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Research Paper

Qualification And Validation of Spray Dryer (SPD D-111)

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ABSTRACT

Equipment qualification is a critical process in ensuring the reliability and consistency of machinery used in pharmaceuticals manufacturing. Equipment qualification involves rigorous testing and documentation to verify that equipment functions as intended and meets predefined specifications. This process not only safeguards product quality but also ensures compliance with regulatory standards, such as current Good Manufacturing Practices (cGMP). Study focusses on the qualification and validation of the Spray Dryer SPD D-111. Spray dryer is an equipment used to convert liquid solutions or suspensions into dry powder form through a process of atomization and rapid evaporation of the solvent. All the critical components of equipment was qualified i.e. Feed Pump, Atomizer, Drying Chamber, Cyclone Separator, and Exhaust System. The qualification followed the 4Q model, which consists of Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ). The SPD D-111 spray dryer, manufactured by Techno Search Instruments, The dryer is equipped with advanced control systems for regulating inlet temperature, atomization rates, and airflow, making it suitable for a wide range of pharmaceutical formulations. This study highlighted SPD D-111's capable in delivering uniform particle size distribution which are essential for achieving optimal product quality. Quality attributes such as moisture content, particle size, yield, and uniformity have been tested, and results meet the predefined specifications. The spray dryer has successfully passed all qualification stages, confirming that it meets qualification requirements, has been installed correctly, operates within specified limits, and consistently delivers the desired product quality

INTRODUCTION

In the pharmaceutical industry, equipment qualification is not just a regulatory obligation but also a cornerstone of quality assurance and risk

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management. By systematically verifying that equipment performs within specified limits and operates reliably, pharmaceutical companies can prevent costly production errors, reduce downtime, and avoid product recalls.[1] Moreover, thorough documentation of the qualification process provides a transparent record of compliance, which is essential during audits and inspections. Ultimately, robust equipment qualification practices contribute to the overall efficacy, safety, and reliability of pharmaceutical products, reinforcing trust in the industry.[2] Equipment qualification is a critical process in ensuring the reliability and consistency of machinery used in various industries, from pharmaceuticals to manufacturing.[3] At its core, equipment qualification involves rigorous testing and documentation to verify that equipment functions as intended and meets predefined specifications. This process not only safeguards product quality but also ensures compliance with regulatory standards, such as Good Manufacturing Practices (GMP).[4] The Quality Assurance department plays an important role in managing and coordinating qualification and validation processes. The qualification and validation technique has been studied because of its critical role within a productive process in terms of product quality qualities such as purity, safety, and efficacy.[5,6] Validation consists of a sequence of criteria that include tests, system verifications, and crucial process parameters that serve as regulating keys that can fluctuate within an acceptable range.[7-9]

QUALIFICATION OF EQUIPMENT:

Instrument qualification is not a single continuous process, but instead results from several discrete activities. For convenience, these activities can be grouped into four phases as per figure No. 01. Design qualification (DQ), installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ).[9-13]

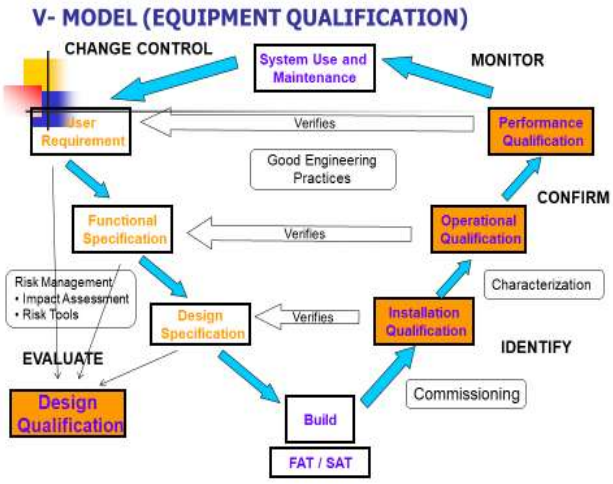

Fig 01 "V" model for Qualification of equipment's

Spray drying technology

This technology of continuously converting feed from a fluid condition into dried particle form through spraying the feed into a hot drying medium is known as spray drying. As long as it can be pumped and atomized, the feed can be a solution, slurry, emulsion, or gel. It entails combining a highly dispersed liquid with an adequate amount of hot air to cause liquid droplet evaporation and drying.[14] Spray dryer should

operate successfully and meet powder specifications, sprays with the necessary droplet size distribution must form.

