



## Electronics Devices

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

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

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

Sr. No.:124/11-12

Equipment code: \_\_\_\_\_ (to be assigned by client)

Doc No: \_\_\_\_\_ (to be assigned by client)

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### INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

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#### Original Document :

Submitted by : ( **Electronics Devices.**) Date: \_\_\_\_\_

Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

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### INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

#### 1.0 OBJECTIVE:

To prove that each operation proceeds as per the design specification as 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.

The objectives of the validation program are:

1. To provide record of the key features of the equipment and components as currently installed
2. To ensure that there is sufficient information available to enable the equipment to be operated and maintained safely, effectively and consistently.
3. To ensure equipment as installed
  - a) Meets the customer's specifications & requirements.
  - b) Complies with the Good Manufacturing Practices.
4. To test the operational aspects of the Electronics Devices, Induction Cap Sealing Machine, Model: Sigma – , at customers facility that are considered critical for satisfactory performance.
5. To compare the results obtained with approved specification and customers requirements.

#### 2.0 SCOPE:

The scope of this qualification protocol is limited to the Installation and Operational Qualification of the Electronics Devices, Induction Cap Sealing Machine, Model: Sigma - III PLUS, at **M/s. Alkem Laboratories Limited**.

This qualification protocol is part of a validation activity for the Electronics Devices, Induction Cap Sealing Machine, Model: Sigma - III PLUS

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### INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

#### **IQ/OQ**

The validation will include the Operational Qualification of the Electronics Devices, Induction Cap Sealing Machine, Model: Sigma - III PLUS once the Installation Qualification of the equipment has been completed. Qualification activities will include the equipment and associated utilities.

#### **3.0 RESPONSIBILITIES:**

##### **CLIENT:**

1. To perform the Factory Acceptance test (FAT).
2. To perform the Site Acceptance test (SAT)

##### **MANUFACTURER:**

1. Machine overview
2. Installation Qualification Tests
3. Operational Qualification Tests

#### **Original Document :**

Submitted by : ( **Electronics Devices.**) Date: \_\_\_\_\_

Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

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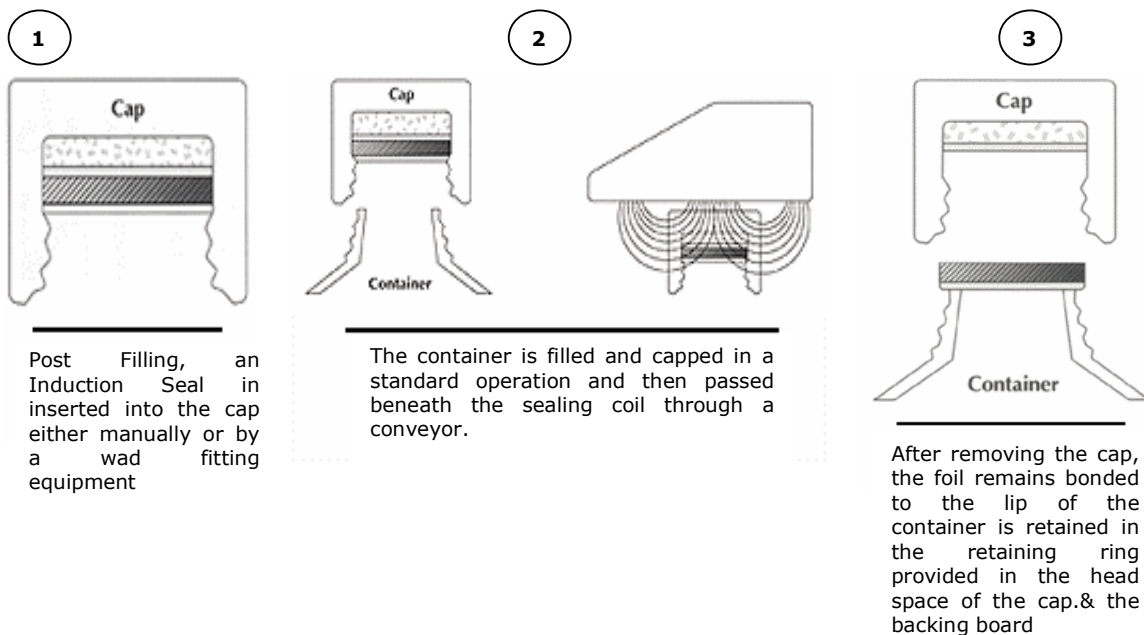
Sr. No.:124/11-12

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## INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

### 4.0 MACHINE DESCRIPTION:

#### 4.1 Process Description



#### 4.2 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)

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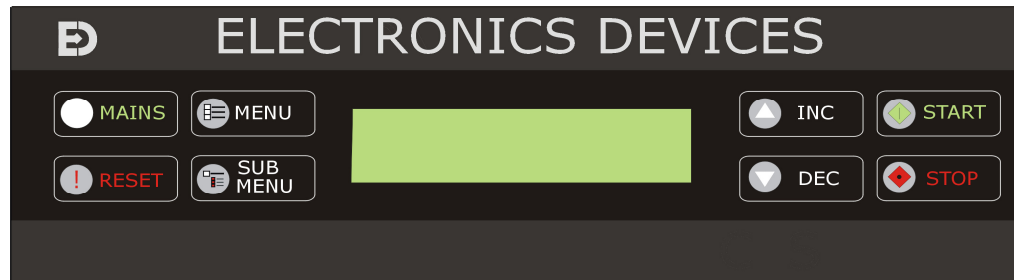
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### INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

