

“Formulation Of The Tablets”

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Abstract:

Tablets are solid dosage forms prepared by compressing active pharmaceutical ingredients (APIs) along with excipients into a defined shape and size. They are among the most widely used forms of medication in the pharmaceutical industry, offering convenience, stability, and precision in dosing. Designed for oral administration, tablets are formulated to release the active drug in a controlled manner, depending on the intended therapeutic use. The composition of tablets typically include active ingredients that provide the therapeutic effect and excipients that enhance stability, manufacturability, and patient acceptability. Common excipients include binders (to hold the components together), disintegrants (to aid in breaking down the tablet), lubricants (to prevent sticking during manufacturing), and fillers (to add bulk for ease of handling). Tablets are classified into various types based on their release characteristics and mode of administration. Immediate-release tablets dissolve rapidly in the gastrointestinal tract, offering quick onset of action, while extended-release tablets allow the drug to be released gradually over time. Other specialized types include chewable tablets, effervescent tablets, and sublingual tablets, which are designed for specific patient needs and conditions. Tablets offer numerous advantages, including accurate dosing, portability, and a long shelf life when stored under appropriate conditions. They are easy to handle and administer, making them suitable for a wide range of patients, including children and the elderly. Additionally, their compact size and lightweight nature contribute to their cost-effectiveness in manufacturing and distribution. Tablets are an essential pharmaceutical dosage form, providing a reliable, efficient, and versatile method for drug delivery. Their adaptability to various therapeutic requirements ensures their continued prominence in modern medicine.

Keywords: Dosage Forms, Administered, Formulations, Characters, Volumetric, Granulation, Manufacturing, Etc.

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I. Literature Of Review:

- **Reynir Eyjolfsson**- Design and Manufacture of Pharmaceutical Tablets: This book provides practical examples of actual formulations and outcomes in tablet design and manufacturing, offering real-world solutions to major challenges in the field.
- **Larry L. Augsburger and Stephen W. Hoag**- Pharmaceutical Dosage Forms – Tablets: Manufacture and Process Control: This comprehensive resource covers the design, formulation, manufacture, and evaluation of tablet dosage forms, with detailed insights into process control.

II. Introduction:

Oral solid dosage forms are administered for attaining a local therapeutic effect in the mouth, throat and digestive tract or for a systemic effect in the body after oral or gastrointestinal absorption. For preparing oral solid dosage forms, active ingredients and suitable excipients can be milled, dried, encapsulated, blended, granulated or tableted. Various oral solid dosage forms such as tablets, capsules, lozenges, powders and granules etc. have been widely used for delivering active pharmaceutical ingredients (API) due to their convenience and consequent patient compliance[1]. Tablet is the most widely used dosage form among the total available dosage forms because it is simple for administration, lower price of production and elegance[2]. Tablets are a solid dosage form of medicaments with or without excipients which are prepared by compression method. According to the Indian Pharmacopoeia tablets are solid, flat or biconvex unit dosage form of a medicament alone or medicament along with excipients prepared by compressing technique. They may vary in its size shape and weight depending on the medicament and its mode of administration. Tablets are said to be most widely used conventional dosage forms due to its variety of advantages and 70% of the medicaments were dispensed in tablet forms. Most of the medicaments can be processed into tablets but there are some exceptions like medicaments with low density characters, hygroscopic and the medicaments which were not possible to administer[3-7]. Tablet formulations which provide a unit dose which is either immediate drug release or modified release or is taste masked are some

