ISSN: 0976-7126
Malviya *et al.*, 11(7):6769-6773, 2020

International Journal of Pharmacy & Life Sciences
Open Access to Researcher

Qualification of Ganscoater according to various Regulatory Guidelines: An Overview

Minkashi Malviya*, Deepika Bairagee, Mahavir Chhajed and Braesh Parmar

Oriental College of Pharmacy and Research, Oriental University, Indore, (M.P.) - India

Article info

Received: 23/05/2020

Revised: 11/06/2020

Accepted: 25/07/2020

© IJPLS

www.ijplsjournal.com

Abstract

The main objective of this project is to define the qualification requirements and acceptance criteria supported various regulatory guidelines to gather sufficient data to make sure that Ganscoater Machine is installed, qualified and use as intended within the processing environment. Tablet coating may be a process by which an essentially dry, outer layer of coating material is applied to the surface of a dosage form so as to confer specific benefits over uncoated variety. It comprises function of a sugar or polymeric coat on the tablet. The benefits of tablet coating are taste masking, odor masking, physical and chemical protection, protects the drug within the stomach, and to regulate its release profile. Various sorts of coating machine is employed to coat the tablets, in our project we've used Ganscoater Coating machine, which is one among the simplest coating machine and widely used across pharmaceutical industries. To use any coating machine qualification of the machine and validation of its process is usually required before put it into operational exercise.

Keywords: Ganscoater; Coating Machine; Qualification; Installation; Regulatory Guidelines

Introduction

Tablet coating is a process by which an essentially dry, outer layer of coating material is applied to the surface of a dosage form in order to confer specific benefits over uncoated variety. It involves application of a sugar or polymeric coat on the tablet. The advantages of tablet coating are taste masking, odor masking, physical and chemical protection, protects the drug in the stomach, and to control its release profile. Various types of coating machine is used to coat the tablets, project demonstrate here used Ganscoater Coating machine, which is one of the simplest coating machine and widely used across pharmaceutical industries. Equipment Qualification is the final series of inspections and tests to ensure that critical requirements necessary for related product quality are satisfied and that documents and procedures necessary to properly operate and maintain the system are in place.1,2

To use any coating machine qualification of the machine and validation of it's process is always required before put it into operational exercise. Equipment qualification is a prerequisite for any Process validation and thus must be considered as a vital basis of quality in pharmaceutical processes.

***Corresponding Author**
E.mail: m9907887403@gmail.com

There is a well-established system of qualification phases— User Requirement Specification, Design Qualification, Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ).

IQ establishes that the instrument is received as designed and that it is properly installed. OQ is carried out modularly with the intention to ensure that the specific modules of the system and the whole system are operating according to the defined specifications. PQ as the last step of the initial qualification is supposed to ensure continued satisfactory performance of equipment under actual running conditions over the anticipated working range during daily use.1-3

Material and Methods

For Qualification of the Ganscoater coating machine V-Model Approach has been followed which is widely used and accepted methodology for the equipment qualification.

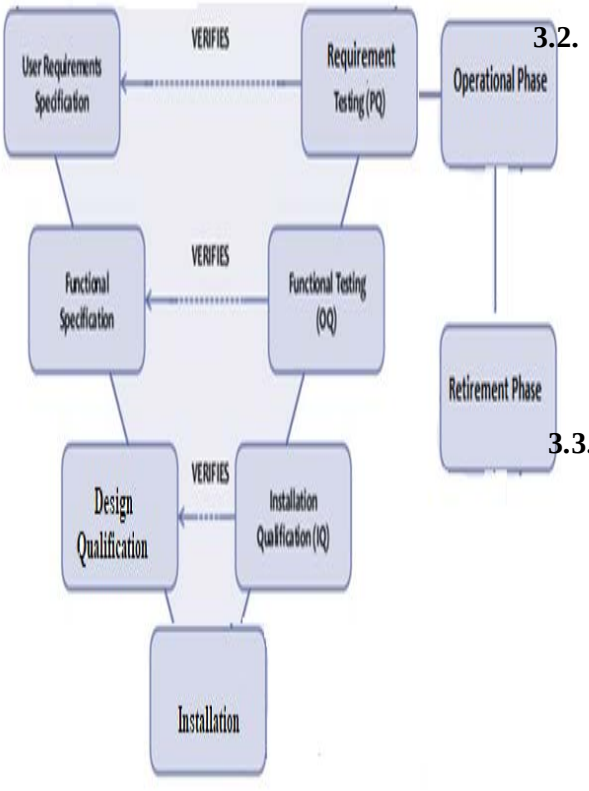

Fig. 1: An overview of Instrument Qualification

Qualification

User Requirement Specification

A requirement gathering should include identification, analysis, and documentation of information about the system and its intended use

