PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Procedure for Printout Verification of PLC/HMI/IPC System according to BMR	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

1.1 To lay down a procedure for Printout verification of PLC/HMI/IPC system according to BMR.

2.0 SCOPE:

2.1 This procedure is applicable to Printout verification of PLC/HMI/IPC system located in manufacturing area.

3.0 RESPONSIBILITY:

3.1 Officer and Executive Production: Generation and review of PLC/HMI/IPC system printout

3.2 Head Production : SOP Implementation and compliance

3.3 IPQA : Review of PLC/HMI/IPC system printout

4.0 DEFINITION (S):

4.1 NA

5.0 PROCEDURE:

5.1 All manufacturing equipment shall be operated as per respective operational SOP of individual equipment and specific process printout shall be assured through BMR.

5.2 Before start of batch, officer/executive production and IPQA shall verify recipe printout. In equipment where recipe printout comes after completion of process ensure that the process parameter in loaded recipe shall be as per respective BMR (wherever applicable).

5.3 Officer/Executive production shall generate process printout after completion of cycle/batch (as per suitability of equipment).

5.4 Generated printout shall be attached to respective BMR and Officer/Executive production shall review printouts along with BMR. The generated printout shall be reviewed for correctness and completeness of the process along with legibility of printout.

5.5 Officer/Executive production shall sign on process printout after review the obtained printout followed by IPQA sign on process printout after review.

5.6 During review, if any discrepancy found i.e. minimum CPV data along with all available parameters come in printout shall be verified with BMR and if any out of limit parameter observed in printout, the same shall be handled through SOP (Event Management).

5.7 In case, process printout is not generated after completion of process, then breakdown shall be raised for rectification as per SOP (Procedure For Breakdown Maintenance) and if not rectify the same further action shall be decided on the basis of Head QA decision.

5.8 Following general points to be verified in Recipe and Batch printout of equipment (but not limited to and as applicable)

5.8.1 Product name

5.8.2 Bach size

5.8.3 User name

5.8.4 Recipe no.

5.8.5 Batch no. /Lot no.

5.8.6 Equipment ID

5.8.7 Date/Time

5.8.8 Optimum/Minimum/Maximum set limits against the BMR

5.9 **Alarm Report: -** Generated Alarm report shall be verified for its description Date/Time, user and evaluated for the action taken against the same shall be handled as per SOP (Critical Alarm Control Management).

5.10 **Login - Logout: -** Generated login-logout report shall be verified for the details like Date/ time, login ID, description against the same details available in respective BMR (wherever applicable).

5.11 Following critical process parameters (wherever applicable), but not limited to shall be checked from printouts against the specified parameter in BMR.

5.11.1 Process parameters for Rapid Mixer Granulator (but not limited to)

5.11.1.1 Dry mixing start / end time /Date

5.11.1.2 Binder addition time

5.11.1.3 Addition time of additional Water/IPA etc. quantity used (if required)

5.11.1.4 Impeller speed/ Chopper speed

5.11.1.5Total granulation time

5.11.1.6 Impeller Amperage

5.11.2 Process parameters for Fluid Bed Dryer (but not limited to)

5.11.2.1 Inlet Temperature

5.11.2.2 Outlet Temperature

5.11.2.3 Total Drying Time/ Process time

5.11.3 Process parameters for Extruder cum Spheronizer (but not limited to)

5.11.3.1 Roller speed (RPM)

5.11.3.2 Spheronizer Speed (RPM)

5.11.3.3 Spheronizer time (minute)

5.11.4 Process parameters for Compression Machine (but not limited to)

5.11.4.1 Machine (Turret) speed

5.11.4.2 Feeder speed

5.11.4.3 Hydraulic Pressure/Mean pressure (compaction force)

5.11.4.4 Main compaction force (Average) (Where ever applicable)

5.11.4.5 Critical alarm

5.11.4.6 Batch report

5.11.4.7 Batch start/end time/Date

5.11.5 Process parameters for Coating Machine (but not limited to)

5.11.5.1 Inlet Temperature

5.11.5.2 Bed temperature

5.11.5.3 Atomization pressure

5.11.5.4 Spray Rate

5.11.5.5 Pan speed

5.11.5.6 Pump speed

5.11.5.7 Inlet/Exhaust air velocity (Air Volume) (Where ever applicable)

5.11.6 Process parameters for Capsule Filling Machine (but not limited to)

5.11.6.1 Machine Speed (SPM)

5.11.6.2 Batch start/end time/Date

5.11.7 Process parameters for (Fluid Bed Processor) Drug Loading / Seal Coating / Delayed Released Coating / Polymer Coating / Polyethylene Glycol Coating / Barrier Coating/Drying, etc. (but not limited to)

5.11.7.1 Inlet Temperature

5.11.7.2 Outlet Temperature

5.11.7.3 Product Bed Temperature

5.11.7.4 Inlet air relative humidity / Dew point (Where ever applicable)

5.11.7.5 Spray rate

5.11.7.6 Atomization pressure

5.11.7.7 Pump speed

5.11.7.8 Needle Air pressure

5.11.7.9 Blower Air velocity (CFM / HZ)

5.11.8 Process parameters for Blender (but not limited to)

5.11.8.1 Blender Speed/Blender RPM

5.11.8.2 Date

5.11.8.3 Start / end time

5.11.9 Process parameters for Roll compactor (but not limited to)

5.11.9.1 Horizontal feed screw speed

5.11.9.2 Vertical feed screw speed

5.11.9.3 Roll Gap

5.11.9.4 Roller speed

5.11.9.5 Roller pressure

5.11.9.6 Mill speed (Where ever applicable)

Note: Recipe, Batch detail, Alarm report and login-logout reports shall be generated and verified by Production / IPQA. The same shall be attached to BMR (wherever applicable).

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6.0 ABBREVIATION (S):

6.1 SOP	Standard Operating Procedure
6.2 BMR	Batch Manufacturing Record
6.3 PG	Production
6.4 IPQA	In-process Quality Assurance
6.5 RPM	Rotation per Minute
6.6 SPM	Strokes per minute
6.7 CPV	Continued Process Verification

7.0 REFERENCE (S):

7.1 NIL

8.0 ANNEXURE (S):

8.1 NIL

9.0 DISTRIBUTION:

9.1 Master Copy : Quality Assurance.

9.2 Controlled copy (S) : Production department (01), Quality Assurance (03).

9.3 Reference copy (S) : Production department (03).