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Description of Pharmaceutical Tablet Punching Machine

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Abstract
Tablet press tool since its invention 19 century improving the efficiency of the basic model by studying various parameters, overcoming their problems, and developing into a fully automated machine meeting the demands of high quality with low-cost medicines production in time to ever-growing population, complying with cGMP (current good manufacturing practices) cleanliness standards, multiple ailments. Every pharmacy institution plans to have either of the tablets punching machine for sure. Various manufacturers develop their tablet press with improvised number of punches, stations, compression points and its speed. Hence there is a need to study and understand the whereabouts of pharmaceutical tablet punching machine like its principal, working and types of tablets prepared on them by any or combination of three established methods i.e., compression granulation, wet granulation, and direct compression. The common tableting process defects caused and to overcome these problems by the tablet press tooling and performance to be evaluated parameters are studied to estimate the working efficiency of the machine at every stage with the help of ISTMs (instrumented single tablet punching machine), IRTMs (instrumented rotary tablet punching machine) investigated with the achieved data is interpreted for selection of suitable tablet press to work on.

Keywords
Dies, IRTMs, ISTMs, pharmaceutical tablet punching machine, punches

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DEFINITION: Pharmaceutical tablet press also known as tablet punching machine and tablet compression machine is a mechanical device that compresses powders or granules into tablets of uniform size shape and weight containing approximately the same quantity of active pharmaceutical ingredient and excipient [1,2].

INVENTION: In 1843 patent on tablet punching machine received by William Brockedon.

DESCRIPTION OF TABLET PUNCHING MACHINE: It includes pictures of single punch tablet machine, rotary type tablet punching machine and compression cycle with tooling systems with labeling parts. coating of the tooling systems with various metals.

GENERAL INFORMATION

MATERIAL: stainless steel.
FEED FRAME: chrome plated gun metal.
POWER: 5.5KW
NUMBER OF STATIONS: 8-65
MAXIMUM DEPTH OF FILL: 50mm
MAXIMUM SIZE OF TABLET: 100 mm
DIE DIAMETER: 130mm.
DEPTH OF DIE: 90 mm.
MAXIMUM STROKE PRESSURE: 20-25 per minute
MAXIMUM STROKE PRESSURE: 25-30 Tons approximately.
ELECTRIC MOTOR: 5H.P/440V/50 CYLS/PHASE /960 RPM.
LUBRICATION: oiling and greasing.
CAPACITY: 1,000,000 tablets per hour.

DETAILED PICTURE OF THE TABLET PRESS TOOLING: the pictures of single station punching machine, rotary type punching machine, compression cycle, single punching machine, bilayered multi-station rotary machine and press tooling (upper, lower punch and dies) depicted clearly in figures from 1-6.

TOOLING TERMS: these include names of the parts and their function

1. **Anneal:** punch tip heating process to protect from fracturing.
2. **Bakelite tip relief:** assists in scraping adhered product to the die wall.
3. **Barrel chamfer:** located at ends of the punch
4. **Barrel flutes:** helps in product removal from punch guides.
5. **Barrel or shank:** punched vertical bearing surface giving vertical guidance in machine turret.
6. **Barrel to stem radius:** radius covering punch barrel to the stem.
7. **Cup depth:** covering highest point to the tip edge to the lowest point of the cavity.
8. **Die:** place of compaction related to tablet design.
9. **Die bore:** cavity in die responsible for tablet size and shape.
10. **Die chamfer:** angled area guides upper punch into die bore.
11. **Die groove:** radial groove around the die.
12. **Die taper:** helps in air release in die formed during compression cycle.
13. **Head:** largest diameter of punch meeting machine cams, receives pressure from rollers.
14. **Head flat:** flat portion responsible for maximum compression dwell time.
15. **Neck:** part below the punch head.
16. **key:** mild steel projection above the punch barrel surface.
17. **Stem:** the area from the barrel to the edge of the punch tip.
18. **Tooling set:** complete set punches and dies accommodating all stations of tablet press.
19. **Paddle feeders:** facilitate constant and efficient die filing.

[www.pharmapproach.com/tablet tooling terminology].

PUNCHES AND DIES

Tablet press tooling refers to arrangement of punches (upper, lower) and dies.

