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REVIEW ARTICLE

Automation of Tablet Compression Machine

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ABSTRACT
The production of fully automated tablets is a fascinating and developing technology in the pharmaceutical sector. The increasing importance of automated technology is mostly due to improved tablet quality, production effectiveness, and process validation. This article covers the numerous alternatives and possibilities connected to tablet press automation. It proposes a specific modular strategy where the tablet maker specifies the scope and timing of the automation transition. The tablet press control system is the foundation for a range of control modules built using this modular strategy to enable automated material flow, data gathering, and remote process monitoring. Since its creation in the 19th century, the tablet press tool has improved the performance of the fundamental model by analysing numerous parameters, resolving their issues, and creating a completely automated system. A machine capable of producing medicines of high quality and affordability in time for a population that is always expanding and cGMP (current good manufacturing practises) compliance norms of cleanliness, various illnesses. Each pharmaceutical establishment intends to have one or both of the Definitely a tablet punching machines. Different producers create their tablet presses with Punches, stations, compression points, and speeds were all improvised. There is a result. It is necessary to research and comprehend where the pharmaceutical tablet punching machine is located, such as its fundamentals, operation, and the different sorts of pills made on them by any one or a combination of three specified procedures. The typical flaws in the tablet manufacturing process and how to fix them to determine the working parameters, press tooling and performance are examined.

Keywords: *Advancement maintenance, Die, Punch, Qualification, Tablet compression machine, Tooling designs, URS, Validation,*

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INTRODUCTION

A mechanical device known as a tablet compression machine, also known as a tablet press machine, tablet making machine, tablet machine, or tablet punching machine, is used to compress API (active pharmaceutical ingredient) and excipient granules or mixtures into tablets of a uniform and predetermined size, shape, and weight for research, pilot-scale manufacturing, and full production. The design of the control system and the mechanical elements have advanced in the past several years as Tablet Press technology has continued progressing. Additionally, the validation standards related to tablet press automation have increased, in addition to providing a broad validation design to support a fully automated tablet press. [1,2]

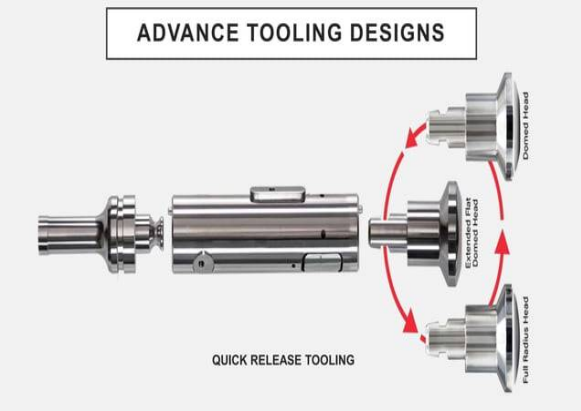

Figure No 1: Advance tooling designs

ADVANCED TOOLING DESIGNS IN TABLET COMPRESSION MACHINE [3]

DIAMOND COATING	CHROME NITRIDE COATING	ALUMINUM TITANIUM NITRIDE OR TITANIUM NITRIDE COATING
- These tools are appropriate for effervescent tablets. -Tools with diamond coatings are often long-lasting and resistant to abrasion. -They are approximately six times as hard as standard tablet presses and do not stick.	-The tablet press tooling's final surface is superior to that after galvanic treatment, and it has a good quality-to-price ratio with improved wear protection.	-This process is widely known for its excellent surface hardness and smooth finish. - Therefore, the ideal option for most pharmaceutical tablet compression applications.

