INSTALLATION QUALIFICATION FOR INDUCTION CAP SEALING MACHINE

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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 Installation 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		

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2.0 OVERVIEW:

2.1 OBJECTIVE:

The objective of developing and executing this protocol is to collect sufficient data pertaining to the Induction Cap Sealing Machine and define the installation qualification requirements and acceptance criteria for the Induction Cap Sealing Machine. Successful completion of these installation qualification requirements will provide assurance that the Induction Cap Sealing Machine was installed as required in the manufacturing area.

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 documentary evidence to ensure that the Induction Cap Sealing Machine system received matches the Design specification and also to ensure that it is properly and safely installed.

2.3 SCOPE:

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

Once the installation qualification of Induction Cap Sealing Machine has been completed successfully, the equipment shall be preceded for the operational 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.

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- The installation checks, operational checks, calibration, SOP identification, identification features, identification of utility supply shall be carried out by engineering persons
- 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 installation 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 installed satisfactorily.

Execution team is responsible for the execution of installation of Induction Cap Sealing Machine .Execution team comprises of:

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE

3.0 ACCEPTANCE CRITERIA:

3.1 The Induction Cap Sealing Machine shall meet the system description given in design qualification.

3.2 The Induction Cap Sealing Machine shall meet with the acceptance criteria mentioned under the topic “Identification of major components”

3.3 The safety feature of machine should be in place

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

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5.0 INSTALLATION 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 In case of identification of major component actual observation should be written in specified location.

5.2.2 In case of the compliance of the test actual observation should be written in specified location.

5.2.3 For identification of utilities actual observation should be written in specified location.

5.2.4 Give the detailed information in the summary and conclusion part of the installation Qualification report.

5.2.5 Actual observation of the component should be written in specified location.

5.2.6 Whichever column is blank or not used ‘NA’ shall be used.

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5.3 INSTALLATION CHECKLIST:

Installation checklist is as follows:

S.No.	Statement	Method Of Verification	Actual Observation	Checked By Sign/Date
1	Verify purchase order copy and write down P.O. number	Physically		
2	Verify that there is no observable physical damage	Physically		
3	Examine All access ports are cleared of any debris.	Physically		
4	Verify that all components are properly assembled, securely anchored and shock proof.	Physically		
5	Verify that all electrical connections are properly done and safe	Physically		
6	Verify that the equipment is properly earthed	Physically		
7	Verify that utility line is properly connected	Physically		
8	Verify the proper leveling of equipment	Physically		
9	Verify that there is sufficient space provided for operation, cleaning, preventive maintenance	Physically		
10	Equipment/system identification no. is visible	Physically		

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

Reviewed by (Sign/Date)

5.4 IDENTIFICATION OF MAJOR COMPONENTS:

Describe each critical component and check them and fill the inspection checklist.

System Components	Design Specification		Method of Verification	Actual Observation	Checked By Sign/Date
Equipment Description	Name	Induction cap sealing m/c	Physically		
	Make	Electronic devices	Physically		
	Model	SIGMA-II ACE	Physically		
	Sr. No.	To be recorded	Physically		
	Bottle dia range	20 mm to 70 mm	Physically / Technical Specification		
	Surface Finish	Matt finish	Physically / Technical Specification		
Conveyor Motor	Make	Bonfiglioli	Physically		
	Spec.	0.25 HP / 1320 RPM	Physically/ Technical Specification		
	Sr. No.	To be recorded	Physically		
Conveyor variable frequency drive	Make	DELTA -L	Physically		
	Spec.	0.2 Kw,230 V, Single phase,	Physically/ Test Certificate		
	Sr. No.	To be recorded	Physically		
Conveyor Gear Box	Make	Bonfiglioli	Physically		
	Ratio	60:1	Physically/ Technical Specification		

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System Components	Design Specification		Method of Verification	Actual Observation	Checked By Sign/Date
MCB	Make	Merlin Jerin - 16A	Physically/ Technical Specification		
Side Motion Bearings	Make	LIC Japan	Physically/ Technical Specification		
	Model	FBJ 5302Z	Physically/ Technical Specification		
Conveyor Bearings	Make	KHK	Physically/ Technical Specification		
	Type	UCF-205	Physically/ Technical Specification		
Cooling fan	Make	SUNON	Physically/ Technical Specification		
	Type	A2175-HBL	Physically/ Technical Specification		
	Spec.	230V,50 /60 HZ,0.25 /0.22 A	Physically/ Technical Specification		
Instruments					
Bottle JAM Sensor	Make	Panasonic	Physically/ Technical Specification		
	Model	EX14	Physically/ Technical Specification		

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System Components	Design Specification		Method of Verification	Actual Observation	Checked By Sign/Date
No cap sensor	Make	Pepperl +Fuchs	Physically/ Technical Specification		
	Model	EX13	Physically/ Technical Specification		

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

Reviewed by (Sign/Date)

5.5 VERIFICATION OF MATERIAL OF CONSTRUCTION:

Name of Components	Material of Construction	Method of Verification	Observation	Verified By Sign/Date
Body structure	SS 304	By Molybdenum Kit/ Test Certificate		
Side panels	SS 304	By Molybdenum Kit/ Test Certificate		
Conveyor frame	SS 304	By Molybdenum Kit/ Test Certificate		
Conveyor side plates	SS 304	By Molybdenum Kit/ Test Certificate		
Drive shaft	SS 304	By Molybdenum Kit/ Test Certificate		

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

Reviewed by (Sign/Date)

5.6 IDENTIFICATION OF SUPPORTING UTILITIES:

S.No.	Utility	Method Of Verification	Observation	Checked By Sign/Date
1.	**Electrical Power Supply:** 1 phase, 240 V, 50Hz / 60 Hz supply with neutral and proper earthing	Physically with clamp meter		

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

Reviewed by (Sign/Date)

5.7 IDENTIFICATION OF SAFETY FEATURES:

Identify and record the safety/interlocking features (if any) and their function in following tables:

Safety Features Description	Location/Identification	Method of Verification	Observation	Identified By Sign/Date
Earthing	Equipment connected with earthing induction cap sealing machine	Physically		
Jam sensor	If Excesses bottle on the conveyor machine shall be trip with alarm	Physically		

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

Reviewed by (Sign/Date)

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5.8 IDENTIFICATION OF COMPONENT TO BE CALIBRATED

Name of Components	Range	Make	Location	Identified By Sign/Date

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

Reviewed by (Sign/Date)

5.9 IDENTIFICATION OF STANDARD OPERATING PROCEDURE (SOP)

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

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S.No.	SOP Title	Verified By Sign/ Date

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

Reviewed by (Sign/Date)

5.10 VERIFICATION OF DRAWING AND DOCUMENTS:

Following documents are reviewed and attached as listed below:

S.No.	Drawing And Document Detail	Verified By Sign/Date

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

Reviewed by (Sign/Date)

5.11 ABBREVIATIONS

Following Abbreviations are used in the installation qualification protocol of Induction Cap Sealing Machine.

MOC: Material of construction

Spec.: Specification

V: Voltage

Hz: Hertz

A: Ampere

SS: Stainless Steel

RPM: Rotation per minute

HP: Horse Power

NA: Not Applicable

VFD : Variable Frequency Drive

5.12 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 by:(Sign/Date)

Deviation Approved (Sign/Date)

5.13 Annexure (S)

Annexure No.	Details Of Annexure

Remarks (if any)**:**

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

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6.0 INSTALLATION 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. 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 installation qualification of the Induction Cap Sealing Machine, the equipment can be taken for operational qualification.

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