**VALIDATION OF EQUIPMENTS USED IN FORMULATION OF SOLID DOSAGE FORM**

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**ABSTRACAT**

Validation is one of the important step towards achieving and maintaining the quality of batches of the final product. Without equipment, we cannot manufacture products .If the equipment is validated, we can ensure that our products are of the highest quality. The validation of the equipment is called qualification. In order to manufacture solid dosage forms, different devices are used. The article focuses on equipment certification for Dry powder Mixer, Electronic balance, Vibro-sifter, RMG,& Compression machine .It details the qualifying steps of the equipment used for the manufacturing process.

**Key words :** Validation, Qualification, Acceptance criteria, Mixer, Granulator, Coating equipment, Compression machine

**VALIDATION**

The validation process is the documented evidence which provides a high degree of assurance to a desired result with pre-dermined compliance. The term validation is widely used in pharmaceutical industries. This term comes from the word “valid or validity” which means “legally defined”.

The validation concept was first proposed by the Food and Drug Administration (FDA) in the mid-1970s to improve the quality of pharmaceutical products.

**EQUIPMENT VALIDATION**

The process of equipment validation is based on the principle that equipment must be designed, constructed, maintained, and adapted to perform the operations which are to be carried out .

Equipment validation is Vital for-

* Safety.
* Fewer interruptions of work.
* Reduction of variation in results.
* Greater confidence in the reliability of results.

**PHASES OF EQUIPMENT VALIDATION**

**EQUIPMENT VALIDATION PLAN**

Equipment validation is the process of validating the requirements, specifications, and uses of a piece of equipment to ensure it meets user needs as well as various regulatory and safety requirements.

The various stages of the process are thoroughly investigated and documented in accordance with approval from pharma industry. The process of procurement starts by the production of required documentation and user requirement specification (URS).

To perform validation project/plan (VP), a form of change request (CR) should be taken from the existing facilities. As earlier the management agreed to proceed, the request is issued to perform validation project (VP). Then with approved VP, the validation protocol can be started that required to verify that all the requirements documented in the URS and all cGMP requirements are fulfilled.

**DRY POWDER MIXER**



**DESIGN QUALIFICATION:**

* Equipment name, made by & model number shall be noted down ,location for the installation of equipment shall be checked
* Utilities required shall be listed down
* Required capacity of the mixer, type of materials to be mixed & mixing time also should be taken into consideration
* Any deviation observed while following above procedure shall be informed for corrective action.

**INSTALLATION QUALIFICATION**

The IQ process is intended to demonstrate that the Dry Powder Mixer meet all specification Installed properly

* Supporting program like SOP, Maintenance sheet is in place
* After checking all the specifications as mentioned in the selection criteria, service engineer shall commission the equipment.
* Authorized validation team shall carry out installation checks as per the specification criteria.

**IQ checks:**

* Manufacturer name & address shall be checked.
* Equipment name & model no. shall be noted down
* Check Gear Box, Control Panel, Buttons & Driving Motor

**OPERATIONAL QUALIFICATION**

* After completion of IQ, initiate the actual operation, to ensure that machine is operating within the specification.
* Check the operation qualification parameters against their specifications.
* It includes following checks:
* On/off Switch
* Gross Capacity
* RPM
* After that, document the deviation details.
* The quality head & the department head shall decide whether the deviation is acceptable or not.

**PERFORMANCE QUALIFICATION**

**ELECTRONIC BALANCE**

**TYPES OF BALANCES**

|  |  |  |  |
| --- | --- | --- | --- |
| **Type** | **Ordinary name** | **Number of digits after decimal position (g)** | **Accuracy class** |
| 1. | Ultra Micro Balances | 7 | I |
| 2. | Micro Balances | 6 | I |
| 3. | Semi Micro Balances | 5 | I |
| 4. | Analytical Balances | 4 | I |
| 5. | Precision Blalances | 1 to 3 | II |
| 6. | Technical Balances | 0 to 1 | III |

