



**PROTOCOL FOR FACTORY ACCEPTANCE TEST OF DOUBLE HEAD OINTMENT FILLING  
AND SEALING MACHINE**

**PROTOCOL  
FOR  
FACTORY ACCEPTANCE TEST  
OF  
DOUBLE HEAD OINTMENT FILLING AND SEALING  
MACHINE**

<b>LOCATION</b>	<b>Ointment Section</b>
<b>SUPERSEDES No.</b>	<b>NIL</b>



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AND SEALING MACHINE**

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# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## PROTOCOL FOR FACTORY ACCEPTANCE TEST OF DOUBLE HEAD OINTMENT FILLING AND SEALING MACHINE

### 1.0 APPROVAL:

#### INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

#### REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING )			

#### APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



**PROTOCOL FOR FACTORY ACCEPTANCE TEST OF DOUBLE HEAD OINTMENT FILLING AND SEALING MACHINE**

**2.0 PURPOSE:**

- To ensure that the Double Head ointment filling and sealing machine manufactured by M/s ..... is manufactured as per design specification.
- The machine is performing as per agreed performance specification at manufacturer's site.

**3.0 SYSTEM OVERVIEW:**

Double Head Ointment filling and sealing combo machine which consists of Cassette in feed, I mark Registration, cleaning, filling, Product Reservoir, sealing and Ejection system.

**4.0 EQUIPMENT COMPONENTS / BOUGHT OUTS:**

S.No.	Component	Expectation	Actual	Remarks
01	Equipment Name	Double Head Double Head Ointment filling and sealing combo machine		
02	Modal /Type	GAN Combi		
	Machine Sr. no.			
03	Type of Tube	Aluminum/Lami/Plastic		
04	Speed	120 tubes/min.		
05	No. of head filling	2 Head		
06	filling nozzle	Two Nozzles		
07	Double Jacketed Hopper	Single with level sensor (SS 316 L)		
08	Stirrer	01 No. (SS 316 L)		
09	Cassette Box	Fully automatic in feed Device		
10	Photo Electric Registration device	For 'I' mark registration		
11	Central Lubrication System	Motorized		
12	Tube Cleaning System	Ionized System		
13	Level Sensor	For Hopper		
14	Machine body	All Contact Parts SS316		



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S.No.	Component	Expectation	Actual	Remarks
		15 Non Contact part SS304		
15	Overload Clutch	Self Centering		
16	Motor	1.5 HP , worm reduction gear box with sprockets		
17	Pump for filling	15mm (1-6cc) to 60mm (30-250cc) bulk transfer lobe pump.		
18	Drive	Ferguson Frequency Drive		
19	Link up Programme	With Autocartinator		
20	PLC	Allen Bradley 3 level Password		
21	Emergency Switch	Push Button		
22	Safety Features	<ul style="list-style-type: none"><li>➤ Emergency push button shall be provided.</li><li>➤ Machine shall not be started without safe earthing.</li><li>➤ All moving parts to be protected with safety guards.</li><li>➤ All upper guards provided with interlocks.</li><li>➤ Noise pollution shall be kept below 85 db.</li></ul> Alarm should be provided		
23	Earthing	Whole body Earthing		
24	Data Integrity (Software)	21 CFR complies		
25	Password policy	3 level		
26	Printout Facility	Available		
27	Recipe Printout	Available		



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S.No.	Component	Expectation	Actual	Remarks
<b>Other Components</b>				
28	VFD			
29	Safety Guard			
30	Limit Switch / Inter Locking System			
31	Indicating lamp			
32	Cladding			
33	Tube Ejector			
34	Trim Collector			

### 5.0 OTHER REQUIREMENTS:

- Complete Change Parts: 16 mm dia., 19 mm dia., 22 mm dia., 25 mm dia. With minimum range of tube length of 65 mm tubes.
- Approximately 300 tubes shall be taken for each Trial.
- % of Rejection should be Less than 1%.
- Filling accuracy i.e. wt variation should be  $\pm 1.0\%$ .
- One set of tools.
- Inkjet printing facility on tube inbuilt machine with online features.
- Lami tube sealer for sealing both Lami as well as Plastic tubes with or without seams.
- Gauges, flow meters, filters, interconnecting chilled water and compressed air piping.

### 6.0 OPERATIONAL FEATURES:

Should be Compiled as **Annexure-I**.

### 7.0 TEST & CHECKS :

#### 7.1 VERIFICATION OF FILLING MACHINE SPEED:

- The test should be carried out for each size of Tube
- Run the machine at a particular speed for 60 min.



