PERFORMANCE QUALIFICATION PROTOCOL FOR COMPRESSION MACHINE

PERFORMANCE QUALIFICATION PROTOCOL FOR COMPRESSION MACHINE

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 BY			QUALITY ASSURANCE		
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			QUALITY CONTROL		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			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.

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

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.

PERFORMANCE QUALIFICATION PROTOCOL FOR COMPRESSION MACHINE

6.0 ENVIRONMENTAL CONDITION:

Tablet shape	*Temperature(Limit: 22 ± 3^0 C)		*RH (Limit: 50 + 5 %)	
	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 Compression parameter for round and capsule shape		
1.	**COMPRESSION M/C ROUND SHAPE PUNCH SPECIFICATION (Option I)**	**COMPRESSION M/C CAPSULE SHAPE PUNCH SPECIFICATION (Option II)**
2.	**UPPER PUNCH** **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	**DIE:** 10.00 x 4.00 mm
5.	**RPM:** Minimum 12 & Maximum 40	**RPM:** 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 ± 0.2 mm (3.50 mm – 3.90 mm)	3
6	Hardness	55 ± 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

7.4 In process observation for round shape tablet:

INPROCESS CHECKS FOR ROUND SHAPE TABLETS (Option I)															
RPM	Date	Time	Appearance of the tablets Frequency: Every 1 Hour (Alternatively by Production & QA)										% Defects	Verified By Sign	
			Capping		Chipping		Sticking		Broken tablets		Discoloration				
			LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS		(Prod.)	(QA)

Put “x” for nil rejection

PERFORMANCE QUALIFICATION PROTOCOL FOR COMPRESSION MACHINE

INPROCESS CHECKS FOR ROUND SHAPED TABLETS (Option I) Frequency: Every 1 Hour (Alternatively by Production & QA)												
RPM	Date	Time	%Friability (Limit NMT 1% w/w)		Thickness (In mm.) 3.50 mm – 3.90 mm		Hardness 25 – 85 N		D.T. (NMT 15 Minutes)		Verified By Sign	
			LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS	(Prod.)	(QA)

INPROCESS CHECKS FOR ROUND SHAPED TABLETS (Option I)
Frequency: Every 1 Hour (Alternatively by Production & QA)

RPM	Date	Time	%Friability (Limit NMT 1% w/w)		Thickness (In mm.) 3.50 mm – 3.90 mm		Hardness 25 – 85 N		D.T. (NMT 15 Minutes)		Verified By Sign	
			LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS	(Prod.)	(QA)

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION PROTOCOL FOR COMPRESSION MACHINE

Uniformity of weight for Round shape Tablets

Limit: 240.0 mg ± 5 %(228.0 mg to 252.0 mg) Frequency: Every 1 hour (Alternatively by Production & QA)

Date :	Time :			Date :	Time :			Date :	Time :			Date :	Time :		
Dept.: Production			RPM:					Dept.: QA			RPM:				
LHS				RHS				LHS				RHS			
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.		41.		1.		41.		1.		41.		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.		11.		51.		11.		51.		11.		51.	
12.		52.		12.		52.		12.		52.		12.		52.	
13.		53.		13.		53.		13.		53.		13.		53.	
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.	
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.		---	---	30.		---	---	30.		---	---	30.		---	---
31.		---	---	31.		---	---	31.		---	---	31.		---	---
32.		---	---	32.		---	---	32.		---	---	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 of 60 tablets								Weight of 60 tablets							
g				g				g				g			
Average Weight								Average Weight							
mg				mg				mg				mg			
Verified By Sign								Verified By Sign							
(Production)				(QA)				(Production)				(QA)			

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION PROTOCOL FOR COMPRESSION MACHINE

Uniformity of weight for Round shape Tablets

Limit: 240.0 mg ± 5 %(228.0 mg to 252.0 mg) Frequency: Every 1 hour (Alternatively by Production & QA)

Date :	Time :			Date :	Time :			Date :	Time :			Date :	Time :		
Dept.: Production			RPM:					Dept.: QA			RPM:				
LHS				RHS				LHS				RHS			
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.		41.		1.		41.		1.		41.		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.		11.		51.		11.		51.		11.		51.	
12.		52.		12.		52.		12.		52.		12.		52.	
13.		53.		13.		53.		13.		53.		13.		53.	
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.	
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.		---	---	30.		---	---	30.		---	---	30.		---	---
31.		---	---	31.		---	---	31.		---	---	31.		---	---
32.		---	---	32.		---	---	32.		---	---	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 of 60 tablets								Weight of 60 tablets							
g				g				g				g			
Average Weight								Average Weight							
mg				mg				mg				mg			
Verified By Sign								Verified By Sign							
(Production)				(QA)				(Production)				(QA)			