**Requirements of the Balance**

It should work under optimal conditions like weighing room, weighing bench, temperature, light, air etc

|  |  |  |
| --- | --- | --- |
| **S.No.** | **REQUIREMENTS** | **ACCEPTANCE** |
| 1. | Weighing balance | Should be Non-magnetic, Vibrant proof and dust free |
| 2. | Temperature | Constant temperature should be maintained  Deviations should not exceed 5 degree celcius |
| 3. | Atmospheric humidity | Should be between 40-60% |
| 4. | Light | Should be protected from direct sunlight |
| 5. | Weighing Vessel | Smallest possible weighing vessel used. Weighing vessel and sample it contains should have same temperature. |

**INSTALLATION QUALIFICATION**

* Checking of all requirements set during the selection of instrument such as electricity, humidity, temperature, etc.
* Allowing sufficient shelf space for the equipment, SOPs, operating manuals, etc.
* Comparing equipment, as received, with purchase order, including accessories, spare parts, etc.
* Checking documentation for completeness like operating manuals, maintenance instructions, health and safety instructions, etc.
* Checking equipment for any damage.
* Reading the supplier's safety instructions, if there are any.
* Installing hardware following the manufacturer's recommendation.
* Switching on the electronic balance and ensuring that all the modules power up.
* Preparing an installation report.

**OPERATIONAL QUALIFICATION**

|  |  |  |
| --- | --- | --- |
| **Test Procedure** | **Acceptance limits** | **Test Frequency** |
| Measurement of reference weight by using 10mg, 50mg, 100mg, 500mg, 1g, 5g, 10g and 20g. | 0.1% | Daily or when used, whatever is longer with internal reference weights. |
| Comparing the actual results with reference weights . |  | Yearly with tracable external weights through instrument vendor. |

**PERFORMANCE QUALIFICATION**

* Defining weights and weight classes to be used.
* Defining acceptance limits of results.
* Defining test intervals.
* Defining corrective actions on what to do if the electronic balance does not meet the criteria, in other words if the results are out of specification.

Following parameters to be checked while performing validation.

* Accuracy
* Linearity
* Precision
* Corner Load Test

**FREQUENCY**

Every 3 months (± 7 days)

Note: If balance is not calibrated within the time period, stop using the balance till satisfactory calibration is done.

**ACCURACY**

Check the accuracy of the balance by using 5 standard stamped weights.

Place standard weight one by one in the ascending order in the center of the platform and record the observations in the balance calibration record.

Acceptance Criteria: Standard Weight ± 2 x Least Count

**LINEARITY**

Draw the linearity curve for the above readings and find out the correlation factor. Record the observations.

**VALIDATION OF VIBRO SIFTER**

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**DESIGN QUALIFICATION**

Vibro sifter is an efficient & compact unit self contained & mounted on castor wheels. Vibro sifter have circular unitary vibrating screen used for gradation of material & its proven records over the rotary or longitudinal movement used in the conventional type of sieving machine, both in term of output & uniform grading of materials. Specially designed motor with eccentric weights imparts vibratory motion to the hopper, which have a screen in between them. Material finer than the screen mesh pass through the screen & are collected in the bottom hopper. Coarse material is retained on top of the screen. The amplitude of vibration can be varied from minimum to maximum by adjusting the eccentric weights to suit the process requirement in base minimum time. The machine is generally as per enclosed specs & consists of:

**1. Motor:** It is fitted with top & bottom eccentric weights designed as per required centrifugal force. This whole assembly is covered by SS plate. The motor is flanged mounted & is fixed on the mounting plate by hex. Bolts. The top weights are fixed on the output shaft over the mounting plate.

**2. Spring:** the eight number chrome plated spring are fixed on the base flange at equi- distance. These springs are provided with the ends of the springs. The springs are then screwed on at both the bolts at one end to the base & on the mounting plate at the top. These rugged springs amplify the vibration & restrict them from being transmitted to the floor.

**3. Hopper**: It is a cylindrical, flanged body with an inverted cone at the bottom. This is placed over the mounting plate. The bottom flange is used for clamping to the base plate with a rubber gasket in between the hopper & plate. Hopper is provided with an outlet, tangential to the periphery for discharge of sieved material. The top flange is to provide for holding the charging/ intermediated hopper with a sieve in between them. It is fabricated from stainless steel sheet and works for loading the materials for sifting.

