

PROTOCOL No.:

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



PROTOCOL No.:

### **REPORT CONTENTS**

S.No.	TITLE	PAGE No.
1.0	Report Pre Approval	3
2.0	Objective	4
3.0	Scope	4
4.0	Responsibility	5
5.0	Equipment Details	5
6.0	System Description	6
7.0	Pre-Qualification Requirement	7
8.0	Tests & Checks	8
9.0	Checklist of All Tests & Checks	41
10.0	References	41
11.0	Documents To Be Attached	41
12.0	Noncompliance	41
13.0	Deviation From Pre–Defined Specification, If Any	41
14.0	Change Control, If Any	42
15.0	Review (Inclusive Follow up ,Action)	42
16.0	Conclusion	42
17.0	Recommendation	42
18.0	Abbreviations	43
19.0	Report Post Approval	44



PR(	OT	O'	CO	$\mathbf{L}$	N	0.

### 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)			



PROTOCOL No.:

### 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.



PROTOCOL No.:

### **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	<ul> <li>Preparation, Review, Approval and Compilation of the Performance Qualification Protocol.</li> <li>Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity.</li> <li>Monitoring of Performance Qualification.</li> </ul>
Production	<ul> <li>Review of Protocol.</li> <li>To co-ordinate and support Performance Qualification Activity.</li> </ul>
Engineering	<ul> <li>Reviewing of qualification Protocol for correctness, completeness and technical excellence.</li> <li>Responsible for trouble shooting (if occurred during execution).</li> <li>Maintenance &amp; preventive maintenance as per schedule.</li> </ul>
Quality Control	<ul> <li>Review of Performance Qualification report.</li> <li>Approval of report post approval.</li> </ul>

### **5.0 EQUIPMENT DETAILS:**

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



P	R	O	$\mathbf{T}$	O	$\mathbf{C}$	O	L	No.
_	T.	$\mathbf{\mathbf{\mathcal{I}}}$	_	v	$\overline{}$	v	_	T 10.

### **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.



PRO	TO	COI	L No.

### 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.	DQ Protocol Document No.: IQ			
2.	Protocol Document No.: OQ			
3.	Protocol Document No.:			
4.	SOP of "Operation and Cleaning of Six Head Lotion filling machine"			

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



PR	വ	$\Gamma O$	C	$\cap$ 1	Γ. `	N	n

- 8.0 **TESTS & CHECKS:**
- **Performance Evaluation For Machine Speed Optimization: 8.1**

Trial No.: 01			
Date of Test		Equipment ID	
Total Bottles taken for test		Bottle Size	
Parameter	Low Speed ( )	Optimum Speed( )	High Speed ( )
Sample after mi	in)		
Machine jam			
<b>Bottle Breakage</b>			
Rejection			
Sample after m	in)		
Machine jam			
<b>Bottle Breakage</b>			
Rejection			
Sample after( mi	in)		
Machine jam			
<b>Bottle Breakage</b>			
Rejection			
Total rejection			
Checked By		Verifie	d By
Production			y Assurance
Sign/Date:	•••••	Sign/D	ate:
Inference:			
		Review Manag Sign/D	ger QA



PR	$\mathbf{O}$	$\Gamma O$	C	()I	[ , ]	N	n.	•

Trial No.: 02

1 riai No.: 02			
Date of Test		<b>Equipment ID</b>	
Total Bottles taken for test		Bottle Size	
Parameter	Low Speed ( )	Optimum Speed( )	High Speed ( )
Sample after( mi	in)		
Machine jam			
<b>Bottle Breakage</b>			
Rejection			
Sample after( mi	in)		
Machine jam			
<b>Bottle Breakage</b>			
Rejection			
Sample after ( mi	in)		
Machine jam			
<b>Bottle Breakage</b>			
Rejection			
Total rejection			
Checked By		Verifie	ed By
Production			y Assurance
Sign/Date:	•••••	Sign/D	ate:
Inference:			
			ger QA
		Sign/D	ate:



D	D	A	т	A	$\mathbf{C}$	$\cap$ 1	r	N	_	
Г	$\mathbf{r}$	v	′	v	יטי	U	L	T	v.	

