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A Review on qualification of the tablet compression machine

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ABSTRACT

Validation is the art of designing and practicing the designed steps alongside with the documentation. Validation is one of the most important steps in maintaining & achieving the quality of the final product group after batch. The qualification of the equipment and systems are planning to carry out the tests and record the tests. We cannot be manufacturing the product,without an equipment. If the equipment is validated, we can ensure that our product is of the top-quality. Validation of the equipment is known as Qualification. To making different kinds of dosage forms, various equipment's are used. Here, this article concentrates on the equipment qualification for the Tablet compression machine. It gives in detail, qualification steps of the equipment, which is used for the manufacturing process through wet granulation. Qualification, an ideal step for equipment validation, is the action undertaken to demonstrate the intended use and performance of the utilities and equipment. The individual steps of qualification such as design, installation, operational and performance qualification, were done in order to qualify the equipment. Blueprint of equipment validation was also included and the tablets were tested for physical parameters such as appearance, punch Shape, punch diameter, upper punch, lower punch, hardness, weight variation, friability, and thickness.

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INTRODUCTION

Qualification is an important part of a pharmaceutical manufacturer's quality assurance system: it should exhibit that facilities are suitable for their intended use and should also guarantee that the medicinal product is of suitable quality (Tirunagari *et al.*, 2012). The validation master plan controls and describes the essential responsibilities and activities for qualification & validation (Reddy *et al.*, 2014). The high level of document evidence is provided by the equipment qualification, and it also provides conform to the standard. The tablets are designed according to the predetermined design by a machine called as tablet compression. This tablet compression machine in the industry are also called as tablet press. The compression machine is designed for high-speed production. It's a capable as a modular system in the tablet compression chamber for manufacturing of tablets or press forming preparation. The tablets of uniform size and weight are formed from powders by using a mechanical device known as tablet compressor. The compression of tablets is one of the major steps in the formulation of tablets. The material that is used for compression should have sufficient flow and compression properties (Nayak *et al.*, 2016). During compression, the following features to be considered.

1. The dies and punches and their setup on compress/ion machine is called Tooling,
2. Compression speed

Importance of validation

1. Minimized rework and ejection.
2. Reduces the defect cost
3. Make process better understood
4. The process of smooth running should be assured.
5. Reduces risk problems
6. Reduces the chances of product recall from the market
7. May results in reduced time to market for new product
8. It helps to analyze the deviations caused during the process.
9. Decreases the chances of failure of the batches
10. The cost of validation can be decreased by decreasing Flotsam, Revamp, Dependence un In-process controls,
11. Decrease testing during in-process and also in finished goods
12. Maintenance of equipment is easy.
13. The lengthy investigations of the process or analysis that are related to variance should be avoided to stop the delayed and complication causes (Reddy *et al.*, 2014; Nandhakumar *et al.*, 2011).

Equipment validation is divided into four phases

Design Qualification

The design which is proposed for the instrument should ensure with the functional requirements of the end-users, which is the very first step in DQ. Before the construction and procurements of the parts, the proposed design must assure the DQ (Validation Online. Net, 2008).

Installation Qualification

The instruments which contains all its components and documentation and is used to check the performance according to the requirement (Validation Online. Net, 2008).

Operation Qualification

In this, all the important parts of the instrument are tested and they ensure that they all perform correctly and are synced with the entire system (Validation Online. Net, 2008).

Performance Qualification

The instrument which is monitored for a certain period of time to check the required parameters are consistently delivered (Validation Online. Net, 2008).

Typical equipment validation blueprint

1. Installation Qualification(IQ)

(a).Utilities, Facility and Equipment's

1. OQ: Equipment's & utilities testing procedures
2. Validation: Cleaning systems & products testing protocols
3. Documentation
4. Quality assurance testing laboratory validation
5. Standard operating procedures
6. Organization tables
7. Personnel training procedure
8. List of events (Ramasubramaniyan *et al.*, 2013).