Two standard designs widely considered are

1. TSM (tablet specification manual) is American standard.
2. EU (euro standard) European standard.

Where Punch length of EU is 0.010inches longer than TSM, head thickness of TSM is larger than EU and punch heads are angled in TSM and doomed in EU.

DIES: materials used for making die should have high wear resistance and compression strength include stainless steel, high chrome steel, high carbon steel and Tungsten carbide[www.rwhartnett.com].

capping, delamination, and tablet ejecting are the Problems affecting efficiency of the tablet press [3].

Tool maintenance monitored for cleaning, evaluation, measurements, and lubrication to achieve productivity enhancing machine life.

CLASSIFICATION OF TABLET TOOL ING SYSTEM:

Punches and dies with their detailed labeling given in table I

Table I: classification of tablet tooling system with measurements.

Tooling set types	D	B	BB	DB
Barrel diameter(inch)	1	0.75	0.75	0.75
Head diameter(inch)	1.25	1	1	1
Length (inch)	5.25	5.25 & lower punch is 8.8125	5.25	5.25
Dies outer diameter (mm)	38.10	30.16	24	30.16

Table II: details of tablet coating

S.NO	TYPE	PROPERTIES	APPLICATIONS
1.	Diamond coating	Abrasive resistant and durable. Don't stick and six times harder that of ordinary tablet press.	Suitable for Effervescent tablets.
2.	Galvanic chrome treatment and physical vapour deposition (PVD)	Protects the tooling system during compression from wear and tear. Ensure better stability as coating thickness is 5µ.	Standard tablet press utilizes this treatment.

3.	Chrome nitride coating	Has high quality to price ratio with enhanced wear protection.	Final surface finishing is better than the galvanic treatment.
4.	Aluminium–titanium nitride or titanium nitride coating	Smooth finish and high surface hardness. Tooling is heat treated to enhance its performance.	Preferred choice for most tablet press.

NEED OF COATING TREATMENT IN TABLET PRESS TOOLING

To enhance service life, product yield and to reduce sticking and picking problems coating is done. Details of tablet coating like types, properties and applications of the coating treatment are listed in table 2[info@sainyco.com].

Different types of tablets and their uses which are prepared on this machine: along with pills, tablet triturates various types of tablets manufactured are buccal, sublingual, bilayered, coated (sugar, film, enteric), sustained, controlled, immediate release, chewable, dispensing, effervescent, hypodermic, multiple compressed (where fill material is compressed more than once) tablets and multiple unit pellet systems (MUPS) contain drug mixture of excipients & pellets etc. [4].

Common requirements for preparing them generally include a) Diluents or fillers to provide necessary size to the tablet. b) Binders or adhesives providing adhesion and integrity between particles. C) Disintegrants provide ready breakup of tablet into particles enhancing bioavailability. D) Lubricants or antiadherents enhance the flow properties and others include flavours and colourants[5,6].

Principle: Hydraulic pressure and any externally pressure applied transmitted via static fluid to all direction in same proportion compress the feed material in a die hole by upper and lower punches where increase in hydraulic pressure related to hardness of the tablet.

WORKING: Streamlined procedure involved in tabletting from feed to final ejection of tablet from the tablet press explained by the stages of working of single station and rotary type as follows [7].

WORKING OF SINGLE STATION PUNCHING MACHINE

Stages involved are various positions in filing, compression, and ejection.

FILING

Position 1: upper punch & lower punch are raised and lowered respectively creating cavity in the die.

Position 2: feed shoe moves over the die cavity granules fall into it under the influence of gravity from the hopper.

COMPRESSION

Position 3: feed shoe moves out of the way powder mixture or granules descends from hopper get compressed by progressive reduction of the die porosity forcing particles into close contact with one another.

EJECTION

Position 4: at a time, upward movement of lower punch and retraction of the upper punch ejects the compressed tablet. This entire event continued till the feed material is exhausted.

WORKING OF THE ROTARY COMPRESSION MACHINE:

Stages involved are filing, metering, compression, and ejection.

Filling: this process involves transfer of prior processed raw materials by wet, dry granulation (roller compaction) sizing or other process. The final formulation yields a homogeneous blend flowing to punch die cavity. The position of lower punch within the die determines the volume of the punch die cavity approximately sized for the tablet.