Table No 1: Advanced tooling designs in a tablet compression machine

Different Shapes of Dies and Punches

Table No 2: Different Shapes of Dies and Punches [3]

DIFFERENT SHAPES	ROUND PUNCH DIE SHAPE	OVAL SHAPE PUNCH DIE SET	CAPSULE SHAPES OF DIES AND PUNCHES	GEOMETRIC SHAPE PUNCH DIE SET
FOLLOWING TYPE OF TABLET-	1)Shallow convex ball shape	1)Flat faced with bevel edges	1)Convex with edges	1)Triangular
	2)Deep convex flat faced	2)Convex/deep/deep convex with bevel edges	2)Deep convex flat faced	2)Benzene
	3)Convex with edges flat with bevel edges		3Normal convex flat with bevel edges	3)Rhombus
	4)Normal convex			4)Rectangular square
USE	The pharmaceutical and veterinary industry	Ayurvedic industries	Pharmaceutical and Ayurvedic industries	Pharmaceutical, Confectionary, chemical
Diagram				

Table No 3: Types of die in a tablet compression machine

LINED DIES	CARBIDE LINED DIES	CERAMIC LINED DIES	GALVANIC CHROME TREATMENT
- Commonly called insert dies. -They are specifically utilised to compress composition that is corrosive and abrasive. BENEFITS OF LINED DIES - -It extended the life of the tool. -Lower headwear. It decreased friction. -The removal of rusting. -It improved the tablet's quality.	-They are Recommended with abrasive granulations. - It works effectively for applications involving nutraceuticals. - It offers high wear resistance when abrasive items are compressed. -Due to their wear liner, it increases mortal life by more than 10 times.	-For corrosive products Over several tablet compression cycles, it lowers the coefficient of friction. -It works with rectangular and rounded tablets. - Add a wear liner to stop them from wearing it. Enhance the die life by 5–10 times.	-This tablet press tooling is suitable for most common tablet press applications. -The coating is typically about 5 microns thick. -One of the most common treatment methods in most pharmaceutical companies is the coating, which improves stability and protects the tooling system of a tablet compression machine from wear.

USER REQUIREMENT SPECIFICATION-

The equipment defined in this specification shall conform to the following:

The current state-of-the-art GMP European machine agency (EMA) and FDA regulations and guidelines may be applied to this type of equipment.

Machine Functions

Product:

Tablets of different shapes (Round, Caplet, Oblong, Oval) and sizes ranging from 6 to 25 mm in diameter for round tablets and from 10/5 mm to 25/10 mm for Caplet tablets.

Capacity:

The normal working capacity of the machine should be 300000 (Three lacs) tablets/hour. Design & Tooling: Double-sided, D-type tooling

Autoloading system:

Autoloading equipment will be set for loading the powder/granules from the storage drum/container to Machine Hopper. Autoloader will be On/OFF according to the product level of the hopper.

Hopper arrangement:

Hopper arrangement will allow connection of lay-flat tube to the hopper, ensuring proper feeding of materials to the feed frame. Level sensor required in the hopper to control feed **from** IBC above. The level sensor will be integrated with the existing control panel. Inside the hopper, there should be looking glass for monitoring the powder level. The surface finishes of the hopper will be Internal: 0.38 to 0.51 micron Ra and External: 0.51 to 0.64 micron Ra.

Compaction force:

Machine to have a pre-compression facility with a 100 KN (Maximum) capacity and a 100 KN (Maximum) compaction force.

Key Component:

Upper punch guides will have keyways installed for contoured punches.

connections for the central dust extraction system's dust control between the tabletting machine and the dedusted

- Strong glass viewing panels with hinges.
- Automatic lubrication when necessary.
- Variable speed rotary paddle granule feeder.
- Dedusting equipment

Dedusting / polishing equipment to be set for polishing the final product. Its speed must be matched with the Extra dust from the machine's various points should be collected using a dust collector. For dust control, the device needs to have a way to regulate suction pressure.

Thickness:
Calculate the mean and per cent deviation for the first 20, last 20, and middle 20 (for the entire run). The required Standard Deviation is 5% or less. Variations allowed: +/-5% of specified thickness.
Hardness:
Calculate the mean and per cent deviation for the baseline using the first 20, last 20, and middle 20 (across the entire run). It must satisfy each tablet's requirements.
Allowable variation is +/- 5% of the specified hardness.
Weight variation:
In weight variation, the homogeneity of the die filling can be evaluated. Perform on 20 pills.
Calculate the mean and the per cent deviation. No tablet has a variation that is twice as large as the two tablets that have the largest variation, as shown below.
The following formula is used:
Weight Variation (IW-AW) AW X 100%
Where,
A.W.: The typical weight
I.W.: Individual weight **[5]**
Tablet compression machine manufacturers [4]
1) Bosch:
Tablet manufacturing capacity – 400,000 per hour.
Station -56

