PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE

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

REPORT CONTENTS

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE	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 provide documented evidence that the Equipment is performing as per the parameter defined in operational qualification and that it gives result as per the predetermined acceptance criteria.

To demonstrate that the system 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 system.

The document also provides the observed and obtained values indicating compliance to the PQ Protocol.

3.0 SCOPE:

The Protocol covers all aspects of Performance Qualification for the Six Head Lotion filling machine.

This Protocol will define the methods and documentation used to qualify the Six Head Lotion filling machine 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 Protocol.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review, Approval and Compilation of the Performance Qualification Protocol. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification.
Production	• Review of Protocol. • 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.
Quality Control	• Review of Performance Qualification report. • Approval of report post approval.

5.0 EQUIPMENT DETAILS:

Equipment Name	Six Head Lotion filling machine
Equipment ID.	
Manufacturer's Name	
Supplier's Name	
Location of Installation	

6.0 SYSTEM DESCRIPTION:

It is a Fully Automatic Volumetric Filling machine. A Square fabricated out of S.S.316L imported sheet is provided at the center of filling section at both side of which 6equidistant piston- Cylinder assemblies are mounted. The volume in all the cylinders can be adjusted by adjusting the ring. Also, micro settings up to ½ ml can be done by turning the knob of square guide blocks in desired direction. The complete machine has been constructed in ASTM and AISI grade S.S.304/SS316 sheets/plates/rods. All product contact parts are in S.S.316 and filling bowl in S.S316L to make the machine chemically inert.

7.0 PRE-QUALIFICATION REQUIREMENTS:

7.1 SYSTEM PRE-REQUISITES:

Verify that the DQ / IQ / OQ of the Six Head Lotion filling machine have been executed and approved.

Verify that the SOP for Operating, Cleaning and Preventive Maintenance of the Six Head Lotion filling machine has been prepared.

S.No.	DESCRIPTION OF PRE-REQUISITE	COMPLETED (YES / NO)	CHECKED BY ENGINEERING SIGN / DATE	VERIFIED BY QA SIGN / DATE
1. 2. 3.	DQ Protocol Document No.: IQ Protocol Document No.: OQ Protocol Document No.:			
4.	SOP of "Operation and Cleaning of Six Head Lotion filling machine"			

Checked By
Production
Sign/Date: _____

Verified By
Quality Assurance
Sign/Date: _____

Inference:……

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Reviewed By
Manager QA
Sign/Date:_____

8.0 TESTS & CHECKS:

8.1 Performance Evaluation For Machine Speed Optimization:

Trial No.: 01

Date of Test		**Equipment ID**	
Total Bottles taken for test		**Bottle Size**	
Parameter	**Low Speed ( )**	**Optimum Speed( )**	**High Speed ( )**
Sample after …….(min)			
Machine jam			
Bottle Breakage			
Rejection			
Sample after …….(min)			
Machine jam			
Bottle Breakage			
Rejection			
Sample after …….(min)			
Machine jam			
Bottle Breakage			
Rejection			
Total rejection			

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date:……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE	PROTOCOL No.:

Trial No.: 02

Date of Test		**Equipment ID**	
Total Bottles taken for test		**Bottle Size**	
Parameter	**Low Speed ( )**	**Optimum Speed( )**	**High Speed ( )**
Sample after …….(min)			
Machine jam			
Bottle Breakage			
Rejection			
Sample after …….(min)			
Machine jam			
Bottle Breakage			
Rejection			
Sample after …….(min)			
Machine jam			
Bottle Breakage			
Rejection			
Total rejection			

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date:……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE	PROTOCOL No.:

Trial No.: 03

Date of Test		**Equipment ID**	
Total Bottles taken for test		**Bottle Size**	
Parameter	**Low Speed ( )**	**Optimum Speed( )**	**High Speed ( )**
Sample after …….(min)			
Machine jam			
Bottle Breakage			
Rejection			
Sample after …….(min)			
Machine jam			
Bottle Breakage			
Rejection			
Sample after …….(min)			
Machine jam			
Bottle Breakage			
Rejection			
Total rejection			

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date:……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE	PROTOCOL No.:

8.2 FILL VOLUME VARIATION TEST:

8.2.1 Fill Volume Variation At Full Tank Level:

Date of test	
Product Name	
Batch No.	
Fill vol. - …….(Limit: ± …….. % of Target Filled volume)	
Trial No.: 01	

Nozzle No.	Bottle No.	Low Speed (10 Bottles/ min)			Optimum Speed (30 Bottles / min)			High Speed (50 Bottles/Minute)		
		Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
01	1									
	2									
	3									
	4									
	5									
02	1									
	2									
	3									
	4									
	5									
03	1									
	2									

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE	PROTOCOL No.:

Nozzle No.	Bottle No.	Low Speed (10 Bottles/ min)			Optimum Speed (30 Bottles / min)			High Speed (50 Bottles/Minute)		
		Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
	3									
	4									
	5									
04	1									
	2									
	3									
	4									
	5									
05	1									
	2									
	3									
	4									
	5									
06	1									
	2									
	3									
	4									
	5									
Min fill vol.										
Max. fill vol.										

