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A REVIEW ON QUALIFICATION OF LABORATORY EQUIPMENT

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ABSTRACT

This project focuses on the qualification of laboratory equipment used in the pharmaceutical industry, emphasizing the importance of ensuring reliability, accuracy, and compliance with regulatory standards. The qualification process encompasses installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ), which collectively verify that equipment operates as intended and meets specified requirements. Through systematic testing and documentation, this project evaluates critical equipment, including spectrophotometers, chromatographs, and balances. By adhering to industry guidelines, such as those set forth by the FDA and ICH, this qualification ensures that laboratory results are reproducible and trustworthy, ultimately contributing to the safety and efficacy of pharmaceutical products. The outcomes of this project highlight best practices for equipment qualification, fostering a culture of quality in pharmaceutical laboratories.

Qualification as a part of validation is the task performed to identify or check that utilities, equipment and Ancillary systems are capable of operating within limits for their intended use. Equipment qualification is a key Element in the pharmaceutical quality system. In recent times regulatory agencies are more focusing on Qualification of equipment. Qualification of the equipment starts from design of the equipment based on the User requirement specification and functional requirement specification. The review article provides Information on Design Qualification which is done to identify whether the proposed design of facilities, system And equipment is suitable for intended purpose, Installation Qualification which is done to check whether the Equipment is built and installed in compliance with design specification, Operational Qualification in which the Process parameters shall be challenged to assure that product meets all requirements and finally Performance Qualification to demonstrate that the process will produce acceptable product consistently under normal Operating conditions

KEY WORDS : *Qualification, equipment, Regulatory requirement , calibration*

1.INTRODUCTION

QUALIFICATION

It refers to activities undertaken to demonstrate that utilities and equipment suitable for their intended use and performing properly.

It is the action of providing that process work correctly and consistently any equipment and produces the expected result.

DEFINATION

It is the action of providing, and documenting that equipment or ancillary system ↓ are properly installed, work correctly and accurately lead to the expected results."

Qualification is a part of validation but individual qualification steps alone do not constitute process validation.

Qualification of Analytical instrumentation is essential for accurate and precise measurement of Analytical data. (if instrumentation is not qualified, all other work based upon the use of that instrumentation is suspect

It proof that new equipment is fit for its intense purpose. This is achieved by fully defining all of the required characteristics of the measuring system and then proving that the selected equipment meet these requirements before using it for analysis characteristics of the measuring system and then proving that the selected equipment meet these requirements before using it for analysis.

reduced likelihood of incorrect test result as the equipment Performance has been Proved to be suitable for its intended Purpose both before it is used for test Sample analysis and during its working life.

Documentation can act as a checklist for determine and rectifying the source of any measuring problem

Equipment qualification Plays a fundamental role in a laboratory quality system as it assists the development and validation of suitable test methods and helps identity the quality Control and quality assurance measured that will be required to ensure that test measurements are fit for Purpose.

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- equipment qualification ensures that equipment is capable for generating test measurement

2.PHASES OF QUALIFICATION

Qualification of equipment has been grouped into 8 phases-

1. Design Qualification (DQ)
2. Installation Qualification (IQ)
3. Operational Qualification(OQ)
4. Performance Qualification (PQ)
5. Verification Qualification (VQ)
6. Safety Qualification (SQ)
7. Maintenance Qualification (MQ)
8. Re-Qualification

(1) DESIGN QUALIFICATION (DQ)

It is the documented verification that the proposed design of the facilities, system and equipment is Suitable for intended purpose.

DQ should be performed existing equipment is being used for new process. When new equipment is being per chased

DQ serves as precursor to defining equipment IQ and OQ. Has it been designed and selected correctly?

(2) INSTALLATION QUALIFICATION (IQ)

It is documented evidence that the premises, supporting utilities, the equipment Have been built and installed in compliance with design specifications.

It verifies that the equipment has been installed in accordance with manufacturers recommendation in a proper manner and Plaid in an environment suitable for intended purpose.

