SS INSTITUTE OF PHARMACY

INDUSTRIAL PHARMACY-1

UNIT-2

TABLETS

CONTENTS

- Introduction
- Classification of Tablets
- Excipients used in Formulating Tablets
- Tablet Granulation & Its Importance
- Methods of Granulation
- Tablet Compression Machines
- Equipment tooling
- Compression Processing Problems during Tablet Manufacturing Process

INTRODUCTION

Pharmaceutical Tablets :- are solid dosage forms containing one or more drugs with or without the addition of excipients.

- Addictives or excipients are mainly incorporated to enhance physical appearance, stability, disintegration, or breakup of tablet after administration.
- **According to Indian Pharmacopoeia, pharmaceutical tablets are flat or bi-convex discs manufactured by compressing a drug or a mixture of rugs with or without suitable excipients.**

Ideal Characteristics of Tablets

The objective of the design and manufacture of the compressed tablet is to deliver orally the correct amount of drug in the proper form, at or over the proper time and in the desired location, and to have its chemical integrity protected.

- Should be an elegant product, free from defects.
- Should have strength to withstand the harshness of mechanical shock that can be encountered in its production, packaging, shipping etc.
- Must be able to release the medicinal agent in the body in a predictable and reproducible manner.
- Must be uniform in weight and drug content.
- Size and shape of tablets influence the passing of product through GIT.
- Tablets should be physically and chemically stable so that no alternation of Active ingredient with time.