A spray nozzle atomizer produces atomization. The fluid bed's placement inside the drying chamber allows for drying at lower temperatures. Higher thermal efficiency and colder handling conditions for powder are the outcomes. Particle size is directly influenced by the mass flow of the liquid, its viscosity, solids content, and surface tension. [15-20]

Fig 2 Spray dryer

The qualification of a spray dryer is critical to ensure that the equipment is functioning correctly and consistently produces high-quality products in compliance with industry standards. The following points outline the key reasons why spray dryer qualification is necessary. The Performance Qualification (PQ) ensured that the Spray Dryer consistently performed according to the specifications and intended use. PQ evaluates the performance of the spray dryer using actual production conditions and product formulations to ensure it consistently produces the desired product quality.[21-23]

The PQ included: [24-29]

- Specification of sampling plans, sample handling procedures, and test protocols
- Production Testing: Formulation of Nifedipine Microsphere, Run the spray dryer under actual production conditions using the specific feed material or solution.
- Batch Reproducibility: Demonstrate that the dryer produces consistent results across multiple batches.
- Documentation: Record all parameters and results during the production process, including deviations, if any, and ensure product quality meets predefined specifications.

In order to obtain a product with appropriate morphology, firstly, the parameters of spray drying were determined.

Formulations of microspheres [30]

- The polymethyl methacrylate (PMMA) was first dissolved in dichloromethane.

- The drug in the solid form was dissolved in the polymer solution under high-speed homogenization

- This resultant solution was atomized in a stream of hot air.

- The atomization led to the formation of the small droplets or the fine mist from which the solvent evaporates instantaneously leading the formation of the microspheres in a size range 1-100µm.

- Micro particles were separated from the hot air by means of the cyclone separator while the trace of solvent is removed by vacuum drying

So, 6 formulations (F1, F2, F3, F4, F5 and F6) of microspheres were made with the same procedure.

EVALUATION OF MICROSPHERES [31-37]

Quality Testing: Test the dried powder product for critical quality attributes (CQA) such as particle size, moisture content, and uniformity.

1. **Organoleptic characteristics:**
   - The colour and appearance of the drug was characterized and recorded.

2. **Percentage yield**
   - The Nifedipine microspheres obtained after drying are weighed.

$$\text{Percent Yield} = \frac{\text{Weight of microsphere}}{\text{Total expected weight of drug and polymer}} * 100$$

3. **Average particle size**

   - Average particle size and of the Nifedipine was measured using a Malvern zeta sizer instrument.

Re-Qualification Criteria [38]

Re-qualification of the Instrument shall be carried out through the change control procedure in case of Modification or change in the main component. The magnitude of re-qualification shall depend on the nature of change(s) and its impact on the quality/functions.

RESULTS AND DISCUSSION

The qualification of a spray dryer ensures that the equipment operates according to specified standards and consistently produces the desired product quality. This process typically involves the following stages:

Design Qualification (DQ): The design of the spray dryer has been reviewed and confirmed to meet the specified user requirements and Current Good Manufacturing Practices (cGMP) standards. The design aligns with the necessary operational conditions, including temperature, airflow, and atomization technology to achieve the desired product characteristics as per design specifications.

Installation qualification study: Flow diagrams, isometric drawings, electrical & mechanical drawings, and P&ID Drawing were verified with the DQ and it was found to be meeting with the actual installation. Installation of all the major and minor components was verified and found to be properly installed. Utility connection (compressed air, electrical connections) were found to be properly connected. The instruments which require calibration were identified. Material of construction for all the product contact parts was found to be Borosilicate Glass (Pyrex equivalent), all the gaskets and tubing were found to be constructed with the food grade material which meets specified acceptance criteria.