**4. Screen:** based on the product size required a suitable screen is clamped in between the two hopper. Finer mesh sieves can be or with back up cross support to ensure longevity of sieve. This is recommended for sieves finer than 150 meshes.

**5. Discharge port:** To collect the processed materials.

**TECHNICAL SPECIFICATIONS:**

|  |  |  |
| --- | --- | --- |
| **S.NO.** | **NAME OF THE COMPONENT** | **TECHNICAL SPECIFICATION** |
| 1. | Model | CGMP |
| 2. | All contact parts | SS316 |
| 3. | All non-contact parts | SS304 |
| 4. | Capacity | Std. |
| 5. | Dimension | 1300 (W) x 800 (D) x 1250 (H) in mm |
| 6. | Charging height | Approx.: 1350 mm |
| 7. | Discharging height | Approx.: 780 mm  As per your specifications and purchase order. |
| 8. | Electric motor | Type: Vibratory  H.P : 0.5 HP  RPM: 1440  Volt: 415±10V  Amp: 1.2 |
| 9. | Screen Diameter | 750 mm |

**MATERIAL OF CONSTRUCTION:**

|  |  |  |
| --- | --- | --- |
| **MACHINE PARTS** | **ACCEPTANCE CRITERIA** | **REFERENCE** |
| Top Lid | AISI 316L | GMP Requirements |
| Top Deck | AISI 316L | GMP Requirements |
| Bottom Deck | AISI 316L | GMP Requirements |
| Mesh | AISI 316L | GMP Requirements |
| Base | AISI 304 | GMP Requirements |
| ‘C’- Clamp | AISI 304 | GMP Requirements |
| Gasket | White food grade | GMP Requirements |
| Spring | AISI 304 | Design Requirements |
| Motor mounting plate | MS | Design Requirements |
| Motor | STD | Design Requirements |
| Castor Wheel | Polyurethane (PU) | GMP Requirements |

**Safety Requirement**

|  |  |  |
| --- | --- | --- |
| **CRITICAL VARIABLES** | **ACCEPTANCE CRITERIA** | **REFERENCE** |
| MCB | MCB is provided so that when there is an overload in current or any short circuit then the MCB trips | Safety Requirement |
| Mechanical Guard | Mechanical guard for all rotating parts. | Safety Requirement |
| Joints | Welding of joints without any welding burrs | Safety Requirement |
| Metal Parts | All the metal parts should be Properly grind without any sharp edges. | Safety Requirement |
| Leveling and Balancing | Equipment should be properly balanced & leveled | Safety Requirement |
| Electrical Wiring and Earthing | Electrical wiring should be as per approved drawings. Single external Earthing to control machine (panel and motors) and operator should be provided | GMP and safety Requirement |
| Noise Level | Below 80 db | GMP and safety Requirement |
| Emergency Switch | Provided easy access position | Process Requirement |

**INSTALLATION QUALIFICATION**

Verification of Documents:

Executed and approved design qualification document

Piping and instrumentation diagram (P& ID)

Electrical circuits diagram

Technical specification of equipment

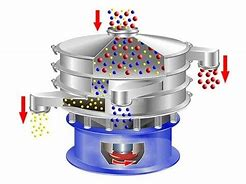
Certificate of material of construction of components.

**Procedure:**

Verify the above mentioned documents for availability, completeness and approval status

If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.

Approved Drawings and supporting documents would form a part of the IQ Protocol cum report.



**Acceptance Criteria:**

All the documents should be available, complete and approved by respective authorities.

|  |  |
| --- | --- |
| **REQUIRED** | **ACCEPTANCE CRITERIA** |
| Confirm equipment / system installed, I.Q. complete and ready for operation | IQ documents reviewed and approved. |
| Confirm SOP exists | SOP exists |
| Confirm instruments calibrated and recalibration date not expired | All instruments calibrated. |
| Verify all materials and test equipment available | Test equipments available |
| Verify electrical supplies are “ON” | All utilities available in right capacity. |
| Verify equipment cleaning | Should be cleaned |
| Sieving screen | Fits properly |
| Should not generate noise from damp and feed hopper | No noise |
| Material should move in circulation direction | Material movement in circulation direction |
| Continuous material movement through discharge chute | Material moves out of discharge chute continuously |

