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#### **1.0 PROTOCOL APPROVAL:**

Signing of this approval page of protocol indicates agreement with the qualification approach described in this document. If modification to the qualification approach becomes necessary, an addendum shall be prepared and approved. The protocol cannot be used for execution unless approved by the following authorities.

This Performance Qualification protocol of 55 Station compression machine has been reviewed and approved by the following signatories:

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
PREPARED			QUALITY		
BY			ASSURANCE		
			QUALITY		
			ASSURANCE		
REVIEWED			ENGINEERING		
BY			QUALITY		
			CONTROL		
			PRODUCTION		
			HEAD		
APPROVED			OPERATION		
BY			QUALITY		
			ASSURANCE		



#### PERFORMANCE QUALIFICATION PROTOCOL FOR COMPRESSION MACHINE

#### 2.0 **OVERVIEW** :

#### 2.1 **OBJECTIVE:**

The objective of developing and executing this protocol is to

- Document the verification of all aspects of the equipment that can affect product quality.
- To make an impact assessment of the critical components of the equipments on the material.
- To establish, check and document the performance of equipment in the established/ predetermined operating ranges.

#### 2.2 PURPOSE:

The purpose of this protocol is to verify that the equipment produces the desired output. Performance qualification of the equipment is planned after the successful completion of the installation and operational qualification.

The performance of the compression machine is verified by charging the hopper with the lubricated blend and verification of physical and chemical parameters of the tablets.

The compressions of the tablets are challenged by analyzing the compressed tablets collected at different speed and varying other parameters.

#### 2.3 SCOPE

The protocol shall define the test procedures, documentation, references and acceptance criteria to establish that the performance of the equipment shall meet the predetermined acceptance criteria.

The Scope of this protocol is limited to the performance qualification of 55 station compression machine in Compression II of manufacturing facility.

Once the performance qualification of compression machine has been completed successfully, the equipment shall be released for the production purpose.

Once the compression of tablets are completed, it shall be taken for coating.



### PERFORMANCE QUALIFICATION PROTOCOL FOR COMPRESSION MACHINE

#### 2.4 **RESPONSIBILITY:**

In accordance with protocol, following functions shall be responsible for the qualification of system.

# **Execution Team (Comprising members from Production, Quality Control, Engineering and Quality Assurance) and their responsibilities are following:**

- > Prepares the performance qualification protocol.
- Ensures that the protocol is in compliance with current policies and procedures on system Qualification.
- > Distributes the finalized protocol for review and approval signatures.
- Execution of Qualification protocol.
- > Review of protocol, the completed qualification data package, and the final report.
- > The chemical analysis of sample shall be carried out by quality control department and physical parameter shall be carried out by production/QA department.
- > Engineering department shall support for execution.
- > The production operator / supervisor shall carry out the cleaning and operation of machine.

#### Head – Quality control / Production / Engineering:

- > Review of protocol, the completed qualification data package, and the final report.
- > Assist in the resolution of validation deficiencies.

#### Head – Operation and Quality Assurance:

Review and approval of protocol, the completed qualification data package, and the final report.



#### 2.5 EXECUTION TEAM:

The satisfactory operation of the 55 station compression machine shall be verified by executing the performance qualification studies described in this protocol. The successfully executed protocol documents that the 55 station compression machine is operational and is satisfactorily working. Execution team is responsible for the execution of performance qualification of the 55 station compression machine. Execution team comprises of

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE



### PERFORMANCE QUALIFICATION PROTOCOL FOR COMPRESSION MACHINE

#### 3.0 GENERAL CONSIDERATION/PREREQUISITE

- 3.1 Approved Standard operating procedure of the equipment shall be available.
- 3.2 The impact analysis of the equipments shall be recorded in the summary sheet.
- 3.3 The installation and operational qualification of the equipment shall be successfully completed before the execution of the performance qualification.
- 3.4 All the deficiencies and discrepancies related to the equipment which affect the product quality and corrective action taken shall be recorded in the appropriate section of the protocol.
- 3.5 The analytical test results and other reports related with the equipment shall be attached with the performance qualification of the equipment and finally verified.
- 3.6 After completion of PQ activities, equipment shall be cleaned as per respective cleaning SOP's and released for manufacturing.

#### 4.0 **REVALIDATION CRITERIA:**

The machine shall be revalidated if

- There are any major changes, which affect the performance of the equipment.
- After major changes in the components of the equipments.
- As per date and revalidation schedule.



