVIATION (S) /DEFINITION (S) :

SOP : Standard Operating Procedure

RLAF: Reverse Laminar Air Flow

LAF : Laminar Air Flow

BMR: Batch Manufacturing Record

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
01	00	--	--	New SOP	