#### 4.3 Main Control Panel Description

### MAIN CONTROL PANEL



SWITCH	DESCRIPTION
	<p><b>Start Switch</b></p> <p>This switch is used to start the heating process. When HEATING is ON, power percentage will be indicated on the LCD SCREEN. If the Induction Cap Sealer is in <i>FAULT MODE</i>, the co-responding <i>FAULT MESSAGE</i> will be displayed on the LCD SCREEN and heating will not be turned on even if this button is pressed.</p>

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Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

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### INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

#### Stop Switch



This switch is used to stop the heating process when heating is on. As HEATING is turned OFF the power percentage and current readings will be indicated as '0' on the LCD SCREEN. If the Induction Cap Sealer is in *FAULT MODE*, the corresponding *FAULT MESSAGE* will be displayed on the LCD SCREEN.

#### Reset Switch



This switch is used to *reset* any critical fault alarm after it has been attended to. When pressed, the LCD SCREEN will display a reset message and return back to the VIEW STATISTICS SCREEN, if the critical fault does not persist. If there is no critical fault then pressing this button has no effect on the operation of the machine.

#### Menu Switch



This switch is used to navigate through different main menus of the system. When this switch is pressed the LCD SCREEN will show the next MAIN MENU. After the last MAIN MENU if this switch is pressed it will wrap around to the first MAIN MENU.

#### Sub Menu Switch



This switch is used to navigate through different sub-menus of each main menu. When this switch is pressed the LCD SCREEN will show the next SUB MENU of the current MAIN MENU. After the last SUB MENU of the current MAIN MENU, if this switch is pressed it will wrap around to the first SUB-MENU.

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## INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)



### Increment Switch

This switch is used to increment the value of various parameters.



### Decrement Switch

This switch is used to decrement the value of various parameters.



### Mains On Led

This is a green LED used to indicate the presence of supply to the control card. When SIGMA-II is turned ON, this LED will glow.

## 5.0 VALIDATION REQUIREMENTS:

### 5.1 IQ Requirements for Online Induction Cap Sealer

The following requirement / practices apply to Electronics Devices, Induction Cap Sealing Machine, Model: Sigma - III PLUS , IQ activities:

- Verify that systems are installed in accordance with approved engineering drawings and documents, which shall include the following (as applicable).
- Isometric drawings, electrical & mechanical drawings.
- Equipment and Installation specification; and
- Vendor drawings and equipment manuals
- Verify that the equipment and instrumentation are clearly described as per vendor, model, capacity, materials of construction and any critical criteria.
- All the critical process instrumentation will be calibrated according to the appropriate SOPs before the Operational Qualification has started.
- Confirm that the Electronics Devices, Induction Cap Sealing Machine, Model: Sigma II is installed properly and that the documentation is available.

#### Original Document :

Submitted by : ( **Electronics Devices.**) Date: \_\_\_\_\_

Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

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### INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

#### 5.2 OQ Requirements for Online Induction Cap Sealer.

The following requirement / practices apply to all OQ activities:

Verify that the Electronics Devices, Induction Cap Sealing Machine, Model: Sigma - III PLUS perform and operate in accordance with the client specification and requirements.

Verify that critical instrumentation is calibrated against a traceable standard according to approved procedures.

Review the preventive maintenance program and procedures to ensure that they are comprehensive and support continued, reliable performance of the equipment.

Verify that operating personnel are trained on the SOPs before being permitted to work on the equipment.

#### Original Document :

Submitted by : ( **Electronics Devices.**) Date: \_\_\_\_\_

Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

#### Revision control (if any):

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### INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

#### 6.0 QUALIFICATION TEST SHEETS:

The Installation tests are specified according to the Validation Master Plan for Electronics Devices, Induction Cap Sealing Machine, Model: Sigma - III PLUS. The following is specified for each test (as applicable)

- Test number
- Rationale or purpose for test
- Test equipment to be used (if applicable)
- Procedure
- Acceptance criteria
- Results or data to be recorded
- Comments / Conclusions
- Reviewed by
- Clarification certificate verification (if applicable)

#### Original Document :

Submitted by : ( **Electronics Devices.**) Date: \_\_\_\_\_

Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

#### Revision control (if any):

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### INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

#### 7.0 INSTALLATION QUALIFICATION TESTS:

The table below lists the tests to be performed as part of the Installation Qualification phase.

TEST NUMBER	CRITICAL FEATURE
7.1	Documents & Drawings Verification
7.2	Verification of Technical Specification for In-House & sub-components / bought out items
7.3	Utilities Verification
7.4	Critical instrument Calibration Verification
7.5	Material of construction verification

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### INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

#### 7.0 Installation Qualification Test: (Continued)

##### 7.1 Documents & Drawings Verification

###### 7.1.1 Rationale –

To verify that the documentation provides complete and correct technical references and permits servicing of the units.

###### 7.1.2 Test equipment –

None Required.

###### 7.1.3 Procedure –

1. Verify that the required documents and drawings listed in the tables below are available.
2. Review the documents and drawings for completeness and exactness with the installed units.  
  