### PERFORMANCE QUALIFICATION PROTOCOL FOR COMPRESSION MACHINE

#### 5.0 PERFORMANCE QUALIFICATION PROCEDURE

#### 5.1 METHODOLOGY:

- > The principle of compression machine is to compress the Lubricated granules into tablets within the tablet specification limit and at a specified speed.
- This machine can be used to compress blended granules into tablets of desired hardness so as to achieve post compression tests such as Disintegration time, Friability, thickness, hardness and weight variation within permissible limit.
- The compression process shall be followed as per procedure mentioned in BMR Batch No. -
- > The round, capsule shaped tablet shall be challenged during performance qualification.
- Lubricated granules shall be charged to hopper of the compression machine. Compressed tablets are collected in the SS IPC.
- > The samples shall be collected at 12 and 40 rpm.
- > All the observed result at different RPM shall be noted in observation table.
- The physical parameter shall be verified at minimum and maximum speed of the machine and finally composite sample shall be sent for QC analysis for assay.



#### 6.0 ENVIRONMENTAL CONDITION:

Tablet chang	*Temperature(	(Limit: $22 \pm 3^{\circ}$ C)	*RH (Limit: 50 + 5 %)				
Tablet shape	Max.	Min.	Max.	Min.			
Round							
Capsule							

\*Minimum and maximum temperature and relative humidity to be noted from BMR.

**Remark:** 


Checked by (Sign/Date):

#### 7.0 COMPRESSION PARAMETERS AND OBSERVATION

### > Round / Capsule shaped tablet specification :

7.1 Co	ompression parameter for round and capsule	e shape
1.	COMPRESSION M/C ROUND SHAPE PUNCH SPECIFICATION (Option I)	COMPRESSION M/C CAPSULE SHAPE PUNCH SPECIFICATION (Option II)
2.	<b>UPPER PUNCH</b> Size : 8.80 mm Shape: Round standard concave, break line	UPPER PUNCH Size : 10.00 x 4.00 mm Shape : SC CAPLET, EMBOSSED 25
3.	LOWER PUNCH Size : 8.80 mm Shape: Round standard concave, Plain surface	LOWER PUNCH Size : 10.00 x 4.00 mm Shape : SC CAPLET, EMBOSSED BL
4.	DIE: 8.80 mm Round	<b>DIE:</b> 10.00 x 4.00 mm
5.	<b>RPM:</b> Minimum 12 & Maximum 40	<b>RPM:</b> Minimum 12 & Maximum 40
6.	Hydraulic pressure:	Hydraulic pressure:



### • 7.2 Round shape In process specification (Option I):

S.No	Parameter	In-process Specification (55 stn.)	No of tablets Req./side
1	Appearance	Circular Biconvex Uncoated Tablet Having Break line On One Side And Plain On Other Side	60
2	Weight of 60 tablets	14.40 g ± 2.5 % (14.04 g to 14.76 g)	60
3	Average Weight	240.0 mg ± 2.5 % (234.0 mg to 246.0 mg)	60
4	Uniformity of weight	240.0 mg ± 5 % (228.0 mg to 252.0 mg)	60
5	Thickness	3.70 mm <u>+</u> 0.2 mm (3.50 mm – 3.90 mm)	3
6	Hardness	55 <u>+</u> 30 N (25 N – 85 N)	3
7	Disintegration time	NMT 15 minutes	6
8	Friability	NMT 1.0% w/w	28

### 7.3 Capsule shape in process specification (Option II);

S.No.	Parameter	In-process Specification (55 stn.)	No of tablets Req./side
1	Description	Capsule shaped biconvex uncoated tablet, 25 embossed on one side and breakline on another side.	60
2	Weight of 60 tablets	7.50 g ± 5 % (7.125 g - 7.875 g)	60
3	Average Weight	125.0 mg ± 5 % (118.75 mg – 131.25 mg)	60
4	Uniformity of weight	125.0 mg ± 7.5 % (115.63 mg – 134.38 mg)	60
5	Thickness	2.90 mm ± 0.20 mm (2.70 mm - 3.10 mm)	3
6	Hardness	25 - 100  N	3
7	Disintegration time	NMT 15 minutes	6
8	Friability	NMT 1.0% w/w	52



