PERFORMANCE QUALIFICATION REPORT FOR VIAL OPTICAL INSPECTION MACHINE

EQUIPMENT ID. No.	
LOCATION	**Packing Hall**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

REPORT CONTENTS

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR VIAL OPTICAL INSPECTION MACHINE	PROTOCOL No.:

1.0 PRE – 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)			

2.0 OBJECTIVE:

- To provide documented evidence that the Equipment is performing consistently, repeatedly and reproducibly within its established operating range and the results of all the test parameters meet the pre-defined acceptance criteria.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

3.0 SCOPE:

- The scope of this report is limited for qualification of Vial Optical Inspection Machine installed in Packing Hall.
- This report provides all the relevant information of the performance qualification activity, In-process observations.

4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• 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.
Production	• Review of Report. • To co-ordinate and support Performance Qualification Activity.
Engineering	• Reviewing of qualification protocol for correctness, completeness and technical excellence. • Responsible for trouble shooting (if occurred during execution). • Maintenance & preventive maintenance as per schedule.

5.0 EQUIPMENT DETAILS:

Equipment Name	Vial Optical Inspection Machine
Equipment	……..
Manufacturer's Name	Ambica Pharma Machines Private Limited
Model	AVIN - 240
Supplier's Name	Ambica Pharma Machines Private Limited
Location of Installation	Packing Hall

6.0 PRE – QUALIFICATION REQUIREMENTS:

Verification for availability, completeness and approval status of all the required relevant documents shall be done and observations shall be recorded in the performance qualification report.

7.0 TESTS AND CHECKS:

7.1 VERIFICATION OF MACHINE SPEED:

Date of Test	
Vial Size	

Parameter	Trial-I	Trial-II	Trial-III
	No. of Vial in One Minutes	No. of Vial in One Minutes	No. of Vial in One Minutes
At 10 (Speed knob Setting)			
At 20 (Speed knob Setting)			
At 30 (Speed knob Setting)			
At 40 (Speed knob Setting)			
At 50 (Speed knob Setting)			
At 60 (Speed knob Setting)			
At 70 (Speed knob Setting)			
At 80 (Speed knob Setting)			
At 90 (Speed knob Setting)			
At 100 (Speed knob Setting)			

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

7.2 LUX LEVEL :

Date of Test	

Parameter	Table No.-I	Table No.-II	Table No.-III	Table No.-IV
Lux Level (NLT 2200)				

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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……

Reviewed By
(Manager QA)
Sign/Date: ……

7.3 CHALLENGE TEST:

Date of Test	
Vial Size	

Parameter		**Observation**	
		Visual Inspector-I	**Visual Inspector-II**
At 40 (Speed knob Setting)	**Trial-I** **Total 400 Vials** **Good -350 Vials** **Rejected-50 Vials** (Sealing-15, Cracked-21, Empty-14)		
	Trial-II **Total 400 Vials** **Good -342 Vials** **Rejected-58 Vials** (Sealing-17, Cracked-22, Empty-15)		
	Trial-III **Total 400 Vials** **Good -346 Vials** **Rejected-54 Vials** (Sealing-11, Cracked-26, Empty-17)		
At 50 (Speed knob Setting)	**Trial-I** **Total 500 Vials** **Good -443 Vials** **Rejected-57 Vials** (Sealing-21, Cracked-17, Empty-19)		
	Trial-II **Total 500 Vials** **Good -449 Vials** **Rejected-51 Vials** (Sealing-20, Cracked-14, Empty-17)		
	Trial-III **Total 500 Vials** **Good -427 Vials** **Rejected-73 Vials** (Sealing-24, Cracked-29, Empty-20)		
At 60 (Speed knob Setting)	**Trial-I** **Total 600 Vials** **Good -518 Vials** **Rejected-82 Vials** (Sealing-31, Cracked-26, Empty-25)		
	Trial-II **Total 600 Vials**		

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR VIAL OPTICAL INSPECTION MACHINE	PROTOCOL No.:

Parameter		Observation	
		Visual Inspector-I	Visual Inspector-II
	Good -520 Vials **Rejected-80 Vials** (Sealing-30, Cracked-22, Empty-28)		
	Trial-III **Total 600 Vials** **Good -517 Vials** **Rejected-83 Vials** (Sealing-33, Cracked-28, Empty-22)		
At 70 (Speed knob Setting)	**Trial-I** **Total 700 Vials** **Good -609 Vials** **Rejected-91 Vials** (Sealing-37, Cracked-13, Empty-41)		
	Trial-II **Total 700 Vials** **Good -602 Vials** **Rejected-98 Vials** (Sealing-36, Cracked-14, Empty-48)		
	Trial-III **Total 700 Vials** **Good -611 Vials** **Rejected-89 Vials** (Sealing-30, Cracked-41, Empty-18)		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

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.

Tests or Checks	Executed (Yes/No)	Remarks
Verification of Machine Speed.		
Lux Level		
Challenge Test		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

9.0 DOCUMENTS TO BE ATTACHED:

- Any Other Relevant Documents.

10.0 NON COMPLIANCE:

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11.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:

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12.0 CHANGE CONTROL, IF ANY:

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13.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
cGMP	:	Current Good Manufacturing Practices
EU	:	European Union
CQA	:	Corporate Quality Assurance
QC	:	Quality Control
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PQ	:	Performance Qualification
SOP	:	Standard Operating Procedure
NLT	:	Not Less Than
KW	:	Kilo watt
SS	:	Stainless Steel
ID.	:	Identification
mm	:	Mili meter
MCB	:	Miniature Circuit Breaker
ID	:	Inner Diameter

17.0 POST 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)			