- Sign and date all copies of the drawings once verification is completed.
3. Attach the copies of the drawings to this protocol or reference the location from where they can be easily retrieved.
4. Any items in the installation, which are not conforming to the corresponding drawings, must be commented on in the appropriate space. List the non-conformances and the reasons for them in an attachment if necessary.

#### 7.0 Installation Qualification Test: (Continued)

###### 7.1.4 Acceptance Criteria –

1. The documents must be accurate and complete.
2. The drawing information must correspond to the physical installation.

#### Original Document :

Submitted by : ( **Electronics Devices.**) Date: \_\_\_\_\_

Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

#### Revision control (if any):

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Checked by/ date \_\_\_\_\_

Approved by/ date \_\_\_\_\_



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### INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

#### 7.1.5 Documentation Verification Results.

Title	Document Number	Reference & Rev. Date	Location	Initial / Date mm/dd/yy	
Installation, Maintenance and Operation Manual					
Acceptance criteria Met? (Yes / No)					

#### 7.0 Installation Qualification Test: (Continued)

Test # 7.1 - Conclusions / Comments:

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PASS

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FAIL

Verified By: \_\_\_\_\_

Date: \_\_\_\_\_

Reviewed By: \_\_\_\_\_

Date: \_\_\_\_\_

#### Original Document :

Submitted by : ( **Electronics Devices.**) Date: \_\_\_\_\_

Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

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Checked by/ date

Approved by/ date



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### INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

#### 7.0 Installation Qualification Test: (Continued)

##### 7.2 Verification of Technical Specification for In-House & sub-components / Bought out items

###### 7.2.1 Purpose

To verify that each major component of the Electronics Devices, Induction Cap Sealing Machine, Model: Sigma - III PLUS are present and identified.

###### 7.2.2 Test Equipment

None Required

###### 7.2.3 Procedure

1. Confirm that identification nameplates have been applied to the units and that these indicate the following (where applicable).
  - Capacity
  - Sr. No
  - Manufacturer
  - Model Number
2. Confirm that the various components of Electronics Devices, Induction Cap Sealing Machine, Model: Sigma - III PLUS are present as per specifications and drawings, in the proper number and configuration.
3. Record the method of verification (i.e. purchase order, equipment drawing, manual, packing slip, etc.)
4. Note any deviations or discrepancies and recommend follow up action If required.

###### 7.2.4 Acceptance Criteria

All units and parts specified in design qualification and on latest revision of drawings must be present, documented and tagged.

#### Original Document :

Submitted by : ( **Electronics Devices.**) Date: \_\_\_\_\_

Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

#### Revision control (if any):

Date : \_\_\_\_\_ Rev. No \_\_\_\_\_

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### INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

#### 7.2.5 Electronics Devices, Induction Cap Sealing Machine, Model: Sigma – II Major Component Result

Description	Specification	Meets Spec. (Yes/No )	Verification Source	Initials	Date
<b>1 Equipment Description</b>					
Name	Online Induction Cap Sealer				
Capacity	1 Kw				
Model	Sigma - III PLUS				
Weight	Machine - 110 Kg				
Surface Finish	Matt Finish				

#### Original Document :

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### INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

#### 7.0 Installation Qualification Test: (Continued)

#### 7.2.5 Electronics Devices, Induction Cap Sealing Machine, Model: Sigma - II, Major Components Results (Continued)

Description	Specification	Meets Spec. (Yes/No)	Verification Source	Initials	Date
<b>7.2 Slide Motion Bearings</b>					
Make	LIC Japan				
Model	FBJ 5302Z				

#### Original Document :

Submitted by : ( **Electronics Devices.**) Date: \_\_\_\_\_

Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

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### INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

#### 7.0 Installation Qualification Test: (Continued)

Test # 7.2 - Conclusions / Comments:

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PASS



FAIL

Verified By: \_\_\_\_\_

Date: \_\_\_\_\_

Reviewed By: \_\_\_\_\_

Date: \_\_\_\_\_

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### INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

#### 7.0 Installation Qualification Test: (Continued)

#### 7.3 Utilities Verification

##### 7.3.1 Rationale –

To verify that all necessary utilities are correctly installed.

##### 7.3.2 Test equipment –

Calibrated digital multi-meter

##### 7.3.3 Procedure –

1 Confirm that utilities connections are configured as per specification and in compliance with local codes.

2 Record the results in the table below. Note any deviations or discrepancies.

##### 7.3.4 Acceptance Criteria

1. All services and connections must be installed and documented.

##### 7.3.5 Utilities Specification Results

Description	Specified	Measured Results	Meets. Spec. (Yes/No)	Initial / Date mm/dd/yy	
Electrical	Phase: 1 Phase				
	Voltage: 230 V				
	Frequency: 50Hz				

#### Original Document :

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Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

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### INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

#### 7.0 Installation Qualification Test: (Continued)

Test # 7.3 - Conclusions / Comments:

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PASS

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FAIL

Verified By: \_\_\_\_\_

Date: \_\_\_\_\_

Reviewed By: \_\_\_\_\_

Date: \_\_\_\_\_

#### Original Document :

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### **INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)**

#### **7.0 Installation Qualification Test: (Continued)**

#### **7.4 Critical Instrument Calibration Verification - (NA)**

##### **7.4.1 Rationale –**

To verify that all critical instruments if any for the Electronics Devices, Online Induction Cap sealer- Model, Sigma-III PLUS has been calibrated before starting the Operational Qualification.