It involves the co-ordination efforts of the vendor, the operating department and the project team. Has it been built or installed correctly?

(3)OPERATIONAL QUALIFICATION(OQ)

OQ is the process of demonstrating that an instrument will function according to its operational specifications Which result in product of predetermined requirements.

Does it work correctly?

(4) PERFORMANCE QUALIFICATION (PQ)

qualification Plays a fundamental role in a laboratory quality system as it assists the development and validation of suitable test methods and helps identity the quality

•After IQ and OQ the instrument continued suitability for its intended use is provided through performance qualification.

•It refers to establishing evidence that the process, under anticipated conditions, consistently produces a product which meet all predetermined requirements.

Equipment Qualification also Documents regular performance checks Conducted throughout the equipment's operational life. As well as being a regulatory requirement for some industries, Equipment Qualification gives the following benefits to all analyst:

Proof that new equipment is fit for its intended purpose. This is achieved by fully defining all of the required characteristics of the measuring system and then proving that the selected equipment meets these requirements before using it for analysis.

A template for troubleshooting any problem that may occur whilst the conductivity measuring system is in service. The Equipment Qualification documentation can act as a checklist for determining and rectifying the source of any measuring problems. Equipment Qualification plays a fundamental role in a laboratory's quality system as it assists the development and validation of suitable test methods and helps identify the Quality Control and Quality Assurance measures that will be required to ensure that test measurements are fit for purpose. Equipment Qualification ensures that measuring equipment is capable of generating test measurements that are fit for purpose.

(5) VERIFICATION QUALIFICATION (VR)

The documented verification that the equipment And system, as connected together, still in the state Of art and actually leads to the expected results and User requirements.

(6) SAFETY QUALIFICATION (SQ)

The documented verification that the equipment And system as installed or modified, comply with The safety requirements of process, facility and Personnel.

(7) MAINTENANCE QUALIFICATION (MQ)

The documented verification that the proposed Maintenance program of the equipment and system Is suitable for the intended purpose.

(8) RE-QUALIFICATION (RQ)

The documented verification that the systems, as Connected together, are still performing Satisfactorily. Re-qualification is required as an Outcome of relocation, major modification and due To ageing.