Figure No 2: Bosch tablet compression machine

2) Korsch:
Tablet manufacturing capacity-1,000,000 per hour (single-layer tablet.)
Weight-15,000kg.
Models-1) X.T. 600HD
2) TRP 700
3)TRP 1200

Figure No 3: Korsch tablet compression machine

3) Kilian:[8]
Tablet manufacturing capacity-1,020,000 tablets per hour
Weight-1855kg

Figure No 4: Killian tablet compression machine

4) Fette:[7]
Tablet manufacturing capacity-1,000,000 tablets per hour.
Weight -4,400kg**.**

Figure No 5: Fette tablet compression machine

5) Natoli: [8]
Tablet manufacturing capacity-168,000 tablets per hour
Weight-2,835I

Figure No 6: Natoli tablet compression machine

6)Cadmach:

Figure No 7: Cadmach tablet compression Machine

Tablet manufacturing capacity-439,200 tablets per hour Weight 1075kg.
Tablet manufacturing capacity-367,200 tablets per hour.

7) GAE:[4]

Tablet manufacturing capacity-367,200 tablets per hour

Figure No 8: GAE tablet compression machine

8)Access:

Tablet manufacturing capacity-18000 tablets per hour,

Figure No 9: Accupress tablet compression machine

ERWEKA TESTER: [7]

- The ERWEKA is a tablet hardness and combination tester for half-automatic measuring up to 10 samples.
- The samples are inserted in a star-shaped feeder and automatically transported to the test station.

Figure No 10: Erweka tester for tablet compression machine

Table No 4: Old Technique and New Technique of tablet compression machine

Parts	Old Technique	New Technique
Vacuum feeding	Manually added powder	Powder filled with the help of a vacuum
Weight variation	The weight fluctuation and hardness of compression machines are manually adjusted.	Servo motors and cams are installed in advanced compression machines to automatically regulate tablet weight and hardness.
Alarm System	No alarm system is installed; if there is one, it does not provide visual cues.	It guarantees the security of machine parts and the operator. On the HMI, the alert is indicated when it sounds. A fault is quickly found when a specific location on the HMI is highlighted.
Monitoring of punch load	No information is available to indicate the force used for each punch individually.	For each punch load, graphical data is displayed on the HMI of the advanced compression machine. When overflowing, the punch is immediately identifiable from the graph. It shows a punch location about the punch numbering scheme.
Metal detector	In the past, metal detecting and dusting devices were distinct. Tablets go past a metal detector after first going through a de-duster. There needs to be more room. It will need more time.	The two technologies are merged into a single device that performs metal detecting and de-dusting as part of new technology.
Fill Cams	Granules or powder are poured into dies in conventional compression machines, and weight is controlled by turning the weight adjustment cam's knob. The lower punch is pushed upward or downward in the dice, and the space inside the die is expanded or decreased by twisting the weight adjustment cam's knob.	Fill cam charges are determined by the weight of the tablet and the bulk density of the powder or granules. Millimetre depths are available for filling cams. Each cam can only hold a certain amount of grains or powder. Thus, we must switch cams if we want to add more weight.

Bilayer tablet:

PTK (pharma tech Korea) Rotary tablet press model, PR3000 double-sided press, is suitable for producing mono-layer or bi-layer tablets.

Bilayer Tablet Compression Machine, Capacity: 1800 TO 175000 TABLETS/ HOUR

PR3500 Model triple-layer tablet press permits the production of single-layer, bi-layer and tri-layer tablets

C3LP is a cGMP model, Triple layer tablet press. It is capable of Triple-layered, Bi-layered & Mono Tablets. The machine has got sampling facility for checking the weight of the individual layers. C3LP is offered in 31D, 39B & 47BB Turret Configurations.**[7]**

Critical check parameter of tablet compression machine-Compression speed

1) Force Pre-compression
2) Force the main compression
3) Force Feed frame type and speed
4) Hopper design, height,
5) Depth of fill
6) Punch penetration depth
7) Turret speed
8) compression force.

