PERFORMANCE QUALIFICATION REPORT FOR AUTOCOATER 66" LOCATION: COATING AREA (……..BLOCK) EQUIPMENT ID: …….

LOCATION	
DATE OF REQUALIFICATION	
SUPERSEDE REPORT No.	

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR AUTOCOATER 66”	PROTOCOL No.:

REPORT CONTENTS

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR AUTOCOATER 66”	PROTOCOL No.:

1.0 REPORT PRE -APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- To demonstrate that the equipment will operate reproducibly and consistently within its operating range.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the equipment.

3.0 SCOPE:

- The Protocol covers all aspects of Performance Qualification for the Auto coater being used at ……...
- This Protocol will define the methods and documentation used to re-qualify the Auto coater for PQ.

4.0 RESPONSIBILITY:

The Qualification Team, 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, Review, Approval and Compilation of the Performance Re-Qualification Report. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Re-Qualification Activity • Monitoring of Performance Re-Qualification activity.
Production	• Review of the Report. • To co-ordinate and support Performance Re-Qualification Activity.
Quality Control	• Review of Protocol • Analytical Support (Microbiological Testing/Analysis)
Engineering	• Review of the Report. • To co-ordinate and support Performance Re-Qualification Activity.

5.0 EQUIPMENT DETAILS:

EQUIPMENT NAME	**Auto Coater 66”**
MANUFACTURER’S NAME	**Solace Pharma**
LOCATION OF INSTALLATION	**Auto coater area**
EQUIPMENT ID No.	**…….**

6.0 PRE-QUALIFICATION REQUIREMENTS:

The results of any tests should meet the limits and acceptance criteria specified in the test documents. Any deviations or issues should be rectified and documented prior to PQ commencing. Following instrument should be verified before Performance Qualification.

- Calibrated **DT Apparatus.**
- Calibrated **Vernier Caliper.**
- Calibrated **Weighing Balance.**
- Calibrated Tachometer for measuring Pan RPM

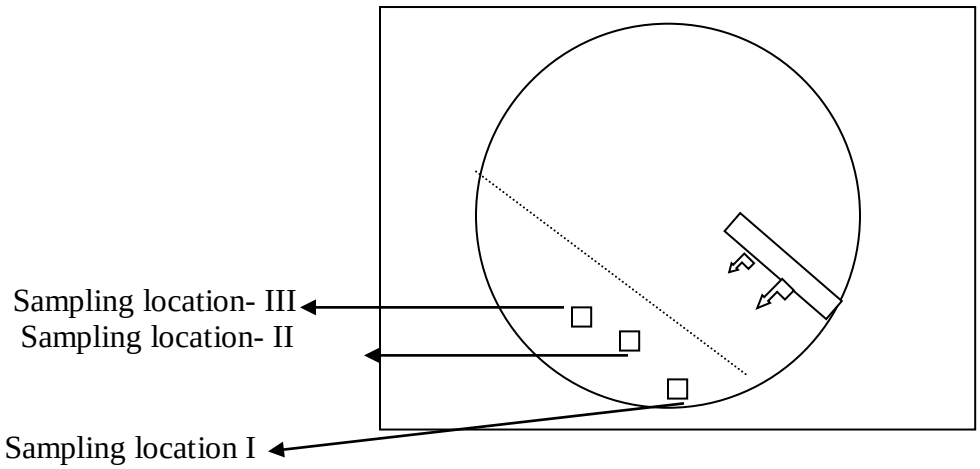
6.1 SYSTEM PRE-REQUISITES:

Verify that the DQ/IQ/OQ of the Auto coater has been executed and approved.

Verify that the Operating and Cleaning SOP of the Octagonal Blender has been prepared.

S.No.	DOCUMENT NAME	DOCUMENT/ SOP No.	COMPLETED (YES/NO)	CHECKED BY (PRODUCTION) (SIGN/DATE)	VERIFIED BY (QA) (SIGN/DATE)
1.	**DQ Protocol**				
2.	**IQ Protocol**				
3.	**OQ Protocol**				
4.	**Operating Procedure SOP**				
5.	**Cleaning Procedure SOP**				

7.0 SAMPLING LOCATION:



AUTOCOATER

Sampling Locations: As indicated in figure

8.0 PROPOSED PRODUCT BATCH INFORMATION:

S.No.	Product Name	Batch no.	Batch size	Mfg date	Expiry date

9.0 VERIFICATION OF RPM AT EMPTY CONDITION:

S.No.	Instrument	Calibration status	Calibration Done on	Calibration Due on	Set RPM	Observed RPM (One complete rotation)

