PROTOCOL FOR CERTIFICATION PROGRAM

COMPETENCY AREA: PRIMARY PACKAGING

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

CERTIFICATION PROGRAM PREAPPROVAL:

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

	PHARMA DEVILS
	QUALITY ASSURANCE DEPARTMENT

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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.

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

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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 SOP's 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.

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 Deviation Log if any deviations are present.

4.4.6 After evaluation make summary report.

4.4.7 Provide Certificate after successful completion of listed competencies.

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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	**TABLET/CAPSULE ELEVATION** (TABLET/CAPSULE ELEVATOR)	
2	**DESICCANT INSERTION** (DESICCANT INSERTER)	
3	**COUNTING AND FILLING** (COUNTING AND FILLING MACHINE)	
4	**WEIGHING** (CHECKWEIGHER)	
5	**COTTON INSERTION** (COTTON INSERTER)	
6	**IN-LINE CAPPING** (IN-LINE CAPPING MACHINE)	
7	**CONVEYOR BELT OPERATION** (CONVEYOR BELT)	
8	**BLISTER INSPECTION** (BLISTER INSPECTION SYSTEM)	
9	**BLISTER PACKAGING** (BLISTER PACKAGING MACHINE)	
10	**METAL DETECTION** (METAL DETECTOR)	
11	**TABLET THICKNESS SORTING** (TABLET/CAPSULE INSPECTION MACHINE)	

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6.0   **Materials and other accessories:**

List materials / product name and accessories needed for execution (if applicable)

S.No.	Particulars	Ref. Doc / Batch No.

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7.0 **Incidence Log:**

    7.1.1   All deviations shall be property documented on the Deviation Log.

    7.1.2   All deviation reports and corrective action forms, if necessary, shall be approved prior to final approval of the Certification.

    7.1.3   As the activities are closely monitored by Expert, corrective actions shall be taken immediately.

    7.1.4   Complete attachment with signature and date.

INCIDENCE LOG			
S.No.	**Description**	**Resolved Yes/No**	**Sign & Date**

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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 SOPs 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   *Head/Designee*
                                                       QA/Training
  Sign / Date   *Sign / Date*

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10.0 **Attachment List:**

Write Incidence details & On Job Evaluation Form

S.No.	Title	No. of Pages	Remarks