PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

OPERATIONAL QUALIFICATION FOR INDUCTION CAP SEALING MACHINE

OPERATIONAL QUALIFICATION FOR INDUCTION CAP SEALING MACHINE

1.0 PROTOCOL APPROVAL:

Signing of this approval page of Protocol indicates agreement with the qualification approach described in this document. If modification to the qualification approach becomes necessary, an addendum shall be prepared and approved. The protocol cannot be used for execution unless approved by the following authorities.

This Operation Qualification protocol of Induction Cap Sealing Machine has been reviewed and approved by the following Persons :

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
PREPARED BY			QUALITY ASSURANCE		
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		

OPERATIONAL QUALIFICATION FOR INDUCTION CAP SEALING MACHINE

2.0 OVERVIEW:

2.1 OBJECTIVE:

The objective of the operational qualification is to prove that each operation proceeds as per design specification and the tolerances prescribed there in the document are the same at utmost transparency.

The Qualification of Induction Cap Sealing Machine performed in view of Dry Syrup of production cepha oral manufacturing facility.

2.2 PURPOSE:

The purpose of this protocol is to establish the documentary evidence to ensure that the installed Induction Cap Sealing Machine shall operate reproducibly and consistently within its full dynamic range of operation according to manufacturer's specification.

2.3 SCOPE:

The Scope of this protocol is limited to the Operational Qualification of Induction Cap Sealing Machine, installed in Dry Syrup of Production Cepha Oral manufacturing facility.

Once the Operational qualification of Induction Cap Sealing Machine has been completed successfully, the equipment shall be preceded for the Performance qualification procedure.

2.4 RESPONSIBILITY:

In accordance with protocol, following functions shall be responsible for the qualification of system.

Execution Team (Comprising members from Production, Engineering and Quality Assurance) and their responsibilities are following:

- Prepares the qualification protocol.
- Ensures that the protocol is in compliance with current policies and procedures on system Qualification.
- Distributes the finalized protocol for review and approval signatures.
- Execution of Qualification protocol.
- Review of protocol, the completed qualification data package, and the final report.
- The operational checks, calibration, SOP verification, verification of safety features, verification of utility supply shall be carried out by engineering persons and

production person.

- The production operator / supervisor shall carry out the cleaning and operation of machine.

Head – Production/ Engineering:

- Review of protocol, the completed qualification data package, and the final report.
- Assist in the resolution of validation deficiencies.

Head – Operation and Quality Assurance:

- Review and approval of protocol, the completed qualification data package, and the final report.

2.5 EXECUTION TEAM:

The satisfactory operation of the Induction Cap Sealing Machine shall be verified by executing the qualification studies described in this protocol .The successfully executed protocol documents that the Induction Cap Sealing Machine is operational and is satisfactorily working.

Execution team is responsible for the execution of operation of Induction Cap Sealing Machine. All executors involved with this protocol shall sign within the prescribed format given below.

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE

3.0 ACCEPTANCE CRITERIA:

3.1 The equipment shall be operational as per its specified operating instructions

3.2 All SOP's for the equipment to be verified and checked

3.3 Training shall be given to all the concerned personnel

3.4 All the functionality of equipment components to be checked

3.5 The RPM of motor should be in the range of ± 5%.

4.0 REQUALIFICATION CRITERIA:

The Induction Cap Sealing Machine shall be requalified if

- There are any major changes in system components which affect the performance of the system
- After major breakdown maintenance is carried out.
- As per revalidation date and schedule

OPERATIONAL QUALIFICATION FOR INDUCTION CAP SEALING MACHINE

5.0 OPERATIONAL QUALIFICATION PROCEDURE:

5.1 SYSTEM DESCRIPTION:

1	Equipment Name	:	Induction Cap Sealing Machine
2	Supplier/Manufacturer	:	Electronic Device Worldwide Pvt. Ltd.
3	Model	:	SIGMA -II ACE
4	Serial no.	:	…….
5	Sealing Capacity	:	120 Bottle Per Minute
6	Dimension	:	650 mm (D) X 650 mm (W) X 1685 mm (H)
7	Location	:	Dry Syrup-2

5.1.1 Brief process description:

Induction Cap Sealing Machine is specially designed for post filling .an Induction seal in inserted into the cap either manually or by a wad fitting equipment.

The container is filled and capped in a standard operation and then passed beneath the sealing coil through a conveyor.

After removing the cap, the foil remains bonded to the lip of the container is retained in the retaining ring provided in the head space of the cap & the backing board.

5.1.2 EQUIPMENT DESCRIPTION:

The purpose of the Induction Cap Sealing Machine is to provide tamper evidence, prevent the ingress of moisture and oxygen and avoid leakages. Proper sealing can be achieved by selecting caps, induction wads & containers having proper fit & compatibility.

