

QUALITY ASSURANCE DEPARTMENT

## PERFORMANCE QUALIFICATION REPORT FOR FORM FILL SEAL MACHINE



QUALITY ASSURANCE DEPARTMENT

## PERFORMANCE QUALIFICATION REPORT FOR FORM FILL SEAL MACHINE

EQUIPMENT ID. No.	
LOCATION	Filling Area
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	NIL

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## PERFORMANCE QUALIFICATION REPORT FOR FORM FILL SEAL MACHINE

#### 1.0 REPORT PRE – APPROVAL:

#### PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

#### **REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			

#### **APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			



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#### PERFORMANCE QUALIFICATION REPORT FOR FORM FILL SEAL MACHINE

#### 2.0 OBJECTIVE:

- To verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Form Fill Seal Machine and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

#### **3.0 SCOPE:**

The scope of this Performance Qualification Report is limited to qualification of Form Fill Seal
 Machine (Model No. SPEED 500 L) installed in the FFS Filling Room.



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#### 4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments, shall be responsible for the execution of Performance Qualification Report.

DEPARTMENTS		RESPONSIBILITIES
<b>Quality Assurance</b>	•	Preparation, Authorization, Approval and Compilation of the
		Performance Qualification report.
	•	Co-ordination with Quality Control, Production and Engineering to
		carryout Performance Qualification Activity.
	•	Monitoring of Performance Qualification.
	•	Post Approval of Performance Qualification Report after Execution.
Production	•	Review of Performance Qualification Report.
	•	To co-ordinate and support Performance Qualification Activity.
	•	Post Approval of Performance Qualification Report after Execution.
Engineering	•	Reviewing of qualification report for correctness, completeness and
		technical excellence
	•	Responsible for trouble shooting (if occurred during execution).
	•	Maintenance & preventive maintenance as per schedule.
	•	Post Approval of Performance Qualification Report after Execution.



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#### PERFORMANCE QUALIFICATION REPORT FOR FORM FILL SEAL MACHINE

#### **5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	Form Fill Seal Machine
Equipment ID.	
Manufacturer's Name	Form Fill Automation (Micro Tool)
Supplier's Name	Form Fill Automation (Micro Tool)
<b>Location of Installation</b>	Filling Room

#### **6.0 PRE - QUALIFICATION REQUIREMENTS:**

The below mentioned activities should be completed prior to commencing the performance qualification activity:

- Design Qualification.
- Installation Qualification.
- Operational Qualification.
- Approved Performance Qualification Protocol
- SOP For Operation & Cleaning of Form Fill & Seal Machine
- SOP For Preventive Maintenance of Form Fill & Seal Machine



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## PERFORMANCE QUALIFICATION REPORT FOR FORM FILL SEAL MACHINE

#### 7.0 TESTS AND CHECKS:

The following performance test have been carried out in order to demonstrate the Performance By Using drug Product.

#### **7.1** Verification of Documents:

Record the observations for documents in the below mentioned table.

S.No.	Document Name	Document/SOP No.	Completed (Yes/No)
1.	Executed and approved Design		
	Qualification document		
2.	Executed and approved Installation		
	Qualification document		
3.	<b>Executed and approved Operational</b>		
	Qualification document		
4.	PQ Protocol approved		
5.	SOP For Operation & Cleaning of		
	Form Fill & Seal Machine		
6.	<b>SOP For Preventive Maintenance of</b>		
	Form Fill & Seal Machine		

Checked By	Verified By
(Production)	(Quality Assurance)
Sign/Date:	Sign/Date:
Inference:	
	Reviewed By
	(Manager QA) Sign/Date:



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## PERFORMANCE QUALIFICATION REPORT FOR FORM FILL SEAL MACHINE

#### 7.2 TEST PRODUCT BATCH INFORMATION:

S.No.	Product Name	Batch No.	Batch Size	Mfg. Date	Expiry Date

Compiled By	
$(\mathbf{Q}\mathbf{A})$	
Sign/Date:	
Inference:	
	Reviewed By
	(Manager QA)
	Sign/Date:



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7.3 7.3		MANCE E VALUATIO	N SI EED USING I RODO	
7.3				
	Pack Size: Batch No.:			
	Date:			
	Test Parameters	Start of the batch (30 Second/Cycle)	Middle of the batch (30 Second/Cycle)	End of the batch 30 Second/Cycle)
	<b>Total No of Respoules</b>		,	•
A	Time ( by Stop Watch)			
	Time in PLC			
В	Total No of Respoules			
	Time ( by Stop Watch)			
	Time in PLC			
C	Total No of Respoules			
	Time ( by Stop Watch)			
	Time in PLC			
(Pr Sig	ecked By oduction) n/Date:			By Assurance) e:
(Pr Sig	oduction)		(Quality A	Assurance)
(Pr Sig	oduction) n/Date:		(Quality A	Assurance)
(Pr Sig	oduction) n/Date:		(Quality A	Assurance)
(Pr Sig	oduction) n/Date:		(Quality A	Assurance)
(Pr Sig	oduction) n/Date:		(Quality A Sign/Date Reviewed (Manage	Assurance) e:
(Pr Sig	oduction) n/Date:		(Quality A Sign/Date Reviewed (Manage	Assurance) e:  By r QA)
(Pr Sig	oduction) n/Date:		(Quality A Sign/Date Reviewed (Manage	Assurance) e:  By r QA)
(Pr Sig	oduction) n/Date:		(Quality A Sign/Date Reviewed (Manage	Assurance) e:  By r QA)



7.3.2 Second Product Name:

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	Pack Size: Batch No.: Date:						
	Test Parameters	Start of the batch (30 Second/Cycle)	Middle of the batch (30 Second/Cycle)	End of the batch 30 Second/Cycle)			
A	Total No of Respoules						
A	Time ( by Stop Watch)						
	Time in PLC						
В	Total No of Respoules						
	Time ( by Stop Watch)						
	Time in PLC						
С	Total No of Respoules						
	Time ( by Stop Watch)						
	Time in PLC						
Checked By (Production) Sign/Date: Sign/Date: Verified By (Quality Assurance) Sign/Date:							
(Pr Sig	oduction) n/Date:		(Quality	Assurance)			
(Pr Sig	oduction)		(Quality	Assurance)			
(Pr Sig	oduction) n/Date:		(Quality	Assurance)			
(Pr Sig	oduction) n/Date:		(Quality Sign/Da	Assurance) te:			
(Pr Sig	oduction) n/Date: erence:		(Quality Sign/Da Reviewe (Manage	Assurance) te: d By			



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	Date:	Start of the batch	Middle of the batch	End of the batch
	Test Parameters	(30 Second/Cycle)	(30 Second/Cycle)	30 Second/Cycle)
<b>\</b>	Total No of Respoules			
•	Time ( by Stop Watch)			
	Time in PLC			
3	Total No of Respoules			
	Time ( by Stop Watch)			
	Time in PLC			
7	<b>Total No of Respoules</b>			
	Time ( by Stop Watch)			
	Time in PLC			
Pr	ecked By oduction) n/Date:			By Assurance) te:
Pr	oduction)		(Quality	Assurance)
Pr ig	oduction)		(Quality	Assurance)
Pr ig	oduction) n/Date:		(Quality	Assurance)
Pr ig	oduction) n/Date:		(Quality	Assurance)
Pr lig	oduction) n/Date:		(Quality	Assurance)
Pr Sig	oduction) n/Date:		(Quality Sign/Da	Assurance) te:
Pr Sig	oduction) n/Date:		(Quality Sign/Da	Assurance) te:
Pr Sig	oduction) n/Date:		(Quality Sign/Dar Reviewe (Manage	Assurance) te:
Pr Sig	oduction) n/Date:		(Quality Sign/Dar Reviewe (Manage	Assurance) te:
Pr ig	oduction) n/Date:		(Quality Sign/Dar Reviewe (Manage	Assurance) te: ed By er QA)
Pr Sig	oduction) n/Date:		(Quality Sign/Dar Reviewe (Manage	Assurance) te: ed By er QA)