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE	PROTOCOL No.:

Nozzle No.	Bottle No.	Low Speed (10 Bottles/ min)			Optimum Speed (30 Bottles / min)			High Speed (50 Bottles/Minute)		
		Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
Avg. vol.										

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date……

Inference:

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Reviewed By
Manager QA)
Sign/Date: ……

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE	PROTOCOL No.:

8.2.2 Fill volume Variation At Half Tank level:

Date of test	
Product Name	
Batch No.	
Standard. Fill vol. - ……..(Limit: ± …….. % of Target Filled volume)	
Trial No.:01	

Nozzle No.	Bottle No.	Low Speed (10 Bottles/ min)			Optimum Speed (30 Bottles / min)			High Speed (50 Bottles/Minute)		
		Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
01	1									
	2									
	3									
	4									
	5									
02	1									
	2									
	3									
	4									
	5									
03	1									
	2									

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE	PROTOCOL No.:

Nozzle No.	Bottle No.	Low Speed (10 Bottles/ min)			Optimum Speed (30 Bottles / min)			High Speed (50 Bottles/Minute)		
		Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
	3									
	4									
	5									
04	1									
	2									
	3									
	4									
	5									
05	1									
	2									
	3									
	4									
	5									
06	1									
	2									
	3									
	4									
	5									
Min fill vol.										
Max. fill vol.										

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE	PROTOCOL No.:

Nozzle No.	Bottle No.	Low Speed (10 Bottles/ min)			Optimum Speed (30 Bottles / min)			High Speed (50 Bottles/Minute)		
		Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
Avg. vol.										

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date……

Inference:

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Reviewed By
Manager QA)
Sign/Date: ……

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE	PROTOCOL No.:

8.2.3 Fill volume Variation At 1/3rd Tank level:

Date of test	
Product Name	
Batch No.	
Standard. Fill vol. - ……..(Limit: ± …….. % of Target Filled volume)	
Trial No.:01	

Nozzle No.	Bottle No.	Low Speed (10 Bottles/ min)			Optimum Speed (30 Bottles / min)			High Speed (50 Bottles/Minute)		
		Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
01	1									
	2									
	3									
	4									
	5									
02	1									
	2									
	3									
	4									
	5									
03	1									
	2									

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE	PROTOCOL No.:

Nozzle No.	Bottle No.	Low Speed (10 Bottles/ min)			Optimum Speed (30 Bottles / min)			High Speed (50 Bottles/Minute)		
		Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
	3									
	4									
	5									
04	1									
	2									
	3									
	4									
	5									
05	1									
	2									
	3									
	4									
	5									
06	1									
	2									
	3									
	4									
	5									
Min fill vol.										
Max. fill vol.										

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE	PROTOCOL No.:

Nozzle No.	Bottle No.	Low Speed (10 Bottles/ min)			Optimum Speed (30 Bottles / min)			High Speed (50 Bottles/Minute)		
		Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
Avg. vol.										

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date……

Inference:

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Reviewed By
Manager QA)
Sign/Date: ……

8.2.4 Fill volume Variation At Full Tank Level:

Date of test	
Product Name	
Batch No.	
Fill vol. - …….(Limit: ± …….. % of Target Filled volume)	
Trial No.: 02	

Nozzle No.	Bottle No.	Low Speed (10 Bottles/ min)			Optimum Speed (30 Bottles / min)			High Speed (50 Bottles/Minute)		
		Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
01	1									
	2									
	3									
	4									
	5									
02	1									
	2									
	3									
	4									
	5									
03	1									
	2									

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE	PROTOCOL No.:

Nozzle No.	Bottle No.	Low Speed (10 Bottles/ min)			Optimum Speed (30 Bottles / min)			High Speed (50 Bottles/Minute)		
		Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
	3									
	4									
	5									
04	1									
	2									
	3									
	4									
	5									
05	1									
	2									
	3									
	4									
	5									
06	1									
	2									
	3									
	4									
	5									
Min fill vol.										
Max. fill vol.										