##### **7.4.2 Test equipment –**

None.

##### **7.4.3 Procedure –**

1. Verify that all critical instruments are calibrated using an approved procedure, against a traceable standard.
2. Note any deviations or discrepancies and recommend follow up actions if required.
3. For all critical instruments, attach copies of calibration certificates to this protocol.

##### **7.4.4 Acceptance Criteria**

1. All critical instrumentation for the Electronics Devices, Online Induction Cap sealer- Model, Sigma-III PLUS, shall be in a state of calibration.

#### **Original Document :**

Submitted by : ( **Electronics Devices.**) Date: \_\_\_\_\_

Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

#### **Revision control (if any):**

Date : \_\_\_\_\_ Rev. No \_\_\_\_\_

Description :

Checked by/ date \_\_\_\_\_

Approved by/ date \_\_\_\_\_



## Electronics Devices

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

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

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

Sr. No.:124/11-12

Equipment code: \_\_\_\_\_ (to be assigned by client)

Doc No: \_\_\_\_\_ (to be assigned by client)

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### INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

#### 7.4 Critical Instrument Calibration Verification (Continued)

7.4.5 Instrumentation List Results (NA)

#### 7.4 Installation Qualification Test: (Continued)

Test # 7.4 - Conclusions / Comments:

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PASS



FAIL

Verified By: \_\_\_\_\_

Date: \_\_\_\_\_

Reviewed By: \_\_\_\_\_

Date: \_\_\_\_\_

#### Original Document :

Submitted by : ( **Electronics Devices.**) Date: \_\_\_\_\_

Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

#### Revision control (if any):

Date : \_\_\_\_\_ Rev. No \_\_\_\_\_

Description :

Checked by/ date \_\_\_\_\_

Approved by/ date \_\_\_\_\_



## Electronics Devices

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

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

Sr. No.:124/11-12

Equipment code: \_\_\_\_\_ (to be assigned by client)

Doc No: \_\_\_\_\_ (to be assigned by client)

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### INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

#### 7.0 Installation Qualification Test: (Continued)

#### 7.5 Material of Construction Verification

##### 7.5.1 Rationale –

To verify that all assembly of the Electronics Devices, Online Induction Cap sealer- Model, Sigma-III PLUS has been manufactured in Stainless Steel 304 Grade as per the specification provided by the customer.

##### 7.5.2 Test equipment –

Moly testing unit (To identify 304 materials)

##### 7.5.3 Procedure –

1. Put a drop of Molybdenum solution on the material to be tested.
2. Take battery & keep anode at one end of the material and cathode at Moly drop.
3. If the solution turns pink and stays for around one minute, then it is SS316

##### 7.5.4 Acceptance Criteria

1. All material of construction for the Electronics Devices, Online Induction Cap sealer- Model, Sigma-II shall meet the MOC provided in Design Qualification.

#### 7.5 Material of Construction Verification (Continued)

##### 7.5.5 Material of Construction verification Results

Description	Specification	Meets Spec. (Yes/No)	Verification Source	Initials	Date
Body structure, Side Panels, Conveyor frame, Conveyor Side Plates, Drive Shaft	SS 304				

#### Original Document :

Submitted by : ( **Electronics Devices.**) Date: \_\_\_\_\_

Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

#### Revision control (if any):

Date : \_\_\_\_\_ Rev. No \_\_\_\_\_

Description :

Checked by/ date \_\_\_\_\_

Approved by/ date \_\_\_\_\_



## Electronics Devices

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

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

Sr. No.:124/11-12

Equipment code: \_\_\_\_\_ (to be assigned by client)

Doc No: \_\_\_\_\_ (to be assigned by client)

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### INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

#### 7.0 Installation Qualification Test: (Continued)

Test # 7.5 - Conclusions / Comments:

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PASS



FAIL

Verified By: \_\_\_\_\_

Date: \_\_\_\_\_

Reviewed By: \_\_\_\_\_

Date: \_\_\_\_\_

#### Original Document :

Submitted by : ( **Electronics Devices.**) Date: \_\_\_\_\_

Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

#### Revision control (if any):

Date : \_\_\_\_\_ Rev. No \_\_\_\_\_

Description :

Checked by/ date \_\_\_\_\_

Approved by/ date \_\_\_\_\_



## Electronics Devices

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

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Sr. No.:124/11-12

Equipment code: \_\_\_\_\_ (to be assigned by client)

Doc No: \_\_\_\_\_ (to be assigned by client)

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### INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

#### 7.0 Installation Qualification Test:

#### 7.6 Installation Qualification Tests Status

The table below lists the tests performed and related results.

Test Number	Critical Feature	Pass / Fail		Deviation Found	
		Pass	Fail	Yes	No
7.1	Documents & Drawings Verification				
7.2	Verification of Technical Specification for In-House & Sub-contract / bought out items.				
7.3	Utilities Verification				
7.4	Critical Instrument Calibration Verification				
7.5	Material of Construction Verification				

Description	Yes	No	Initials Date
All critical test/verification have been performed and acceptance criteria and/or major deviation completed before starting Operational Qualification.			