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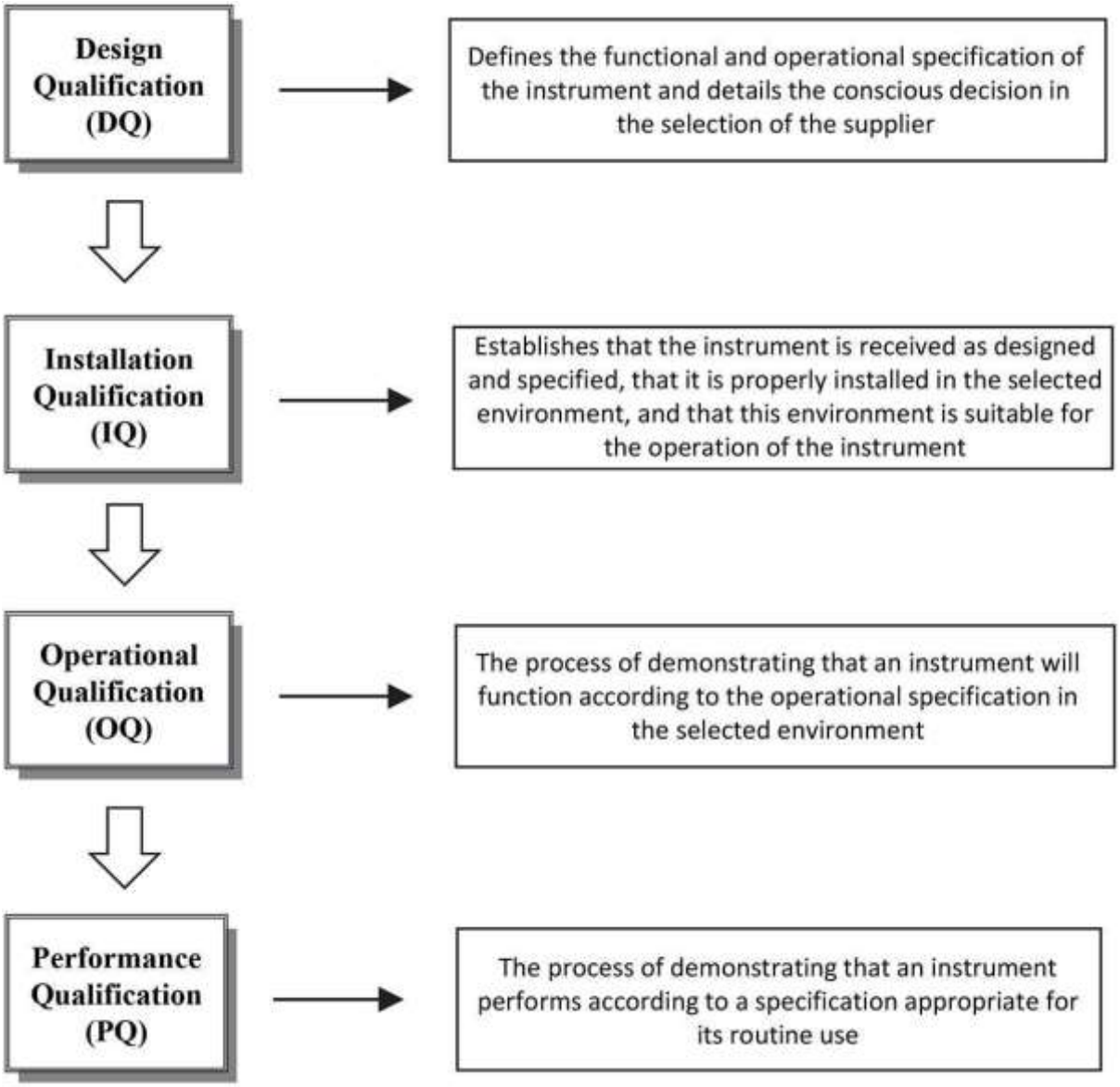

3. NEED FOR CALIBRATION

Calibration can be called for :
•With a new instruments
• When a specified time period is elapsed
•When a specified usage (operating hours)

4 REGULATORY GUIDELINES

The ICH Q7a guideline demonstrates that facilities, System, equipment and utilities are properly Qualified and maintained to assure data and Product integrity. Additional guidance is provided by PIC/S: "While it is not possible to undertake the Details of neither an Installation Qualification for Established equipment nor the detailed approach For an Operational Qualification, nevertheless there Should be data available to support and verify the Operating parameters and limits for the critical Variables of the operating equipment. Additionally, The procedures such as calibration, cleaning, Preventative maintenance, operating procedures And operator training for the use of the equipment Should be documented and in use kept as standard Operating procedures (SOPs)

4.1GUIDELINES FOR EQUIPMENT QUALIFICATION

Equipment design, size and location, equipment shall be of appropriate design ,adequate size and suitably located to facilities operations, Cleaning and maintenance

4..2 EQUIPMENT CONSTRUCTIONS

-Equipment material of Construction not be reactive with product.
-Lubricants /Coolant shall not come into Contact with Product to alter the quality of the product

4.3QUALIFICATION OF EQUIPMENT GENERALLY INCLUDE THE FOLLOWING ACTIVITIES

-Based on the specific uses of equipment Construction materials operating Principles and performance characteristics is done
-In compliance with the design specifications, verification of Utility systems equipment are built and installed,

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-Verifying that equipment operates in accordance with the process requirements in all anticipated operating range