### PERFORMANCE QUALIFICATION PROTOCOL FOR COMPRESSION MACHINE

### 7.4 In process observation for round shape tablet:

	INPROCESS CHECKS FOR ROUND SHAPE TABLETS (Option I) Appearance of the tablets														
						Арр	earanc	e of the	tablets vely by	; Produc	tion & (			Verifie	d By
RPM	Date	Time		ping		oping		king	Broken tablets			oration	% Defects	Sig	n
			LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS		(Prod.)	(QA)
-															

Put "x" for nil rejection



		INP	ROCES Fre	S CHEC	CKS FOR Every 1 Ho	ROUND S ur (Alternat	SHAPED	TABLE	TS (O & OA)	ption I	)	
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		INP			KS FOR					ption I	)	
RPM	Date	Time	%Fria (Limit N	ability JMT 1% /w)	Thicl (In r	kness	Hard 25 –	lness	D.T. (NMT 15 Minutes)		Verified	By Sign
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						ma								mg
						шg					_			mg
		    	          Max. Weight of g Averag mg	29.            30.         31.            31.         31.            32.         33.            33.         34.            35.         36.            36.         37.             38.             38.             39.             39.             39.             39.             39.             39.             39.             39.             39.           g         Average Weight of 60 table           g         Average Weight           mg         Verified By Sign	29.           30.           31.           32.           33.           34.           35.           36.           37.           38.           39.           40.         Max.       Min.         Weight of 60 tablets       g         Average Weight       mg         Verified By Sign       Verified By Sign	29.         30.         31.         32.         33.         34.         35.         36.         36.         37.         38.         39.         39.        Max.     Min.     Max.       Weight of 60 tablets     g       g     Average Weight       mg     Verified By Sign	29.            30.             31.             32.             33.              33.             35.             36.             37.             38.             39.             40.           Max.       Min.       Max.           g       g       g       g          Average Weight       mg       mg          Verified By Sign	29.          30.          31.          32.          33.          33.          34.          35.          36.          35.          36.          37.         38.       38.         39.         39.         39.       39.         40.        g     g     g       Min.     Max.     Min.       Weight of 60 tablets     g       g     g     g       Yerified By Sign	29.         29.          30.         30.       30.       31.           31.         31.       31.       31.           32.         32.       33.       31.           33.         32.       33.       33.           33.         33.       33.       34.           35.         35.       35.       36.           37.         36.       37.       38.       39.           39.         38.       39.       39.           40.        40.       Min.       Min.         Weight of 60 tablets       g       g       g       g        40.       Min.         Min.       Max.       mg       mg	29.         30.        30.        30.        30.        30.        30.        30.        30.        30.        30.        30.        30.        30.        30.        30.        30.        31.        31.        31.        32.        32.        32.        32.        32.        32.        33.        32.        33.        33.        33.        33.        33.        34.        35.        35.        36.        37.        37.       37.        39.       39.        39.       39.        39.       39.        39.        40.        39.        39.        39.        39.        39.		29.       29.         30.       30.         31.       30.         31.       30.         32.       31.         33.       32.         33.       32.         33.       33.         34.       34.         35.       35.         36.       36.         38.       36.         37.       37.         38.       39.          39.         38.       39.     40.        Min.     Max.     Min.     Max.     Min.       Min.     Max.     mg	29.       29.         30.       30.         31.       30.         31.       30.         32.       31.         33.       32.         33.       32.         33.       33.         35.           36.           36.           37.         38.       37.     38.         39.         39.       39.        40.       39.        40.       39.        40.       39.        10.     Min.     Max.     Min.       11. <td>           29.           30.         30.           31.         30.           32.         31.           33.         32.           33.         33.              33.              33.             33.        33.      </td>	29.           30.         30.           31.         30.           32.         31.           33.         32.           33.         33.              33.              33.             33.        33.



