EUROPEAN JOURNAL OF BIOMEDICAL AND PHARMACEUTICAL SCIENCES
http://www.ejbps.com

ISSN 2349-8870
Volume: 3
Issue: 6
330-333
Year: 2016

A QUALIFICATION OF EQUIPMENT: COMPRESSION MACHINE

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Article Received on 31/03/2016 **Article Revised on 20/04/2016** **Article Accepted on 11/05/2016**

ABSTRACT
Qualification is the action of proving that any equipment works correctly and leads to expected results. The main objective of the present study was to perform the performance qualification of critical tablet manufacturing equipment like Compression machine. The performance qualification protocols were prepared, approved and studies were performed as per the approved protocols. The performance qualification of compression machine, core tablets of smallest size were compressed and checked for their parameters such as appearance, average weight, hardness, friability, disintegration time and thickness. The results of all performance qualification works were satisfactory and demonstrated the efficiency of the equipment for their intended use.

KEYWORDS: Equipment qualification, Compression machine.

INTRODUCTION

Validation is an integral part of quality assurance; it involves the systematic study of systems, facilities and processes aimed at determining whether they perform their intended functions adequately and consistently as specified.[1] Qualification is an essential part of a pharmaceutical manufacturer's quality assurance system; it should demonstrate that facilities are suitable for their intended use and should also guarantee that the medicinal products are of an appropriate quality.[2,3] Regarding the "Qualification of Equipment," chapter 3.34 of the GMP Guideline states: "Manufacturing equipment should be designed, located and maintained to suit its intended purpose." Annexure 15 to the EU GMP Guideline specifies how this requirement must be implemented. Chapter 2.5.1 of Pharmaceutical Inspection Convention/Scheme (PIC/S) document PI 006 therefore expressly states that the contract giver is ultimately responsible for proper implementation of the validation work: "In such cases, the responsibility lies with the contract giver to ensure that the required standards of the quality of the work which is carried out, for program control and for documentation are made.[4,5] The GMP Guidelines for documentation apply in general for the layout and compilation of qualification documents which must be authorized by the head of production and quality assurance.[6,7] The documentation should be retained for at least five years once the facility or equipment has been shut down. According to Annex 15, No. 2 of the EU GMP Guideline, a company's current qualification projects must be described in a validation master plan. The first stage of a qualification should be the (DQ).[8] Conformance of the design with the GMP requirements should be demonstrated and documented. Before the facility's delivered, it may be necessary to make sure that the user requirements are complied with at the manufacturer's premises (Factory Acceptance Test, FAT).[9] The objective of the present study was to perform the performance qualification of critical tablet manufacturing equipment Compression machine. The compression machine is used to produce core tablets of various sizes and shapes. Qualification phases must be implemented on the basis of qualification protocols that have been approved beforehand.

MATERIALS AND METHODS

Compression machine (LAB Press Machine, Cemach Pvt. Ltd., 12 stations double rotary "B" tooling). Performance Qualification of Compression Machine: The compression machine was fitted 8.0 mm circular, deep concave upper and lower punches and dies. The lubricated granules were loaded in both hoppers and compression cycle was started by operating the machine at 20 rpm and physical parameters were recorded every one hour till the end of the cycle.

Acceptance Criteria

Table 1: Process parameters and Specifications.

Parameter	Specifications
Average weight	195 TO 205 mg
Weight per tablet	185 to 215 mg
Thickness	2.65 to 3.25 mm
Hardness	60 to 100 N
Friability	NMT 1%w/w
Disintegration time	NMT 10 minutes

RESULTS AND DISCUSSION

COMPRESSION MACHINE

Samples of compressed tablets were evaluated for average tablet weight, thickness, hardness, disintegration time, and friability. Samples were collected after every 15 minutes throughout the entire compression cycle for the determination of average weight. The average weight of the tablets determined during the trials 1, 2 and 3 were 200.57, 200 and 198.33 mg respectively. The average thickness of the tablets determined during the trials 1, 2 and 3 were 2.97, 2.98 and2.97 mm. The average hardness of the tablets determined during the trials 1, 2 and 3 were 79.73, 80.90 and 80.80 N respectively. The average percentage friability of the tablets determined during the trials 1, 2 and 3 were 0.214, 0.216 and 0.218 percentages respectively. The average disintegration time of the tablets determined during the trials 1, 2 and 3 were 336.60, 388.83 and 333.63 seconds respectively. The results were within the limits and these were presented in the Table 2 to 6

Table 2: Average tablet weight of various trials of compressed tablet (mg)

Trials / Sampling	Trial 1		Trial 2		Trial 3	
	RHS	LHS	RHS	LHS	RHS	LHS
1	198	199	201	200	198	194
2	200	203	200	204	200	203
3	201	200	195	200	198	200
4	200	201	201	200	201	200
5	201	200	204	201	200	198
6	200	200	199	200	201	195
7	204	198	203	199	200	201
8	201	203	200	198	203	201
9	200	201	204	207	201	200
10	200	204	196	194	195	197
11	198	207	195	204	203	199
12	199	201	200	201	196	197
13	199	203	204	200	195	203
14	200	200	196	199	197	196
15	200	196	200	195	199	197
Mean	200.57		200		198.33	
SD	2.16		3.17		2.70	