Trial No.: 03

1 riai No.: 03			
Date of Test		<b>Equipment ID</b>	
Total Bottles taken for test		Bottle Size	
Parameter	Low Speed ( )	Optimum Speed( )	High Speed ( )
Sample after( mi	in)		
Machine jam			
<b>Bottle Breakage</b>			
Rejection			
Sample after( mi	in)		
Machine jam			
<b>Bottle Breakage</b>			
Rejection			
Sample after ( mi	in)		
Machine jam			
<b>Bottle Breakage</b>			
Rejection			
Total rejection			
Checked By		Verifie	ed By
Production			y Assurance
Sign/Date:	•••••	Sign/D	ate:
Inference:			
	,		ved By ger QA vate:
		Signi	



n	T	$\sim$		$\sim$	~	$\sim$ T		т	
μ	w	6 D			•			NO .	
L	1/	v	1	v	v	v	⊿ l'	<b>lo.:</b>	

### **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	

O1	Bottle	Bottle				Optimum Speed (30 Bottles / min )			High Speed (50 Bottles/Minute)		
	No.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	
	1										
	2										
01	3										
	4										
	5										
	1										
	2										
02	3										
	4										
	5									_	
03	1										
03	2										



•	_	$\sim$		_	~	$\sim$			
,	21	1 1	""	4 1	$\mathbf{C}$		NI.	$\mathbf{a}$	•
	•	.,		•		. ,		u,	

Nozzle No.	Bottle	Low Speed	( 10 Bottles/ mi	in )	Optimum S	peed (30 Bottl	les / min )	High Speed	(50 Bottles/Mi	inute)
NUZZIE NU.	No.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
	3									
	4									
	5									
	1									
	2									
04	3									
	4									
	5									
	1									
	2									
05	3									
	4									
	5									
	1									
	2									
06	3									
	4									
	5									
Min fill vol.							<u> </u>			<u> </u>
Max. fill vol.										



	-	$\boldsymbol{\wedge}$		$\boldsymbol{\wedge}$		$\sim$ T	- Ta 1	r	
μ	w	4 1	11	. 1				o.:	
L	1	v	_	v	v	$\mathbf{U}$	Τ.	<b>U</b>	

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.										
		1			1					

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



n	T	$\sim$		$\sim$	~	$\sim$ T		т	
μ	w	6 D			•			NO .	
L	1/	v	1	v	v	v	⊿ l'	<b>lo.:</b>	

### 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				Optimum Speed (30 Bottles / min )			High Speed (50 Bottles/Minute)		
Nozzie No.	No.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
	1									
	2									
01	3									
	4									
	5									
	1									
	2									
02	3									
	4									
	5									
03	1									
US	2									



TI	$\Delta$ r	-	~	$\sim$ T	<b>T</b> T	
νv				$\mathbf{OL}$		n •
1 1/	<b>\)</b>		,	UL	171	ı,

Nozzle No.	Bottle Low Speed ( 10 Bottles/ min )		Optimum S	peed (30 Bottl	les / min )	High Speed	(50 Bottles/Mi	inute)		
TOLLIC TO.	No.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
	3									
	4									
	5									
	1									
	2									
04	3									
	4									
	5									
	1									
	2									
05	3									
	4									
	5									
	1									
	2									
06	3									
	4									
	5									
Min fill vol.							I			I
Max. fill vol.										



Nozzle No.

Avg. vol.

**Bottle** 

No.

### PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE

Net wt.

Optimum Speed (30 Bottles / min )

**Empty wt** 

Net wt.

Low Speed (10 Bottles/min)

**Empty wt** 

Gross wt.

	-	$\boldsymbol{\wedge}$		$\boldsymbol{\wedge}$		$\sim$ T	- Ta 1	r	
μ	w	4 1	11	. 1				o.:	
L	1	v	_	v	v	$\mathbf{U}$	Τ.	<b>U</b>	

High Speed (50 Bottles/Minute)

**Empty wt** 

Net wt.