Complete machine can be divided in following sub sections

- Generator
- ED-Vantage system consisting various sensors & rejection arms
- Conveyor fitted with variable speed drive

5.2 INSTRUCTION FOR FILLING THE CHECKLIST

5.2.1 Write down the actual observation in observation column as per design specification

5.2.2 Observation functional parameter should be write actual function in specified column.

5.2.3 Give the detailed information in the summary and conclusion part of the Operational Qualification report.

5.2.4 Whichever column is blank or not used 'NA' shall be used.

5.3 TEST INSTRUMENT DETAILS

This test is intended to describe the equipments / instruments and its complete details to have a traceability to the national standard which is to be used for the verification of the operation of the Induction Cap Sealing Machine.

S.No.	Name Of Instrument	Inst. ID. Number	Calibration done on	Calibration Due date	Certificate Number

Checked by Date:

Remark: ----------

Reviewed by (Sign/Date)

OPERATIONAL QUALIFICATION FOR INDUCTION CAP SEALING MACHINE

5.4 Verification of Calibrated component :

This test is intended to describe the equipments/instruments and its complete details to have a traceability to the national standard, which is to be used for the verification of the operation of the Induction Cap Sealing Machine.

S.No.	Name of Instrument	Inst. ID. Number	Calibration done on	Calibration valid up to	Certificate number

Checked by Date:

Remark: ----------

Reviewed by (Sign/Date)

5.5 VERIFICATION OF FUNCTIONAL CHECKS:

Name of system component	Procedure	Acceptance Criteria	Observation	Checked By Sign/Date
Verification of Operational Functionality Checks:				
Main menu Run menu	This screen displays whenever power is ON. This is called as a run menu. Press INCREMENT switch to increase the power %.Press DECREMENT switch to decrease the power &.Pass the bottle through the system to check the production count. pass the bottle without foil to check the rejection count.	When power is ON menu will display. When INCREMENT switch pressed power % will increase, when DECREMENT switch pressed power % will be decreased. If a bottle passes through the system the production count will increase .If bottle without foil passes through the system rejection count will increase.		

OPERATIONAL QUALIFICATION FOR INDUCTION CAP SEALING MACHINE

Name of system component	Procedure	Acceptance Criteria	Observation	Checked By Sign/Date
Basic System Set up	Press the MENU key at RUN MENU to enter this menu .This menu is used to view the TOTAL BOTTLES and RESET VARIABLES.	Operator will see this screen when he press the MENU key once at Run menu.		
Total Bottles	Press the sub MENU key once at the Basic system set up screen.	The screen will show total bottles passed through the system. The value is 000000-999999., this value cannot be changed only RESET.		
Reset Counters	Allows the operator to reset the production, rejection, total bottles count, the number of consecutive faults and number of excess faults that have occurred.	If the INCREMENT or DECREMENT switch is pressed on this sub menu, the counters are reset to ZERO		

OPERATIONAL QUALIFICATION FOR INDUCTION CAP SEALING MACHINE

Name of system component	Procedure	Acceptance Criteria	Observation	Checked By Sign/Date
Timer Fault	Pressing the MENU KEY from any of the BASIC SYSTEM SETUP menus enters the TIMER FAULT SETUP menu	Used to change the JAMM TIME and POWER SAVE SETTINGS.		
JAMM TIMER	Allows the operator to Display /Enter the JAMM TIMER 1-20 (in seconds).This value is used to determine how to long ,in seconds ,the counter and jam detector can see a bottle .If the time expires before the bottle moves away from the counter or jam detector ,a BOTTLE JAMMED AT FNT /END will be displayed.	If the INCREMENT switch is pressed on this sub -menu, the JAM TIME will increment in steps of 1 sec. If the DECREMENT switch is pressed on this sub-menu, the JAMM TIME will decrement in steps of 1 sec.		

OPERATIONAL QUALIFICATION FOR INDUCTION CAP SEALING MACHINE

Name of system component	Procedure	Acceptance Criteria	Observation	Checked By Sign/Date
Power save set up	The purpose of this feature is to throttle down the power of the machine when no bottles are coming down the conveyor. The number of seconds set can be between 01-255 seconds. If a bottle is not detected for this set amount of time then the machine is powered down to save energy .when a bottle is sensed by the bottle jam sensor the machine is powered on again.	If the INCREMENT switch is pressed on this sub -menu, the value will increment by 1 sec. If the DECREMENT switch is pressed on this sub-menu ,the value will decrement by 1 sec.		
Run Test:				
Run the machine in empty	There should not be any effect	There should not be any abnormal effect		
Power Failure & Restoration Test:				
Main power restored	Equipment will be restarted	Equipment can be restarted with NO problems or adverse conditions.		