**PROTOCOL FOR FACTORY ACCEPTANCE TEST OF DOUBLE HEAD OINTMENT FILLING AND SEALING MACHINE**

- Check that machine speed synchronize with ointment filling assembly speed.
- Observed the following parameters in below for each Size of Tube (LAMI and ALU.) i.e. 5 gm, 10 gm , 15gm, 20 gm & 30 gm.

S. No.	Parameters to be observed
1.	Tube Dent
2.	Machine jam/ Held up
3.	Folding
4	Engraving

- **Acceptance Criteria:** Filling Machine should run at 100 % Speed of designed speed
- Record the results in **Annexure: II & III**

**7.2 TEST FOR FILL WEIGHT VARIATION:**

- The test should be carried out for each size of Tube
- Tube (LAMI and ALU.) I.e. 5 gm, 10 gm, 15gm, 20 gm & 30 gm.
- Switch “ON” the machine.
- Note down the number of each Tube filled by each needle. Run the machine at Particular speed for 60 min.
- Collect the Tube after filling note down the fill Wt. of these Tubes.
- **Acceptance Criteria:**
- Filling Machine should deliver the Material in each Tube as per standard filled wt. record the observation as **annexure-IV.**

S.No.	STANDARD WT.	VARIATION
01.	5 gm	± 2%
02.	10 gm	± 1%
03.	15 gm	± 1%
04.	20 gm	± 1%
05.	30 gm	± 1%

**7.3 Leak Test & Physical Appearance:**

- The test should be carried out for each size of Tube
- Carry out the test simultaneously.
- Load the Cassette Box with the Tube.



**PROTOCOL FOR FACTORY ACCEPTANCE TEST OF DOUBLE HEAD OINTMENT FILLING AND SEALING MACHINE**

- Switch “ON” the machine & Operate.
- Collect the Tube and Carry out the leak test& physical appearance.
- **Acceptance Criteria:**
  - Filled Tube should be passed in leak tester machine.
- Record the results in **Annexure: V**





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## PROTOCOL FOR FACTORY ACCEPTANCE TEST OF DOUBLE HEAD OINTMENT FILLING AND SEALING MACHINE

### ANNEXURE-I

Test to be carried out	Observation	Remarks	Checked By
Machine should started by pressing the ON button.			
Machine should stop by pressing the OFF button.			
Tube Heater should ON when pressing.			
Tube should not get damage during tube loading operation			
Tubes get loaded into the tube holder automatically			
Tube should stop orient once the eye mark is detected by the eye mark sensor			
The tube I mark matter should be centre of the tubes			
Tube Cleaning device working Properly (no dust particle inside the after cleaning)			
Syringe pump and filling station does not operate when tube is absent in particular tube holder.			
No burning should Observe on I mark or sealing areas of the tube during Heating and sealing of Tube			
Trimming edges should be parallel to the cap edges.			
Folding unit should not operate, where tube is unavailable at below folding unit			
Auto feeder should Smooth working after pressing.			
Stirrer Motor should Smooth working after pressing.			
Vacuum Pump should Smooth working after pressing.			



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Test to be carried out	Observation	Remarks	Checked By
Machine stop immediately red light blows on tower lamp and "TUBE LEVEL LOW 1 & 2" alarm is generated on HMI.			
Machine stop immediately red light blows on tower lamp and "MATERIAL LEVEL LOW" alarm is generated on HMI.			
Machine stop immediately red light blows on tower lamp and "TUBE NOT EJECTED" alarm is generated on HMI.			
Machine stop immediately red light blows on tower lamp and "MOTOR OVER LOAD" alarm is generated on HMI.			
After Pressing ON button on the HMI panel Machine should start operating. After Pressing OFF button on the HMI panel Machine should stop operating			



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**ANNEXURE: II**  
**VERIFICATION OF FILLING MACHINE SPEED**

<b>Date of test</b>		<b>Machine Speed</b>	
<b>Type of Tube</b>	<b>LAMI</b>	<b>No. of Tubes taken</b>	
<b>Tube Size</b>		<b>Trial No.</b>	

<b>Parameter</b>	<b>Low Speed</b> ( )	<b>Optimum Speed</b> ( )	<b>High Speed</b> ( )
<b>Sample after .....( min)</b>			
Tube Dent			
Machine jam/ Held up			
Crimping			
Engraving			
<b>Rejection</b>	<b>.....(B1)</b>	<b>.....(B2)</b>	<b>.....(B3)</b>
<b>Sample after .....( min)</b>			
Tube Dent			
Machine jam/ Held up			
Crimping			
Engraving			
<b>Rejection</b>	<b>.....(B1)</b>	<b>.....(B2)</b>	<b>.....(B3)</b>
<b>Sample after .....( min)</b>			
Tube Dent			
Machine jam/ Held up			
Crimping			
Engraving			
<b>Rejection</b>	<b>.....(B1)</b>	<b>.....(B2)</b>	<b>.....(B3)</b>
<b>Total rejection</b>	<b>Σ B1=</b>	<b>Σ B2=</b>	<b>Σ B3=</b>

- **Acceptance Criteria:** Filling Machine should run at 100 % Speed of designed speed.