**General Checks and Location Suitability:**

|  |  |
| --- | --- |
| **INSTALLATION CHECKS** | **ACCEPTANCE CRITERIA** |
| Leveling | Should be properly balanced and leveled |
| Edges of parts | Metal parts should be properly grind without any sharp edges |
| Welding of Joints | Welding of joints should be without any welding burrs |
| Place of Installation | Granulation Area- 08 |
| Room Condition | General working condition |
| Illumination in area | NLT 300 Lux. |
| Working space around the equipment | Should be sufficient for easy operation, cleaning, sanitation and maintenance |

|  |  |
| --- | --- |
| **INSTALLATION CHECKS** | **ACCEPTANCE CRITERIA** |
| Equipment | Vibro Sifter |
| Model | cGMP Model |
| Capacity | 30 Inch |

**ELECTRICAL INSTALLATION:**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Electricity | |  |  | | --- | --- | | Voltage | 415 V | | Phases | 3Phases | | Frequency | 50 Hz | |
| Electrical connections have been provided and secured. | Should be provided & secured |
| All components in the panel are properly secured | Should be provided & secured |
| All terminals are tightened | Should be tightened |
| Earthing connection to control panel & equipment | Earthing connection to control panel & equipment should be provided. |

|  |
| --- |
| **SPECIFICATION** |
| The machine should positioned as per the room layout drawing, |
| The machine should leveled |
| The machine should cleaned |
| Utility should properly connected |
| Visually check the M/C for damage due to transportation. Etc |

|  |  |  |
| --- | --- | --- |
| **S. No.** | **NAME OF COMPONENTS** | **ACCEPTANCE CRITERIA** |
| 1. | Model | cGMP |
| 2. | All contact parts | AISI 316 |
| 3. | All non-contact Parts | AISI 304 |
| 4. | Capacity | Std |
| 5. | Dimension (in mm) | 1300 (W) x 800 (D) x 1250 (H) |
| 6. | Charging height | Approx.: 1350 mm, |
| 7. | Discharging height | Approx.: 780 mm, |
| 8. | Electric motor | Type : vibratory  H.P : 0.5 H.P  RPM : 1440  Volt : 415± 10 V  Amp : 1.2 |
| 9. | Screen Diameter | 750 mm |

**OPERATIONAL QUALIFICATION**

* Ensure that the main electrical supplies are ‘ON’
* Switch ‘ON’ the power at the main switch cabinet.
* Ensure that equipment is cleaned before operation.
* Checks that sieving screen fits properly.
* Ensure that all gaskets are closed.
* Ensure that material moves in circulation motion
* Start the sifting operation
* Run the machines for 30 mins.

**ACCEPTANCE CRITERIA:**

* All operations should be smooth.
* Noise Generation.
* Run the Vibro Sifter for some time and observe for generation of noise.
* No noise generation.
* Direction of Rotation
* check the direction of motor
* Seals
* Visually check for leaks from top lid and top deck.
* Visually check for leaks from ‘C’ Clamp.

**PERFORMANCE QUALIFICATION**

* Ensure that the working bench and instrument is clean.
* Switch ON the instrument
* Display indicates: ELECTROMAGNETIC SIEVE SHAKER EMS-8
* Setup the instrument
* All the sieve diameter and pore size should be as per IP standard. Received certificate keep in an appropriate place.
* Set the sieve on the instrument, shaker ensures that the value of the amplitude is set at the lowest.
* Set the desired time (0.0 to 99 minute) by pressing the ▲▼ time key provided below the TIME display.
* Set the desired amplitude (power level 5 to 20 ) by pressing the ▲▼ power key provided below the POWER LEVEL display

**Mode of Operation**

There is two type mode:

A] Continuous mode

B] Intermittent mode

**Control of Continuous Operation**

* Select continuous mode by pressing “CONTINUOUS” key.
* Start the vibration by pressing the “START” key.
* The shifter operates during the time and with the power level programmed.