of the most popular and extensively explored aspects of oral solid dosage form development. Tablet manufacturing (apart from the direct compression method) is a multistep process and hence is a complex process with many potential variables. The processes and parameters associated with tablet manufacture are still not fully understood. Extensive research is ongoing to develop understanding in all areas of the tablet manufacturing process. Numerous advances have been introduced to improve material attributes, engineering of manufacturing equipment and development of efficient analytical techniques. Qualities by design-based formulation development approaches have been applied to reduce the variability in the processes to develop robust tablet dosage forms. In addition, new raw materials have been deployed to improve manufacturability and functionality of tablet formulations. These include the modification of existing excipients with enhanced purity or physical properties (e.g. particle size) and co processing with other materials to improve their performance in manufacturing processes. Moreover, development and use of multi-functional materials provide lean manufacturing opportunities with significant economic impact. The last few years have seen the development of novel tableting technologies which improve machine performance. These advances in machine design aim to overcome limitations associated with conventional manufacturing approaches such as the denaturation of thermolabile active ingredients, material wastage, multiple processing steps and elevated costs due to protracted processing time, labour and maintenance of equipment. In addition, lean and continuous manufacturing concepts have been employed to ensure rapid, safe and efficient manufacturing operations. Developments relating to engineering and machine design have also been implemented in the pharmaceutical industry. The concept of quality by design has been applied to enhance productivity by the application of novel process analytical technologies that track quality attributes of formulations. These also can document data as a function of input variables (materials and process) in a real time manner.[11]

A] Advantages

- Unit dosage forms with dose precision,
- Least content variability,
- Administration of accurate amounts of minute doses of a drug is possible,
- Economical of all oral dosage forms as its production doesn't requires additional processing steps,
- Easy transportation,
- Sustain release of a drug can be achieved through enteric coating,
- Medicaments with bitter taste can be masked with coating technique (Sugar coating),
- Tablet dosage form is stable when compared to all oral dosage forms.

B] Disadvantages

- Administration of drugs is not easy in case of children,
- Drugs with slow dissolution is not acceptable for tableting with good bioavailability,
- Medicaments with low density characters and amorphous in nature are difficult to compress.
- Hygroscopic nature of drugs is not acceptable for tablet compression.

III. Tablet Manufacturing Techniques:

Direct Compression:

The direct compression method is by far the most effective technique of tablet manufacturing. This technique is least tedious and hence is preferred over the other techniques. Direct compression is the simplest and most economical method for the manufacturing of tablets because it requires less processing steps than other techniques such as wet granulation and roller compaction. However, most pharmaceutical active ingredients cannot be compressed directly into tablets due to lack of flow, cohesion properties and lubrication. Therefore they must be blended with other directly compressible ingredients to manufacture satisfactory tablets.[4]

Wet Granulation:

Wet granulation is a process of using a liquid binder to lightly agglomerate the powder mixture. The amount of liquid required to be properly adjusted, as over-wetting will cause the granules to be too hard and under-wetting will cause them to be too soft and friable. Aqueous solutions have the advantage of being safer to deal with solvent-based systems but may not be suitable for drugs which are degraded by hydrolysis.[8]

Dry Granulation:

Dry granulation requires drugs or excipients with cohesive properties. Dry granulation is simpler than wet granulation, therefore the cost is reduced. This process is often used when the product to be granulated is sensitive to moisture and heat. Dry granulation can be conducted on a tablet press using slugging tooling or on a roll press called a roller compactor. Dry granulation often produces a higher percentage of fine granules, which can compromise the quality or create yield problems for the tablet. Steps-by-step tablet manufacturing processes

which are being utilized by various manufacturers are enlisted in Table [1]. Evaluations of these tablets are being carried out by using various response variables. Both preformulation and post formulation parameters are being evaluated to cement the effectiveness of formulated preparations.[11]

Table 1. Various Manufacturers & Process:

PROCESS	DEFINITION
Wet granulation	Milling and mixing of drugs and excipients. Preparation of binder solution. Wet massing by addition of binder solution or granulating solvent. Screening of wet mass followed by drying of the wet granules. Screening of dry granules. Blending with lubricant and disintegrant to produce running powder, Compression of tablet.
Dry granulation	Milling and mixing of drugs and excipients, Compression into slugs or roll compaction, Milling and screening of slugs and compacted powder, Mixing with lubricant and disintegrant, Compression of tablet.
Direct compression	Milling and mixing of drugs and excipients, Compression of tablet.
Nanonization	Involves size reduction of drug to nanosize by milling the drug using a proprietary wet-milling technique. The nanocrystals of the drug are stabilized against agglomeration by surface adsorption on selected stabilizers, which are then incorporated.
Cotton candy process	Involves the formation of matrix of polysaccharides by simultaneous action of flash melting and spinning. This candy floss matrix is then milled and blended with active ingredients and excipients after re-crystallization and subsequently compressed to FDT.
Mass extrusion	Involves softening the active blend using the solvent mixture of water soluble polyethylene glycol, methanol and expulsion of softened mass through the extruder or syringe to get a cylindrical shape of the product into even segments using heated blade to form tablets.
Sublimation	Inert solid ingredients that volatilize rapidly like urea, camphor ammonium carbonate, ammonium bicarbonate, and hexamethylenetetramine were added to the other tablet ingredients and the mixture is compressed into tablets. The volatile materials were then removed sublimation, which generates porous structure.
Moulding	Water-soluble ingredients with a hydro alcoholic solvent is used and is molded into tablets under pressure lower than that used in conventional tablet compression.
Freezedrying/Lyophilization	The drug is dissolved or dispersed in an aqueous solution of a carrier. The mixture is poured into the wells of the preformed blister packs. The trays holding the blister packs are passed through liquid nitrogen freezing tunnel to freeze the drug solution. Then the frozen blister packs are placed in refrigerated cabinets to continue the freeze drying. Finally the blisters are packaged and shipped.
Disintegrant	Involves the addition of superdisintegrants in optimum concentration to the formulation to achieve rapid disintegration/dissolution.

IV. Advances In Tablet Manufacturing Processes:

Tablet manufacturing routines involving advanced granulation approaches, hot melt extrusion, extrusion/spheronization, injection molding, spray drying, spray congealing, coprecipitation and nanotechnology-based approaches have been developed over a number of years to produce robust tablet formulations with improved performance characteristics.

Size And Shape:

Size and shape of a tablet has been determined by its thickness. Size and shape of table plays an important role in its patient compliance as the size of the tablet increases it is not much easier for its administration. Micrometer is the devise which is used to determine the thickness of a tablet. It can be acceptable if the batch falls within the • ±5% of standard deviation.

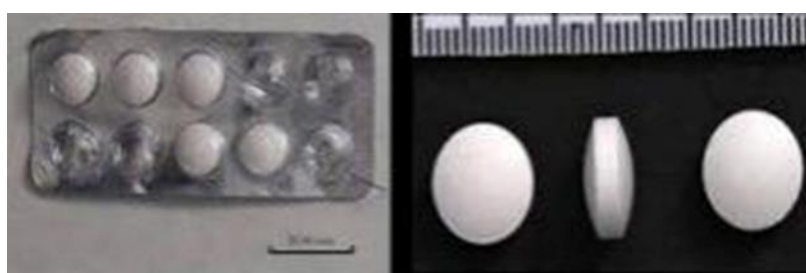


Figure: 1. Size And Shape

- It can be dimensionally described & controlled.
- The thickness of a tablet is only variables.
- Tablet thickness can be measured by micrometer or by another device.
- Tablet thickness should be controlled within a $\pm 5\%$ variation of standard value.

Organoleptic Properties:

Color should be distributed uniformly without appearance of any signs of mottling. Colour of the tablet should be compared with the standard colour for comparison.

- Color distribution must be uniform with no mottling.
- For visual color comparison compare the color of sample against standard color.
- The presence of odor in a batch of tablet indicates a stability problem such as the characteristics odor of acetic acid in an aspirin tablet.
- The presence of odor could be characteristic of the drug (Vitamin), added ingredients (flavoring agent) or the dosage form (film-coated tablet have a characteristic odor).
- For chewable tablet presence or absence of specified taste can be checked.
- A tablet level of flaws such s chip, cracks, contamination from foreign solid substances (hair, drops of oil, dirt), surface texture (smooth vs rough) and appearance (shining vs dull) may have zero defect.