#### Original Document :

Submitted by : ( **Electronics Devices.**) Date: \_\_\_\_\_

Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

#### Revision control (if any):

Date : \_\_\_\_\_ Rev. No \_\_\_\_\_

Description :

Checked by/ date \_\_\_\_\_

Approved by/ date \_\_\_\_\_



## Electronics Devices

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

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

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

Sr. No.:124/11-12

Equipment code: \_\_\_\_\_ (to be assigned by client)

Doc No: \_\_\_\_\_ (to be assigned by client)

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### INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

#### 7.0 Installation Qualification Test:

Test # 7.6 - Conclusions / Comments:

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PASS



FAIL

Verified By: \_\_\_\_\_

Date: \_\_\_\_\_

Reviewed By: \_\_\_\_\_

Date: \_\_\_\_\_

#### Original Document :

Submitted by : ( **Electronics Devices.**) Date: \_\_\_\_\_

Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

#### Revision control (if any):

Date : \_\_\_\_\_ Rev. No \_\_\_\_\_

Description :

Checked by/ date \_\_\_\_\_

Approved by/ date \_\_\_\_\_





## Electronics Devices

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

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Equipment code: \_\_\_\_\_ (to be assigned by client)

Doc No: \_\_\_\_\_ (to be assigned by client)

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### INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

#### 8.0 Operational Qualification Tests

The table below lists the tests to be performed as part of the Operational Qualification phase.

TEST NUMBER	CRITICAL FEATURE
8.1	Testing of sealed bottles
8.2	Testing of Screens And Settings
8.3	Testing of Sensors.
8.4	Verification of Alarms
8.56	Power and Communication Failure Recovery

#### 8.0 Operational Qualification Test (Continued)

##### 8.1 Testing of Sealed bottles

###### 8.1.1 Rationale -

To verify the normal operation of induction cap sealer by sealing bottles and then conducting Drop test

###### 8.1.2 Test Equipment -

None required.

###### 8.1.3 Procedure -

1. Turn panel MCB to ON position
2. Place filled and capped bottles with induction seals on the conveyor
3. After sealing wait for 3 mins.
4. Drop the filled, capped & sealed bottle from the height of 1.5 mtrs
5. Uncap the sealed bottle.

#### Original Document :

Submitted by : ( **Electronics Devices.**) Date: \_\_\_\_\_

Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

#### Revision control (if any):

Date : \_\_\_\_\_ Rev. No \_\_\_\_\_

Description :

Checked by/ date \_\_\_\_\_

Approved by/ date \_\_\_\_\_



## Electronics Devices

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

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

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

Sr. No.:124/11-12

Equipment code: \_\_\_\_\_ (to be assigned by client)

Doc No: \_\_\_\_\_ (to be assigned by client)

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### INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

#### 8.1.4 Acceptance Criteria -

The leakage should not occur after dropping the filled and sealed bottle.

#### 8.1 Testing of sealed bottle

Test # 8.1 - Conclusions / Comments:

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PASS



FAIL

Verified By: \_\_\_\_\_ Date: \_\_\_\_\_

Reviewed By: \_\_\_\_\_ Date: \_\_\_\_\_

#### Original Document :

Submitted by : ( **Electronics Devices.**) Date: \_\_\_\_\_

Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

#### Revision control (if any):

Date : \_\_\_\_\_ Rev. No \_\_\_\_\_

Description :

Checked by/ date \_\_\_\_\_

Approved by/ date \_\_\_\_\_



## Electronics Devices

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

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

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

Sr. No.:124/11-12

Equipment code: \_\_\_\_\_ (to be assigned by client)

Doc No: \_\_\_\_\_ (to be assigned by client)

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### **INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)**

#### **8.0 Operational Qualification Test (Continued)**

##### **8.2 Verification of Screens & Settings**

###### **8.2.1 Rationale -**

To verify that the screen and settings displaying according to the system requirements.

###### **8.2.2 Test Required -**

Following procedure should be followed:

###### **8.2.3 Procedure -**

1. Access the screen & settings and verify that all of the functions on each of the screens listed below confirm to the Manual.
2. Record the results for each verification on test data sheets.

###### **8.2.4 Acceptance Criteria -**

The system shall operate as per design specification.

#### **Original Document :**

Submitted by : ( **Electronics Devices.**) Date: \_\_\_\_\_

Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

#### **Revision control (if any):**

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Description :

Checked by/ date \_\_\_\_\_

Approved by/ date \_\_\_\_\_



# Electronics Devices

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

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

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

Sr. No.:124/11-12

Equipment code: \_\_\_\_\_ (to be assigned by client)

Doc No: \_\_\_\_\_ (to be assigned by client)

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## INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

### 8.2 Testing of Screens and Settings (Continued)

#### 8.2.5 Verification results -

Stimulate	Procedure	Expected Result	Meet Test (Yes / No)	Initial / Date mm/dd/y
<b>Main Menu - Run Menu</b>				
Power=xx% Prod=xx Rejt=xx	This screen displays whenever power is ON. This is called as a run menu. Press <i>INCREMENT</i> switch to increase the power%. Press <i>DECREMENT</i> 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 run menu will display. When <i>INCREMENT</i> switch pressed power % will increase., when <i>DECREMENT</i> switch pressed power % will be decreased. If a bottle passes through the system the <i>production</i> count will increase. If bottle without foil passes through the system <i>rejection</i> count will increase.		
<b>Main Menu - Basic System Setup</b>				
Basic System Setup	Press the MENU key at the 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		
<b>Sub Menu - Total Bottles</b>				
Total Bottles	Press the sub MENU key once at the Basic system setup screen.	The screen will show total bottles passed through the system. The value is 000000-999999; this value cannot be changed only RESET.		
<b>Sub Menu - Reset Counters</b>				
Reset Counters	Allows the operator to reset the production, rejection, total bottles count, the number of consecutive faults and number of excess faults	If the <i>INCREMENT</i> or <i>DECREMENT</i> switch is pressed on this sub menu, the counters are reset to ZERO.		