MATERIALS AND METHODS

Tableting equipment

Tableting equipment is a mainly automatic, high-speed rotatory press. The speeds of the motor drives vary from 410 - 1630 tablets per minute. Tablets are prepared when the material is compressed in between the punches and then it will pass between compression rolls. Ejection, the top punches are rise within the die & free from the feed body and decrease the ejection cam lifts the decrease punches to push the pills out of the dies. Take-off bars has removed the pills from a press on the feed frame (Reddy *et al.*, 2014) in Figure 1.

Installation Qualification

1. The approved purchase order should be verified.
2. The invoice check manufacturing and supplier should be verified.
3. The model and the sequential number should be verified.

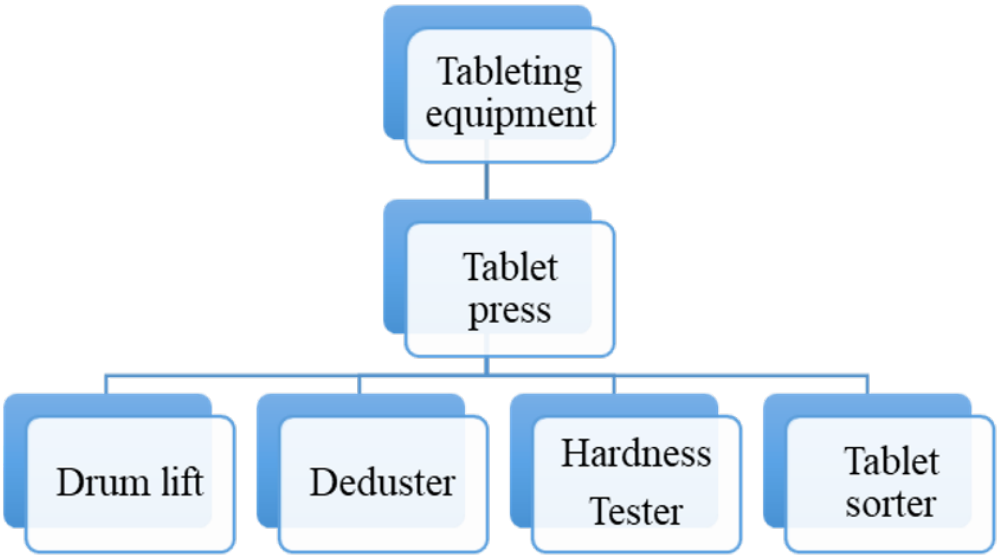

Figure 1: Tableting equipment components

4. If there any physical damage should be checked.
5. To fit in with the area and establishment prerequisite per the suggestion of the producer
6. Check that the ideal utilities are accessible (Validation Online. Net, 2008)

Installation qualification establishes of confidence that the instrument was properly installed. And the installation have to meet the producers identified guidelines as well as the design variations at installation.

The material is involved for an installation qualification evolution is instrument identification, utilities, document requirements, major component specification, material component, lubrication, specification, and instrument safety feature in Figure 2, (Vázquez, 1998).

Identification of equipment

Record the identification instrument number, as well as the following, required information: Equipment purchase order number, Serial number of the equipment, Model number, The company allocated instrument number and The area of the instrument.

Documentation requirements

Record the manufacturer's operation instrument, manual preservation and designs. Collect the standard operating procedures that protect the operation, setup, and tablet compression cleaning.

Required utilities

The equipment utility requirements is to contrast the producers specified amps (A) & volts (V), as the requirements are found the specification at the period of testing for the qualification and record the results. And also, record the areas were current supply source present.

Major component specification

It is a part of the procedure, make sure that the tableting compression elements were purchased, installed & delivered. Major components were recorded.

Component material

Each component of the material was recorded and that the components contact the product in the Table 1 below.

Lubricants

It should be recorded and is used to carry out the tableting equipment. Specify if they make a connection with the result.

Instrument safety characteristics

The safety features of tablet press functioning according to the producer's requirements are considered as the objectives for testing equipment safety features. The test is been carried out with the empty tablet press in order to check whether all of the guards are present and record the results (Reddy *et al.*, 2014; Vázquez, 1998).