Gross wt.

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

Gross wt.



PROTOCOL N	0.:	
------------	-----	--

### 8.2.3 Fill volume Variation At 1/3<sup>rd</sup> Tank level:

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

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



-	$\sim$	$\mathbf{r}$	$\sim$	$\sim$ T	-	r
w	•		M '			0.:
- 17	<b>\</b> ,		'	$\mathbf{U}$	/ I T	V

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



•	$\mathbf{r}$	$\boldsymbol{\wedge}$	$\boldsymbol{\wedge}$		$\sim$ T	- N.	r	
,	ĸ	( 1	 ( )	•	$\mathbf{OL}$	. 1	n'	•

Nozzle No.	Bottle	Low Speed ( 10 Bottles/ min )			Optimum S <sub>1</sub>	Optimum Speed (30 Bottles / min )			High Speed (50 Bottles/Minute)		
No.		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:	
	Reviewed By
	Manager QA) Sign/Date:
	Sign/Date:



n	T	$\sim$		$\sim$	~	$\sim$ T		т	
μ	w	6 D			•			NO .	
L	1/	v	1	v	v	v	⊿ l'	<b>lo.:</b>	

### 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/ mi	in )	Optimum S <sub>1</sub>	peed (30 Bottl	es / min )	High Speed	(50 Bottles/Mi	nute)
Nozzie No.		Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
	1									
	2									
01	3									
	4									
	5									
	1									
	2									
02	3									
	4									
	5									
03	1									
03	2									



TIT		$\sim$	$\sim$	•	<b>T 4</b>	
νv	OT.					•
1 1/		``	_,,		1 <b>7</b> ()	• •

Nozzle No.	Bottle	Low Speed (	(10 Bottles/ mi	in )	Optimum S	peed (30 Bottl	es / min )	High Speed	(50 Bottles/Mi	inute)
INUZZIE INU.	No.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	<b>Empty wt</b>	Net wt.
	3									
	4									
	5									
	1									
	2									
04	3									
	4									
	5									
	1									
	2									
05	3									
	4									
	5									
	1									
	2									
06	3									
	4									
	5									
Min fill vol.			I	L		L	L		ı	<u>I</u>
Max. fill vol.										



Nozzle No.

Avg. vol.

**Bottle** 

No.

### PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE

Net wt.

Low Speed (10 Bottles/min)

**Empty wt** 

Gross wt.

	-	$\boldsymbol{\wedge}$		$\boldsymbol{\wedge}$		$\sim$ T	- Ta 1	r	
μ	w	4 1	11	. 1				o.:	
L	7.	v	_	v	v	$\mathbf{U}$	Τ.	<b>U</b>	

High Speed (50 Bottles/Minute)

Manager QA)

Sign/Date: .....

**Empty wt** 

Net wt.

Gross wt.

Checked By Production Sign/Date:					Verified By Quality Assurance Sign/Date
Inference:	•••••	 	 		
	••••••	 	 	•••••	
					Reviewed By

Gross wt.

Optimum Speed (30 Bottles / min )

**Empty wt** 

Net wt.



PROTOCOL N	0.:	
------------	-----	--

### 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	Low Speed (	10 Bottles/ mi	in )	Optimum Sp	peed (30 Bottl	es / min )	High Speed (50 Bottles/Minute)		
THOEETC THO	No.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
	1									
	2									
01	3									
	4									
	5									
	1									
	2									
02	3									
	4									
	5									
03	1									
	2									



-	$\sim$	$\mathbf{r}$	$\sim$	$\sim$ T	-	r
w	•		M '			0.:
- 17	<b>\</b> ,		'	$\mathbf{U}$	/ I T	V

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



Nozzle No.

Avg. vol.

**Bottle** 

No.

### PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE

Net wt.

Optimum Speed (30 Bottles / min )

**Empty wt** 

Net wt.