5. QUALIFICATION OF LABORATORY EQUIPMENT

5.1 FRIABILITY TEST APPARATUS

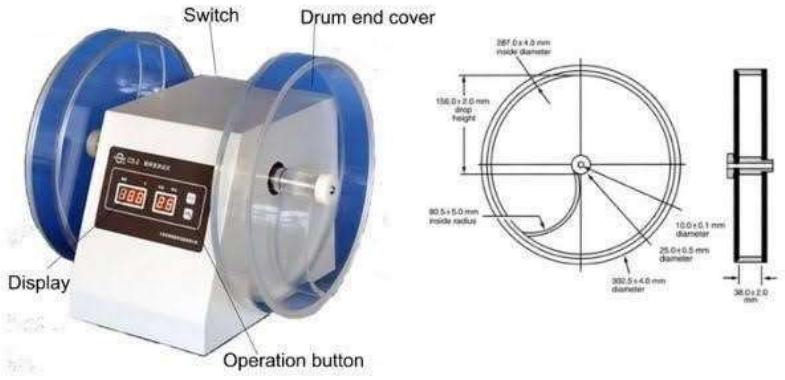
Friability is the condition of being friable, describes the tendency of a solid substance to break into smaller pieces under duress or contact, especially by rubbing.

Friability is defined as the % weight loss by tablets due to mechanical action during the test

Minimum weight loss of the tablet should not b NMT 1 %

Friability is usually measured by use of Roche or tumbler test.

Applicable for compressed uncoated tablet & tended to determine the strength of tablet during transportation & storage the tablets should retain its shape & size.



This testing involves repeatedly dropping sample of tablets over a Fixed time, using a rotating wheel .The result is inspected for broken tablets and the percentage of tablet mass lost through chipping.

PROCEDURE

-Switch on the power supply.

-Set the RPM to 25 and start the machine Simultaneously with the stop watch. Count the

Actual rotations and not the time required for the

-Similarly set the RPM to 100 and note the time Required and actual rotations.

-**Apparatus is in proper working condition if,**

- Time required for 25 rotations is 1 min ± 05 Sec.
- Time required for 100 rotations is 4 min ± 20 sec.

-Record the observation in the calibration record.

-Affix a “Calibration Status” label on the Instrument.

- In case of any discrepancy, report the Observations to QC manager / QA Manager and Notify the defect to Eng. Department. Affix an ‘UNDER MAINTENANCE” label on the Instrument.

Frequency: Once in a month and after each Maintenance job.

5.2 DISSOLUTION TEST APPARATUS

DISSOLUTION

"The process by which a known amount of drug substance goes into solution per unit of time under standardized conditions."

Dissolution testing is used as a qualitative tool to provide measurements of the bioavailability of a drug as well as to demonstrate bioequivalence from batch-to-batch.

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INSTALLATION QUALIFICATION
PROCEDURE
-Details of the Equipment
-Supplier or Manufacturer Name & Address
-Equipment Name, Make & Model No.
-In-house Equipment Code No.
-Location

INSTALLATION PROCEDURE
Site Inspection, Environmental Conditions and Prerequisite Parts Identification List
-Validation of Physical Parameter
-SOPS
-Computerized System

ACCEPTANCE CRITERIA
-Fulfil the Selection Criteria & its Purpose of Application
-Material of Construction and Name of the Manufacturer & Supplier shall be as mentioned in the Purchase order
-Meet pre-selected design Parameters
-Equipment Manual shall be provided
-Utilities of recommended capacities are to be provided.

CONCLUSION
The equipment shall be considered qualified for installation provided it meets all the parameters mentioned in the acceptance criteria.
After receiving installation report, it shall be evaluated & released for operational qualification, provided installation report is evaluated & the equipment is found meeting all parameters of acceptance criteria**.**

OPERATIONAL QUALIFICATION
PROCEDURE:
•Power ON Check
•Lift Movement Check
•Temperature Accuracy
•Accuracy of Shaft Rotation
•Control of Paddle Wobbling

ACCEPTANCE CRITERIA
All operating inputs provided on the equipment when tested shall successfully comply to their intended use & meet tolerance limit given by the manufacturer.
Perform successfully when operated as per SOP.
Critical indicators provided on the equipment are calibrated.
Equipment when operated shall not produce any abnormal sound or show any discrepancy in its smooth operation.

