



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

PROTOCOL FOR CERTIFICATION PROGRAM

COMPETENCY AREA: SECONDARY PACKAGING

The signature below indicate Preapproval of this protocol.
Once the signature are obtained, Execution of the Protocol may begin.

CERTIFICATION PROGRAM APPROVAL:

| APPROVED BY | NAME | SIGNATURE | DATE |
|-------------------------------|------|-----------|------|
| DEPT HEAD / DESIGNEE | | | |
| HEAD /DESIGNEE QA/TRAINING | | | |

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1.0 Objective:

The objective of this activity is to provide On Job practical training about the Competency & Evaluate through demonstration by the trainee. After satisfactory completion of on job training certify the trainee for the particular competency.

2.0 Scope:

This Operator Certification Program is applicable to all the operators in Production departments. This program shall be specific to the competencies mentioned in the list.

3.0 Responsibilities:

3.1 Operator Certification Program (OCP)

- 3.1.1 It is the responsibility of Section Head to write and execute this OCP. He shall mention the equipments list on which the operator shall have competency.
- 3.1.2 Provide on job training to the operator.
- 3.1.3 It is the responsibility of Section Head to write a final report that includes a summary of work performed, any exceptions noted during the execution of the protocol, and conclusions derived from the data gathered.
- 3.1.4 Based on the requirement updation of competency list.

3.2 Approval

- 3.2.1 Head of Department / Designee, Head QA / Designee will approve the OCP for execution.
- 3.2.2 It shall be responsibility of Head of Department / Designee & Head of Quality Assurance / Designee to review, approve & certify the competencies.



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4.0 Procedure:

4.1 After completion of reading of all relevant Standard Operating Procedures (SOP's), the operator shall be briefed about the process & the related equipments. The list of equipments & the SOP's shall be as in the Section 5. Reference Documents.

4.2 The operator shall be informed about following activities, but not limited to

- 4.2.1. Cleaning of equipment & change parts
- 4.2.2. Assembling / Setting of equipment
- 4.2.3. Checking / Challenging of Safety Mechanism
- 4.2.4. Checking of the Accessories
- 4.2.5. Setting of the Accessories
- 4.2.6. Setting of Parameters on PLC as applicable
- 4.2.7. Loading , Handling of the material
- 4.2.8. Actual Operation of the machine
- 4.2.9. Checking of the actual parameters & adjustments accordingly
- 4.2.10. Stopping of equipment
- 4.2.11. Checking of In process parameters (as applicable)
- 4.2.12. Recording of the data
- 4.2.13. Environmental Monitoring
- 4.2.14. Rejects Handling
- 4.2.15. Procedures after power failure

4.3 Practical Demonstration:

- 4.3.1 Step by step demonstrate the activities as per the SOP.
- 4.3.2 Manually operate the control switches as applicable.
- 4.3.3 Visually verify and document the actual responses in Operator Evaluation Record.
- 4.3.4 Complete all applicable SOPs required for the listed competency.

4.4 Documentation:

- 4.4.1 The Operator Certification Program shall be numbered as OCP / ABCD / XY
- 4.4.2 OCP – Operator Certification Program, ABCD – Four digit employee code, XY – Serial number, which shall start from 01 till 99. This will about the proficiency of the operator in different areas.



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- 4.4.3 Record all the observations in the On Job Evaluation Form.
- 4.4.4 Fill separate On Job Evaluation Form (Annexure – I) for each competency & record in the attachment.
- 4.4.5 Document any discrepancies in Incidence Log if any Incidences are present.
- 4.4.6 After evaluation make summary report.
- 4.4.7 Provide Certificate after successful completion of listed competencies.

5.0 Competency List & Reference Documents:

Following shall be the list of Competencies required. This list shall be updated based on the training needs after approval from Head of Department & Head of QA.

| S.No. | Competency List / Equipment Name | SOP No. |
|-------|--|---------|
| 1 | UNSCRAMBLING (UNSCRAMBLER MACHINE) | |
| 2 | INDUCTION CAP SEALING (INDUCTION CAP SEALER MACHINE) | |
| 3 | LABELING (LABELING MACHINE) | |
| 4 | OUTSERT APPLICATION (OUTSERT APPLICATOR MACHINE) | |
| 5 | CARTON SEALING (CARTON SEALING MACHINE) | |
| 6 | CARTON PACKING (CARTON PACKING MACHINE) | |
| 7 | SHRINK PACKAGING (SHRINK PACKAGING MACHINE) | |
| 8 | INKJET PRINTING (INKJET PRINTING MACHINE IMAJE) | |
| 9 | INKJET PRINTING (INKJET PRINTING MACHINE IMAJE) | |
| 10 | RETORQUERING (RETORQUER MACHINE) | |



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8.0 Summary Report:

This summary report will be generated on the completion of the respective competencies.

Generate a final summary report on completion of the execution of all competencies. Include a statement of conformance to the specified acceptance criteria.

SUMMARY REPORT

DECLARATION BY THE TRAINEE:

I have undergone practical demonstration of the activities as listed in Section No. 5. I have understood & can perform the activities in accordance to the SOP's and as per regulations laid down from time to time:

1. **Understanding of Activities:** _____
2. **Demonstration of Activities:** _____
3. **In-Process Testing** : _____
4. **Documentation** : _____
5. **Handling of the Rejects** : _____

Trainee (Sign / Date): _____

REMARKS:

EXPERT / SECTION HEAD:

Sign / Date : _____



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9.0 Certificate:



CERTIFICATION

This is to certify Mr. /Ms. _____ has satisfactorily completed the competencies mentioned in the list.

He / she can independently carry out the activities in the following functional area,

_____.

Head of Dept./Designee

Sign / Date

Head /Designee

QA/Training

Sign / Date