### PERFORMANCE QUALIFICATION PROTOCOL FOR COMPRESSION MACHINE

Tin Production Li Wt in mg	ne : n		Date :			8/ 1				inder i ong		duction		
L Wt in	n			Tin	1e :		Date :	Time	:		Date :	Time	:	
Wt in	TTC:	RPM:					Dept.: Q			RPM:	1			
	HS Sr.	Wt in	Sr.	Wt in	HS Sr.	Wt in	Sr.	LH Wt in	Sr.	Wt in	Sr.	Wt in	HS Sr.	Wt in
	Sr. No.	mg	No.	mg	No.	mg	No.	mg	No.	mg	No.	mg	No.	mg
mg	41.	ms	1.	mg	41.	ms	1.	mg	41.	mg	1.	mg	41.	mg
	42.		2.		42.		2.		42.		2.		42.	
	43.													
	44.													
	46.		6.		46.		6.		46.		6.		46.	
	47.		7.		47.		7.		47.		7.		47.	
	48.		8.		48.		8.		48.		8.		48.	
	49.		9.		49.		9.		49.		9.		49.	
	50.		10.		50.		10.		50.		10.		50.	
	51.		11.		51.		11.		51.		11.		51.	
	52.		12.		52.		12.		52.		12.		52.	
	53.		13.		53.		13.		53.		13.		53.	
	54.		14.		54.		14.		54.		14.		54.	
	55.		15.		55.		15.		55.		15.		55.	
	56.		16.		56.		16.		56.		16.		56.	
	57.		17.		57.		17.		57.		17.		57.	
	58.		18.		58.		18.		58.		18.		58.	
	59.				59.				59.				59.	
	60.		20.		60.				60.				60.	
			21.											
								ļ			-			
					 M				 M					
	wax.	Woight -	•	te	wax.		Min.	1		Woight of			wax.	I
			t ou table	15						weight of	1	6		
		g				g					g			g
		Averag	e Weight							Average	Weight			
		mg				mg				n	ıg			mg
		Verified	l By Sign							Verified	By Sign			
tion)							(Drodros	tion)						
	Lion)	43.         44.         45.         46.         47.         48.         49.         50.         51.         52.         53.         54.         55.         56.         57.         58.         59.         60.   <	43.         44.         45.         46.         47.         48.         49.         50.         51.         52.         53.         54.         55.         56.         57.         58.         59.         60.   <	43.       3.         44.       4.         45.       5.         46.       6.         47.       7.         48.       8.         49.       9.         50.       10.         51.       11.         52.       12.         53.       13.         54.       14.         55.       15.         56.       16.         57.       17.         58.       18.         59.       19.         60.       20.          21.          22.          23.          24.          25.          26.          27.          28.          31.          32.          33.          34.          35.          36.          37.          37.          38.	43.       3.         44.       4.         45.       5.         46.       6.         47.       7.         48.       8.         49.       9.         50.       10.         51.       11.         52.       12.         53.       13.         54.       14.         55.       15.         56.       16.         57.       17.         58.       18.         59.       19.         60.       20.          21.          22.          23.          24.          25.          26.          27.          28.          30.          31.          32.          33.          34.          35.          36.          37.          38.	43.       3.       43.         44.       4.       44.         45.       5.       45.         46.       6.       46.         47.       7.       47.         48.       8.       48.         49.       9.       49.         50.       10.       50.         51.       11.       51.         52.       12.       52.         53.       13.       53.         54.       14.       54.         55.       15.       55.         56.       16.       56.         57.       17.       57.         58.       18.       58.         59.       19.       59.         60.       20.       60.          21.           23.           24.           22.           23.           24.           31.           32.           33.	43.       3.       43.         44.       4.       44.         45.       5.       45.         46.       6.       46.         47.       7.       47.         48.       8.       48.         49.       9.       49.         50.       10.       50.         51.       11.       51.         52.       12.       52.         53.       13.       53.         54.       14.       54.         55.       15.       55.         56.       16.       56.         57.       17.       57.         58.       18.       58.         59.       19.       59.         60.       20.       60.          22.           23.           24.           27.           28.           30.           31.            33.	43.       3.       43.       3.         44.       4.       44.       44.         45.       5.       45.         46.       6.       46.         47.       7.       47.         48.       8.       48.         49.       9.       49.         50.       10.       50.         51.       11.       51.         52.       12.       52.         53.       13.       53.         54.       14.       54.         15.       55.       15.         56.       16.       56.         57.       17.       57.         58.       18.       58.         19.       59.       19.         60.       20.       60.           23.           23.            24.        24.          25.            27.            27.            31.	43.       3.       43.         44.       4.       44.         45.       5.       45.         46.       6.       46.         47.       7.       47.         48.       8.       48.         49.       9.       49.         50.       10.       50.         51.       11.       51.         52.       12.       52.         53.       13.       53.         54.       14.       54.         55.       15.       55.         56.       16.       56.         57.       17.       57.         58.       18.       58.         59.       19.       59.         60.       20.       60.          21.           22.           23.           24.           25.           26.           30.           32. <td>43.       3.       43.         44.       4.       