



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR ONLINE VISUAL  
INSPECTION CONVEYOR**

**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
ONLINE VISUAL INSPECTION  
CONVEYER**

|                               |                     |
|-------------------------------|---------------------|
| <b>EQUIPMENT ID. No.</b>      |                     |
| <b>LOCATION</b>               | <b>Packing Hall</b> |
| <b>DATE OF QUALIFICATION</b>  |                     |
| <b>SUPERSEDE PROTOCOL No.</b> | <b>NIL</b>          |



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**1.0 PROTOCOL PRE – APPROVAL:**

**PREPARED BY:**

| DESIGNATION                              | NAME | SIGNATURE | DATE |
|--|------|-----------|------|
| OFFICER/EXECUTIVE<br>(QUALITY ASSURANCE) |      |           |      |

**REVIEWED BY:**

| DESIGNATION                              | NAME | SIGNATURE | DATE |
|--|------|-----------|------|
| OPERATING MANAGER<br>(QUALITY ASSURANCE) |      |           |      |
| HEAD<br>(ENGINEERING)                    |      |           |      |
| HEAD<br>(PRODUCTION)                     |      |           |      |

**APPROVED BY:**

| DESIGNATION                 | NAME | SIGNATURE | DATE |
|-----------------------------|------|-----------|------|
| HEAD<br>(QUALITY ASSURANCE) |      |           |      |



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**2.0 OBJECTIVE:**

- To verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of online visual inspection conveyer and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

**3.0 SCOPE:**

- The scope of this operational qualification protocol cum report is limited to qualification of online visual inspection conveyer (**Make:** .....) Installed.
- This Protocol cum Report will define the methods and documentation used to perform OQ activity of online visual inspection conveyer.
- Successful completion of this Protocol will verify that online visual inspection conveyer meet all acceptance criteria and ready for Performance Qualification.



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**4.0 RESPONSIBILITY:**

The Validation Group, comprising of a representative from each of the following departments shall be responsible for the overall compliance of this Protocol cum Report:

| <b>DEPARTMENTS</b>       | <b>RESPONSIBILITIES</b>  |
|--------------------------|--|
| <b>Quality Assurance</b> | <ul style="list-style-type: none"><li>• Preparation, Review, Authorization and compilation of the operational Qualification Protocol cum Report.</li><li>• Co-ordination with Production and Engineering to carryout Operational Qualification.</li><li>• Monitoring of Operation Process.</li><li>• Post approval of Operational Qualification Protocol cum Report after execution.</li></ul> |
| <b>Production</b>        | <ul style="list-style-type: none"><li>• Pre Approval of Operational Qualification Protocol cum Report.</li><li>• To Co-ordinate and support for execution of Operational Qualification study as per Protocol.</li><li>• Post Approval of Operational Qualification Protocol cum Report after Execution.</li></ul>  |
| <b>Engineering</b>       | <ul style="list-style-type: none"><li>• Review of Operational Qualification Protocol cum Report.</li><li>• To co-ordinate and support Operational Qualification Activity..</li><li>• Post approval of Operational Qualification Protocol cum Report after execution.</li></ul>   |



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**5.0 EQUIPMENT DETAILS:**

|                                 |                                   |
|---------------------------------|-----------------------------------|
| <b>Equipment Name</b>           | Online Visual Inspection Conveyor |
| <b>Equipment ID.</b>            |                                   |
| <b>Manufacturer's Name</b>      |                                   |
| <b>Machine No.</b>              |                                   |
| <b>Model No.</b>                |                                   |
| <b>Supplier's Name</b>          |                                   |
| <b>Location of Installation</b> | Packing Hall                      |

**6.0 EQUIPEMENT DESCRIPTION:**

The purpose of the **Online Visual Inspection Conveyor 15 Feet (Model: .....)** is to convey & inspect the specific size and shape of IV Bottle at the variable speed according to requirement of feeding to the next unit.

Complete machine can be divided in following sub sections.