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION PROTOCOL FOR COMPRESSION MACHINE

Uniformity of weight for Round shape Tablets

Limit: 240.0 mg ± 5 %(228.0 mg to 252.0 mg) Frequency: Every 1 hour (Alternatively by Production & QA)

Date :	Time :			Date :	Time :			Date :	Time :			Date :	Time :		
Dept.: Production			RPM:					Dept.: QA			RPM:				
LHS				RHS				LHS				RHS			
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.		41.		1.		41.		1.		41.		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.		11.		51.		11.		51.		11.		51.	
12.		52.		12.		52.		12.		52.		12.		52.	
13.		53.		13.		53.		13.		53.		13.		53.	
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.	
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.		---	---	30.		---	---	30.		---	---	30.		---	---
31.		---	---	31.		---	---	31.		---	---	31.		---	---
32.		---	---	32.		---	---	32.		---	---	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 of 60 tablets								Weight of 60 tablets							
g				g				g				g			
Average Weight								Average Weight							
mg				mg				mg				mg			
Verified By Sign								Verified By Sign							
(Production)				(QA)				(Production)				(QA)			

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION PROTOCOL FOR COMPRESSION MACHINE

Uniformity of weight for Round shape Tablets

Limit: 240.0 mg ± 5 %(228.0 mg to 252.0 mg) Frequency: Every 1 hour (Alternatively by Production & QA)

Date : Time :				Date : Time :				Date : Time :				Date : Time :			
Dept.: Production RPM:								Dept.: QA RPM:							
LHS				RHS				LHS				RHS			
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.		41.		1.		41.		1.		41.		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.		11.		51.		11.		51.		11.		51.	
12.		52.		12.		52.		12.		52.		12.		52.	
13.		53.		13.		53.		13.		53.		13.		53.	
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.	
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.		---	---	30.		---	---	30.		---	---	30.		---	---
31.		---	---	31.		---	---	31.		---	---	31.		---	---
32.		---	---	32.		---	---	32.		---	---	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 of 60 tablets								Weight of 60 tablets							
g				g				g				g			
Average Weight								Average Weight							
mg				mg				mg				mg			
Verified By Sign								Verified By Sign							
(Production)				(QA)				(Production)				(QA)			

REMARK:

Checked by Sign/Date:

PERFORMANCE QUALIFICATION PROTOCOL FOR COMPRESSION MACHINE

7.5 In process observation for capsule shape tablet

INPROCESS CHECKS FOR CAPSULE SHAPE TABLETS (Option II)															
RPM	Date	Time	Appearance of the tablets Frequency: Every 1 Hour (Alternatively by Production & QA)										% Defects	Verified By Sign	
			Capping		Chipping		Sticking		Broken tablets		Discoloration				
			LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS		(Prod.)	(QA)

Put "x" for nil rejection

INPROCESS CHECKS FOR CAPSULE SHAPED TABLETS (Option II)
Frequency: Every 1 Hour (Alternatively by Production & QA)

RPM	Date	Time	%Friability (Limit NMT 1% w/w)		Thickness (In mm.) 2.70 mm – 3.10 mm		Hardness 25 – 100 N		D.T. (NMT 15 Minutes)		Verified By Sign	
			LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS	(Prod.)	(QA)

INPROCESS CHECKS FOR CAPSULE SHAPED TABLETS (Option II)
Frequency: Every 1 Hour (Alternatively by Production & QA)

RPM	Date	Time	%Friability (Limit NMT 1% w/w)		Thickness (In mm.) 2.70 mm – 3.10 mm		Hardness 25 – 100 N		D.T. (NMT 15 Minutes)		Verified By Sign	
			LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS	(Prod.)	(QA)

PERFORMANCE QUALIFICATION PROTOCOL FOR COMPRESSION MACHINE

Uniformity of weight for Capsule shape Tablets

Limit: 125.00 mg ± 7.5 % (115.63 mg – 134.37 mg)Frequency: Every 1 hour (Alternatively by Production & QA)