#### Original Document :

Submitted by : ( **Electronics Devices.**) Date: \_\_\_\_\_

Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

#### Revision control (if any):

Date : \_\_\_\_\_ Rev. No \_\_\_\_\_

Description :

Checked by/ date \_\_\_\_\_

Approved by/ date \_\_\_\_\_



# Electronics Devices

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

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

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

Sr. No.:124/11-12

Equipment code: \_\_\_\_\_ (to be assigned by client)

Doc No: \_\_\_\_\_ (to be assigned by client)

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## INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

	that have occurred.			
<b>Main Menu - Timer Fault</b>				
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.		
<b>Sub Menu - Jamm Timer</b>				
Jamm Timer	Allows the operator to Display/Enter the JAMM TIMER 00.00 - 19.99 (in seconds). This value is used to determine how long, in seconds, the counter and jamm detector can see a bottle. If the time expires before the bottle moves away from the counter or jamm detector, a BOTTLE JAMMED AT FNT/END will be displayed.	If the <i>INCREMENT</i> switch is pressed on this sub-menu, the JAMM TIME will increment in steps of 1 Sec. If the <i>DECREMENT</i> switch is pressed on this sub-menu, the JAMM TIME will decrement in steps of 1 Sec.		
<b>Sub Menu - Power Save Setup</b>				
Power Save Setup	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 - 30 sec. 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 <i>INCREMENT</i> switch is pressed on this sub-menu, the value will increment by 1 sec. If the <i>DECREMENT</i> switch is pressed on this sub-menu, the value will decrement by 1 sec.		

### Original Document :

Submitted by : ( **Electronics Devices.**) Date: \_\_\_\_\_

Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

### Revision control (if any):

Date : \_\_\_\_\_ Rev. No \_\_\_\_\_

Description :

Checked by/ date \_\_\_\_\_

Approved by/ date \_\_\_\_\_



## Electronics Devices

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

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

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

Sr. No.:124/11-12

Equipment code: \_\_\_\_\_ (to be assigned by client)

Doc No: \_\_\_\_\_ (to be assigned by client)

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### INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

#### 8.2 Testing of Screens & Settings

Test # 8.2 - Conclusions / Comments:

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PASS



FAIL

Verified By: \_\_\_\_\_

Date: \_\_\_\_\_

Reviewed By: \_\_\_\_\_

Date: \_\_\_\_\_

#### 8.0 Operational Qualification Test (Continued)

##### 8.3 Testing of Sensors

8.3.1 Rationale -

To verify the sensors as per their function

8.3.2 Test equipment -

None required.

#### Original Document :

Submitted by : ( **Electronics Devices.**) Date: \_\_\_\_\_

Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

#### Revision control (if any):

Date : \_\_\_\_\_ Rev. No \_\_\_\_\_

Description :

\_\_\_\_\_

Checked by/ date \_\_\_\_\_

Approved by/ date \_\_\_\_\_



## Electronics Devices

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

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

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

Sr. No.:124/11-12

Equipment code: \_\_\_\_\_ (to be assigned by client)

Doc No: \_\_\_\_\_ (to be assigned by client)

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### **INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)**

#### 8.3.3 Procedure -

Adjust the sensors as per shown in manual and reset the counters.

### **8.3 Testing of Sensors (Continued)**

#### 8.3.4 Results: Testing of Sensors

<b>Sensor Verification</b>					
Simulation	Procedure	Excepted Result	Actual Result as Expected? (Yes / No)	Initial / Date mm/dd/yy	
Bottle Jamming	Put some obstacle to the block flow of bottles running on the conveyor.	If the Jamm 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			

#### **Original Document :**

Submitted by : ( **Electronics Devices.**) Date: \_\_\_\_\_

Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

#### **Revision control (if any):**

Date : \_\_\_\_\_ Rev. No \_\_\_\_\_

Description :

Checked by/ date \_\_\_\_\_

Approved by/ date \_\_\_\_\_



## Electronics Devices

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

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

Sr. No.:124/11-12

Equipment code: \_\_\_\_\_ (to be assigned by client)

Doc No: \_\_\_\_\_ (to be assigned by client)

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### INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

#### 8.3 Testing of Sensors (continued)

Test # 8.3 - Conclusions / Comments:

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PASS

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FAIL

Verified By: \_\_\_\_\_

Date: \_\_\_\_\_

Reviewed By: \_\_\_\_\_

Date: \_\_\_\_\_

#### 8.0 Operational Qualification Test (Continued)

##### 8.4 Verification of Alarms.

8.4.1 Rationale -

To verify alarms function and respond according to the system design.