**MAIN ASSEMBLY:**

1. Structure of Machine
2. Mechanism of drive unit with selector switch operating panel
3. Conveyor belt and platform
4. Inspection booth with both side black & white radium film



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**7.0 PRE - QUALIFICATION REQUIREMENTS:**

**7.1 Verification of Documents:**

- DQ Protocol cum Report.
- IQ Protocol cum Report.
- Draft SOP for Operation & Cleaning of online visual inspection conveyer .
- Draft SOP for Preventive Maintenance of online visual inspection conveyer .

**7.1.1 Procedure:**

- Verify the above mentioned documents for availability, completeness and approval status.
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the OQ Protocol cum Report.

**7.1.2 Acceptance Criteria:**

All the documents should be available, complete and approved by respective authorities.



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**8.0 CRITICAL VARIABLES TO BE MET:**

**8.1 Verification of documents:**

The results of any tests should meet the limits and acceptance criteria specified in the test documents. Any deviations or issues should be rectified and documented prior to OQ commencing.

| S.No. | DOCUMENT NAME  | COMPLETED (YES/NO) | CHECKED BY (ENGINEERING) SIGN/DATE |
|-------|--|--------------------|------------------------------------|
| 1.    | DQ Protocol cum Report   |                    |                                    |
| 2.    | IQ Protocol cum Report   |                    |                                    |
| 3.    | Draft SOP for Operation & Cleaning of Online Visual Inspection Conveyor.   |                    |                                    |
| 4.    | Draft SOP for Preventive Maintenance of Online Visual Inspection Conveyor. |                    |                                    |

Checked By  
Production  
Sign/Date: .....

Verified By  
Quality Assurance  
Sign/Date: .....

**Inference:**

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Reviewed By  
(Manager QA)  
Sign/Date: .....





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**8.2 Functional Checks:**

| FUNCTIONAL CHECK  | ACCEPTANCE CRITERIA  | OBSERVATIONS | OBSERVED BY<br>(ENGINEERING)<br>SIGN/DATE |
|---|--|--------------|---|
| Main ON/ Key switch.  | To Connect/ disconnect the power supply to the control panel /machine.       |              |   |
| All Function key  | As stated in related operating manual.                                       |              |   |
| Emergency stop push button.   | To stop machine in emergency.  |              |   |
| Turn the Knob for desired speed.  | Speed will Increase / Decrease.  |              |   |
| Power UP after Power failure  | The machine should start smoothly after recovery of Power from power failure |              |   |
| <b>SYSTEM SETTING</b>   |  |              |   |
| System start up is OK   | Should be Satisfactory   |              |   |
| Level of the machine height to be match with next/Previous operation machine height.          | Should be Satisfactory   |              |   |
| Synchronized the conveyor speed as per other machines speed if it will be in continuous line. | Should be Satisfactory   |              |   |
| Synchronized the machine speed from variable port.  | Should be Satisfactory   |              |   |
| Reduce the speed of the machine to zero.  | Should be Satisfactory   |              |   |
| Switch OFF the tubelight.   | Should be Satisfactory   |              |   |
| Switch OFF the selector switch.   | Should be Satisfactory   |              |   |
| Switch OFF Main Control.  | Should be Satisfactory   |              |   |



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| <b>FUNCTIONAL CHECK</b>     | <b>ACCEPTANCE CRITERIA</b> | <b>OBSERVATIONS</b> | <b>OBSERVED BY<br/>(ENGINEERING)<br/>SIGN/DATE</b> |
|-----------------------------|----------------------------|---------------------|--|
| Speed of the conveyor belt. | Should be Satisfactory     |                     |  |
| Required data input in VFD. | Should be Satisfactory     |                     |  |

**Checked By**  
**Production**  
**Sign/Date:** .....

**Verified By**  
**Quality Assurance**  
**Sign/Date:** .....

**Inference:**

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**Manager QA**  
**Sign/Date:** .....