CALIBRATION Of Dissolution Test Apparatus

PART 'A'
The instrument shall be calibrated for RPM and Temperature.
For Temperature Calibration :
Measure the temperature of the water bath and of Each jar with a calibrated thermometer and Compare the result against the digital display on the Apparatus.
Acceptance Criteria: 37°C ± 0.5°C

For RPM Calibration
Calibrate the apparatus at 50 and 100 RPM. Compare the RPM shown on the digital display of The apparatus with the RPM measured with a Stopwatch or Taco meter.
Acceptable criteria: ± 1 RPM – for 50 RPM
± 2 RPM – for 100 RPM

Part 'B' Apparatus Suitability Test Disintegrating Type
-Use USP dissolution calibrator disintegrating Type 50 mg prednisone tablets.
-This USP Dissolution Calibrator is provided For the Apparatus Suitability Test in the
General chapter of USP 24 or as per the Method specified in the documents received Along with the respective lot of the tablet.
-Do not expose the tablets to excessive Humidity. Store in dry, cool place.
-Dissolution Media: Distilled water 500 ml.
-Using a membrane filter, with stirring for About 5 minutes.
-Weigh accurately about 10 mg of prednisone Reference standard (already dried on 105°C)For 3 hour into a 100 ml volumetric flask and Dissolve in 5 ml of ethanol. Make up to Volume with distilled water.
-Dilute 10 ml of the solution to 50 ml with Distilled water.
-Conduct the suitability test at conditions Mentioned in the certificate of tablets using Apparatus I and II.
-After completion of the dissolution time Withdraw filter and aliquot of the solution.
-Heat the medium with gentle stirring, to About 45° C, immediately filter under vacuum Discard the first 2 ml of solution and measure the concentration of prednisone at 242 nm against the absorbance of prednisone USP reference standard solution.
- The apparatus is suitable if each of the individual calculated values for each apparatus at all indicated speeds are within the specified ranges.

5.3 QUALIFICATION OF HARDNESS TESTER
HARDNESS (crushing strength):
It is the load required to crush the tablet when placed on its edge.
If the tablet is too hard, it may not disintegrate in the required period of time. And if the tablet

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Monsanto tester

Pfizer tester

is too soft, it will not withstand the handling during subsequent processing such as coating or packaging.
Some of devices used to test tablet hardness are:

1. Monsanto tester
2. Strong-cobb tester
3. Pfizer tester
4. Erwika tester

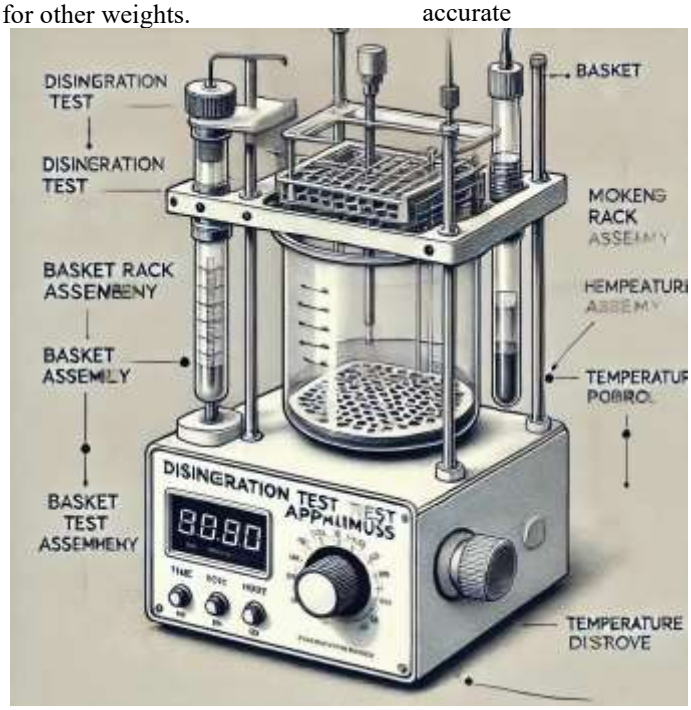
PROCEDURE

•Take out the force gauge to be calibrated and hold vertically up.
•Adjust the zero on the force gauge.
•Standard Weights are then applied to the hook of force gauge and measure the tension of the spring on the force gauge.
•When I kg of standard weight is applied, scale on the force gauge should also show 1 kg tension produced from the initial point where pointer is adjusted.
•Adjust the zero on the force gauge again.
•Follow the same procedure for other weights.
•The test to be carried out for 1.0 kg. 2.0 kg, 5.0 kg. 10.0 kg. 20.0 kg & 30.0 kg standard weights.
Tolerance: ± 0.25 kg/±0.1 kg
Frequency: Once in 6 months.

Maintenance / Repair When the instrument does Not comply with the requirement specified above; The instrument should be labelled as "Out of Calibration" and should get repaired / serviced.
After repairing / servicing the instrument before Taking for use, the instrument must be calibrated as Per the above-mentioned procedure.

5.4 QUALIFICATION OF DISINTEGRATION TEST APPARATUS

For a drug to be readily available to the body, it must be soluble and form solution. For most tablets, the first important step toward solution is break down of the smaller particles or granules, a process called disintegration.Disintegration Tester is designed for the accurate



estimation of disintegration time of tablets as per IP/USP standards. The instrument is designed to test two batches of six tablets. Simultaneously.

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USER REQUIREMENTS AND SPECIFICATIONS (URS) OF DISINTEGRATION TEST APPARATUS

•Operating criteria must be adequate.
•Easy maintenance.
•Equipment should not disseminate dust.
•Low cost.
•Spares should be available
•Non reactive surface.
•Audio visual indicators for system status.
•Printer attachment facility.

OPERATIONAL QUALIFICATION

After completions of successful installation qualification initiate the actual operation to ensure that machine is operating within specification.
Check the operation qualification parameters against their specifications.
Document the deviation details.
The quality head and the department head shall decide whether deviation is acceptable or not.

CALIBRATION FOR NUMBER OF OSCILLATIONS PER MINUTE

Take a pre-calibrated stopwatch. Operate the Apparatus as per SOP. Start the apparatus and Stopwatch simultaneously and count the number Of oscillations per minute.
Repeat the same for five times and note down The number of oscillations per minute for each Time.
The oscillations per minute shall be within the Limit of 29 to 32 through a distance of 53 to 57 Mm throughout the period of operation. Record The observation.

CALIBRATION FOR TEMPERATURE

-Switch on apparatus and press key.
-Turn on the heater by pressing 'ON' key.
-Set the bath temperature by pressing scroll Keys.
-Wait till the temperature of beaker A and beaker B attain the set value.
-Screen shall show the set temperature of bath And the temperature of beaker A and beaker B. -Take a pre-calibrated thermometer and check The temperature of beaker A and beaker B.
- Record the observation.

TIMER CALIBRATION

-Set the timer for '30 minutes' and start the Equipment and stop watch simultaneously. Note
Down the stop watch reading immediately when the equipment stops and note down the observation.
- observed time should not deviate by '+1min' of set time

SEIVE INTEGRITY TEST

Check the 'integrity' of woven stainless steel Cloth (sieve) attached to the base plate of each Basket with a pre-calibrated Vernier calliper. The Sieve has weave squares of aperture of 1.8 – 2.2 mm and wire diameter of 0.57 to 0.66 mm. Note the observations.
Affix the 'CALIBRATION STATUS' tag duly filled And signed on the equipment after completion of Calibration.
If the instrument is out of calibration then affix 'UNDER MAINTENANCE' tag and inform to
Maintenance department.
The frequency for calibration of Disintegration Test apparatus shall be after every one month Or after every maintenance work.