Latest technology in tablet compression machine- [6]

1) PR-LT LABORATORY TABLET PRESS

LABORATORY TABLET PRESS PR-LT

PTK-GB Ltd. is the manufacturer of it.

PR-LT can create single, double, and triple-layer tablets with only a few granules of powder needed and no additional changing components.

PRIMARY FEATURES

Tablets with a 1, 2, or3-layer core and a low-capacity sequence feeder

Dwell time profiles and single station analysis Producing 1 tablet is simple and requires few resources.

Manufacturing of triple-layer tablets without the use of additional changing parts

Utilise the add-on production feeder to make single-layer tablets at maximum production speed.

Different Tablet Formats

- One Layer

Two Layers

Three Layers

- Tablet Core
- Formats with one or more punches.

Tablet with three layers

(Tablet in Tablet) Core Tablet

Figure No 11: PR-LT laboratory tablet press machine

2) D.R. PHARM: HIGH-SPEED TABLET PRESS January 07, 2019:

Figure No 12: High speed tablet press machine

Dr Pharm Inc. is delighted to introduce the NEW GZPS-83 High-Speed Tablet Press.
Developed and constructed specifically for the industries involved in feeding and pharmaceuticals.

PRIMARY FEATURES:

The filling system on the GZPS-83 is driven by strong and precise Servo motors controlled by the Siemens touch HMI display. Other important features were dosing, pre-pressing, primary pressing, ejection, double force-feeding, two powder-filling hoppers, and double compression.

3) ROTARY TABLET PRESS MODULE Q:

The MODULTMQ rotating tablet press raises the bar for dependability, efficiency, and productivity.
The next-generation ECM, however, provides a better restriction performance and is even easier to operate.
Additionally, a dust-free operation is feasible.[4]

Figure No 13: Rotary tablet press module Q machine

KEY FEATURES:

Powerful and accurate
servo motors power the GZPS-83's filling system via the Siemens touch HMI control display. Other key features included double discharge, two powder-filling hoppers, pre-pressing, main pressing and ejection.

THE MODULE Q ROTARY TABLET PRESS:

The MODULTMQ rotary tablet compression sets new efficiency, productivity and reliability standards.

The upcoming-generation version of the ECM is even more convenient to use and offers a higher level of containment performance.

→ Dust-free operation is also possible.

Validation of tablet compression machine:

Equipment identification: To validate a tablet compression device, one must record the equipment identification number, the model number, and the location of the equipment and serial number.

Essential documentation: document the operation and maintenance manuals provided by the equipment maker in the required documents. Keep a copy of the SOP that addresses tablet press setup, use, and cleanup.

Utility requirement for equipment: Compare the volts and amps specified by the manufacturer to the equipment's as already established state at the time of qualification testing and recording. Make a note of the location of the power source.

Major component specifications: The protocol's component specification section verifies that the tablet press's purchased components were installed and delivered.

Document the material of each component that comes into contact with the product.

Lubricants:

Please keep track of the lubricants used to run the tablet press and note whether they come into touch with the product.

Equipment safety characteristic: Testing equipment safety features aims to ensure that tablet press deceptive characteristic operate by manufacturer specifications.

Operational qualification:

An assessment of the equipment's operational qualification should show that it can operate within the given tolerance and limits. Along with the fundamental tablet press operations, the automatic aspects of the tablet press present a challenge. Information essential for the operational qualification estimation involves calibration of the systems used to control the tablet press, equipment control functions and equipment operation.

Calibration need:

Please prove that all the critical instruments on the equipment have been logged into the calibration system and have calibration procedures in place, and us in calibration at the time of qualification testing. Testing the equipment control function aims to ensure that the tablet's push button and switches function according to the manufacturer's specifications.

Equipment Operation:

One can track and test-verify the upper and lower cam track. Install the punches and verify that the cams hit the punch head angles on both sides of the double-sided cams. Check if the points are making full contact with one side of the single-sided cam.