Operation Qualification

1. The alarm control should be verified.
2. The calibration requirements should be performed and identified by the validation team
3. The equipment should be operated at lower medium speed and higher medium speed as per

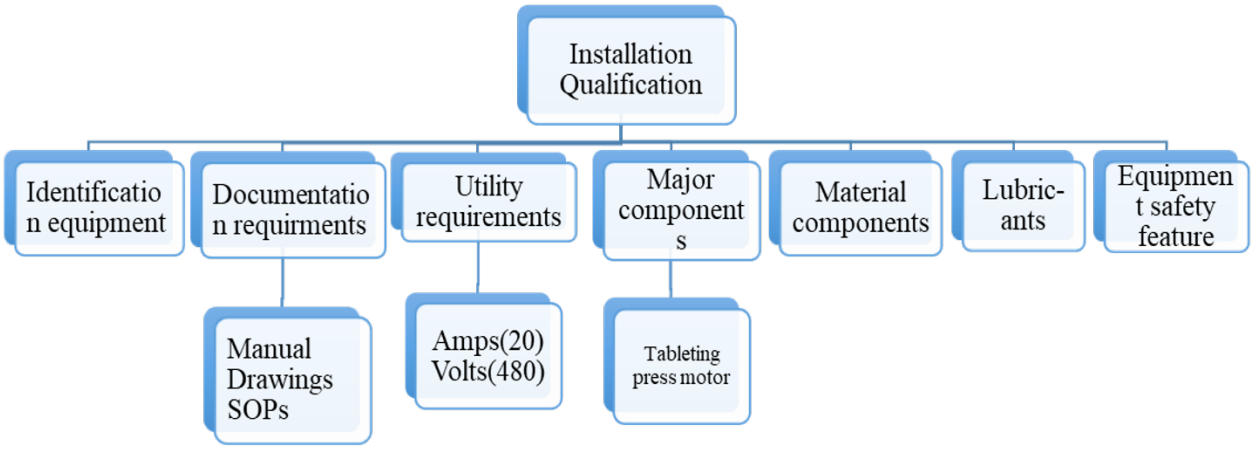

Figure 2: Installation qualification elements

Table 1: Component material

Components	Materials
Dies	Mild steel
Punches	Stainless steel
Hopper	Mild steel
Head of the rotor	Mild steel

the manual operation to prove the operation switch.

4. Whether all the pushbuttons and switches are working properly and should be verified.
5. When the procedure should be initiated for calibration, operation, and maintenance.
6. Organize a training program for relevant employees.
7. Start at least one pilot batch for every product (Sigvardson *et al.*, 2001).

The operation qualification evaluation must initiate that the instrument can perform within the specified limits & tolerances. The OQ mechanical series of the tablet press is challenged, together with the fundamental tablet press processes. The tableting equipment should be confirmed for its working capacity, not how nicely it makes drugs.

The information is involved for an operation qualification evaluation is calibrated of the equipment having already been used to restrict the tableting press, instrument control function (push buttons & switches) & operation of the equipment (upper punches, lower punches, cam tracks, tablet press speed, take-off bars, feed frames, rotor head rotation direction) (Vázquez, 1998) in Figure 3.

Calibration requirements

All equipment instrumentation should be verified and has to log into a calibration system, while qualification, calibration should be on time and procedure of the calibration is to in place. The information on calibrated equipment is to be recorded and control the tableting equipment.

Equipment control functions

Verify the testing instruments and the equipment push buttons & switches on the equipment work according to the producer requirements and specification. The test will be conducted with the empty tablet press.

Equipment process

Cams Track Test

The objective test is to make sure that the superior cam tracks test and inferior cam tracks test is a direct connection with upper punches following to the processer requirements. And the following methods are used and the result should be recorded.

The punches are installed to check whether the cams are make contact with the punch head angles on both parts of the double-sided cams.

The punches are verified to check whether they are make contact with one side of the single-sided cam through a full cam track, including upper and lower cam.