44.         45.       5.       45.         46.       6.       46.         47.       7.       47.         48.       8.       48.         49.       9.       49.         50.       10.       50.         51.       11.       51.         15.       12.       52.         53.       13.       53.         54.       14.       54.         55.       15.       55.         56.       16.       56.         57.       17.       57.         58.       18.       58.         59.       19.       59.         60.       20.       60.                    22.                23.           24.           25.           27.         </td> <td>43.       3.       43.         44.       4.       44.         45.       5.       45.         46.       6.       46.         47.       7.       47.         48.       8.       48.         49.       9.       49.         50.       10.       50.         51.       11.       51.         52.       12.       52.         53.       13.       53.         54.       14.       54.         14.       54.       14.         55.       15.       55.         56.       16.       56.         57.       17.       57.         58.       18.       58.         59.       19.       59.         9.      </td> <td>43.       3.       43.       3.       43.       3.       43.       3.         44.       4.       44.<td>43.       3.       43.       3.       43.       3.         44.       4.       4.       4.       4.       4.       4.         45.       5.       45.       5.       45.       5.         46.       6.       46.       6.       46.       6.         47.       7.       47.       7.       7.         48.       8.       48.       6.       46.       6.         49.       9.       49.       9.       9.       9.         50.       10.       50.       10.       50.       10.         51.       11.       51.       11.       51.       11.       51.         55.       15.       55.       15.       55.       15.       15.         56.       16.       56.       16.       56.       16.       56.       16.         57.       17.       57.       17.       57.       17.       17.       17.         58.       18.       58.       18.       58.       18.       18.         59.       19.       59.       19.       19.       20.       60.       20.        </td><td>43.       3.       43.       3.       43.       3.       43.       43.       43.       44.</td></td>	43.       3.       43.         44.       4.       44.         45.       5.       45.         46.       6.       46.         47.       7.       47.         48.       8.       48.         49.       9.       49.         50.       10.       50.         51.       11.       51.         15.       12.       52.         53.       13.       53.         54.       14.       54.         55.       15.       55.         56.       16.       56.         57.       17.       57.         58.       18.       58.         59.       19.       59.         60.       20.       60.                    22.                23.           24.           25.           27.	43.       3.       43.         44.       4.       44.         45.       5.       45.         46.       6.       46.         47.       7.       47.         48.       8.       48.         49.       9.       49.         50.       10.       50.         51.       11.       51.         52.       12.       52.         53.       13.       53.         54.       14.       54.         14.       54.       14.         55.       15.       55.         56.       16.       56.         57.       17.       57.         58.       18.       58.         59.       19.       59.         9.	43.       3.       43.       3.       43.       3.       43.       3.         44.       4.       44. <td>43.       3.       43.       3.       43.       3.         44.       4.       4.       4.       4.       4.       4.         45.       5.       45.       5.       45.       5.         46.       6.       46.       6.       46.       6.         47.       7.       47.       7.       7.         48.       8.       48.       6.       46.       6.         49.       9.       49.       9.       9.       9.         50.       10.       50.       10.       50.       10.         51.       11.       51.       11.       51.       11.       51.         55.       15.       55.       15.       55.       15.       15.         56.       16.       56.       16.       56.       16.       56.       16.         57.       17.       57.       17.       57.       17.       17.       17.         58.       18.       58.       18.       58.       18.       18.         59.       19.       59.       19.       19.       20.       60.       20.        </td> <td>43.       3.       43.       3.       43.       3.       43.       43.       43.       44.</td>	43.       3.       43.       3.       43.       3.         44.       4.       4.       4.       4.       4.       4.         45.       5.       45.       5.       45.       5.         46.       6.       46.       6.       46.       6.         47.       7.       47.       7.       7.         48.       8.       48.       6.       46.       6.         49.       9.       49.       9.       9.       9.         50.       10.       50.       10.       50.       10.         51.       11.       51.       11.       51.       11.       51.         55.       15.       55.       15.       55.       15.       15.         56.       16.       56.       16.       56.       16.       56.       16.         57.       17.       57.       17.       57.       17.       17.       17.         58.       18.       58.       18.       58.       18.       18.         59.       19.       59.       19.       19.       20.       60.       20.	43.       3.       43.       3.       43.       3.       43.       43.       43.       44.