##### Original Document :

Submitted by : ( **Electronics Devices.**) Date: \_\_\_\_\_

Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

##### Revision control (if any):

Date : \_\_\_\_\_ Rev. No \_\_\_\_\_

Description :

\_\_\_\_\_

Checked by/ date

Approved by/ date





## Electronics Devices

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

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

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

Sr. No.:124/11-12

Equipment code: \_\_\_\_\_ (to be assigned by client)

Doc No: \_\_\_\_\_ (to be assigned by client)

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### **INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)**

#### 8.4.2 Test equipment -

None Required.

#### 8.4.3 Procedure -

1. Place the equipment into normal operation mode.
2. Trigger each alarm outline in the table below.
3. Verify that the specified alarm response is obtained and the correct alarm is displayed on the LCD Screen.
4. Once the alarm has been activated, resolve the problem and reset.
5. Verify that the equipment returns to normal operation mode.

#### 8.4.4 Acceptance criteria -

The alarms function and respond according to the system design.

#### **Original Document :**

Submitted by : ( **Electronics Devices.**) Date: \_\_\_\_\_

Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

#### **Revision control (if any):**

Date : \_\_\_\_\_ Rev. No \_\_\_\_\_

Description :

Checked by/ date \_\_\_\_\_

Approved by/ date \_\_\_\_\_



## Electronics Devices

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

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

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Equipment code: \_\_\_\_\_ (to be assigned by client)

Doc No: \_\_\_\_\_ (to be assigned by client)

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### INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

#### 8.5 Verification of Alarms. (Continued)

##### 8.5.5 Results: Verification of Alarms

###### Alarm Verification

Simulation	Procedure	Excepted Result	Actual Result as Expected? (Yes / No)	Initial / Date mm/dd/yy
Low Flow	Cut off water supply to the equipment	"Low flow" error message will be generated on the LCD screen and sealing will stop.		
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.		

#### Original Document :

Submitted by : ( **Electronics Devices.**) Date: \_\_\_\_\_

Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

#### Revision control (if any):

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Description :

Checked by/ date \_\_\_\_\_

Approved by/ date \_\_\_\_\_



## Electronics Devices

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

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Sr. No.:124/11-12

Equipment code: \_\_\_\_\_ (to be assigned by client)

Doc No: \_\_\_\_\_ (to be assigned by client)

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### INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

#### 8.5 Verification of Alarms. (Continued)

Test # 8.5 - Conclusions / Comments:

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PASS



FAIL

Verified By: \_\_\_\_\_

Date: \_\_\_\_\_

Reviewed By: \_\_\_\_\_

Date: \_\_\_\_\_

#### Original Document :

Submitted by : ( **Electronics Devices.**) Date: \_\_\_\_\_

Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

#### Revision control (if any):

Date : \_\_\_\_\_ Rev. No \_\_\_\_\_

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Checked by/ date \_\_\_\_\_

Approved by/ date \_\_\_\_\_



## Electronics Devices

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

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Sr. No.:124/11-12

Equipment code: \_\_\_\_\_ (to be assigned by client)

Doc No: \_\_\_\_\_ (to be assigned by client)

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### INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

#### 8.0 Operational Qualification Test (Continued)

##### 8.5 Power & Communication Failure Recovery Verification

###### 8.5.1 Rationale -

To verify that in the event of a power loss or communications failure, the equipment will stop in safe condition and the operating parameter will not be lost or corrupted.

###### 8.5.2 Test equipment -

None Required.

###### 8.5.3 Procedure for main power fail test -

1. Operate the equipment in automatic mode.
2. Record power percentage of the machine in the main power fail test table of results (below).
3. Record the displayed production count and rejection count in the main power fail test table of results (below).
4. While the equipment is operating, shut down the power to the main control panel. Record if the equipment stops in a safe and secure condition.
5. Wait for 3 minutes then restore power to the equipment.
6. Restart the equipment. Record whether the equipment starts normally, and note any adverse condition.
7. Verify that the parameters recorded in the step 2 are unchanged after the power failure.

#### Original Document :

Submitted by : ( **Electronics Devices.**) Date: \_\_\_\_\_

Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

#### Revision control (if any):

Date : \_\_\_\_\_ Rev. No \_\_\_\_\_

Description :

Checked by/ date \_\_\_\_\_

Approved by/ date \_\_\_\_\_



## Electronics Devices

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

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

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

Sr. No.:124/11-12

Equipment code: \_\_\_\_\_ (to be assigned by client)

Doc No: \_\_\_\_\_ (to be assigned by client)

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### INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

#### 8.6 Power & Communication Failure Recovery Verification (Continued)

##### 8.5.4 Acceptance criteria -

In all test:

1. At step 4, the equipment shall stop in safe and secure condition.
2. At step 6, the equipment shall restart normally, with no problems or adverse conditions.
3. After restart, the configurable parameters remain unchanged and the date and time are correct.