Uniformity Of Thickness:

To determine the uniformity of thickness random selection of tablets has to be done from each and every batch and need to measure its thickness independently. If the thickness of any single tablet varies then the batch containing that batch will not be dispatched. [5]

- Randomly select 30 tablets.
- 10 of these assayed individually.
- The Tablet passes the test if 9 of the 10 tablets must contain not less than 85% and not more than 115% of the labeled drug content and the 10th tablet may not contain less than 75% and more than 125% of the labeled content.
- If these conditions are not met, remaining 20 tablet assayed individually and none may fall out side of the 85 to 115% range.

Hardness:

The ability of a tablet to withstand for mechanical shocks is known as hardness. Pfizer hardness tester is the instrument which is used to determine the hardness of tablet. It is expressed in kg/cm². Take three tablets from each batch and hardness should be determined and the selection of tabled should be done randomly. Then the mean and standard deviation values should be determined.[18]



Figure: 2. A) Monsanto Hardness Tester B) Pfizer Tablet Hardness Tester

Friability:

Roche friabilator is the equipment which is used for the determination of friability. It is expressed in percentage. Note down the initial weight of the tablets individually ($W_{initial}$). Tablets are placed in a plastic chamber which revolves at 25 rpm and they are subjected to fall from a height of 6 inches in the friabilator for about 100 revolutions. Then measure the weight of the tablet (W_{final}) and observe any weight difference before tablet and after the friabilator processing (Figure 2). Limits: loss in weight less than 0.5 to 1% of the initial weight of the tablet should be considered as acceptable limits. Percentage of friability is calculated as:

$$F = \frac{(W_{\text{initial}} - W_{\text{final}})}{W_{\text{initial}}} \times 100.$$



Figure: 3. Friabilator Apparatus

Machine Settings:

- *Rotation Speed:* Set the machine to rotate at 25 rpm.
- *Time Duration:* Set the timer for 4 minutes or 100 rotations.

Process Parameters:

- *Temperature and Humidity:* Conduct tests in a controlled environment to avoid variations in tablet behavior due to external conditions.
- *Cleaning:* Ensure the drum and sample holder are clean before starting the test to prevent contamination or inaccurate results.
- *Calibration:* Regularly calibrate the machine to maintain accuracy and compliance with regulatory standards.
- *Fall Height of Tablets During Friability Test:* Tablets fall from the height of 6 inches or 156 ±2 mm during the Friability test.
- *Angle Of Drum Base:* Adjust drum base at 10° to avoid irregular tumbling.

Drug Content Uniformity:

Initially weigh the tablet and then powder it. Now the powdered tablet is transferred into a 100 ml volumetric flask and adds 0.1 N HCl up to mark. Now filter the solution and discard first few ml of filtrate. Take 10 ml of filtrate should be taken into a 50 ml volumetric flask and add 0.1 N HCl up to the mark and analysed spectrophotometrically at 274 nm and 234.5 nm. The concentration of the content of the drug (µg/ml) was calculated by using the standard calibration curve of the respective drug.

Drug content is calculated by using the below formula

$$\text{Concentration of the drug in } (\mu\text{g/ml}) \times 100 \times 50/10 \times 1000$$

Weight Variation Test:

Random selection of 20 tablets from each batch should be done and note down the weight of the tablet individually and check for any variation in its weight. According to US Pharmacopeias small variations in the weight is negligible and can be accepted. Below is the acceptable limit of percentage deviation in weight variation.[12]

$$\text{Weight Variation} = (I_w - A_w)/A_w \times 100\%$$

Where, I_w = Individual weight of tablet; A_w = Average weight of tablet.

- Take 20 tablets and weighed individually.
- Calculate average weight and compare the individual tablet weight to the average.
- The tablet pass the U.S.P. test if no more that 2 tablets are outside the percentage limit and if no tablet differs by more than 2 times the percentage limit.