#### **REMARK:**

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Checked by Sign/Date:



### **7.5 In process observation for capsule shape tablet**

		INP	ROCI	ESS C	HECI	KS FO	R CA	PSUI	LE SH	APE 7	TABLE	ETS (O <sub>l</sub>	otion II)		
						App	bearanc	e of the	e tablet vely by	s Produc	ction & (			Verifie	ed By
RPM	Date	Time	Сар	ping	Chip	ping	Stic	king		oken olets	Discol	oration	% Defects	Sig	'n
			LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS		(Prod.)	(QA)
									1						
									1						

Put "x" for nil rejection



RPM	Date	Time	%Fria (Limit N w/	ability MT 1% w)	Thicl (In n 2.70 mm -	nm.)	Haro 25 – 1		(NM	.T.  T 15 utes)	Verified	By Sign
			LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS	(Prod.)	(QA)
									_			
									-			
									-			
									1			
									1			
									1			
									1			
									]			



RPM	Date	Time	(Limit N	ability JMT 1% 'w)	Thicl (In n 2.70 mm -	nm.)	Hard 25 – 1	lness 100 N	D. (NM Min	T 15	Verified	By Sign
			LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS	(Prod.)	(QA)
									-			
									-			
									-			
									-			
									-			
									-			
									-			
									-			
									-			
									1			
									1			



Date :		ne :	mg ± 7.5	Date :		ne :		Date :	Time			Date :	Time		·
Dept.:	Productio		RPM:					Dept.: Q			RPM:				
		HS	1			HS			LH		1		-	HS	1
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg						
1.	g	41.		1.		41.	<u>s</u>	1.		41.	g	1.		41.	
2.		42.		2.		42.		2.		42.		2.		42.	
3.		43.		3.		43.		3.		43.		3.		43.	
4.		44.		4.		44.		4.		44.		4.		44.	
5.		45.		5.		45.		5.		45.		5.		45.	
6.		46.		6.		46.		6.		46.		6.		46.	
7.		47.		7.		47.		7.		47.		7.		47.	
8.		48.		8.		48.		8.		48.		8.		48.	
9.		49.		9.		49.		9.		49.		9.		49.	
10.		50.		10.		50.		10.		50.		10.		50.	
11.		51. 52.		11. 12.		51. 52.		11. 12.		51. 52.		11. 12.		51. 52.	
12. 13.		52.	<u> </u>	12.	<u> </u>	52.		12.		52.		12.		52. 53.	
13.		54.		13.		54.		13.		54.		13.		54.	
15.		55.		15.		55.		14.		55.		15.		55.	
16.		56.		16.		56.		16.		56.		16.		56.	
17.		57.		17.		57.		17.		57.		17.		57.	
18.		58.		18.		58.		18.		58.		18.		58.	
19.		59.		19.		59.		19.		59.		19.		59.	
20.		60.		20.		60.		20.		60.		20.		60.	
21.				21.				21.				21.			
22.				22.				22.				22.			
23.				23.				23.				23.			
24.				24.				24.				24.			
25.				25.				25.				25.			
26.				26.				26.				26.			
27.				27.				27.				27.			
28.				28.				28.				28.			
29. 30.				29. 30.				<u>29.</u> 30.				29. 30.			
31.				31.				31.				31.			
32.				32.	<u> </u>			32.				32.			
33.				33.				33.				33.			
34.				34.	1			34.				34.			
35.				35.	İ			35.				35.			
36.				36.				36.				36.			
37.				37.				37.				37.			-
38.				38.				38.				38.			
39.				39.				39.				39.			
40.				40.				40.				40.			
Min.		Max.		Min.		Max.		Min.		Max.		Min.		Max.	
			Weight o	f 60 table	ets						Weight of	1	8		
			g				g					g			1
			-	e Weight							Average				
			mg				mg				n				m
			Vorifier	l By Sign				1			Verified	D C!			