URS should defines what the system is intended to do i.e., basic needs or functionality of the system from end user or business prospective. This document links to the process testing, which test for each of the requirements

3.1. Functional specification and Design Qualification

FS defines the detailed function of the system and provides the design objectives. This documents links operational qualification, which tests function. An FS defines what the system should do, and what functions and facilities are to be provided. It provides a list of design objectives for the system

Design Qualification describes how the system will be designed to execute various functionalities as per URS. All the requirements defined in the URS should be translated into logical design document.4-6

3.2. Installation Qualification

It is documented evidence that the premises, supporting utilities, the equipment have been built and installed in compliance with design specifications. Installation qualification consists of documented verification that all key aspects of the coating machine are in working condition and have been properly installed in accordance with manufacturer's specifications in the proper operating environment.

The activities and documentation associated with IQ of coating machine are as follows:

3.3.1. System Description & purchase Order Verification:

Provide a description of the equipment, including its manufacturer, model, serial number, software version, etc. Use drawings and flowcharts where appropriate.

Equipment/ Name	: Ganscoater
Manufacturer / Supplier	: Gansons
Model / Capacity	: GCSi700
P.O Number / date	: PO12546

Acceptance criteria: All the items / equipment shall be received as per the purchase order / packaging list. Record the deviation, if any.

Drawing(s), Manual(s), and related documents

Check for the drawing and manuals received and verify the correctness as mentioned in the URS/DQ.

Verified GA Drawing, P & ID Drawing, and Electrical Drawing

Acceptance Criteria: Drawings and manual shall be available as per equipment / system.

Installation Verification

Verify the proper installation of the equipment with respect to the proper earthling, tight and grounded, sufficient space for moving part, easy cleaning, and no physical damage

Acceptance Criteria: Installation shall meet the requirements.

Utilities/Facility/Environment

Verify that the installation site satisfactorily meets vendor-specified environmental requirements. A commonsense judgment for the environment suffices; one need not measure the exact voltage for a standard-voltage instrument or the exact humidity reading for an instrument that will operate at ambient conditions.

Results

Voltage 417 V, Frequency, 50Htz, 3 phase

Compressed air Pressure 7 bar

Verification of Material of Construction

Check for the material of construction of contact parts and non-contact parts with the actual requirement.

Acceptance Criteria:

Material of construction shall meet the Design specification /User requirement specification. All metallic Contact part should be made from SS316 or SS316L, non-contact part should be made from SS304, and Non-metallic contact parts shall be of food grade material and free from TSE/BSE.

Verification of Filter

Check the filters installed with the equipment as per the manufacturer's specification. Visually check the filter(s) for any damage(s).

Pre-Filter efficacy found to be Down to 10µ

Intermediate Filter efficacy found to be down 3µ

HEPA Filter efficacy found to be down 0.3µ with 99.97% efficiency.

Acceptance Criteria:

The filter(s) installed should meet the manufacturer's specification and free from damage.

Identification of procedures

Identify the list of procedures related to Operation, Cleaning, Calibration and Preventive Maintenance Procedure and mention the list of document(s) to be prepared. Whichever document is not applicable, write "Not Applicable" in the title column.

Major Component Verification

Identify and list out the major components installed with the equipment/instrument/ system.

Acceptance Criteria

Record the details of each component and check the supplied component is installed as per the User Requirement Specification / Design qualification/ Factory Acceptance Test / Manual

Sr. No.	Name of the component
1.	Basic Unit
2.	Pan Assembly
3.	Pan Motor
4.	Dosing Pump, Motor & Gear box
5.	Liquid Vessel Unit
6.	Hot air supply unit
7.	Exhaust air unit
8.	SS Ducting Unit
9.	Washing Pump, Motor & Accessories
10.	M.S. Wet Scrubber with Booster Blower Unit
11.	Pneumatic Panel Unit
12.	Power Panel Unit
13.	Instrumentation & Accessories
14.	Control Panel

All major component installed and verified as per the User Requirement Specification / Design qualification/ Factory Acceptance Test / Manual

3.3.2. Instrument(s) Calibration

List out the measuring instruments provided on the equipment / system / instrument and classify them as Critical and Non -Critical.

Classify the instrument as "critical" if the particular instrument is used to measure the process parameters which have direct impact on the product quality.

Classify the instrument as "non-critical" if the particular instrument is used to know the status of equipment which is not critical, or the value is for reference only.

Following instrument has been listed out and calibrated

S. No.	Instrument Name	Make & Model	Criticality
1	Solenoid Valve	SMC Pneumatics India Pvt. Ltd.	Critical
2	PT 100 Sensor	Maars Technologies	Critical
3	Temperature Indicator	Maars Technologies	Critical
4	Pressure Gauge	Ace Instruments	Critical

Operational Qualification

OQ is the documented verification that the system functions according to written pre-approved functional specification throughout representative or anticipated ranges.