Table 2: Average Weight And Weight Variation %:

S. No	Average Weight	Maximum Percentage Difference Allowed
1	130 Or Less	10
2	130-324	7.5
3	More Than 324	5

Wetting Time:

This method was performed to determine the wetting time of a tablet. A piece of tissue paper which is folded twice is kept in a Petri dish containing 6 ml of water and place the tablet on the tissue paper. Observe the time taken for complete wetting of the tablet. Following procedure should follow three times (three trial) for each batch and standard deviation is also calculated from the obtained results.

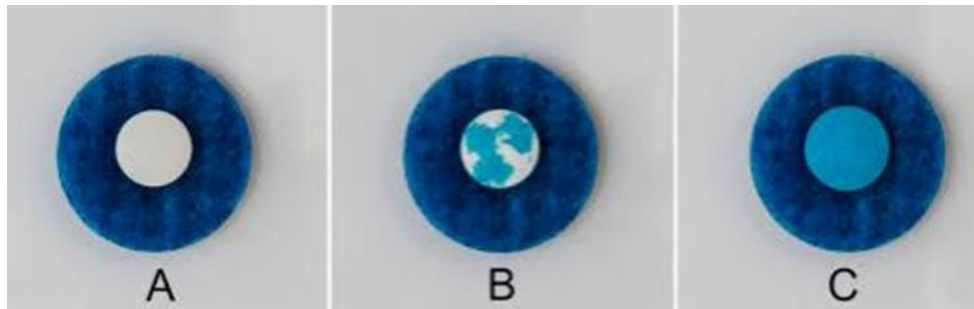


Figure: 4. Wetting Tablet Test By The Tissue Paper

Water Absorption Ratio:

A piece of tissue paper which is folded twice is kept in a Petri dish (i.d.=6.5 cm) containing 6 ml of water and place the tablet on the tissue paper. Observe the time taken for complete wetting of the tablet. Thus wetted tablet was weighed. Now the water absorption ratio R is calculated using the formula

$$R=100 \times \frac{W_a - W_b}{W_b}$$

W_b is the weight of the tablet before absorption, W_a is the weight of the tablet after absorption, Following procedure should follow three times (three trial) for each batch and standard deviation is also calculated from the obtained results.

In Vitro Dispersion Time:

Dispersion time of a tablet is determined by placing a tablet in 6 ml of 6.8 pH phosphate buffer and note down the time taken for complete dispersion of tablet. Following procedure should be done for three tablets from each batch and in vitro dispersion time is calculated. Standard deviation time is also determined from the obtained results. It is expressed in seconds.[9]

Dissolution

In the pharmaceutical industry, dissolution testing is an essential in-vitro method that provides critical data regarding the dissolution profile of solid oral dosage forms. It allows scientists to measure the rate at which a drug is released from its dosage form to surrounding aqueous media in the given apparatus. It is important for developing and manufacturing pharmaceuticals. It ensures consistency of the drug release from formulation into the circulatory system, which guarantees the effectiveness and safety of the oral dosages consumed by patients. User acceptance criteria of these tests are bound by regulations of global pharmacopeial conventions and drug release is assessed under fixed conditions. Dissolution testing is a multi-step process. It includes selection of the right dissolution apparatus, media, and the tablet or capsule itself for the test. Initially, the tablet is placed in a specialized dissolution apparatus filled with a chosen medium. The apparatus is then operated at a set speed and temperature, typically mimicking the conditions of the human digestive system. [Including Review]

Two Set Of Apparatus:

Apparatus-1:

- A single tablet is placed in a small wire mesh basket attached to the bottom of the shaft connected to a variable speed motor.
- The basket is immersed in a dissolution medium (as specified in monograph) contained in a 100 ml flask.
- The flask is cylindrical with a hemispherical bottom.
- The flask is maintained at 37±0.50C by a constant temperature bath.

