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Validation of Equipments Used in Formulation of Soliddosage 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.

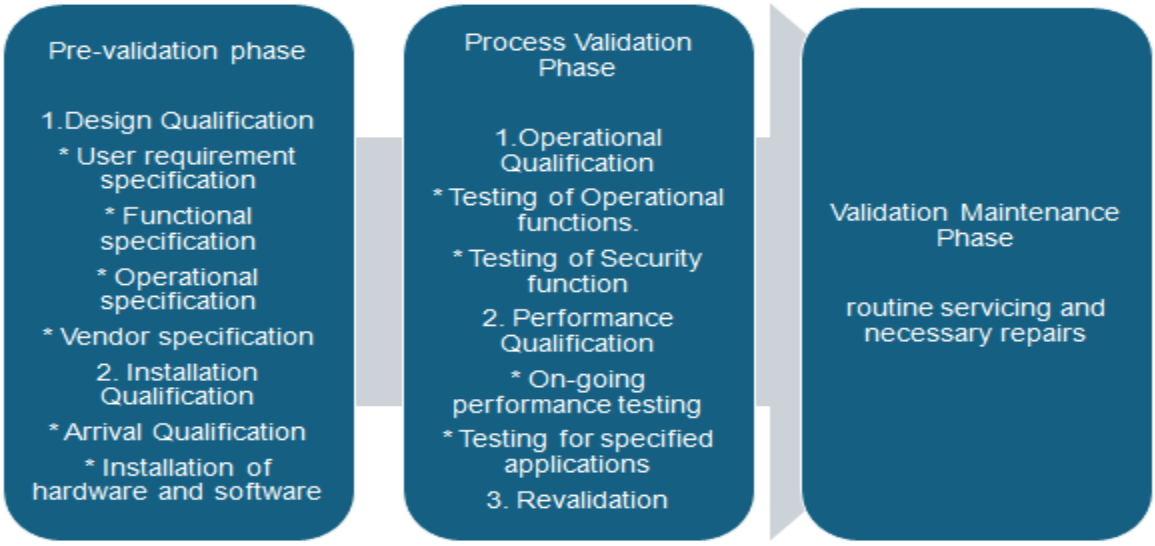
EQUIPMENT VALIDATION

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



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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.

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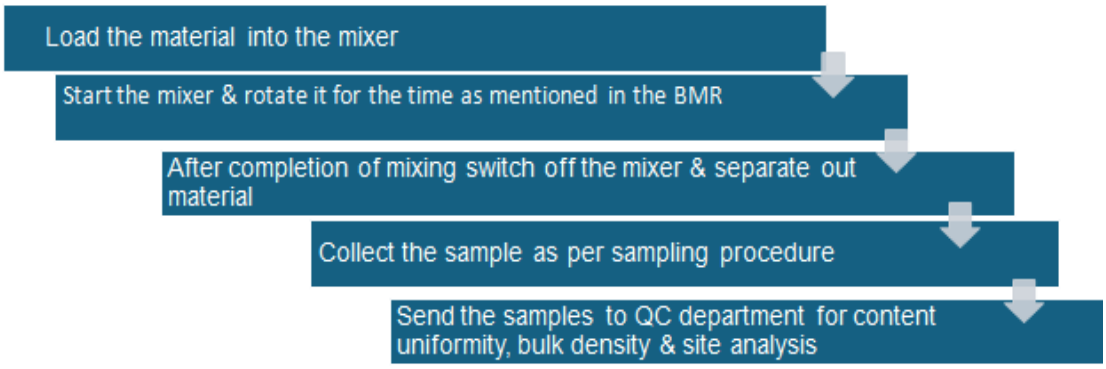
PERFORMANCE QUALIFICATION



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.

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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 tillsatisfactory 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

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.

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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	Safety Requirement

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	welding burrs	
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

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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

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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-purposeprocessor 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

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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 pneumaticallyoperated 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

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9.	Positioning of the equipment	Aligned vertically straight withsufficient space formaintenance
10.	Balancing of the floor	Floor should be perfectlybalanced with no vibrations
11.	General method of electrical wiring	Electrical wiring should be wellinsulated and there should beno hanging cables. It shouldbe located at a safe placeprotected from water sewage and also at convenient placefor 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.

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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 operatingprocedure.
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 • Mixeroff	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,

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- 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:

i) Conventional hopper- by visual check
ii) MOC(master of construction)-using Molybdenum
iii) 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 theoperation 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:

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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 thedata. 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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