Date :		ne :	~	Date :		ne :		Date :	Time			Date :	Time	n & QA	
Dept.:	Productio		RPM:					Dept.: Q			RPM:				
		HS	T			HS			LH					HS	
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg
1.	g	41.		1.	8	41.	<u>s</u>	1.		41.	g	1.	8	41.	
2.		42.		2.		42.		2.		42.		2.		42.	
3.		43.		3.		43.		3.		43.		3.		43.	
4.		44.		4.		44.		4.		44.		4.		44.	
5.		45.		5.		45.		5.		45.		5.		45.	
6.		46.		6.		46.		6.		46.		6.		46.	
7.		47.		7.		47.		7.		47.		7.		47.	
8.		48.		8.		48.		8.		48.		8.		48.	
9.		49.		9.		49.		9.		49.		9.		49.	
10.		50.		10.		50.		10.		50.		10.		50.	
11.		51.		11.		51.		11.		51.		11.		51.	
12.		52. 53.	1	12. 13.		52. 53.		<u>12.</u> 13.		52.		12. 13.		52. 53.	
13. 14.		54.		13.		55.		13.		53. 54.		13.		55. 54.	
14.		55.		14.		55.		14.		55.		14.		55.	
16.		56.		16.		56.		16.		56.		16.		56.	
17.		57.		17.		57.		17.		57.		17.		57.	
18.		58.		18.		58.		18.		58.		18.		58.	
19.		59.		19.		59.		19.		59.		19.		59.	
20.		60.		20.		60.		20.		60.		20.		60.	
21.				21.				21.				21.			
22.				22.				22.				22.			
23.				23.				23.				23.			
24.				24.				24.				24.			
25.				25.				25.				25.			
26.				26.				26.				26.			
27.				27.				27.				27.			
28.				28.				28.				28.			
29.				29.				29.				29.			
30. 31.				30. 31.				<u> </u>				30. 31.			
32.				32.				31.				32.			
33.				33.				33.				33.			
34.				34.				34.				34.			
35.	1			35.				35.				35.			
36.	t			36.				36.				36.			
37.				37.				37.				37.			
38.				38.				38.				38.			
39.				39.				39.				39.			
40.				40.				40.				40.			
Min.		Max.		Min.		Max.		Min.		Max.		Min.		Max.	
			Weight o	f 60 table	ts						Weight of	60 tablets	8		
			g				g					g			
			Averag	e Weight							Average	Weight			
			mg				mg				m	ıg			m
			X7 101	l By Sign							Verified				



Date :		ne :	~	Date :		ne :		Date :	Time			Date :	roductio <sub>Time</sub>		·
Dept.:	Productio		RPM:					Dept.: Q			RPM:				
		HS	1			HS			LH		1			HS	
Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg	Sr. No.	Wt in mg
1.	g	41.		1.	8	41.	<u>s</u>	1.		41.	g	1.	<u>-</u> g	41.	
2.		42.		2.		42.		2.		42.		2.		42.	
3.		43.		3.		43.		3.		43.		3.		43.	
4.		44.		4.		44.		4.		44.		4.		44.	
5.		45.		5.		45.		5.		45.		5.		45.	
6.		46.		6.		46.		6.		46.		6.		46.	
7.		47.		7.		47.		7.		47.		7.		47.	
8.		48.		8.		48.		8.		48.		8.		48.	
9.		49.		9.		49.		9.		49.		9.		49.	
10.		50.		10.		50.		10.		50.		10.		50.	
11.		51.		11.		51.		11.		51.		11.		51.	
12.		52. 53.	1	12. 13.		52. 53.		12. 13.		52.		12. 13.		52. 53.	
13. 14.		54.		13.		54.		13.		53. 54.		13.		55. 54.	
14.		55.		14.		55.		14.		55.		14.		55.	
16.		56.		16.		56.		15.		56.		16.		56.	
17.		57.		17.		57.		17.		57.		17.		57.	
18.		58.		18.		58.		18.		58.		18.		58.	
19.		59.		19.		59.		19.		59.		19.		59.	
20.		60.		20.		60.		20.		60.		20.		60.	
21.				21.				21.				21.			
22.				22.				22.				22.			
23.				23.				23.				23.			
24.				24.				24.				24.			
25.				25.				25.				25.			
26.				26.				26.				26.			
27.				27.				27.				27.			
28.				28.				28.				28.			
29.				29.				29.				29.			
30. 31.				30. 31.				<u> </u>				30. 31.			
32.				32.				31.				32.			
33.				33.				33.				33.			
34.				34.				34.				34.			
35.				35.				35.				35.			
36.				36.				36.				36.			
37.				37.				37.				37.			
38.				38.				38.				38.			
39.				39.				39.				39.			
40.				40.				40.				40.			
Min.		Max.		Min.		Max.		Min.		Max.		Min.		Max.	
			Weight o	f 60 table	ts						Weight of	60 tablets	8		
			g				g					g			
			Averag	e Weight							Average	Weight			
			mg				mg				m	ıg			m
			¥7 101	l By Sign							Verified				