Metering: This stage involves maintaining exact quantity of granulation in the die by adjusting lower punch height controlled by metering cam and removing excess granulation from the machine.

Compression: tablets formed in this stage under pressure within the die cavity by the upper and lower punches and the distance between these punches determines the hardness and thickness of the tablet.

Ejection stage: compressed tablet expelled out of die cavity by the rising lower punch above the turret table and upper punch retraction a scraper then pushes the tablet off the die table.

To understand the Problems that arise during the stages of tabletting [www.scientistlive.com] and to evaluate the performance of machine –steps involved [9].

Differences between the single punch and rotary tablet press are detailed in table III

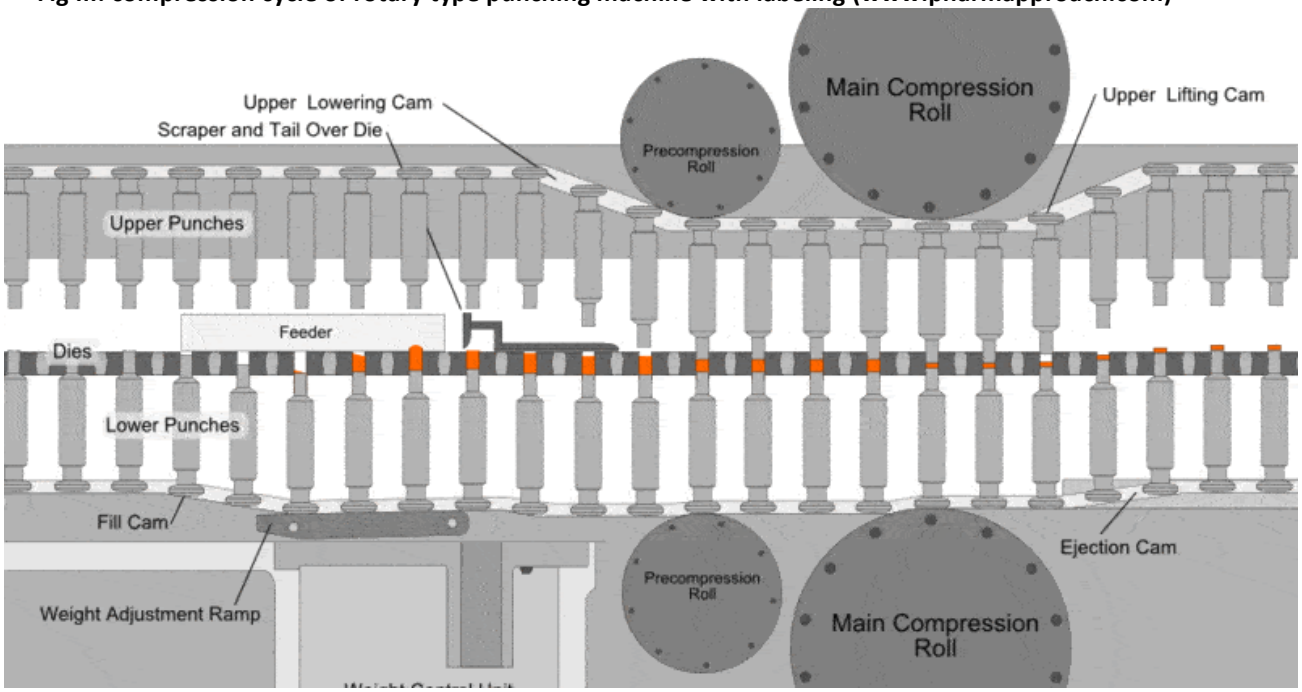
Table III: differences between single punch and rotary type tablet press

Single punching machine	Rotary tablet press
1. Single punching machine also called as eccentric press or single station press, in this press the compaction force on the full material is exerted by only the upper punch while the lower punch is immovable such as action equivalent to hammering motion	**1.** Rotary punching machine has several or multiple tooling stations that rotate to force granules or powder mixture into tablet and pill forms depending on the size, shape and weight on the punch design.
2. Operational flexibility both manual and automatic.	**2.** Operational flexibility both manual and automatic.
3. Tablets prepared by single side compression.	**3.** Tablets prepared by double sided compression.
4. Compression cycles do not have dwell time.	**4.** Compression cycles have dwell time (as the punches passes under compression roller).
5. Weight variation between tablets and noise level is low.	**5.** Weight variation between tablets and noise level is high.