Low Speed (10 Bottles/min)

**Empty wt** 

Gross wt.

<b>T</b>	$\sim$ $\sim$	$\sim$	~	$\sim$ T	<b>T</b>	r
7 K (		4 h				o.:
. 17.	-	v	v	$\mathbf{L}$	Τ.	U

High Speed (50 Bottles/Minute)

**Empty wt** 

Net wt.

Gross wt.

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

Gross wt.



PROTOCOL N	<b>Vo.:</b>
------------	-------------

### 8.2.6 Fill volume Variation At 1/3<sup>rd</sup> Tank level:

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

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



-	$\sim$		$\sim$	$\sim$	$\sim$ 1	_	<b>T</b>		
w	<i>(</i> )	111	1	•	ı		N	0.:	
. 17	<b>\</b> ,	1	.,	v	•		Τ.4	V	

Nozzle No.	Bottle				Optimum S	peed (30 Bottl	es / min )	High Speed (50 Bottles/Minute)		
INUZZIE INU.	No.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	<b>Empty wt</b>	Net wt.
	3									
	4									
	5									
	1									
	2									
04	3									
	4									
	5									
	1									
	2									
05	3									
	4									
	5									
	1									
	2									
06	3									
	4									
	5									
Min fill vol.			I	L		L	L		ı	<u>I</u>
Max. fill vol.										



Nozzle No.

Avg. vol.

**Bottle** 

No.

### PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE

Net wt.

Low Speed (10 Bottles/min)

**Empty wt** 

Gross wt.

	-	$\boldsymbol{\wedge}$		$\boldsymbol{\wedge}$		$\sim$ T	- Ta 1	r	
μ	w	4 1	11	. 1				o.:	
L	7.	v	_	v	v	$\mathbf{U}$	Τ.	<b>U</b>	

High Speed (50 Bottles/Minute)

Manager QA)

Sign/Date: .....

**Empty wt** 

Net wt.

Gross wt.

Checked By Production Sign/Date:	Verified By Quality Assurance Sign/Date
Inference:	
	Reviewed By

Gross wt.

Optimum Speed (30 Bottles / min )

**Empty wt** 

Net wt.



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



TI	$\Delta$ r	-	~	$\sim$ T	<b>T</b> T	
νv				$\mathbf{OL}$		n •
1 1/	<b>\)</b>		,	UL	171	ı,

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



	$\mathbf{r}$		$\boldsymbol{\cap}$	~	$\sim$ T	<b>TA</b> 1		
$\boldsymbol{\nu}$	Z.	D. II.	<i>.</i>		OL		Λ	•
		, ,	v	v	$\mathbf{u}$	Τ.4	v.	•

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



n	T	$\sim$		$\sim$	~	$\sim$ T		т	
μ	w	6 D			•			NO .	
L	1/	v	1	v	v	v	⊿ l'	<b>lo.:</b>	

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



-	$\sim$		$\sim$	$\sim$	$\sim$ 1	_	<b>T</b>		
w	<i>(</i> )	111	1	•	ı		N	0.:	
. 17	<b>\</b> ,	1	.,	v	•		Τ.4	V	

Nozzle No.	Bottle No.	Low Speed ( 10 Bottles/ min )			Optimum S	Optimum Speed (30 Bottles / min )			High Speed (50 Bottles/Minute)		
INUZZIE INU.		Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	<b>Empty wt</b>	Net wt.	
	3										
	4										
	5										
	1										
	2										
04	3										
	4										
	5										
	1										
	2										
05	3										
	4										
	5										
	1										
	2										
06	3										
	4										
	5										
Min fill vol.			I	L		L	L		ı	<u>I</u>	
Max. fill vol.											



Nozzle No.

Avg. vol.

**Bottle** 

No.

### PERFORMANCE QUALIFICATION REPORT FOR SIX HEAD LOTION FILLING MACHINE

Net wt.

Optimum Speed (30 Bottles / min )

**Empty wt** 

Net wt.