Verification of procedures

Check the availability and adequacy of the procedures and other related documents identified during installation qualification as per section 3.3.7. Also ensure that respective person is trained in the procedure to be followed.

Safety Features & Sensors Functionality Testing

To verify the functionality of all the interlock/alarms and warning systems/safety features associated with the system as per the procedure mentioned method of testing. Any alternative method shall be mentioned in the comments column.

3.3. Procedure: Check all the safety features (interlocks)/alarms and warning systems associated with the equipment/system by simulating condition.

Sr. No.	Safety Feature
1.	Emergency Stop
2.	Atomization air low
3.	Pan interlock
4.	Spray bar out
5.	Hot air blower trip
6.	Exhaust air blower trip
7.	Booster Blower Motor Trip
8.	Pan motor trip
9.	Peristaltic pump trip
10.	Scrubber pump trip
11.	Wash pump trip
12.	Bed temperature low
13.	Bed temperature high
14.	DP across HEPA low
15.	DP across HEPA High

3.4.1. Control Panel Testing

Verify the control panel for its menus, submenus, keys and other functionalities and record the results. Check the functionality of control panel with regard to User Requirement Specifications / Design Qualification/ As per Manual.

3.4.2. Critical Operating Function

Verify the critical operating function of the coating machine as below

Sr. No.	Critical Operating Parameters
1.0	Continuity of Operation – Manual Mode
2.0	Continuity of Operation – Auto mode
3.0	Power Failure / Recovery
4.0	Measurement of air velocities
5.0	Differential Pressure across filters
6.0	Printing parameters verification
7.0	Verification of MMI, security, Recipe Management and data back up functionalities.
8.0	System access control verification
9.0	Communication failure data recovery study
10.0	Peristaltic Pump output verification
11.0	Process Parameter Control Study at minimum, maximum and medium set point for the process parameters,

Performance Qualification

PQ is the documented verification that a system is capable of consistently performing or controlling the activities of the processes it is required to perform or control, according to written and pre-approved specifications, while operating in its specified operating environment.

NOTE: PQ should be performed for Minimum and Maximum occupancy capacities of pan with standard baffles as well as reduced baffles.

The article shall not verify and establish the process parameters. The equipment suitability for each product which will be taken on the machine shall be verified as part of Process validation or verification study and this article shall not cover these aspects. 7,8

Conclusion

The purpose of the use of equipment's is to generate reliable data. Equipment qualification helps fulfill this purpose. Tablet coating the major process in tablet manufacturing process, hence coating machine qualification is most important aspect to regulate the coating process. A risk based approach should be followed to qualify the equipment. In this study we have used the V-model approach to qualify the coating machine as per regulatory aspects. As per new regulatory requirements, software validation (HMI verification) should also be considered during equipment qualification. All instruments associated with the equipment should be calibrated and verified for their intended use. Procedures should be in place to ensure that equipment is qualified, clean and suitable for its intended use.

Procedures for the use of facilities should ensure that materials are handled in a manner that minimizes the risk of contamination and cross-contamination. So qualification is very important for equipment's to provide assurance of intended use.

References

1. Laboratory Controls, General Requirements, Code of Federal Regulations, Part 211.160, Title 21, Rev. April 2000.
2. Maintenance and Calibration of Equipment, Code of Federal Regulations, Part 58.63, Title 21, Rev. April 2000.
3. Cloud PA. Validating a Laboratory Incubator, BioPharm 10 (11), 30–42, 1997.
4. Bedson P., The Development and Application of Guidance on Equipment Qualification of Analytical Instruments, Accred. Qual. Assur. 1 (6), 265–274, 1996.
5. Anjaneyulu Y, Marayya R, Quality Assurance and Quality Management in Pharmaceutical industry, Pharmabook Syndicate, 2005.
6. International Conference on Harmonization, Harmonized Tripartite Guideline, Validation of Analytical Procedures, Text and Methodology, Q2(R1), Nov. 2005.
7. International Conference on Harmonization. ICH Q2B: Validation of Analytical Procedures: Methodology. Federal Register. 1997; 62 FR 27463. http://www.fda.gov/cder/guidance/1320fnl.pdf.
8. US Food and Drug Administration. General Principles of Software Validation. Final Guidance for Industry and FDA Staff. Rockville, MD: US Department of Health and Human Services, Food and Drug Admini-stration, January, 2002.

Cite this article as:
Malviya M., Bairagee D., Chhajed M. and Parmar B. (2020). Qualification of Ganscoater according to various Regulatory Guidelines: An Overview, *Int. J. of Pharm. & Life Sci.*, 11(7): 6769-6773.
Source of Support: Nil
Conflict of Interest: Not declared
For reprints contact: ijplsjournal@gmail.com