Upper punch test:

When a purpose is said to have penetrated to a standard depth, affix a piece of tape to denote the death of the insight. Remove the upper punch, measure the depth of insight into the die with a calibrated vernier calliper, and then record the information.

The lower punch test:

aims to ensure that the lower punch height is set following the manufacturer's specifications. There must be a dial indicator test. Major the size of the lowest five around the die that dials an indicator and records the results and the height-measuring tool. The purpose of the examination of the Field Frame purpose is to ensure that the field frame's height over the Rotor head is to the manufacturer's specifications.

Remove bar test:

The remove bar test aims to ensure no bars are in touch with the lower punches. Using a hand press, rotate the tablet.

The tablet press's rotation direction:

is tested to ensure the rotor head rotates appropriately. The tablet press will be empty for the test. Praise this start switch, observe the rotor head's rotational direction from the press's front, and record the outcome.

The tablet press speed test aims to ensure that the major speeds are within 10% of the manufacturer's standard, which calls for a minimum rate of 9 RPM and a maximum speed of 36 RPM. The press will be empty for the test. For this test, the stopwatch is necessary. Ensure the major rates are within +-10% of the manufacturer's standard, and note the outcome and the measuring device.

Qualification of tablet compression machine:[10]

Design Qualification:

Design qualification is required for the tablet compression machine to specify the system's functional requirements and record the vendor selection procedure. Approval of the original protocol format for the system qualification statement and final summary. Presenting written proof that the facility's and the equipment's designs complied with the user's requirements and good manufacturing practices. Procedures must be documented and verified to follow the protocol. Equipment recognition, necessary documentation, equipment utility need, component material, lubricants, and equipment safety features are all needed for an installation qualification evaluation.

Operational Qualification:

Table No 5: Operational qualification of tablet compression machine

Test	Acceptance criteria
1)Cam track test	Verify upper and lower cam track contact with upper punch according to manufacturing specification.
2)Upper punch test	Verify that upper punch penetration is according to manufacturing specifications. Take out the upper punch; use a vernier calliper and measure the depth of penetration into the die.
3)lower punch test	Measure the height of the lower punch above the die with a dial indicator
4)Take off bar test	Verify that Take off bar does not make contact with the lower punch
5)Feed frame test	Verify feed frame distance above rotor head according to manufacturing specification.
6)Tablet press Rotation direction	Verify rotor head direction in the proper order.
7)Tablet press speed test	Verify that measured speeds are within +-10 %of to manufacturing specification of a minimum of 9 RPM and a maximum of 36 RPM. Measure the speed of the rotor head with a calibrated stopwatch.

Equipment should be operationally qualified, and operational qualification evolution developed within defined tolerance and limits. Calibration of the devices used to control the tablet press, equipment control function reaches and push buttons, and equipment operation (cam track upper punch lower punch frame take-off blad) are all necessary information for the operational evolution. [10]

Performance Qualification:

The compression machine is run at a low speed of 20 RPM by operating instructions. After adjusting the following parameters individual tablet weight variation, the weight of 20 tablets, hardness, thickness, disintegration time, and friability the machine is claimed to run for 20 minutes continuously.

Validation of installation qualification-equipment installation is the certification of equipment as it is to be installed; this certification requires a coordinated effort from the vendor, operating department, and project team, who will provide input into the equipment's purchase, installation, operation, and maintenance.

Following the completion of the equipment installation at the final processing location and the production of the installation qualification document, a specific equipment operation qualification is required. The complete equipment operation qualification protocol should outline all aspects of the equipment testing.

Revalidation:[10]

Revalidation is done when the formulation equipment plan, side location batch size, or sequential batches that do not meet specifications change or are replaced. It is also done at predetermined intervals if there are no modifications. It is the validation procedure being repeated.

Revalidation criteria: The equipment's location has changed at the scheduled time for revalidation. Changes to spare components directly impact the performance of the equipment.