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## PERFORMANCE QUALIFICATION REPORT FOR FORM FILL SEAL MACHINE

7.4	LEAKAGE	& SEALING	VERIFICATIO	N BY USING PRODUCT:
/ • T				

7.4.1	First Product Name: -
	Pack Size:
	Batch No.:
	Date:

S.No.	Start of	The Batch	Middle (	of The Batch	End of the Batch		
5.110.	Leakage	Sealing	Leakage	Sealing	Leakage	Sealing	
1.							
2.							
3.							
4.							
5.							
6.							
7.							
8.							
9.							
10.							
11.							
12.							
13.							
14.							
15.							
16.							

Acceptance Criteria:

•	look To	est Should b	Doce of	-500 to	-550 mm	of Ha for	30 minute
•	ieak i e	est Snoma t	e rass at	-500 10	-550 111111	of H2 for	50 minute

•	Sealing A	mpoule	s should	l be	e round	and	l smootl	n and	qualified	l rate	shoul	ld	be 1	not l	less	than	98	%
---	-----------	--------	----------	------	---------	-----	----------	-------	-----------	--------	-------	----	------	-------	------	------	----	---

Checked By	Verified By
(Production)	(Quality Assurance)
Sign/Date:	Sign/Date
Inference:	
	Reviewed By
	(Manager QA)



7.4.2 Second Product Name:

**Pack Size:** 

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	Start of	The Batch	Middle o	f The Batch	End of the	he Batch	
S.No.	Leakage	Sealing	Leakage	Sealing	Leakage	Sealing	
1.							
2.							
3.							
4.							
5.							
6.							
7.							
8.							
9.							
10.							
11.							
12.							
13.							
14.							
15.							
16.							
cceptan	ce Criteria:						
			) mm of Hg for 30	minute fied rate should be 1	not loss than 08%		
Scam	ig rimpoures sire	out be round and	smooth and quan	ied rate should be i	iot iess than 7070.		
Checked By Production) Sign/Date:					Verified By (Quality Assurance) Sign/Date		
nferenc	e:						
· • • • • • • • • • • • • • • • • • • •							
					Reviewed By		
					(Manager QA) Sign/Date:		



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## PERFORMANCE QUALIFICATION REPORT FOR FORM FILL SEAL MACHINE

7.4.3	nira Proauct	Name:				
P	ack Size:					
В	atch No.:					
D	ate:					
C No	Start of	The Batch	Middle of	The Batch	End of th	ne Batch
S.No.	Leakage	Sealing	Leakage	Sealing	Leakage	Sealing
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						
13.						
14.						
15.						
16.						
	e Criteria :					
			mm of Hg for 30 r			
• Sealin	g Ampoules sho	ouid be round and	smooth and qualif	ied rate should be no	ot less than 98%.s	
Checked	Bv				Verified By	
(Product					(Quality Assura	nce)
	e:	• • • • • • • • • • • • • • • • • • • •			Sign/Date	
Inference	e:					
	••••••	• • • • • • • • • • • • • • • • • • • •		• • • • • • • • • • • • • • • • • • • •		••••••
					Reviewed By (Manager QA)	
					. 5	



7.5.1 First Product Name: -

Pack Size:

# PHARMA DEVILS

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## PERFORMANCE QUALIFICATION REPORT FOR FORM FILL SEAL MACHINE

#### 7.5 THICKNESS & VOLUME VERIFICATION BY USING PRODUCT:

	atcn No.: ate:						
S.No.	Start of	f The Batch	Middle o	f The Batch	End of the Batch		
D.110.	Volume	Thickness	Volume	Thickness	Volume	Thickness	
1.							
2.							
3.							
4.							
5.							
6.							
7.							
8.							
9.							
10.							
11.							
12.							
13.							
14.							
15.							
16.							
NLT	ee Criteria : 5.2 ± 0.1 ml of I Thickness of Fi	Filled Volume, lled Respoules NLT	0.6 mm – 0.8 mm				
Checked Product ign/Dat					Verified By (Quality Assu Sign/Date	rance)	
oferenc	e <b>:</b>						
					Reviewed By (Manager QA		



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## PERFORMANCE QUALIFICATION REPORT FOR FORM FILL SEAL MACHINE

1.5.2 80	econa Proau	ct Name:				
P	ack Size:					
	atch No.:					
D	ate:					
S.No.	Start of	The Batch	Middle o	f The Batch	End of t	the Batch
5.110.	Volume	Thickness	Volume	Thickness	Volume	Thickness
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						
13.						
14.						
15.						
16.	~					
	e Criteria :					
	$5.2 \pm 0.1$ ml of 1		706 mm 08 mm			
• Wall	I MUNITESS OF FI	lled Respoules NLT	. v.v mm – v.o mm	1		
Checked	By				Verified By	
(Product				(Quality Assur	ance)	
Sign/Dat	e:	•••••			Sign/Date	• • • • • • • • • • • • • • • • • • • •
Inference	e:					
					Reviewed By	
					(Manager QA)	



7.5.3 Third Product Name:

Pack Size:

# PHARMA DEVILS

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S.No.	Start of	The Batch	Middle o	f The Batch	End of t	the Batch
5.110.	Volume	Thickness	Volume	Thickness	Volume	Thickness
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						
13.						
14.						
15.						
16.						
NLT	ce Criteria : 5.2 ± 0.1 ml of I Thickness of Fil	Filled Volume, lled Respoules NLT	C 0.6 mm – 0.8 mn	1		
Checked By (Production) Sign/Date:			Verified By (Quality Assurance) Sign/Date			
nferenc	e:					
• • • • • • • • • • • • • • • • • • • •						
•••••					Reviewed By (Manager QA	



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## PERFORMANCE QUALIFICATION REPORT FOR FORM FILL SEAL MACHINE

#### 8.0 CHECKLIST OF ALL TESTS & CHECKS:

This checklist is provided to ensure that all tests or checks required for this protocol have been executed..

S.No.	Name of Test or Check	Execution (Yes/No)	Remark	Verified By (Sign & Date)
1.	Performance Evaluation For Machine			
	Speed Optimization			
2.	Test for volume verification			
4.	Test For Sealing Quality			
5.	Wall Thickness Test			
6.	Test For Leak Test			

Inference:	
	ъ
	Reviewed By
	(Manager QA) Sign/Date:



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9.0	0 DOCUMENTS TO BE ATTACHED:				
	Any Other Relevant Documents.				
10.0	NON COMPLIANCE:				
11 0					
11.0	DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:				
12.0	CHANGE CONTROL, IF ANY:				



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	<u> </u>
13.0	REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY ):
14.0	CONCLUSION:
15.0	RECOMMENDATION:



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#### PERFORMANCE QUALIFICATION REPORT FOR FORM FILL SEAL MACHINE

#### **16.0 ABBREVIATIONS:**

cGMP : Current Good Manufacturing Practices

CQA : Corporate Quality Assurance

DQ : Design Qualification

IQ : Installation Qualification

mm : Millimetre

No. : Number

OQ : Operational Qualification

PQ : Performance Qualification

SOP : Standard Operating Procedure

SS : Stain less Steel

AFM : Ampoule Filling & Sealing Machine

WHO : World Health Organization

PVT : Private

LTD. : Limited

ID. : Identification

RPQ : Report performance qualification



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## PERFORMANCE QUALIFICATION REPORT FOR FORM FILL SEAL MACHINE

#### 17.0 REPORT POST APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

#### **REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			

#### **APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			