# PERFORMANCE QUALIFICATION PROTOCOL FOR COMPRESSION MACHINE

Date :		ne :	8-10	Date :		ne :		quency: Ev Date :	Time			Date :	Time		/
	Productio		RPM	:				Dept.: Q			RPM:				
	L	HS			R	HS			LF	IS			R	HS	
Sr. No.	Wt in	Sr. No	Wt in	Sr.	Wt in	Sr.	Wt in	Sr. No.	Wt in	Sr. No.	Wt in	Sr.	Wt in	Sr. No.	Wt in
1.	mg	No. 41.	mg	No. 1.	mg	No. 41.	mg	1.	mg	41.	mg	No. 1.	mg	41.	mg
2.		42.		2.		42.		2.		42.		2.		42.	
3.		43.		3.		43.		3.		43.		3.		43.	
4.		44.		4.		44.		4.		44.		4.		44.	
5.		45.		5.		45.		5.		45.		5.		45.	
6.		46.		6.		46.		6.		46.		6.		46.	
7.		47.		7.		47.		7.		47.		7.		47.	
8.		48.		8.		48.		8.		48.		8.		48.	
9.		49.		9.		49.		9.		49.		9.		49.	
10.		50.		10.		50.		10.		50.		10.		50.	
11.		51.		11.		51.		11.		51.		11.		51.	
12.		52.		12.		52.		12.		52.		12.		52.	
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14.		54.		14.		54.		14.		54.		14.		54.	
15.		55.		15.		55.		15.		55.		15.		55.	
16.		56.		16.		56.		16.		56.		16.		56.	
17.		57.		17.		57.		17.		57.		17.		57.	
18.		58.		18.		58.		18.		58.		18.		58.	
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21.				21.				21.				21.			
22.				22.				22.				22.			
23.				23.				23.				23.	-		
24.				24. 25.				24. 25.				24. 25.			
25. 26.				25. 26.				25.				25. 26.			
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38.				38.				38.				38.			
39.				39.				39.				39.			
40.				40.				40.				40.			
Min.		Max.		Min.		Max.		Min.		Max.		Min.		Max.	
			Weight o	of 60 table	ts						Weight of	60 tablets	8		
			g				g					g			ş
			Averag	e Weight							Average	Weight			
			mg				mg				n	ıg			m
			3				U								

#### **REMARK:**

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Checked by Sign/Date:



### PERFORMANCE QUALIFICATION PROTOCOL FOR COMPRESSION MACHINE

### 7.6 Composite sample analysis detail and results.

S.No.	Shape	Sample Qty.	Result
1.	Round		
2.	Capsule		

**Remarks** (if any):

\_\_\_\_\_

Verified By & Date:



### 8.0 DEFICIENCY AND CORRECTIVE ACTION(S) REPORT(S):

Following deficiency was verified and corrective actions taken in consultation with the validation team.

**Description of deficiency:** 

**Corrective action(s) taken:** 

Deviation accepted by: (Sign/Date) Deviation Approved by: (Sign/Date)



### PERFORMANCE QUALIFICATION PROTOCOL FOR COMPRESSION MACHINE

#### 9.0 Annexure (s):

S.No.	Annexure No.	Title of Annexure

Remarks (if any):

\_\_\_\_\_

Done By & Date:

Verified By & Date:



PERFORMANCE QUALIFICATION PROTOCOL FOR COMPRESSION MACHINE

### **10.0 PERFORMANCE QUALIFICATION FINAL REPORT:**

10.1 SUMMARY:

**10.2 CONCLUSION:** 

Prepared By Sign/Date Checked By Sign/Date



### **10.3 FINAL REPORT APPROVAL:**

It has been verified that all tests required by this report are completed, reconciled and attached to this protocol or included in the qualification summary report.

Verified that all amendments and discrepancies are documented, approved and attached to this protocol.

Signature in the block below indicate that all items in this qualification report of 55 station compression machine have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved. The equipment can be taken for use by production department.

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			QUALITY CONTROL		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		