OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR LEAK CHECK MACHINE

EQUIPMENT ID. No.	
LOCATION	**Packing Area**
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR LEAK CHECK MACHINE

CONTENTS

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR LEAK CHECK MACHINE

1.0 PRE – APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR LEAK CHECK MACHINE

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 Leak Check Machine 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 **Leak Check Machine (Make: ……..)** installed in the **Packing Area**.
- This Protocol cum Report will define the methods and documentation used to perform OQ activity of Leak Check Machine.
- Successful completion of this Protocol will verify that Leak Check Machine meet all acceptance criteria and ready for Performance Qualification.

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:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review, Authorized and compilation of the operational Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Operational Qualification. • Monitoring of Operation Process. • Post Approval of Operational Qualification Protocol cum Report after Execution.
Production	• Review of Operational Qualification Protocol cum Report. • To Co-ordinate and support for execution of Operational Qualification study as per Protocol. • Post Approval of Operational Qualification Protocol cum Report after Execution.
Engineering	• Review of Operational Qualification Protocol cum Report. • To co-ordinate and support Operational Qualification Activity. • Calibration of Process Instruments. • Post Approval of Operational Qualification Protocol cum Report after Execution.

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR LEAK CHECK MACHINE

5.0 EQUIPMENT DETAILS:

Equipment Name	Leak Check Machine
Equipment	
Manufacturer's Name	
Model	
Sr. No.	
Supplier's Name	
Location of Installation	Packing Area

6.0 EQUIPEMENT DESCRIPTION:

Leak Check Machine is designed to check the leakage from specified size and diameter of IV bottles by fix speed and conveying of bottles for next operation.

Complete machine can be divided in following sub sections.

- Structure of machine
- Mechanism of drive unit with DOL starter.
- Slat conveyor.
- Nylon wheel & star plate, Pressure rod.

7.0 PRE - QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- DQ Protocol cum Report.
- IQ Protocol cum Report.

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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.

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR LEAK CHECK MACHINE

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 (Sign / date)
1.	DQ Protocol cum Report		
2.	IQ Protocol cum Report		
3.	SOP for Handling of Leak Tester Apparatus		

Checked By
(Production)
Sign/Date: ……

Verified By
Quality Assurance)
Sign/Date:……

Inference:

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

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR LEAK CHECK MACHINE

8.2 Test Equipment Calibration:

Verify that all critical instruments associated with the system are in a calibrated state. Review the calibration status for the test equipment to be utilised and record the calibration due dates in the table below. All Equipment/Instrumentation must remain within the calibration due date for the duration of OQ test for which the item is used. If a due date potentially occurs during the testing period then the instrument must be recalibrated before it can be utilised.

Equipment/ Instruments Name	Equipment/Instrument I.D.	Calibration On	Due On

Checked By
(Production)
Sign/Date: ……

Verified By
Quality Assurance)
Sign/Date:……

Inference:

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……

……..

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

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR LEAK CHECK MACHINE

8.3 Operational and Functional Checks:

Operate the Leak Check Machine as per Manufacturer's Manual/SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

Component	Acceptance Criteria	Observation (Complies /Non Complies)	Observed By (Engineering) Sign/Date
Pressure Gauge	For measuring pressure level		
Power supply	To be supplied as per demand		
Electrical circuit diagrams	Should be as per diagram		
Level of machine	Should be perfect as sprit level		

Checked By
(Production)
Sign/Date: ……

Verified By
Quality Assurance)
Sign/Date:……

Inference:

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

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR LEAK CHECK MACHINE

8.4 Power Failure Verification:

Item	Acceptance Criteria	Observation (Complies /Non Complies)	Observed By (Engineering) Sign/Date
Main Power Shut Down	Equipment stops in a safe and secure condition.		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions.		

Checked By
(Production)
Sign/Date: ……

Verified By
Quality Assurance)
Sign/Date:……

Inference:

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

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR LEAK CHECK MACHINE

8.5 Operation Verification:

Item	Acceptance Criteria	Observation (Complies /Non Complies)	Observed By (Engineering) (Sign/Date)
ON/OFF Push button • Press Stop Push Button • Press Start Push Button	Equipment should Stop		
	Equipment should Start		
With the OFF Push Button Pressed in, in Try to cause movement of an Operating function.	The Equipment will be inoperative.		

Checked By
(Production)
Sign/Date: ……

Verified By
Quality Assurance)
Sign/Date:……

Inference:

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……..

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

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR LEAK CHECK MACHINE

8.6 Challenge Test: 14 Nos Leakage Bottle Consider as Challenge Bottle**.** Leak Test Should be Performed pre Leakage Bottle for Three Time as Per Desired Pressure.

Test	Time		Pressure	Observation	Observed By (Engineering) (Sign/Date)
	From	To			
Acceptance Criteria: All Challenge Bottle Should be get shrink after Performing Leak Test.					

Checked By
(Production)
Sign/Date: ……

Verified By
Quality Assurance)
Sign/Date:……

Inference:

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

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.
- Copy of Draft SOP's.
- Any other Relevant Documents.

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR LEAK CHECK MACHINE

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
ID.	:	Identification
LTA	:	Leak Check Machine
Ltd.	:	Limited
MOC	:	Material of Construction
NLT	:	Not Less Than
No.	:	Number
OQ	:	Operational Qualification
Pvt.	:	Private
SS	:	Stainless Steel
WHO	:	World Health Organization

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR LEAK CHECK MACHINE

17.0 POST APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			