Date : Time :				Date : Time :					Date : Time :				Date : Time :			
Dept.: Production RPM:									Dept.: QA RPM:							
LHS				RHS					LHS				RHS			
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.		41.		1.		41.			1.		41.		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.		11.		51.			11.		51.		11.		51.	
12.		52.		12.		52.			12.		52.		12.		52.	
13.		53.		13.		53.			13.		53.		13.		53.	
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.	
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.		---	---	30.		---	---		30.		---	---	30.		---	---
31.		---	---	31.		---	---		31.		---	---	31.		---	---
32.		---	---	32.		---	---		32.		---	---	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 of 60 tablets									Weight of 60 tablets							
g				g					g				g			
Average Weight									Average Weight							
mg				mg					mg				mg			
Verified By Sign									Verified By Sign							
(Production)				(QA)					(Production)				(QA)			

PERFORMANCE QUALIFICATION PROTOCOL FOR COMPRESSION MACHINE

Uniformity of weight for Capsule shape Tablets

Limit: 125.00 mg ± 7.5 % (115.63 mg – 134.37 mg)Frequency: Every 1 hour (Alternatively by Production & QA)

Date : Time :				Date : Time :					Date : Time :				Date : Time :			
Dept.: Production RPM:									Dept.: QA RPM:							
LHS				RHS					LHS				RHS			
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.		41.		1.		41.			1.		41.		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.		11.		51.			11.		51.		11.		51.	
12.		52.		12.		52.			12.		52.		12.		52.	
13.		53.		13.		53.			13.		53.		13.		53.	
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.	
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.		---	---	30.		---	---		30.		---	---	30.		---	---
31.		---	---	31.		---	---		31.		---	---	31.		---	---
32.		---	---	32.		---	---		32.		---	---	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 of 60 tablets									Weight of 60 tablets							
g				g					g				g			
Average Weight									Average Weight							
mg				mg					mg				mg			
Verified By Sign									Verified By Sign							
(Production)				(QA)					(Production)				(QA)			

PERFORMANCE QUALIFICATION PROTOCOL FOR COMPRESSION MACHINE

Uniformity of weight for Capsule shape Tablets

Limit: 125.00 mg ± 7.5 % (115.63 mg – 134.37 mg)Frequency: Every 1 hour (Alternatively by Production & QA)

Date : Time :				Date : Time :					Date : Time :				Date : Time :			
Dept.: Production RPM:									Dept.: QA RPM:							
LHS				RHS					LHS				RHS			
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.		41.		1.		41.			1.		41.		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.		11.		51.			11.		51.		11.		51.	
12.		52.		12.		52.			12.		52.		12.		52.	
13.		53.		13.		53.			13.		53.		13.		53.	
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.	
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.		---	---	30.		---	---		30.		---	---	30.		---	---
31.		---	---	31.		---	---		31.		---	---	31.		---	---
32.		---	---	32.		---	---		32.		---	---	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 of 60 tablets									Weight of 60 tablets							
g				g					g				g			
Average Weight									Average Weight							
mg				mg					mg				mg			
Verified By Sign									Verified By Sign							
(Production)				(QA)					(Production)				(QA)			

PERFORMANCE QUALIFICATION PROTOCOL FOR COMPRESSION MACHINE

Uniformity of weight for Capsule shape Tablets

Limit: 125.00 mg ± 7.5 % (115.63 mg – 134.37 mg)Frequency: Every 1 hour (Alternatively by Production & QA)

Date : Time :				Date : Time :				Date : Time :				Date : Time :			
Dept.: Production RPM:								Dept.: QA RPM:							
LHS				RHS				LHS				RHS			
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.		41.		1.		41.		1.		41.		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.		11.		51.		11.		51.		11.		51.	
12.		52.		12.		52.		12.		52.		12.		52.	
13.		53.		13.		53.		13.		53.		13.		53.	
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.	
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.		---	---	30.		---	---	30.		---	---	30.		---	---
31.		---	---	31.		---	---	31.		---	---	31.		---	---
32.		---	---	32.		---	---	32.		---	---	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 of 60 tablets								Weight of 60 tablets							
g				g				g				g			
Average Weight								Average Weight							
mg				mg				mg				mg			
Verified By Sign								Verified By Sign							
(Production)				(QA)				(Production)				(QA)			

REMARK:

Checked by Sign/Date:

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)

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		