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**8.3 Safety Features, Alarms & Interlock:** The equipment shall be provided with safety features as listed below.

| TEST   | ACCEPTANCE CRITERIA  | OBSERVATION | OBSERVED BY (ENGINEERING) SIGN/DATE |
|--|--|-------------|-------------------------------------|
| Emergency Stop   | Machine should stop after pressing emergency stop button             |             |                                     |
| Main On/Off Switch:  | Machine should start / stop after pressing main on/off switch button |             |                                     |
| Speed Control<br>(Set the speed of machine through variable pot. | Machine should run with same speed after setting a fix speed         |             |                                     |

**Checked By**  
**Production**  
**Sign/Date:** .....

**Verified By**  
**Quality Assurance**  
**Sign/Date:** .....

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**Manager QA**  
**Sign/Date:** .....



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**8.4 Emergency Operation Verification:**

| ITEM  | ACCEPTANCE CRITERIA                | OBSERVATION | OBSERVED BY (ENGINEERING) (SIGN/DATE) |
|---|------------------------------------|-------------|---------------------------------------|
| <b>ON/OFF Push button</b> <ul style="list-style-type: none"><li>• Press Stop Push Button</li><li>• Release ON Push Button</li></ul> | Equipment should Stop              |             |                                       |
|   | Equipment should Start             |             |                                       |
| <b>With the OFF button Pressed in, Try to cause movement of an Operating function.</b>  | The Equipment will be inoperative. |             |                                       |

**Checked By**  
**Production**  
**Sign/Date:** .....

**Verified By**  
**Quality Assurance**  
**Sign/Date:**.....

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**Manager QA**  
**Sign/Date:**.....



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**8.5 Power Failure Verification:**

| ITEM                                | ACCEPTANCE CRITERIA   | OBSERVATION | OBSERVED BY (ENGINEERING) SIGN/DATE |
|-------------------------------------|---|-------------|-------------------------------------|
| <b>Power up after power Failure</b> | Machine should not start automatically with power.  |             |                                     |
| <b>Main Power Restored</b>          | Equipment can be restarted with no problems or adverse conditions by Pressing start button. |             |                                     |
| <b>Timer Check</b>                  | Time during Process should hold same as on power lost.                                      |             |                                     |

**Checked By  
Production  
Sign/Date: .....**

**Verified By  
Quality Assurance  
Sign/Date: .....**

**Inference:**

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**Reviewed By  
Manager QA  
Sign/Date:.....**



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**9.0 REFERENCES:**

**The Principle Reference is the following:**

- Validation Master Plan.
- Schedule - M – “Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products.”
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2. Good Manufacturing Practices and Inspection.

**10.0 DOCUMENTS TO BE ATTACHED:**

- Operation and Maintenance Manual.
- Any other Relevant Documents.

**11.0 DEVIATION FROM PREDEFINED SPECIFICATION, IF ANY:**

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**12.0 CHANGE CONTROL, IF ANY:**

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**13.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY ):**

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**14.0 CONCLUSION:**

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**15.0 RECOMMENDATION:**

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**16.0 ABBREVIATIONS:**

- cGMP : Current Good Manufacturing Practices
- DQ : Design Qualification
- HP : Horse Power
- ID. : Identification
- IQ : Installation Qualification
- mm : Millimetre
- No. : Number
- OQ : Operational Qualification
- SOP : Standard Operating Procedure
- WHO : World Health Organization



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**17.0 PROTOCOL POST- APPROVAL:**

**PREPARED BY:**

| DESIGNATION                              | NAME | SIGNATURE | DATE |
|--|------|-----------|------|
| OFFICER/EXECUTIVE<br>(QUALITY ASSURANCE) |      |           |      |

**REVIEWED BY:**

| DESIGNATION                              | NAME | SIGNATURE | DATE |
|--|------|-----------|------|
| OPERATING MANAGER<br>(QUALITY ASSURANCE) |      |           |      |
| HEAD<br>(ENGINEERING)                    |      |           |      |
| HEAD<br>(PRODUCTION)                     |      |           |      |

**APPROVED BY:**

| DESIGNATION                 | NAME | SIGNATURE | DATE |
|-----------------------------|------|-----------|------|
| HEAD<br>(QUALITY ASSURANCE) |      |           |      |