Operational Qualification study: All the measuring instruments which requires calibration were calibrated and it was found to be working as per the design specifications. The instrument was operated at worst-case conditions. The alarms verification, power failure, control panels, interlocks and emergency switch operations were verified and found to be satisfactory.

Performance Qualification Study:

Operation of Spray Dryer

1. Switch on Mains Supply.
2. The Upper display on PID controller shows the Actual In Air temperature & the Lower display shows the set value.
3. The display of the Temperature Indicator shows the actual Out Air temperature.

- In Air TP: (280°C max) set the inlet temperature to 45^{O}C using 'UP' or 'DOWN' keys on the Controller.
- Out Air TP: (280°C max) The Temperature Indicator shows the Outlet temperature Reading. (Out Air TP cannot be set).
- Blower flow rate / Vacuum: (50 Nm³/hr max) set the Blower flow rate to 12 Nm³/hr using UP or DOWN keys on the VFD.
- Feed pump flow rate: (20 ml/min max) set the desired feed pump flow rate in to 4ml/min using SHIFT or UP keys on Stepper motor controller.
- Feed Reversal: Feed can be reversed by using the RV key on the Stepper motor controller.

The performance qualification was done to qualify the Spray Dryer SPD-D-111 installed in the PG Pharmaceutics Lab. by preparing 6 formulations (F1, F2, F3, F4, F5 and F6) of microsphere from the instrument. The results obtained are as follows.

Fig No.3: Formulations F1 to F6

Table No.01: Parameters for operating spray drying

Formulation Code	Inlet Temperature	Outlet Temperature	Feed Rate
F1	43± 2˚C	33± 2˚C	4ml/min
F2	44± 2˚C	32± 2˚C	4ml/min
F3	45± 2˚C	33± 2˚C	4ml/min
F4	43± 2˚C	32± 2˚C	4ml/min
F5	45± 2˚C	34± 2˚C	4ml/min
F6	43± 2˚C	33± 2˚C	4ml/min

EVALUATION OF MICROSPHERES:

1. Percentage yield

Table No.02: Percentage yield

Sl. No	Formulation code	Percent Yield (%w/w)
1	F1	28.56±0.29
2	F2	31.01±0.53
3	F3	35.96±0.10
4	F4	45.35±0,25
5	F5	60.39±0.19
6	F6	53.00±0.20

2. Average particle size and Moisture content.

Table No.03: Average particle size of Microsphere

Sl. No	Formulation code	Particle Size (µm)	Moisture content (%w/w)
1	F1	5.041±0.014	2.30
2	F2	5.205±0.041	1.83
3	F3	4.368±0.002	2.05
4	F4	3.901±0.053	2.22
5	F5	3.558±0.022	2.51
6	F6	3.643±0.036	2.3

The spray dryer has successfully passed all qualification stages, confirming that it meets design requirements, has been installed correctly, operates within specified limits, and consistently delivers the desired product quality. The equipment is now approved for commercial use, and regular monitoring and maintenance plans have been established to ensure ongoing compliance and performance.

CONCLUSION

The Qualification of Spray Dryer (SPD D-111) was performed with respect its design specification, installation, operational and performance criteria. All the major and minor components have been installed as per the design specifications. P&ID drawing, user manual, certificates of material of construction are available. Material of construction of all the product contact parts meets the specified acceptance criteria. Utility connections are done as per the requirement. Instruments which require calibration are identified and calibrated. Alarm verification, verification of safety interlocks, Verification of control panels and other operational parameters are verified and found to be satisfactory. The performance of spray dryer (SPD D-111) is evaluated which meets the acceptance criteria. The system is efficient to produce a product which meets to the required quality attributes consistently. The equipment can be used for the routine purpose.

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