**Control of Intermittent Operation**

* To start the sifter in intermittent mode, select continuous mode by pressing “INTERMITTENT” key.
* Start the vibration by pressing the “START” key.
* Observe the sifter will start to vibrate during the time and power programmed, at an interval of 0.5 second.

**RAPID MIXER GRANULATOR**

The Rapid Mixer Granulator is a multi-purpose processor equally suitable for high speed dispersion of dry powders, aqueous or solvent granulations, and effervescent products and melt pelletization.



**DESIGN QUALIFICATION**

**Technical Specifications**

**Equipment:** Rapid Mixer Granulator

**Service:** Wet Mixing and granulation

**Volume:** 400 Litres Gross; 320 litres Working

**Capacity / Output:** 150 Kgs at 0.5 Kgs/ Liters bulk density of powder

**Design Features**

|  |  |  |
| --- | --- | --- |
| **S.NO** | **ITEM** | **DESCRIPTION / SPECIFICATION** |
| 1 | Temperature | Ambient to 120 degrees ° C |
| 2 | Pressure | Atmospheric |
| 3 | Major Dimensions | As per our standards. |
| 4 | GA Drawing No. | B&A/GEN/RMG |
| 5 | Product Safety | All internal surfaces have smooth rounded edges. Internal surfaces smooth mirror Polished. |
| 6 | Speed | Main agitator 60/120 dual speed approx  Chopper dual speed 1400 & 2800 approx |
| 7 | Drive | Non Ex proof TEFC |
| 8 | Electricals | Non Ex proof TEFC |

OPERATING FEATURES

|  |  |  |
| --- | --- | --- |
| **S.No** | **Item** | **Description / Specification** |
| 1 | Charging | Through the top of the bowl manually or by bin loading arrangement ( Optional ). |
| 2 | Discharge | Through pneumatically operated side discharge valve directly into Cone mill or FBD bowl. |
| 3 | Mobility | The machine is to be placed in one location. |
| 4 | Cleaning | To be cleaned manually or optionally a CIP system can be provided. |

**BOWL**

The bowl should consists of

* Flat bottom
* Central cylindrical shell
* Inverted conical frustum at the top.
* Flanged lid with counter weight for easy opening
* Side mounted chopper assembly
* Side mounted discharge.
* Bottom entry main agitator.

**INSTALLATION QUALIFICATION**

|  |  |  |
| --- | --- | --- |
| **S.No.** | **Check Point** | **Required Specifications** |
| 1. | Model | RMG –150 litre |
| 2. | Power source | 415 + 10%V, 50 + 5 Hz |
| 3. | Impeller Motor rpm | 730 / 1475 |
| 4. | Impeller Motor power | 10 / 15 HP |
| 5. | Chopper motor RPM | 1420 / 2880 |
| 6. | Chopper motor power | 2 / 3 HP |
| 7. | Pneumatic pressure | 4-5 kg/cm2 |
| 8. | Horizontal levelling of  the equipment | Machine should be levelled perfectly horizontal |
| 9. | Positioning of the  equipment | Aligned vertically straight with sufficient space for maintenance |
| 10. | Balancing of the floor | Floor should be perfectly balanced with no vibrations |
| 11. | General method of  electrical  wiring | Electrical wiring should be well insulated and there should be no hanging cables. It should be located at a safe place protected from water sewage and also at convenient place for operator convenience. |

**BOWL CHECK:**

1. Check the dimension and orientation of the bowl for Rapid Mixer Granulator.

2. Check the finish of the bowl from inside and outside.

3. Check for

unevenness, dents or marks on all the surfaces of the bowl.

4. Check the conditions of the gaskets used with the bowl of the equipment.

5. Check the operation of bowl top lid.

|  |  |
| --- | --- |
| **Item** | **Specification** |
| Dimension &  orientation of the bowl | Should be as per the  approved drawing |
| Bowl  Material | Material -SS 316  External surface –Matt polish  Internal surface –Mirror polish |
| Unevenness, dents or marks | Should be no dents / marks or unevenness of the surface of the bowl |
| Conditions of  the gaskets | Should be in proper and intact condition |
| Operation of  bowl top lid | Should be easily operate -able and counter weight provides ease in operation |