5.5 QUALIFICATION OF TAP DENSITY TESTER

The tapped density is an increased bulk density attained after mechanically tapping a container (graduated measuring cylinder) containing the powder sample.
The tap density of a material(powder) can be used to predict both flow properties and its compressibility.

URS FOR TAP DENSITY TESTER

Operating criteria must be adequate.
•Easy maintenance.
•Equipment should not disseminate dust.
•Low cost.
•Non reactive surface.
•Capacity(100ml,250ml)

Tap Density Tester

•The test can be performed in 2different modes.
USP mode
User Mode
• any possible separation of mass during tapping down.

DESIGN QUALIFICATION (D.Q)

The DQ outline the key features of the system designed to address the user requirement, regulatory compliance and selection rationale of a particular supplier.
The following are the key considerations for DQ:
•Physical dimensions of the equipment and accessories.
•Suitable operating environment of the instrument.
•Health and safety requirement.

INSTALLATION QUALIFICATION

Details of the Equipment

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- Equipment name, made by & model no. Shall be noted down.
- Location for the installation equipment shall be checked.

Utilities required shall be listed down.
Any deviation observed while following above procedure should be informed for corrective action.

INSTALLATION PROCEDURE

After checking all the specifications as mentioned in the selection criteria, service engineer shall commission the equipment.
Authorized validation team shall carry out installation

OPERATIONAL QUALIFICATION

After completions of successful installation qualification initiate the actual operation to ensure that machine is operating within specification.
•Check the operation qualification parameters against their specifications.
•Document the deviation details.
•The quality head and the department head shall decide whether deviation is acceptable or not.

PERFORMANCE QUALIFICATION

Measure the tapping height(3mm or 14mm) with A ruler
Obtain calibrated cylinder(250mL or other Volume) from qualified supplier Measure the length of the cylinder
Set the count number and start tapping Count the tapping number using a stopwatch Setting to 1 minute, check the allowed tap Number error range as per specific international Standard. Weigh the tapping device including the cylinder

6.CONCLUSION

The qualification of laboratory equipment is a critical aspect of ensuring accuracy, reliability, and compliance in scientific research and industrial processes. By implementing systematic qualification protocols, including design qualification (DQ), installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ), laboratories can mitigate risks, meet regulatory standards, and maintain data integrity. The continuous review and requalification of equipment further support long-term performance and adaptability to evolving technological and regulatory requirements. Emphasizing a robust qualification framework enhances laboratory efficiency and fosters confidence in experimental outcomes, making it a cornerstone of quality management in laboratory environments.

The purpose of the use of analytical instruments Is to generate reliable data. Manufacturing is Mainly depends on the performance of the Equipment. Consistent performance of the Equipment is only possible when the equipment is Properly qualified, verified and maintained. Equipment Qualification's components of fully Defining the equipment's required performance, Ensuring that suitable equipment is selected and Ensuring that the equipment's performance is Consistently of the required standard have many Benefits for the analyst:

Incorporating continuous monitoring, periodic maintenance, and requalification further extends the operational lifespan of equipment and ensures its adaptability to evolving technological advancements and regulatory changes. Additionally, leveraging digital tools and automated systems in qualification processes has the potential to improve efficiency, reduce human error, and foster proactive issue resolution.

In conclusion, the qualification of laboratory equipment is not merely a regulatory requirement but a strategic approach to achieving operational excellence and fostering innovation in scientific research. By prioritizing thorough qualification protocols and embracing emerging technologies, laboratories can maintain high standards of accuracy, reliability, and compliance, ultimately contributing to the advancement of their respective fields.

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