Upper Punches Test

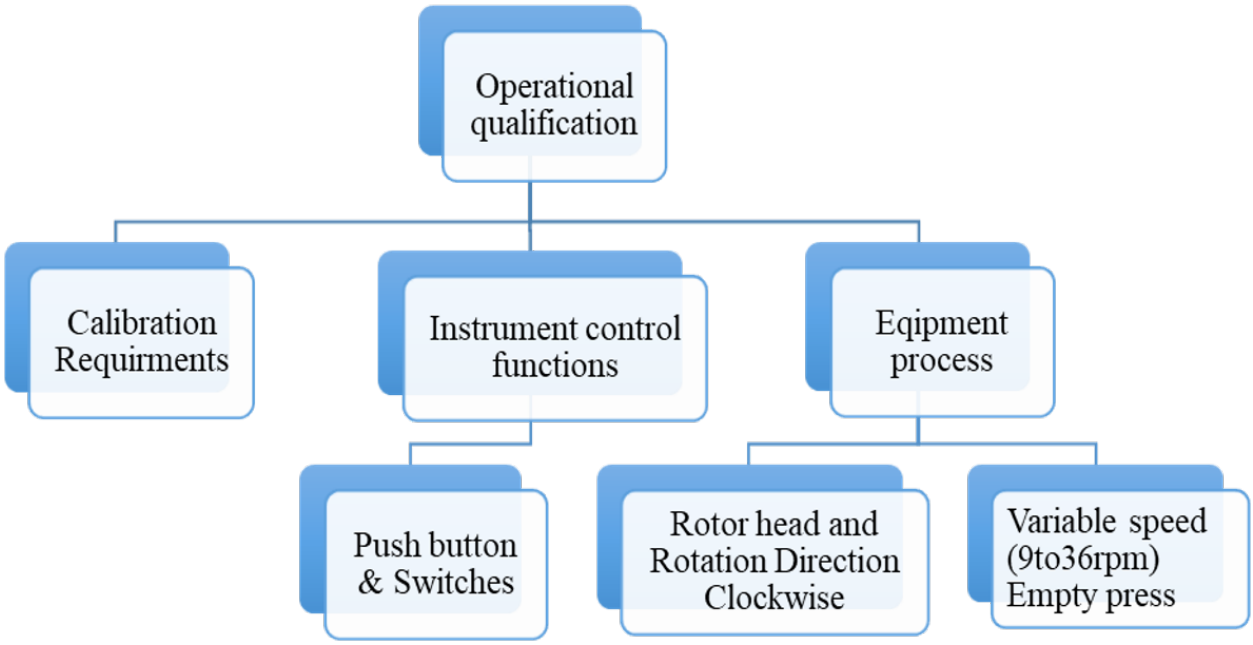

Figure 3: Operational qualification elements

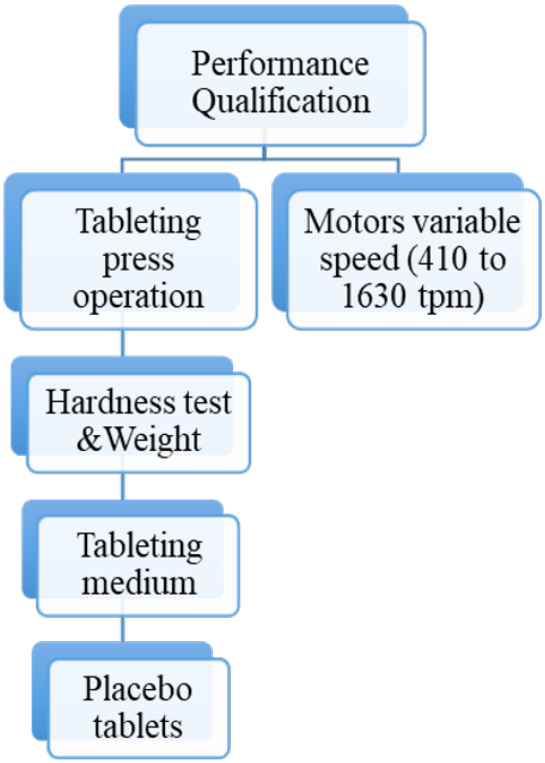

Figure 4: Performance Qualification elements

Verify that the upper punch test and upper punch perforation is matching to the producers requirements. The Vernier caliper equipment is used for the upper punch test and the following performance:

Connect the part of the tape and to point the intensity of penetration of the upper punch when this test is set towards a standard depth.