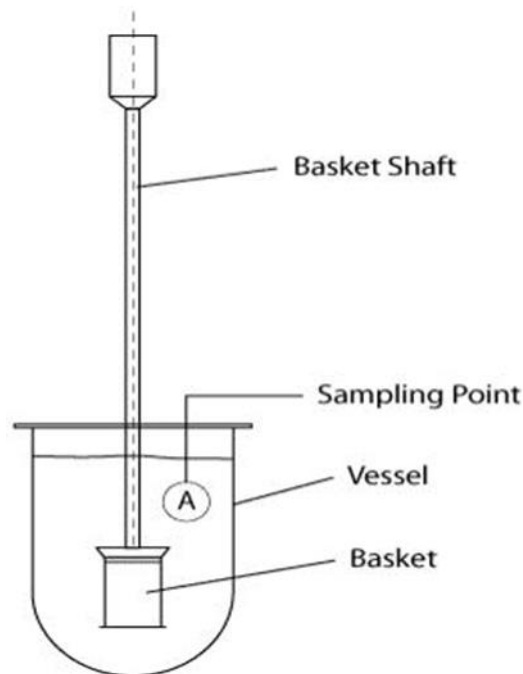


Figure: 5. Basket Dissolution Apparatus -1

The motor is adjusted to turn at the specified speed and sample of the fluid are withdrawn at intervals to determine the amount of drug in solutions.

Apparatus-2:

- It is same as apparatus-1, except the basket is replaced by a paddle.
- The dosage form is allowed to sink to the bottom of the flask before stirring.
- For dissolution test U.S.P. specifies the dissolution test medium and volume, type of apparatus to be used, rpm of the shaft, time limit of the test and assay procedure for.
- The test tolerance is expressed as a % of the labeled amount of drug dissolved in the time limit.
- Dissolution testing and Interpretation can be done in three stages.

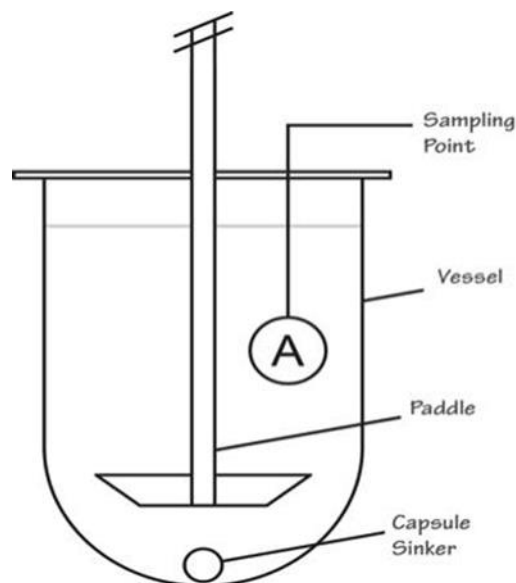


Figure: 6. Paddle Dissolution Apparatus -2

In Vitro Disintegration Test:

Disintegration is defined as the process of breakdown of tablet into small particles. Disintegration time of a tablet is determined by using disintegration test apparatus as per IP specifications. Place each tablet in each

6 tubes of the disintegration apparatus a then add a disc to each tube containing 6.8 pH phosphate buffer. The temperature of the buffer should maintain at $37 \pm 2^\circ\text{C}$ and run the apparatus raised and lowered for 30 cycles per minute. Note down the time taken for the complete disintegration of the tablet without any remittants.[10]

- The U.S.P. device to test disintegration uses 6 glass tubes that are 3” long; open at the top and 10 mesh screen at the bottom end.
- To test for disintegration time, one tablet is placed in each tube and the basket rack is positioned in a 1-L beaker of water, simulated gastric fluid or simulated intestinal fluid at $37 \pm 20^\circ\text{C}$ such that the tablet remain 2.5 cm below the surface of liquid on their upward movement and not closer than 2.5 cm from the bottom of the beaker in their downward movement.
- Move the basket containing the tablets up and down through a distance of 5-6 cm at a frequency of 28 to 32 cycles per minute.
- Floating of the tablets can be prevented by placing perforated plastic discs on each tablet.
- According to the test the tablet must disintegrate and all particles must pass through the 10 mesh screen in the time specified.
- If any residue remains, it must have a soft mass.
- Disintegration time: Uncoated tablet: 5-30 minutes.
- Coated tablet: 1-2 hours.