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

OPERATIONAL QUALIFICATION FOR INDUCTION CAP SEALING MACHINE

Name of system component	Procedure	Acceptance Criteria	Observation	Checked By Sign/Date
Main power Shut Down	Equipment will stops	Equipment stops in a safe and secure condition		
Configurable parameters before shut down	Parameter will shows: Power percentage, production count, rejection count	Parameter shows: Power percentage, production count, rejection count		
Configurable parameters after Power on	Parameter will shows: Power percentage, production count, rejection count	Parameter shows: Power percentage, production count, rejection count		
Verification of sealed bottles (conducting drop test)				
Sealed bottles	Turn panel MCB to ON position. Place filled and capped bottles with induction seals on the conveyor .After sealing wait for 3 mins. Drop the filled ,capped & sealed bottle from the height of 1.5mtrs.Uncap the sealed bottle.	The leakage should not occur the filled and sealed bottle		
Verification of Alarms list :				

OPERATIONAL QUALIFICATION FOR INDUCTION CAP SEALING MACHINE

Name of system component	Procedure	Acceptance Criteria	Observation	Checked By Sign/Date
Emergency	Run machine and press emergency switch	Machine should stop immediately Alarm should generated with Buzzer and Message EMERGENCY PRESSED		
High Temperature	Remove wire No. 15 & 16 from thermal switch	High temperature error will be generated on the LCD screen and sealing will stop.		
Bottle jammed at FNT	Put obstacle in between the transmitter and the receiver of the bottle jammed sensor	"Bottle jammed at FNT" error will be generated on the LCD screen and the sealing will stop .		
Bottle jammed at END	Put obstacle in between the transmitter and the receiver of the bottle counting sensor	"Bottle jammed at END" error will be generated on the LCD screen and the sealing will stop .		

OPERATIONAL QUALIFICATION FOR INDUCTION CAP SEALING MACHINE

Name of system component	Procedure	Acceptance Criteria	Observation	Checked By Sign/Date
Verification of sensor:				
Bottle Jamming	Put some obstacle to the block flow of bottles running on the conveyor	If the Jamn Timer setting time expires BOTTLE JAMMED AT FNT / END will be displayed		
Bottle counter	Send capped bottle with foil inside the cap through the system	Production count and the number of Total Bottles will increase		
No foil Detector	Send bottle without foil inside the cap through the system	The detector will sense the foil,if foil is not there it will send the signal to the system and rejection system will reject that bottle		

Remark: ----------

Reviewed by (Sign/Date)

OPERATIONAL QUALIFICATION FOR INDUCTION CAP SEALING MACHINE

5.6 VERIFICATION OF SAFETY FEATURES :

Safety Features Description	Method of Verification	Acceptance Criteria	Observation	Verified By Sign/Date
Emergency Stop Button	In operation of machine, press the emergency stop button	Machine shall stop & EMERGENCY STOP OPERATE shall be displayed		
Earthing	Run machine and check with multimeter/ clamp meter at the body cover of the machine.	No current should be sensed over whole body		

Remark: ----------

Reviewed by (Sign/Date)

5.7 VERIFICATION OF SUPPORTING UTILITIES:

S.No.	Utility	Method Of Verification	Observation	Checked By Sign/Date
1.	**Electrical Power Supply:** 1 phase, 240V , 50Hz supply with neutral and proper earthing	Physically with clamp meter		
2.	**Compressed Air:** 6 bar	Physically with pressure gauge		

Remark: ----------

Reviewed by (Sign/Date)

5.8 VERIFICATION OF STANDARD OPERATING PROCEDURE (SOP)

The following Standard Operating Procedures were verified as important for effective performance of Induction Cap Sealing Machine.

S.No.	SOP TITLE	SOP NUMBER	VERIFIED BY	DATE

Remark: ----------

Reviewed by (Sign/Date)

5.9 TRAINING RECORD OF PERSONNEL (S) :

S.No.	Name of Personnel	Designation	Sign & Date	Trained By	Remark

Remark: ----------

Reviewed by (Sign/Date)

5.10 DEFICIENCY AND CORRECTIVE ACTION (S) REPORT (S):

Following deficiency was verified and corrective actions taken in consultation with the Engineering Department.

Description of deficiency:
Corrective action(s) taken:

Deviation accepted by
(Sign/Date)

Deviation Approved by
(Sign/Date)

5.11 Annexure (S):

Annexure No.	Details Of Annexure

Remarks (if any)**:**

Done By & Date: **Verified By & Date:**

6.0 OPERATIONAL QUALIFICATION FINAL REPORT:

6.1 SUMMARY:

6.2 CONCLUSION:

Prepared By
Sign/ Date

Checked By
Sign/ Date

6.3 FINAL REPORT APPROVAL

It has been verified that all tests required by this protocol are completed, reconciled and attached to this protocol or included in the qualification summary report. Verified that all amendments and discrepancies are documented, approved and attached to this protocol (If applicable). Signature in the block below indicates that all items in this qualification report of Induction Cap Sealing Machine have been reviewed and found to be acceptable and that all variations or discrepancies (If applicable) have been satisfactorily resolved. After the successful operational qualification of the Induction Cap Sealing Machine, the equipment can be taken for performance qualification.

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		