**OPERATIONAL QUALIFICATION :**

1. The test should be carried out for three batches

2. Switch ON the machine and operate as per SOP.

3. Run the machine at empty condition and verify the RPM of Impeller & Chopper at Slow and Fast Speed.

4. Load the product batch size with respect to capacity load.

5. Run the machine at set parameter of the product & sample from different location at end of mixing time. Upper 3 sampling point, Middle 4 sampling Point and lower 3 sampling point

**PERFORMANCE QUALIFICATION :**

1. After completions of successful installation qualification initiate the actual operation of the

Rapid Mixer Granulator (250 lit.) to ensure that machine is operating within specification.

2. Check the operation qualification parameters against their specifications.

3. Record the observation in the respective Table.

4. In case of any deviation, document in ‘Remark’ column and inform to department head and

Quality head for necessary action.

5. Document the deviation details in Observed deviation section.

6. The Quality head and the department head shall decide whether deviation is acceptable or

not.

7. If the deviation is acceptable and it does not have impact on operation as well as on

performance, initiate performance qualification.

8. If the deviation is not acceptable inform to department head and Quality head for necessary

action.

9. If deviation is acceptable and it will not affect quality of the product and operation, go for

performance qualification.

10. If deviation is not acceptable inform to concern department head and Quality head for

necessary action.

**ACCEPTANCE CRITERIA:**

1. All operating inputs provided on the equipment when tested shall successfully comply to

their intended use & meet tolerance limit given by the manufacturer.

2. The equipment should successfully perform when operated as per standard operating

procedure.

3. Critical gauges/indicators provided on the equipment are calibrated to their correctness as

per laid down procedure.

4. The equipment when operated shall not produce any abnormal sound or show any

discrepancy in its smooth operation.

|  |  |
| --- | --- |
| **Facility Description** | **Specification** |
| Compressed air supply | The power supply should be ON/ OFF respectively when compressed air supply is ON & OFF respectively. Minimum air pressure required is 4.0 kg/ sq.cm. |
| AUTO /MANUAL selector switch | Machine should operate in AUTO/ MANUAL mode as per the selection using this switch. |
| OPEN /CLOSE selector switch for discharge valve | When machine is in MANUAL mode, discharge valve should OPEN / CLOSE as per the selection using this switch. |
| Mixer push button   * Mixer slow * Mixer fast * Mixer off | When machine is in MANUAL mode, discharge valve should OPEN / CLOSE as per the selection using this switch When machine is in MANUAL mode,  When pressed this button beater blade should rotate at slow speed.  When pressed this button beater blade should rotate at Fast speed.  When pressed this button beater blade should stops rotating |
| Chopper push button   * Chopper slow | When machine is in MANUAL mode, When pressed this button chopper blade should rotate at slow speed. |

**TABLET COMPRESSION MACHINE**

A tablet press is a mechanical device that compresses powder into tablets of uniform size and weight.

Tablet Compression Machine is also known as Tablet Press in Pharmaceutical Industry which is used to make the tablets according to a pre-determined design.

Compression is a critical step in the production of a tablet dosage form. The materials being compressed will need to have adequate flow and compression properties.

Factors to be considered during compression are, Tooling Compression speed



**Tooling:**

* Tablet compression machines are made in keeping the view of the type of dies and punches will be used on them,
* The dies and punches and their setup on compression machine is called tooling.
* The shape, size and as well as certain identification markings are determined by compression machine tooling.
* Each tooling set consist of dies, upper and lower punches.
* Production efficiency, dosage uniformity and appearance depend upon tooling set.

**INSTALLATION QUALIFICATION**

* Verify approved purchase order.
* Check manufacturer and supplier.
* Verify Model number and serial number.
* Check any physical damage.
* Confirm location and installation requirements as per recommendation of manufacturer.
* Verify that the required utilities are available.
* Installation shall be conducted per instructions provide in the manual.

**Objectives of IQ:**

* To check all the critical contacts parts which directly affect quality of the product.
* To review proper installation as per checklist.

**IQ Check list:**

Compare all specification and write the observation

* Machine height – measure with measuring tape.
* Overall dimension- measure with measuring tape
* Rpm of turret – check by tachometer.