The standardized Vernier caliper is used to estimate the penetration intensity into the dies. The upper punch should be removed and results should be recorded.

Lower Punches Test

Verify the actual of its lower punch and that the height of the lower punches is to set the accord into producer specification. This test is required for dial indicator and measure the lower punch height with that dial indicator and results were recorded.

Feed Frame

The purpose of this test should be verified and this test distance upper the rotor head is matching to the producer specification. In this test, the feeler gauge is mainly required. And to estimate the approval between the rotor head and feed frame with the feeler gauge.

Take-off Bar Test

Verify that the Take-off bar test and it do not connect with the inferior punches and turn the tableting equipment by using hand and the take-off bar should not connect with the punches. Results should be recorded.

Equipment Rotation Direction

The equipment rotation direction check is to verify the head of the rotor is rotates inside the right course. The test might be achieved with an empty tablet press. And start the equipment by pressing start buttons and observe the route of the rotation of the head of the rotor as considered from the front of the tablet press

Tablet press speed

To measure the speeds are within the +/-10% of manufacturers specification of a minimum of 9rpm and maximum of 36rpm. It will be conducted with the empty press. The Id of the stopwatch is needed for the tableting equipment test. A calibrated stopwatch is used to estimate the speeds of the rotor head (Vázquez, 1998; Reddy *et al.*, 2014).

Performance Qualification

To check the instrument is installed properly and then performing in the specified operating parameters. The equipment can work reliably under minimum, maximum & routine working conditions.

Evaluation of compression characteristics of tablet & capabilities.

The compression characteristics of tablet & capabilities: Thickness, Hardness, weight variation, Content uniformity, Disintegration time and Friability. It should be considered (Vázquez, 1998).

Perf1ormance Qualification Objectives

Starting 3 products of biliary and compressed the one layer batches by using a compression machine.

During the performance, qualification is to check all the critical parameters of the result.

Measure the thickness, hardness, friability, and weight for each triplicate tablet run, as shown below Figure 4

PQ checklist

Compare all description and enter the remark of all three batches,

1. Brand name
2. Average weight (20 tablets)
3. Batch number
4. Size (Batch)
5. Weight of the individual tablet
6. Description of product
7. Rotation per minutes (machine)
8. Thickness (mm)
9. Hardness (kg/cm2)
10. Punch Shape
11. Punch diameter
12. Upper punch and lower punch

Operation

Tablet Hardness test & Weight

Verify that the hardness and weight of the tablet should be consistently maintained throughout the complete hardness and weight of the tablet setting range.

1. The equipment's & materials are used for this test are a placebo and weight, hardness and thickness gauge.
2. The tablets are compressed by using a placebo granulation.

3. Average weight & hardness of the 5 tablets at startup, 10, 20, & 30 minutes, & Record the result.
4. The equipment is mainly used to measure the hardness and weight of the tablet and record the results.

Speed test

1. The speed test was recording the functioning of the equipment using a placebo.
2. The objectives are also to confirm the equipment can preserve consistent tableting speeds during the speed range for tableting.
3. Calculated & recorded the equipment variable speeds.
4. A placebo test, a stopwatch, and a scale this test materials & equipment is required.
5. The tablets should be compressed then applying for placebo granulation. The average weight and hardness of the 5 tablets at startup, 10. 20 and 30 minutes & record the result (Reddy *et al.*, 2014).

CONCLUSIONS

Validation is always taking a longer time than we think, especially with a new installation and allow for extra time for the validation. The main objectives of the qualification of a laboratory instrument is to make sure the validity of data. The current qualification of the equipment procedures and programs used within the pharmaceutical industry are based on industry practice, vendor practice, voluntary requirements and regulatory requirements. A need exists for greater consistency in the qualification and maintenance practices for common analytical instruments used within the pharmaceutical industry. In today's environment, there is a tendency to harmonize practices by simply incorporating new procedures into existing programs. The overall program should be evaluated periodically to ensure that current requirements are met and that excessive or inefficient practices are eliminated or changed.

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