Critical compression characteristics include the machine's speed, the type of feeder it uses, the speed at which it feeds the tablets, and their thickness, hardness, disintegration, and shape.[10]

Line clearance:

Checklist for line clearance to assess compression and confirm that the equipment in the region is visually clean. Verify that the area is free of undesired objects and old products. Per the Batch Manufacturing Record, Ishwar's temperature and relative humidity are within the allowed range. Verify that the area's differential pressure is negative about the nearby corridor. Check that the staff is dressed appropriately. Check the current status label where we display the activity's specifics. Verify that the blend analysis

report passed. Ensure the stage is filled and the batch manufacturing record is available. Make careful to use the proper dies and punches.

All materials and remnants from the previous operation have been removed as part of the procedure for the line clearance of the tablet compression machine. The equipment and accessories from earlier operations have been taken out. Containers from earlier operations have been taken out. Previous operations' paperwork has been erased. The last operation's status labels have been removed. Labelled. Areas are cleaned, and a status indicator is shown. The atmospheric pressure difference between the producing region and its surroundings is the depression differential. The Magnehelic pressure gauge measures it in pascals. According to World Health Organisation guidelines for HVAC systems, the production and adjacent regions must maintain a differential pressure of 10 to 15 pascals. The Magnehelic pressure gauge measures it in pascals. According to World Health Organisation guidelines for HVAC systems, the production and adjacent regions must maintain a differential pressure of 10 to 15 pascals. Airflow should always be from aseptic to non-aseptic areas, and the aseptic regions should always be significantly pressurised compared to the non-aseptic ones. By using HVAC, this pressure difference is kept constant. Differential pressure in the tablet production region aids in preventing cross-contamination. These airlocks help to restrict the entry of contaminated air into the control area by preventing direct air movement from uncontrolled areas to controlled ones. It is vital to keep the corridor under positive pressure compared to the regions where tablets are manufactured, but there should be a positive airlock there before entering the hall.

Working principle of the Tablet Compression Machine: Hydraulic pressure is the fundamental operating principle of the Tablet Compression Machine. Through static fluid, the pressure is distributed evenly in all directions. If necessary, additional force is used.

Maintenance of tablet compression machine:

Table No 6: Maintenance of tablet compression machine

Weekly maintenance	Monthly maintenance	Yearly maintenance
With a hand wheel, make sure the machine is rotating freely. Check the hydraulic oil level. The gearbox oil chamber should be 3/4 full. Check the punch lubrication oil level and keep it at the appropriate level. Verify the powder conveying system's functionality. Check for leaks in all the polyurethane connectors and pipes. Utilise the appropriate lubricant to lubricate all moving parts.	Inspect all the moving parts for proper lubrication and oil them as necessary. Check the hydraulic oil level, lubricating oil level and gearbox oil level. If necessary, top out with lubricant up to the recommended level. Verify that the feeder and main pressure motors are moving freely, and replace the bearings if necessary. Examine the condition of the contactors, relays, and terminals for PROGRAMMABLE LOGIC CONTROL, and clean them using CARBON TETRA CHLORIDE if necessary. Verify the performance of all the interlocks and limit switches and tighten the line connections as necessary. Check the vacuum unit for the powder conveying system and clean the chamber and vacuum assembly, as necessary.	Check the gearbox's oil seals and replace them with new ones if necessary. Remove the gearbox oil and then fill it out with new oil. All moving parts, brackets, and the motor's bearings should be checked; if problems occur, replace the worn-out bearings. Examine the condition of the hydraulic pump's oil seals and replace them as needed. Check the condition of the timing belts and replace them if necessary. Check the condition of each solenoid and pneumatic valve, and replace any worn-out parts if necessary.

CONCLUSION

A quick introduction to tablet compression machines has been made to modern models. Situations, in reality, are inevitable; extensive expertise in the care and upkeep of This multipurpose device is essential. Especially those who desire to comprehend the fundamental specifications, components, operation, and evaluation of machines when making tablets. A tablet press's tooling is essential to the tablet making process. Consequently, selecting a suitable design that fulfils your particular needs. Applications for tablet compression are essential. In order to provide optimum, effective, and uniform productivity, tablet press tool types must also be designed, handled, and standardised.

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