Fig. I rotary type tablet punching machine with labeling (www.pharmapproach.com)

Fig II: single punch tablet punching machine with labeling (www.pharmapproach.com)

Fig III: compression cycle of rotary type punching machine with labeling (www.pharmapproach.com)



PICTURES OF DIFFERENT TYPES OF THEM

Fig IV: Single station punching machine

Fig V: Multi-station Bilayer punching machine (www.pharmapproach.com)

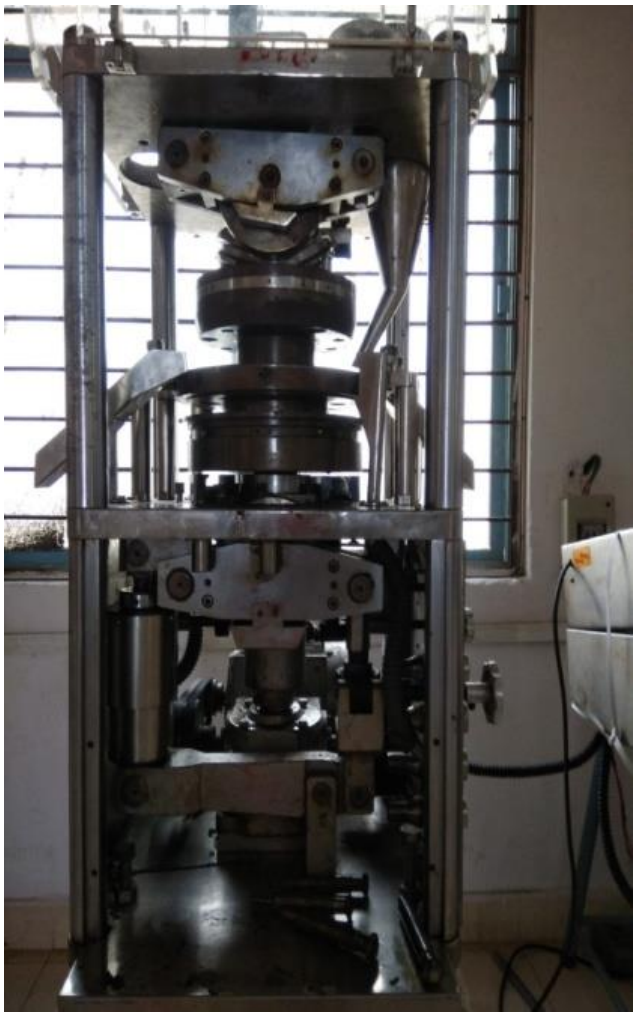
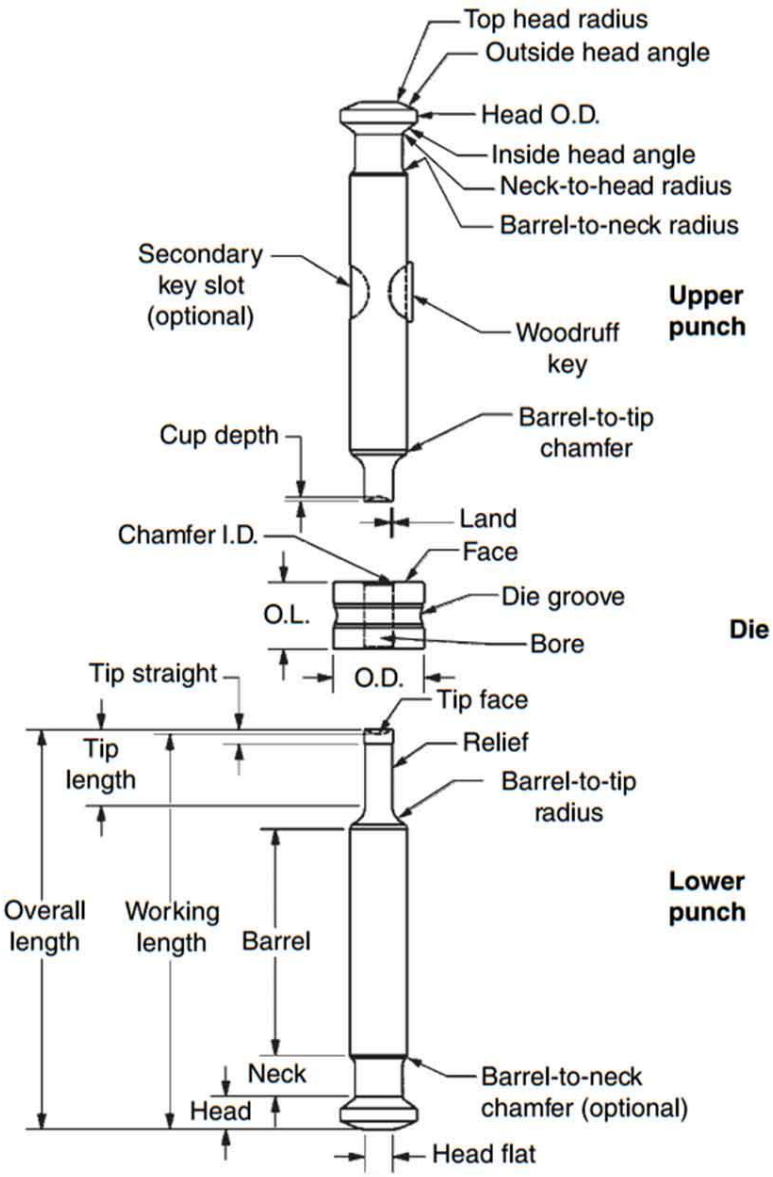