Market Research:

The India active pharmaceutical ingredients market size was estimated at USD 18.29 billion in 2023 and is expected to grow at a CAGR of 7.7% from 2024 to 2030. The market has experienced substantial growth due to the rising burden of chronic diseases, increasing geriatric population, and the consistent demand for cost-effective medications. Increasing prevalence of infectious diseases and hospital-acquired infections is driving market growth. Furthermore, an increase in the prevalence of chronic diseases, such as cardiovascular diseases and cancer, is anticipated to boost the market over the forecast period. According to a recent research report on noncommunicable diseases in India by Thought Arbitrage Research Institute (TARI) the incidence of chronic diseases in India as of 2021 is 116 per 1000 people out of which two third of individuals affected by chronic disorders are between 26-59 years of age.[Businesses Research]

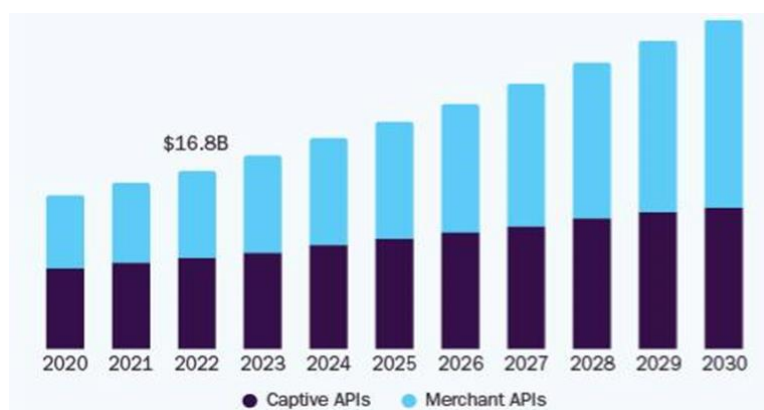


Figure: 7. India Active Pharmaceutical Ingredients Market

Key companies are focusing on expanding their presence across various regions. For instance, in June 2022, Piramal Pharma Solutions invested USD 30 million for expanding its capabilities in Telangana, India. This initiative is expected to increase active pharmaceutical ingredients (API) manufacturing capacity and support drug development. Furthermore, in November 2022, Aurobindo Pharma planned to complete Penicillin G plant approved under the PLI scheme by 2024, with investment of USD 2,000 million to ensure and promote domestic manufacturing of API by increasing the production capacity to 15,000 tons annually.

V. Conclusion:

The formulation of tablets plays a pivotal role in ensuring the safety, efficacy, and stability of pharmaceutical products. It requires a careful balance of active pharmaceutical ingredients (APIs) and excipients to achieve optimal therapeutic outcomes. Tablets, being one of the most widely used oral dosage forms, offer convenience, stability, and cost-effectiveness. Their formulation encompasses several critical considerations, such as drug solubility, stability, bioavailability, and patient compliance. Key steps in tablet formulation include the selection of suitable excipients, such as binders, fillers, disintegrants, and lubricants, which aid in achieving the desired tablet characteristics. The choice of manufacturing method whether direct compression, wet granulation,

or dry granulation is influenced by the physicochemical properties of the API and excipients. Modern techniques like co-processed excipients and nanotechnology are increasingly used to enhance tablet performance, particularly for poorly soluble drugs. Tablet manufacturing and its evaluation has become the backbone of pharmaceutical research. From the various data sources it could be concluded that tablets have got uniqueness and power of adaptability. The tablets have shown vast changes in the last few decades or so both in manufacturing and evaluation. The advances in the evaluation techniques have proven to be both economical and time saving. From the number of manufacturing and evaluation parameters available the scope for the researchers also enhances and makes it possible for tablets to perfectly cement its place in this ever changing drug world.

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