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE	PROTOCOL No.:

Nozzle No.	Bottle No.	Low Speed (10 Bottles/ min)			Optimum Speed (30 Bottles / min)			High Speed (50 Bottles/Minute)		
		Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
Avg. vol.										

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date……

Inference:

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Reviewed By
Manager QA)
Sign/Date: ……

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE	PROTOCOL No.:

8.2.5 Fill volume Variation At Half Tank level:

Date of test	
Product Name	
Batch No.	
Standard. Fill vol. - ……..(Limit: ± …….. % of Target Filled volume)	
Trial No.:02	

Nozzle No.	Bottle No.	Low Speed (10 Bottles/ min)			Optimum Speed (30 Bottles / min)			High Speed (50 Bottles/Minute)		
		Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
01	1									
	2									
	3									
	4									
	5									
02	1									
	2									
	3									
	4									
	5									
03	1									
	2									

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE	PROTOCOL No.:

Nozzle No.	Bottle No.	Low Speed (10 Bottles/ min)			Optimum Speed (30 Bottles / min)			High Speed (50 Bottles/Minute)		
		Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
	3									
	4									
	5									
04	1									
	2									
	3									
	4									
	5									
05	1									
	2									
	3									
	4									
	5									
06	1									
	2									
	3									
	4									
	5									
Min fill vol.										
Max. fill vol.										

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE	PROTOCOL No.:

Nozzle No.	Bottle No.	Low Speed (10 Bottles/ min)			Optimum Speed (30 Bottles / min)			High Speed (50 Bottles/Minute)		
		Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
Avg. vol.										

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date……

Inference:

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Reviewed By
Manager QA)
Sign/Date: ……

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE	PROTOCOL No.:

8.2.6 Fill volume Variation At 1/3rd Tank level:

Date of test	
Product Name	
Batch No.	
Standard. Fill vol. - ……..(Limit: ± …….. % of Target Filled volume)	
Trial No.:02	

Nozzle No.	Bottle No.	Low Speed (10 Bottles/ min)			Optimum Speed (30 Bottles / min)			High Speed (50 Bottles/Minute)		
		Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
01	1									
	2									
	3									
	4									
	5									
02	1									
	2									
	3									
	4									
	5									
03	1									
	2									

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE	PROTOCOL No.:

Nozzle No.	Bottle No.	Low Speed (10 Bottles/ min)			Optimum Speed (30 Bottles / min)			High Speed (50 Bottles/Minute)		
		Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
	3									
	4									
	5									
04	1									
	2									
	3									
	4									
	5									
05	1									
	2									
	3									
	4									
	5									
06	1									
	2									
	3									
	4									
	5									
Min fill vol.										
Max. fill vol.										

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE	PROTOCOL No.:

Nozzle No.	Bottle No.	Low Speed (10 Bottles/ min)			Optimum Speed (30 Bottles / min)			High Speed (50 Bottles/Minute)		
		Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
Avg. vol.										

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date……

Inference:

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Reviewed By
Manager QA)
Sign/Date: ……

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE	PROTOCOL No.:

8.2.7 Fill volume Variation At Full Tank Level:

Date of test	
Product Name	
Batch No.	
Fill vol. - …….(Limit: ± …….. % of Target Filled volume)	
Trial No.: 03	

Nozzle No.	Bottle No.	Low Speed (10 Bottles/ min)			Optimum Speed (30 Bottles / min)			High Speed (50 Bottles/Minute)		
		Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
01	1									
	2									
	3									
	4									
	5									
02	1									
	2									
	3									
	4									
	5									
03	1									
	2									
	3									

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE	PROTOCOL No.:

Nozzle No.	Bottle No.	Low Speed (10 Bottles/ min)			Optimum Speed (30 Bottles / min)			High Speed (50 Bottles/Minute)		
		Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
	4									
	5									
04	1									
	2									
	3									
	4									
	5									
05	1									
	2									
	3									
	4									
	5									
06	1									
	2									
	3									
	4									
	5									
Min fill vol.										
Max. fill vol.										
Avg. vol.										

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE	PROTOCOL No.:

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date……

Inference:

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Reviewed By
Manager QA)
Sign/Date: ……

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE	PROTOCOL No.:

8.2.8 Fill volume Variation At Half Tank level:

Date of test	
Product Name	
Batch No.	
Standard. Fill vol. - ……..(Limit: ± …….. % of Target Filled volume)	
Trial No.:03	

Nozzle No.	Bottle No.	Low Speed (10 Bottles/ min)			Optimum Speed (30 Bottles / min)			High Speed (50 Bottles/Minute)		
		Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
01	1									
	2									
	3									
	4									
	5									
02	1									
	2									
	3									
	4									
	5									
03	1									
	2									

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE	PROTOCOL No.:

Nozzle No.	Bottle No.	Low Speed (10 Bottles/ min)			Optimum Speed (30 Bottles / min)			High Speed (50 Bottles/Minute)		
		Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
	3									
	4									
	5									
04	1									
	2									
	3									
	4									
	5									
05	1									
	2									
	3									
	4									
	5									
06	1									
	2									
	3									
	4									
	5									
Min fill vol.										
Max. fill vol.										

