



Electronics Devices

Client: **M/s. Alkem Laboratories Limited**

Supplier/ Manufacturer: **Electronics Devices, Mumbai**

Item / Job name: **Online Induction Cap Sealing Machine**

Sr. No.:124/11-12

Equipment code: (assigned by client)

Doc No:..... (assigned by client)

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DESIGN QUALIFICATION (DQ)

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Original Document:

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DESIGN QUALIFICATION (DQ)

1.0 OBJECTIVE:

To design, engineer, manufacture and supply the Online Induction Cap Sealing Machine (Model: as per GMP and GEP guidelines and to provide assurance that the machine is manufactured as per the URS and it complies with the Scope of Supply.

To prove that each operation proceeds as per the design specification and the tolerances prescribed there in the document, are the same at utmost transparency. Validation procedure is set for complete satisfaction of the customer & building confidence of the user about the machine.

2.0 SCOPE:

The scope of this qualification document is limited to the Design Qualification of Online Induction Cap Sealer Model: Sigma-III PLUS for the **Alkem Laboratories Limited** This qualification document is part of a validation activity for the Online Induction Cap Sealer Model: Sigma-III PLUS

Qualification of support utilities is not within the scope of this qualification document.

The equipment shall be used to perform sealing of filled & capped bottles. The equipment shall operate under dust free environment and conditions as per the GMP requirements.

3.0 RESPONSIBILITIES:

CLIENT:

1. To provide the URS for the equipment.
2. To perform the Factory Acceptance Test (FAT).

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MANUFACTURER:

1. To design, engineer, manufacture and provide the complete technical details of the equipment pertaining to its design qualification viz.
 - (i) Machine overview,
 - (ii) Equipment orientation with layout,
 - (iii) Specifications of the sub-components/ bought out items, and their make, model & quantity, and backup records/ brochures,
 - (iv) Details of Utilities,
 - (v) Identification of components for calibration
 - (vi) Material of construction of all components,
 - (vii) Brief process description
 - (viii) Pre-installation requirements,
2. To facilitate the client for the Factory acceptance test of the machine at their works/ site.
3. To confirm the safe delivery of the equipment to the user site.
4. To ensure that no un-authorized and / or unrecorded design modifications shall take place. If at any point in time, any change is desired in the mutually agreed design, Change control procedure shall be followed and documented.
5. To ensure the proper installation and commissioning of the equipment.

4.0 USER REQUIREMENTS SPECIFICATION (URS):

DESCRIPTION	SPECIFICATIONS
Equipment	Online Induction Cap Sealing Machine
Specification	Output -1 KW, Operating: 1 phase, 230 V, 50 Hz
Capacity	120 BPM
Model	Sigma – III PLUS
Process	Equipment should be able to perform induction foil sealing on plastic bottles having plastic caps efficiently.

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DESCRIPTION	SPECIFICATIONS
Calibration	NA
Qualifications/ Documentation	<ul style="list-style-type: none"> The manufacturer shall provide the complete documents pertaining to Design, Installation & Operation Qualification and detail functional specifications including control system. Information on purchased/bought-out parts. Circuits & interlocks details.
Safety features	<ul style="list-style-type: none"> Adequate safety features for men and material shall be provided along with the equipment.

5.0 MACHINE DESCRIPTION:

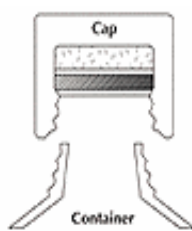
5.1 Process Description

1



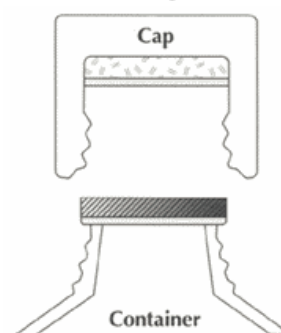
Post Filling, an Induction Seal is inserted into the cap either manually or by a wad fitting equipment

2



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

3



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

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5.2 Equipment Description

The purpose of the induction cap sealer 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 arm.
- Conveyor fitted with variable speed drive. (optional)

For Mobility of the machine, it is mounted on the PU coated nylon castor wheels.

6.0 TECHNICAL SPECIFICATIONS:

6.1 Machine Details

Name of the Machine	Induction Cap sealing Machine
Model	Model Sigma III PLUS
Capacity	1KW
Bottle Dia ranging from	20mm-70mm
M O C	S S 304

7.0 Technical Specification of Accessories

7.1 Accessories

Sensors	Proximity & Inductive
Sealing Capacity	120 BPM
Heating Coil	Material Used: Fiber Glass, Inductor, Epoxy

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7.2 Switch Gear

Fuses 3.15 A - Slow Blow (ISD)

MCB Merlin Jerin - 16A

7.3 Machine Dimensions

Width 660 mm

Depth 615 mm

Height 1920 mm

8.0 Utility Required

Electrical Connection - 3 Pin Connection 230V

Single Phase

50 Hz

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9.0 IDENTIFICATION OF COMPONENT FOR CALIBRATION

Induction cap sealing machine, Sigma -III PLUS doesn't have any critical measuring instruments to be calibrated

10. EQUIPMENT ORIENTATION:

Approval status: APPROVED/ NOT APPROVED

Any change in the approved orientation layout: Yes/ No.

If yes, the reason for change

.....
.....
.....

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11.0 FAT PROCEDURE:

Factory Acceptance Test Procedure shall be as follows:

After the completion of erection work of the machine, client shall be informed to perform the factory acceptance test (FAT).

Client shall perform the FAT at the manufacturer site and record all the data in the prescribed FAT document as per the details given below:

1. Test criteria
2. Design Verification Check list
3. Deficiency & Corrective Action report
4. Pre-installation requirements
5. Final report

12.0 CHANGE CONTROL PROCEDURE:

Change in the agreed design shall be addressed through the well-defined Change control procedure.

13.0 DESIGN QUALIFICATION REPORT APPROVAL

13.1 Summary:

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13.2 Certification:

14.0 APPENDIX

14.1 LIST OF ABBREVIATIONS

cGMP	current Good Manufacturing Practices
GEP	Good Engineering Practices
P.C.D.	Pitch Circle Diameter
NFLP	Non Flame Proof
S.S.	Stainless Steel
M.O.C.	Material Of Construction
KW	Kilo Watt
HP	Horse Power
DQ	Design Qualification
FAT	Factory acceptance test

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14.2 REFERENCE DOCUMENTS

1. Manufactures Brochure (s) / Manual (s). (Title and Location).

To be supplied with the Installation qualification documents

1. Instruction & Operating manual.

2. Details of Bought Out Items

2. Purchase Order Details:

P.O. No : 4530002596 dated 20-01-2012

Remarks (if any) :

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