##### 8.6.5 Main Power Failure Test Results

Main Power Fail Verification			
Test	Results	Meets Test (Yes / No)	Initial/ Date mm/dd/yy
Configurable Parameters before shut down.	Parameter 1: Power Percentage 2: Production Count 3: Rejection Count		
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.		
Configurable parameters after Power On	Parameter 1: Power Percentage 2: Production Count 3: Rejection Count		

#### Original Document :

Submitted by : ( **Electronics Devices.**) Date: \_\_\_\_\_

Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

#### Revision control (if any):

Date : \_\_\_\_\_ Rev. No \_\_\_\_\_

Description :

Checked by/ date \_\_\_\_\_

Approved by/ date \_\_\_\_\_



## Electronics Devices

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

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

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

Sr. No.:124/11-12

Equipment code: \_\_\_\_\_ (to be assigned by client)

Doc No: \_\_\_\_\_ (to be assigned by client)

Page No 38 of 42

### INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

#### 8.6 Power & Communication Failure Recovery Verification (Continued)

Test # 8.5 - Conclusions / Comments:

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PASS



FAIL

Verified By: \_\_\_\_\_ Date: \_\_\_\_\_

Reviewed By: \_\_\_\_\_ Date: \_\_\_\_\_

#### Original Document :

Submitted by : ( **Electronics Devices.**) Date: \_\_\_\_\_

Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

#### Revision control (if any):

Date : \_\_\_\_\_ Rev. No \_\_\_\_\_

Description :

Checked by/ date

Approved by/ date



## Electronics Devices

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

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

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

Sr. No.:124/11-12

Equipment code: \_\_\_\_\_ (to be assigned by client)

Doc No: \_\_\_\_\_ (to be assigned by client)

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### INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

#### 8.0 Operational Qualification Test: (Continued)

##### 8.6 Operational Qualification Tests Status

The table below lists the tests performed and related results.

Test Number	Critical Feature	Pass / Fail		Deviation Found	
8.1	Testing of sealed bottles				
8.2	Testing of Screens & Settings				
8.3	Testing of Sensors				
8.4	Verification of Alarms				
8.5	Power and Communication Failure Recovery				

Description	Yes	No	Initials Date
All critical test/verification have been performed and acceptance criteria were met and/or major deviation completed.			

#### Original Document :

Submitted by : ( **Electronics Devices.**) Date: \_\_\_\_\_

Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

#### Revision control (if any):

Date : \_\_\_\_\_ Rev. No \_\_\_\_\_

Description :

Checked by/ date \_\_\_\_\_

Approved by/ date \_\_\_\_\_



## Electronics Devices

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

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

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

Sr. No.:124/11-12

Equipment code: \_\_\_\_\_ (to be assigned by client)

Doc No: \_\_\_\_\_ (to be assigned by client)

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### INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

#### 8.0 Operational Qualification Test:

Test # 8.0 - Conclusions / Comments:

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PASS



FAIL

Verified By: \_\_\_\_\_

Date: \_\_\_\_\_

Reviewed By: \_\_\_\_\_

Date: \_\_\_\_\_

#### Original Document :

Submitted by : ( **Electronics Devices.**) Date: \_\_\_\_\_

Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

#### Revision control (if any):

Date : \_\_\_\_\_ Rev. No \_\_\_\_\_

Description :

\_\_\_\_\_

Checked by/ date \_\_\_\_\_

Approved by/ date \_\_\_\_\_





## Electronics Devices

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

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

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

Sr. No.:124/11-12

Equipment code: \_\_\_\_\_ (to be assigned by client)

Doc No: \_\_\_\_\_ (to be assigned by client)

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### INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

#### 9.0 Change Control Procedure

Any changes or modifications to the equipment will be performed in accordance with the appropriate change control procedure. A separate assessment will be made if any changes or modifications are requested and to whether relevant re-qualification action steps are required.

#### 10.0 Qualification Document Report Approval

##### 10.1 Summary:


##### 10.2 Certification:


#### Original Document :

Submitted by : ( **Electronics Devices.**) Date: \_\_\_\_\_

Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

#### Revision control (if any):

Date : \_\_\_\_\_ Rev. No \_\_\_\_\_

Description :

Checked by/ date \_\_\_\_\_

Approved by/ date \_\_\_\_\_



## Electronics Devices

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

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

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

Sr. No.:124/11-12

Equipment code: \_\_\_\_\_ (to be assigned by client)

Doc No: \_\_\_\_\_ (to be assigned by client)

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### INSTALLATION / OPERATIONAL QUALIFICATION (IQ/OQ)

#### 11.0 Appendix

##### 11.1 List of Abbreviations

SAT	Site Acceptance Tests
FAT	Factory Acceptance Tests
GMP	Good Manufacturing Practice
IQ	Installation Qualification
N.A	Not Applicable
OQ	Operational Qualification
REV	Revision
PQ	Performance Qualification
Spec.	Specification
SOP	Standard Operating Procedure
MOC	Material Of Construction
LCD	Liquid Crystal Display

##### 11.2 Units of Measure

HP	Horsepower
RPM	Revolution Per Minute
Psi	Pounds per square inch.
Kw	Kilowatt
Kg/cm <sup>2</sup>	Kilogram per centimetre square

#### Original Document :

Submitted by : ( **Electronics Devices.**) Date: \_\_\_\_\_

Checked by: \_\_\_\_\_ Date: \_\_\_\_\_ Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

#### Revision control (if any):

Date : \_\_\_\_\_ Rev. No \_\_\_\_\_

Description :

Checked by/ date \_\_\_\_\_

Approved by/ date \_\_\_\_\_