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**ANNEXURE: III**  
**VERIFICATION OF FILLING MACHINE SPEED**

<b>Date of test</b>		<b>Machine Speed</b>	
<b>Type of Tube</b>	<b>Aluminum</b>	<b>No. of Tubes taken</b>	
<b>Tube Size</b>		<b>Trial No.</b>	

<b>Parameter</b>	<b>Low Speed</b> ( )	<b>Optimum Speed</b> ( )	<b>High Speed</b> ( )
<b>Sample after .....( min)</b>			
Tube Dent			
Machine jam/ Held up			
Folding			
Engraving			
<b>Rejection</b>	<b>.....(B1)</b>	<b>.....(B2)</b>	<b>.....(B3)</b>
<b>Sample after .....( min)</b>			
Tube Dent			
Machine jam/ Held up			
Folding			
Engraving			
<b>Rejection</b>	<b>.....(B1)</b>	<b>.....(B2)</b>	<b>.....(B3)</b>
<b>Sample after .....( min)</b>			
Tube Dent			
Machine jam/ Held up			
Folding			
Engraving			
<b>Rejection</b>	<b>.....(B1)</b>	<b>.....(B2)</b>	<b>.....(B3)</b>
<b>Total rejection</b>	<b>Σ B1=</b>	<b>Σ B2=</b>	<b>Σ B3=</b>

- **Acceptance Criteria:** Filling Machine should run at 100 % Speed of designed speed.





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13									
14									
15									
16									
17									
18									
19									
20									

**ACCEPTANCE CRITERIA:** Filling Machine should deliver the Material in each Tube as per standard filled wt.



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**PROTOCOL FOR FACTORY ACCEPTANCE TEST OF DOUBLE HEAD OINTMENT FILLING AND SEALING MACHINE**

**ANNEXURE: V**

	SEALING QUALITY										Checked by	
	1	2	3	4	5	6	7	8	9	10		
<b>Initial (OK/ Not OK)</b>												
<b>MIDDLE (OK/ Not OK)</b>												
<b>END (OK/ Not OK)</b>												

**ACCEPTANCE CRITERIA: Tube Sealing should be passed in leak test.**

**8.0 OBSERVED DEVIATIONS/DISCUSSIONS:**

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**9.0 CONCLUSION**

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**PROTOCOL FOR FACTORY ACCEPTANCE TEST OF DOUBLE HEAD OINTMENT FILLING AND SEALING MACHINE**

**10.0 RECOMMENDATION**

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**11.0 DOCUMENTS:**

- All MOC Certificates, Manual for Bought out items
- Design Qualification protocol.
- Installation Qualification protocol.
- Operational Qualification protocol.
- Schematic Diagram of machine showing Overall Dimensions.
- Instrument list with manufacturer's calibration certificate.
- Electrical unit Diagram.
- P&ID Diagram / G.A Drawing.
- Operating & Service Manual
- Spare Part List.

**FAT CARRIED OUT BY :**

Sign.                      Date :

Name : \_\_\_\_\_

Sign.                      Date :

Name : \_\_\_\_\_

Sign.                      Date :

Name : \_\_\_\_\_

**\_MANUFACTURER**

Sign.                      Date :

Name : \_\_\_\_\_

Sign.                      Date :

Name : \_\_\_\_\_

Sign.                      Date :

Name : \_\_\_\_\_





**PROTOCOL FOR FACTORY ACCEPTANCE TEST OF DOUBLE HEAD OINTMENT FILLING  
AND SEALING MACHINE**

**12.0 ABBREVIATIONS:**

cGMP	:	Current Good Manufacturing Practices
cGEP	:	Current Good Engineering Practices
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
MOC	:	Material of Construction
SS	:	Stainless Steel
WHO	:	World Health Organization
mm	:	Millimeter
WG	:	Water Gauge
Hz	:	Hertz
V	:	Volt
Cu	:	Copper
Al	:	Aluminum
POM	:	Polyoxymethylene
SS	:	Stainless Steel
FAT	:	Factory Acceptance Test