



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Status labeling in Production Departments	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down the procedure for status labeling in production departments.

2.0 SCOPE:

This procedure is applicable to labeling of area, equipments, instruments, raw material, packing material, finished goods, disinfectant aids, accessories and containers used in production area.

3.0 RESPONSIBILITY:

Officer /Executive/Assistant Manager

Head Production: To ensure execution & compliance.

Head QA: To ensure the compliance.

4.0 PROCEDURE:

In order to avoid mix-ups and contamination, for easy identification and traceability, of product and to ensure working as per GMP standards it is important to affix status label at each stage of process on equipments, products, containers, accessories, disinfectant aids ,lubricants and areas.

- 4.1 The entire Label should be defaced with a cross-line and destroyed by tearing in to pieces immediately after its use.
- 4.2 Ensure that status label is used to exhibit the process that is being carried out in the area / room as per Annexure-I (Font color of “ AREA/ROOM STATUS LABEL” shall be black).The area is labeled at the startup of the batch.
- 4.3 All in-process materials to be labeled with an appropriate status label as per specimen given in Annexure-II (Font color of “ UNDER PROCESS” shall be black).



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- 4.4 All equipment after cleaning shall bear a status label as per the specimen label shown in Annexure-III (Font color of "CLEANED" shall be WHITE with green band background). After Type B cleaning (Change-over of product with different actives / color / descending potency or after maintenance of contact parts.) the cleaning tags of equipments are to be attached in the BMR/BPR of the next product, and others to be destroyed by tearing in to pieces before affixing the new status label in case of start of the operation, this label has to be removed and 'Under Process' label to be affixed.
- 4.5 All the equipment after Type A (Change over from one batch to next batch of same product /same potency / similar product with ascending potency.) cleaning shall bear a status label as per the specimen label shown in Annexure-IV (Font color of "CLEANED" shall be violet with blue band background). The cleaning tags of equipments are to be attached in the BMR/BPR of the next product and others to be destroyed by tearing in to pieces before affixing the new status label.
- 4.6 Ensure that all the FBD/RMG bags stored in a container shall be individually labeled as per Annexure V (Font color of "FBD/RMG BAG STATUS" shall be white with green band background)
- 4.7 Ensure Status label is used to exhibit the process that is being carried out in the equipment as per Annexure-VI (Font color of "UNDER PROCESS (Equipment)" shall be white with orange band background).
- 4.8 All test equipment / apparatus / instrument used in production area to be labeled with an appropriate calibration status label as per Annexure-VII (Font color of " CALIBRATION STATUS " shall be White with black band background).
- 4.9 All cleaning and disinfectants aids, and Isopropyl Alcohol to be labeled with an appropriate status label as per specimen given in Annexure-VIII (Font color of " CLEANING AID" shall be White with black band background).
- 4.10 All lubricants to be labeled as per specimen label given in Annexure-IX (Font color of " LUBRICANT" shall be White with black band background).



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- 4.11 Ensure the label is displayed for the identification of the status of the equipment, accessories and containers after its use and before to be cleaned as per Annexure-X (Font color of "TO BE CLEANED" shall be white with red band background).
- 4.12 All the punch sets to be labeled on storage in respective drawer/Box as per reference SOP.
- 4.13 Ensure that all bulk in-process materials (Blend / Granules / core tablets / coated tablets and capsule) should bear appropriate Q.A. status label as per SOP.
- 4.14 Ensure Status label is used during cleaning (CIP) as per Annexure-XI (Font color of " UNDER CLEANING" shall be red with yellow band background).
- 4.15 Ensure Status label for Non-Recoverable Rejects, which are meant for destruction as per Annexure XII (Font color of " NON RECOVERABLE REJECTS" shall be white with red band background).
- 4.16 Ensure Status label is used to exhibit on the container of On-Line Rejection, for on line rejection which are meant for destruction as per Annexure XIII (Font color of " ON LINE REJECTION " shall be black with red band background).
- 4.17 Ensure Status label is used for scrap which are meant for destruction as per Annexure XIV (Font color of "SCRAP" shall be white with red band background). .
- 4.18 Ensure Status label is used for material as per Annexure XV (Font color of " MATERIAL LABEL" shall be black).

5.0 ANNEXURE (S):

Annexure-I: (Specimen of AREA/ ROOM STATUS Label).

Annexure-II: (Specimen of UNDER PROCESS Status Label).

Annexure-III: (Specimen of CLEANED Status Label).

Annexure-IV: (Specimen of CLEANED Status Label). (Change over from one batch to next batch of same product/same potency / Similar product with ascending potency).

Annexure-V: (Specimen of FBD /RMG BAG STATUS Label).

Annexure-VI: (Specimen of UNDER PROCESS (EQUIPMENT) Status Label).

Annexure-VII: (Specimen of CALIBRATION STATUS Label).

Annexure-VIII: (Specimen of CLEANING AID Status Label).



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- Annexure-IX: (Specimen of LUBRICANT Status Label).
- Annexure-X: (Specimen of TO BE CLEANED Status Label).
- Annexure-XI: (Specimen of UNDER CLEANING Status Label).
- Annexure-XII: (Specimen of NON RECOVERABLE REJECTS Status Label).
- Annexure-XIII: (Specimen of ON-LINE REJECTION Status Label).
- Annexure-XIV: (Specimen of SCRAP Status Label).
- Annexure-XV :(Specimen of MATERIAL Label).

6.0 REFERENCE (S):

- SOP: Preparation, approval, distribution control, revision and destruction of Standard Operating Procedure (SOP).
- SOP: Handling of status labels.
- SOP: Procedure for procurement, inspection, receipt and destruction of dies and punches.

7.0 ABBREVIATION (S) /DEFINITION (S):

- BMR: Batch Manufacturing Record.
- BPR: Batch Packing Record
- QA : Quality Assurance
- SS : Stainless steel
- ID number : Identification number
- CIP: Clean in Place.

REVISION CARD

S. No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	----	----	New SOP	---