**Hopper:**

1. Conventional hopper- by visual check
2. MOC (master of construction)-using Molybdenum
3. Height- Measure with measuring tape

* No. of station- visually count no.of holes on turret.
* Type of tooling- using venire caliper check the die hole diameter.
* Feeder- by visual check.

Required utilities

* electricity.
* Thickness controller cam
* Weight of controller cam

 Main drive:

* ON indicator
* Potentiometer
* Selector Switch
* Emergency switch
* Dust extraction and exhaust system
* Oil pressure gauge
* Select switch for auto/manual

**OPERATIONAL QUALIFICATION:**

* Verify alarm control.
* Perform calibration requirements, identify in the manual or established by the validation team.
* Operate the equipment at low medium and high speed as per operation manual to verify the operation control.
* Verify that all switches and push buttons are functioning properly
* Establish procedures for operation, maintenance and calibration
* Establish training program for relevant staff Run one pilot batch for each product

**Objectives of OQ**:

* To operate machine as per proposed procedure given in manual and record.
* To challenge the operating parameter of machine and record.
* To challenge the safety operation and record.

**OQ Checklist:**

* **Main switch-** check visually by operating the main switch of the machine.
* **Start push button**- illuminated green switch by pressing start button the green switch glows and the main drive motor should start.
* **Stop push button**- illuminated red switch by pressing stop button the red switch glows and the main drive motor should stop
* **Turret RPM challenge test**- set in the digital table counter by rotating knob check by tachometer Rotation direction (clockwise) by visual check
* **Emergency switch** by visual check.
* **Tablet thickness & Hardness controls**- By turning the swing lever to right/left thickness increased hardness/decrease vise versa
* **Machine speed adjustment**- Release the locking knob and rotate the hand wheel anticlockwise /clock wise- increased speed/decreased speed
* **Main upper punch entry**- Remove the bolt and rotate the perforated segment to right/left-upper punch penetration increases/decreases.

**PERFORMANCE QUALIFICATION:**

It’s an Evaluation of compression capabilities and tablet characteristics.

The compression capabilities and tablet characteristics are:

1. Content uniformity
2. Thickness
3. Hardness
4. Friability
5. Weight variation
6. Disintegration test.

Should be investigated.

**Objectives of PQ:**

* First three batches of biliary and single layer product to be compressed on given compression machine.
* All the critical physical parameters of product will be checked during performance qualification.
* Measure the thickness, hardness, friability and weight for each triplicate tablet run, as shown below

**CONTENT UNIFORMITY:**

* Select 30 tablets randomly from batch and Assay individually

**ACCEPTANCE CRITERIA:**

* Out of 30 tablets 3 tablets can be with in 75-125% and all tablets should be with in 85-115%

**THICKNESS:**

* First 20, last 20, middle 20 tablets (throughout the run) Determine mean and standard deviation.

**ACCEPTANCE CRITERIA:**

* The Relative Standard Deviation should be less than or equal to 5%

**HARDNESS:**

* First 20, last 20, middle 20 tablets (throughout the run) Determine mean and standard deviation for baseline

**ACCEPTANCE CRITERIA:**

Must meet each tablet specifications.

* Chewable tablets-3kg/cm2
* Tablets-4-8kg/cm 2
* Sustained release tablets & troches- 10-20kg/cm 2

**CONCLUSION**

Grant additional time for validation. It is always longer than we think, especially when installing a new one. Examine the overall validation process and deviations in order to determine how the process can be improved in the future. The main points are: carefully write protocols and acceptance criteria, try to anticipate problems or solve problems in advance. Coordination with other ongoing activities to ensure that the necessary resources are available when needed. Coordination with vendors. Unless equipment qualifications have not been legally mandated today ,they will have enormous importance in the near future, mainly in the pharmaceutical and food and cosmetics industries. The main objective of laboratory equipment qualification is to ensure the validity of the data. Current equipment qualification programs and procedures used in the pharmaceutical industry are based on regulatory requirements, voluntary standards, supplier practices and industry practices. The result is considerable variation in the way pharmaceutical companies approach the qualification of laboratory equipment and the way they interpret requirements.

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