Table 3: Thickness of various trails of Compressed Tablets (mm)

Trials / Sampling	Trial 1		Trial 2		Trial 3	
	RHS	LHS	RHS	LHS	RHS	LHS
1	3.01	2.96	2.98	2.97	2.95	2.98
2	2.96	2.97	2.96	2.99	3.01	2.98
3	2.99	2.95	2.97	2.99	2.96	2.95
4	2.95	3.01	2.99	3.00	2.97	2.99
5	2.98	2.95	2.97	2.95	3.00	2.95
6	2.99	2.96	2.95	3.01	2.97	2.98
7	2.97	2.96	2.97	2.98	3.01	2.95
8	3.00	3.01	2.96	2.99	3.01	2.97
9	2.96	2.95	2.97	2.98	2.99	2.95
10	2.97	2.99	2.97	2.95	3.00	2.96
11	2.96	3.00	3.01	2.98	2.95	2.99
12	2.95	2.99	2.97	2.96	3.00	2.95
13	2.98	2.96	2.97	3.01	2.97	2.99
14	2.95	3.01	2.95	2.97	2.98	2.96
15	2.98	2.99	2.97	3.00	2.95	2.98
Mean	2.97		2.98		2.97	
SD	0.022		0.018		0.021	

Table 4: Hardness of various trials of compressed tablets (kg/cm^2)

Trials / Sampling	Trial 1		Trial 2		Trial 3	
	RHS	LHS	RHS	LHS	RHS	LHS
1	70	74	76	80	90	81
2	89	76	70	82	80	79
3	75	81	84	89	72	78
4	75	82	79	90	87	71
5	87	76	88	84	79	84
6	76	86	81	79	74	89
7	79	81	77	83	90	79
8	76	89	86	72	78	86
9	71	87	80	79	83	72
10	87	71	70	89	75	77
11	81	89	90	73	87	73
12	79	82	70	87	84	79
13	74	85	80	76	87	90
14	73	85	90	70	83	74
15	79	77	89	84	78	85
Mean	79.73		80.90		80.80	
SD	4.87		6.66		5.81	

Table 5: Friability of various trials of compressed tablet (%w/w)

Trials / Sampling	Trial 1		Trial 2		Trial 3	
	RHS	LHS	RHS	LHS	RHS	LHS
1	0.23	0.20	0.21	0.22	0.23	0.20
2	0.22	0.20	0.23	0.20	0.21	0.22
3	0.23	0.21	0.22	0.20	0.23	0.21
4	0.23	0.22	0.21	0.22	0.20	0.23
5	0.20	0.21	0.23	0.22	0.20	0.22
6	0.20	0.23	0.22	0.20	0.21	0.23
7	0.22	0.21	0.20	0.23	0.22	0.21
8	0.21	0.20	0.21	0.22	0.21	0.23
9	0.23	0.22	0.22	0.20	0.23	0.22
10	0.22	0.20	0.23	0.23	0.22	0.21
11	0.23	0.21	0.20	0.22	0.21	0.23
12	0.23	0.20	0.21	0.23	0.22	0.22
13	0.22	0.21	0.20	0.22	0.21	0.23
14	0.20	0.20	0.22	0.21	0.22	0.21
15	0.22	0.21	0.23	0.22	0.21	0.23
Mean	0.214		0.216		0.218	
SD	0.012		0.012		0.042	

Table 6: Disintegration time of various trials of compressed tablets (sec)

Trials / Sampling	Trial 1		Trial 2		Trial 3	
	RHS	LHS	RHS	LHS	RHS	LHS
1	347	355	348	325	360	321
2	335	338	326	311	309	341
3	352	328	336	354	319	350
4	341	340	326	452	322	315
5	305	344	323	352	339	341
6	321	360	328	300	321	353
7	352	341	353	334	312	301
8	352	343	325	353	341	340
9	330	338	321	357	342	351
10	359	321	352	365	338	357

11	349	307	328	355	326	315
12	340	302	304	357	342	350
13	321	332	354	324	321	320
14	354	328	320	321	354	330
15	306	357	341	320	357	321
Mean	**336.60**		**388.83**		**333.63**	
SD	**16.49**		**58.04**		**16.48**	

CONCLUSION

The present study was done on the performance qualification of some of the equipment designed for the manufacture of tablets namely Compression machine. The performance qualification trials demonstrated that the tablet manufacturing equipment performed consistently under a given set of conditions. The compression machine was evaluated for its intended use of compression of granules into tablets. The average weight, thickness, hardness, disintegration time and friability of tablets were within the specified limits. Reviewing the entire data generated during qualification, it can be concluded that the equipment studied are suitable for which they are used.

ACKNOWLEDGEMENTS

The authors are thankful to the Management of German Remedies Limited, Goa, India for providing the necessary facilities to carry out the research work.

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