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE	PROTOCOL No.:

Nozzle No.	Bottle No.	Low Speed (10 Bottles/ min)			Optimum Speed (30 Bottles / min)			High Speed (50 Bottles/Minute)		
		Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
Avg. vol.										

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date……

Inference:

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Reviewed By
Manager QA)
Sign/Date: ……

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE	PROTOCOL No.:

8.2.9 Fill volume Variation At 1/3rd Tank level:

Date of test	
Product Name	
Batch No.	
Standard. Fill vol. - ……..(Limit: ± …….. % of Target Filled volume)	
Trial No.:03	

Nozzle No.	Bottle No.	Low Speed (10 Bottles/ min)			Optimum Speed (30 Bottles / min)			High Speed (50 Bottles/Minute)		
		Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
01	1									
	2									
	3									
	4									
	5									
02	1									
	2									
	3									
	4									
	5									
03	1									
	2									

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE	PROTOCOL No.:

Nozzle No.	Bottle No.	Low Speed (10 Bottles/ min)			Optimum Speed (30 Bottles / min)			High Speed (50 Bottles/Minute)		
		Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
	3									
	4									
	5									
04	1									
	2									
	3									
	4									
	5									
05	1									
	2									
	3									
	4									
	5									
06	1									
	2									
	3									
	4									
	5									
Min fill vol.										
Max. fill vol.										

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE	PROTOCOL No.:

Nozzle No.	Bottle No.	Low Speed (10 Bottles/ min)			Optimum Speed (30 Bottles / min)			High Speed (50 Bottles/Minute)		
		Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
Avg. vol.										

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date……

Inference:

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Reviewed By
Manager QA)
Sign/Date: ……

8.3 PHYSICAL TEST:

TRIAL NO.: 01

Date of test	
Product Name	
Batch No.	

Nozzle No.	Bottle No.	Physical appearance	Leakage	Foreign particle	Remarks
01	1				
	2				
02	1				
	2				
03	1				
	2				
04	1				
	2				
05	1				
	2				
06	1				
	2				

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date……

Inference:

……

……

……

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

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE	PROTOCOL No.:

TRIAL NO.:02

Date of test	
Product Name	
Batch No.	

Nozzle No.	Bottle No.	Physical appearance	Leakage	Foreign particle	Remarks
01	1				
	2				
02	1				
	2				
03	1				
	2				
04	1				
	2				
05	1				
	2				
06	1				
	2				

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date……

Inference:

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Reviewed By
Manager QA)
Sign/Date: ……

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE	PROTOCOL No.:

TRIAL NO.:03

Date of test	
Product Name	
Batch No.	

Nozzle No.	Bottle No.	Physical appearance	Leakage	Foreign particle	Remarks
01	1				
	2				
02	1				
	2				
03	1				
	2				
04	1				
	2				
05	1				
	2				
06	1				
	2				

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date……

Inference:

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

9.0 CHECKLIST OF ALL TESTS & CHECKS:

The following table lists the number of tests / samples to be carried out & comments on the sample record sheet.

TESTS OR CHECKS	EXECUTED [Y/N]	COMMENT
Machine Speed Optimization		
Fill Variation Test		
Physical Test		

10.0 REFERENCES:

- Validation Master Plan
- Schedule M: "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2: Good Manufacturing Practices and Inspection.

11.0 DOCUMENTS TO BE ATTACHED:

- Training Record.
- Any Other Relevant Documents

12.0 NON COMPLIANCE:

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13.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

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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 ABBREVIATIONS:

gm	:	gram
BSS	:	British Standard Sieve
BMR	:	Batch Manufacturing Record
WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
GMP	:	Good Manufacturing Practices
QA	:	Quality Assurance
CQA	:	Corporate Quality Assurance
SOP	:	Standard Operating Procedure
LOF	:	Six Head Lotion filling machine
^{o}C	:	Degree Centigrade
mm	:	Millimeter
Amp.	:	Amper
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PQ	:	Performance Qualification
Pvt.	:	Private
Ltd.	:	Limited

19.0 REPORT POST 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)			