Fig VI: upper punch, lower punch and die detailed labeling (www.pharmapproach.com)



Maintenance of tablet press

Turn off the power and release the pressure from the punches followed by removing them along with feed shoe and hopper then de-dust using vacuum cleaner. Clean all the surfaces and dry with a cloth, before storage cover the surfaces with thin coating of oil or grease.

Understanding powder flow property being an important consideration to avoid quality issues in tablet such as weight variability, content uniformity or tablet defects.

IRTMs (instrumented rotary tablet machines) are used to study many phases of the tabletting process, evaluation and typical applications in pharmaceutical research development and production studies.

ISTMs (instrumented single tablet machines) using these specialized static compression methods or empirical methods measuring compression force studied.

Efficiency of the machines (IRTMs, ISTMs) were analyzed and depicted graphically by studying the compression force with that of various machine control and process control settings as follows.

MACHINE CONTROL SETTINGS

1. Hardness values.
2. Fracture resistance.
3. Friability.
4. Disintegration.
5. Dissolution.
6. Mean tablet weight.

7. Mean tablet thickness.
8. Compression rates.
9. Compression and ejection force [10].

SETTINGS FOR THE PROCESS CONTROLS

1. Speed setting.
2. Weight cam.
3. Thickness.
4. Punches and die dimensions [11].

Performance Evaluation parameters of tablet manufacturing process: critical step demands selection of tool and equipment to reduce defects of manufacturing process such as capping& lamination, sticking, picking, mottling, chipping, and binding in the die, embossing, low tensile strength, weight variation, double impression [12,13].

Three phases of the tablet manufacturing process are Preformulation, Formulation, and Scale-up.

In preformulation stage to study following properties characterized are.1. mechanical properties of the API (active pharmaceutical ingredient). Deformation, compactibility, ejection force, stickyness, residual & peak radial die wall force and punch adherence force, ISTMs used

In Formulation stage IRTMs used for compaction studies performed with formulation variants while simulating production tablet press rates and dwell time.

In Scale-up process manufacturing conditions, processing variables are evaluated on excipient suppliers, particle size changes. A compaction simulator or emulator is designed to mimic a high-speed rotary tablet press[www.epmmagazine.com].

CONCLUSION

An attempt has been done to provide brief information about tablet punching machine with latest models. In realty situations are inevitable, thorough knowledge in handling and maintenance of this instrument with wide applications is vital especially who want to understand the basic standards, machine parts, functioning and evaluation in tableting process.

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