Low Speed (10 Bottles/min)

**Empty wt** 

Gross wt.

<b>T</b>	$\sim$ $\sim$	$\sim$	~	$\sim$ T	<b>T</b>	r
7 K (		4 h				o.:
. 17.	-	v	v	$\mathbf{L}$	Τ.	U

High Speed (50 Bottles/Minute)

**Empty wt** 

Net wt.

Gross wt.

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

Gross wt.



PROTOCOL N	<b>Vo.:</b>
------------	-------------

### 8.2.9 Fill volume Variation At 1/3<sup>rd</sup> Tank level:

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

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



-	$\sim$		$\sim$	$\sim$	$\sim$ 1	_	<b>T</b>		
w	<i>(</i> )	111	1	•	ı		N	0.:	
. 17	<b>\</b> ,	1	.,	•	•		Τ.4	V	

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



	-	$\boldsymbol{\wedge}$		$\boldsymbol{\wedge}$		$\sim$ T	- Ta 1	r	
μ	w	4 1	11	. 1				o.:	
L	7.	v	_	v	v	$\mathbf{U}$	Τ.	<b>U</b>	

Nozzle No. Bottle		Low Speed ( 10 Bottles/ min )			Optimum Speed (30 Bottles / min )			High Speed (50 Bottles/Minute)		
11022101100	No.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
Avg. vol.										

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



PR	O	$\Gamma O$	CO	T.	N	[N	
1 1/	v.				1.7	w.	

8.3	<b>PHYSICAL</b>	TEST:
0.0		

<b>TRIAL</b>	NO.:	01
	110	U.L

Date of test	
Product Name	
Batch No.	

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

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



.,,,	4 N	 CC	 - N	_
PK		 	 1.04	4 6

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				
02	2				
03	1				
0.5	2				
04	1				
04	2				
05	1				
05	2				
06	1				
	2				

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



DD	$\sim$	•	$\sim$	$\sim$	· •	<b>T</b> 1	-
PR	( )	1.0		''	11		Λ
1 1/	v	т,	$\boldsymbol{\mathcal{F}}$	-	,,,	Τ.4	v.

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				
02	2				
03	1				
0.5	2				
04	1				
U4	2				
05	1				
05	2				
06	1				
	2				

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



DD	$\sim$ r	~~	` T	TA T
PR	. D.	M 'I		
1 17	<b>.</b>	 ,,,,	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	No.

### 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:
	•••••••••••••••••••••••••••••••••••••••
	•••••••••••••••••••••••••••••••••••••••
13.0	DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:
	••••••
	•••••••••••••••••••••••••••••••••••••••



PR	റി	$\Gamma C$	C(	<b>NI</b>	No.	
1 1/	•		,,,		/   11/-	

IIIAM	VIA DE VILS	
14.0	CHANGE CONTROL, IF ANY:	
	••••••	•••••
		•••••
		•••••
	•••••	•••••
15.0	REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):	
		•••••
		•••••
	•••••	•••••
	••••••	•••••
16.0	CONCLUSION:	
	•••••••••••••••••••••••••••••••••••••••	•••••
	••••••	•••••
	•••••••••••••••••••••••••••••••••••••••	•••••
	••••••	•••••
17.0	RECOMMENDATION:	
	••••••	•••••
	•••••••••••••••••••••••••••••••••••••••	••••••
	••••••	•••••
	••••••	•••••



### PERFORMANCE QUALIFICATION REPORT FOR

SIX HEAD LOTION FILLING MACHINE

PROTOCOL No.:

### **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

°C : Degree Centigrade

mm : Millimeter

Amp. : Amper

DQ : Design Qualification

IQ : Installation Qualification

OQ : Operational Qualification

PQ : Performance Qualification

Pvt. : Private
Ltd. : Limited



DD	$\sim$ r	-	_	$\sim$ T	-	r
PR						$\mathbf{n}$
1 17	<b>\</b>		_		<i>_</i>	W.,

### 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)			