Compiled By: _____
(QA)
Sign/Date:

Inference: _____

_____

_____

_____

_____

Reviewed By
(Manager QA)
Sign/Date: _____

10.0 RESULTS OBSERVED:

First batch:

Product Name		
Batch No		
Test Parameter	**Standard Parameter**	**Observed Parameter**
Distance between spraying nozzle assembly and the Tablets bed		
Pan Speed RPM		
Spray Rate		
Pre-warming temperature		
Bed Temperature		
Atomizing Air Pressure		
Inlet Air Temperature		

Location I:

Test Parameter	**Date**		**Mfg Date**		**Exp Date**			
Weight of 20 tablets								
Avg wt. of Tablet								
Individual weight variations								
% Variation		(+)		(-)				
Thickness								

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR AUTOCOATER 66”	PROTOCOL No.:

Location II:

Test Parameter	Date	Mfg Date	Exp Date
Weight of 20 tablets			
Avg wt. of Tablet			
Individual weight variations			
% Variation	(+)	(-)	
Thickness			

Location III:

Test Parameter	Date	Mfg Date	Exp Date
Weight of 20 tablets			
Avg wt. of Tablet			
Individual weight variations			
% Variation	(+)	(-)	
Thickness			

Compiled By: _____
(QA)
Sign/Date:

Inference: _____

_____

_____

_____

_____

Reviewed By
(Manager QA)
Sign/Date: _____

 PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR AUTOCOATER 66”	PROTOCOL No.:

Second batch:

Product Name		
Batch No		
Test Parameter	**Standard Parameter**	**Observed Parameter**
Distance between spraying nozzle assembly and the Tablets bed		
Pan Speed RPM		
Spray Rate		
Pre-warming temperature		
Bed Temperature		
Atomizing Air Pressure		
Inlet Air Temperature		

Location I

Test Parameter	**Date**		**Mfg Date**		**Exp Date**			
Weight of 20 tablets								
Avg wt. of Tablet								
Individual weight variations								
% Variation	(+)		(-)					
Thickness								

 PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR AUTOCOATER 66”	PROTOCOL No.:

Location II:

Test Parameter	Date	Mfg Date	Exp Date
Weight of 20 tablets			
Avg wt. of Tablet			
Individual weight variations			
% Variation	(+)	(-)	
Thickness			

Location III:

Test Parameter	Date	Mfg Date	Exp Date
Weight of 20 tablets			
Avg wt. of Tablet			
Individual weight variations			
% Variation	(+)	(-)	
Thickness			

Compiled By: _____
(QA)
Sign/Date:

Inference:

……

……

……

Reviewed By
(Manager QA)
Sign/Date: _____

 PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR AUTOCOATER 66”	PROTOCOL No.:

Third batch:

Product Name		
Batch No		
Test Parameter	**Standard Parameter**	**Observed Parameter**
Distance between spraying nozzle assembly and the Tablets bed		
Pan Speed RPM		
Spray Rate		
Pre-warming temperature		
Bed Temperature		
Atomizing Air Pressure		
Inlet Air Temperature		

Location I

Test Parameter	Date :-	Mfg Date	Exp Date
Weight of 20 tablets			
Avg wt. of Tablet			
Individual weight variations			
% Variation	(+)	(-)	
Thickness			

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR AUTOCOATER 66”	PROTOCOL No.:

Location II:

Test Parameter	Date	Mfg Date	Exp Date
Weight of 20 tablets			
Avg wt. of Tablet			
Individual weight variations			
% Variation	(+)	(-)	
Thickness			

Location III:

Test Parameter	Date	Mfg Date	Exp Date
Weight of 20 tablets			
Avg wt. of Tablet			
Individual weight variations			
% Variation	(+)	(-)	
Thickness			

Compiled By: _____
(QA)
Sign/Date:

Inference:……
……
……
……

Reviewed By
(Manager QA)
Sign/Date: _____

11.0 DOCUMENTS TO BE ATTACHED:

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12.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

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13.0 NON COMPLIANCE:

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14.0 CHANGE CONTROL, IF ANY:

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

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16.0 CONCLUSION:

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17.0 RECOMMENDATION:

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18.0 ABBREVIATION:

No.	:	Number
WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
cGMP	:	current Good Manufacturing Practices
EU	:	European Union
QA	:	Quality Assurance
PQ	:	Performance Qualification
mm	:	Millimeter
AC	:	Auto coater

19.0 EXECUTED REPORT -APPROVAL

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			