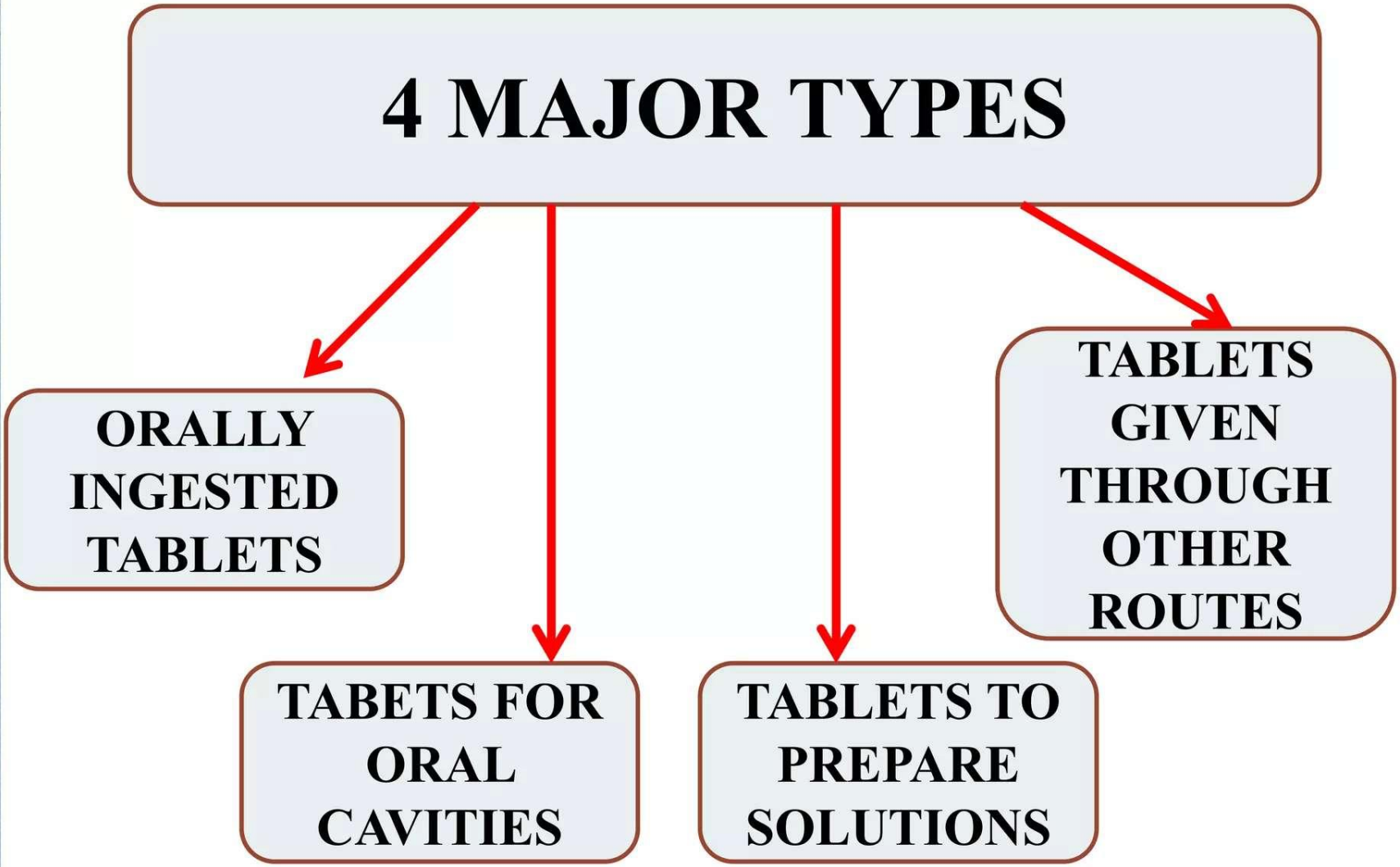
Advantages of Tablets

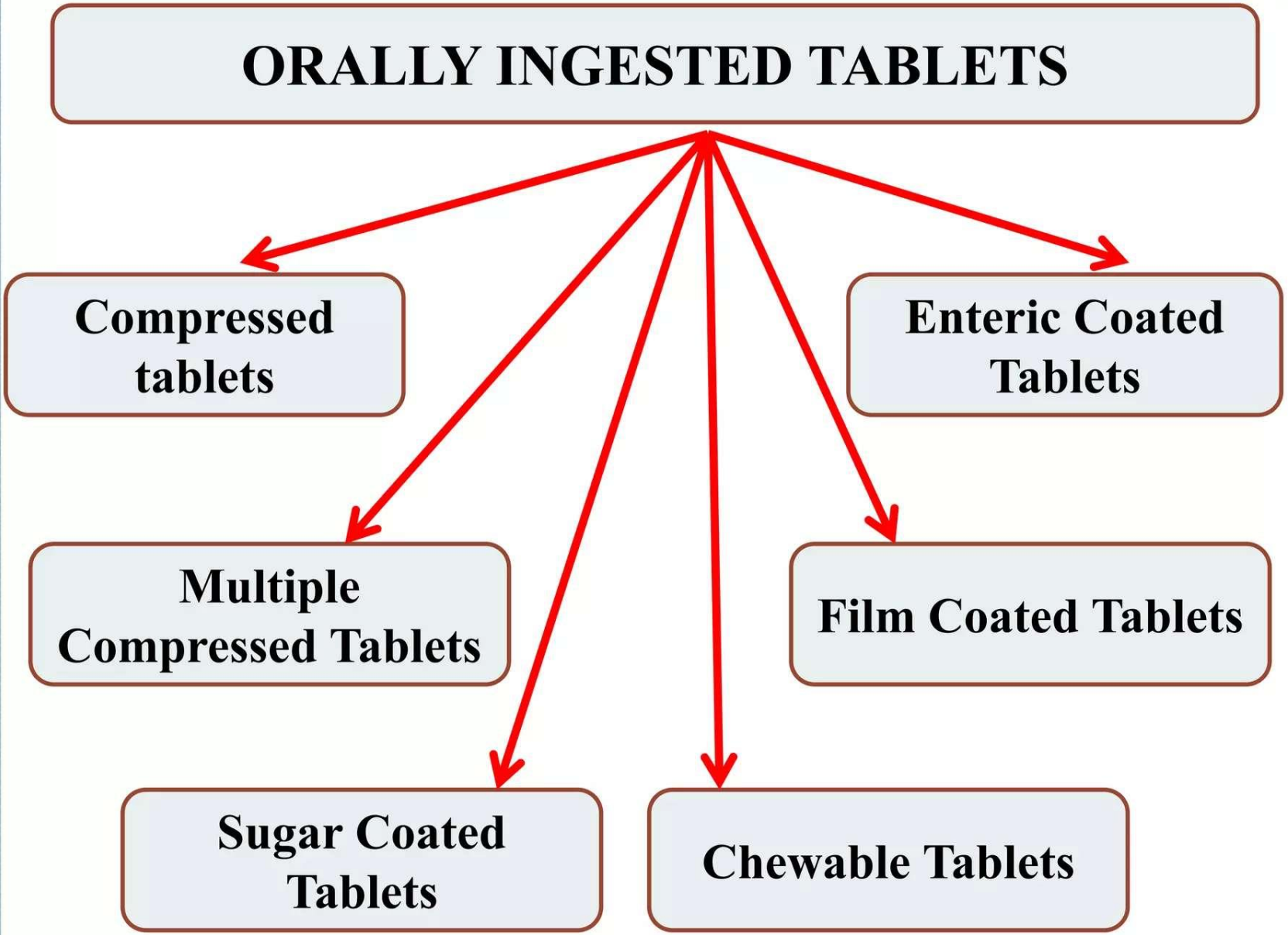
- ✓Cheapest oral dosage form, easy to handle, convenient to administer and offers greatest dose precision.
- ✓Have the best combined properties of chemical, mechanical, and microbiological stability of all the oral forms.
- ✓Greatest ease of swallowing, and less shelf storage space.
- ✓Suitable for large scale production
- ✓Unpleasant and bitter tasting drugs when formulating, the taste can be masked with excipients suitable.
- ✓Provide protection of medicaments from

Disadvantages of Tablets

- ✓Some of drugs, due to their highly amorphous nature and low density, are difficult to compress.
- ✓Chances of loss of ingredients of tablets during manufacturing because of involvement of several unit of operation.
- ✓Drugs with poor wetting properties and slow dissolution rate are difficult to be dispensed in the form of tablets.
- ✓Drugs with objectionable odour and bitter tasting substance need special treatment for compression. This can increase the cost of production.
- ✓Bioavailability problems may arise due to slow disintegration and slow dissolution
- ✓Some drugs can cause irritant effect on the GIT.

CLASSIFICATION OF TABLETS




ORALLY INGESTED TABLETS
Compressed tablets
Enteric Coated Tablets
Multiple Compressed Tablets
Film Coated Tablets
Sugar Coated Tablets
Chewable Tablets

Majority of the tablets are ingested orally. These tablets are swallowed intact along with a sufficient quantity of water.

- **Compressed tablets** – prepared by compression f powdered crystalline or granular materials, by the application of high pressures using punches and die. They do not contain any special coating. Here rapid disintegration occurs which releases the drug rapidly.
- **Multi - compressed tablets** – composed of 2-3 layers. Prepared by introducing the fill material to more than one compression cycle. Multi compression is done in cases where the ingredients are physically or chemically incompatible or when a prolonged action is required. They are further classified into 3 : - compression coated tablets

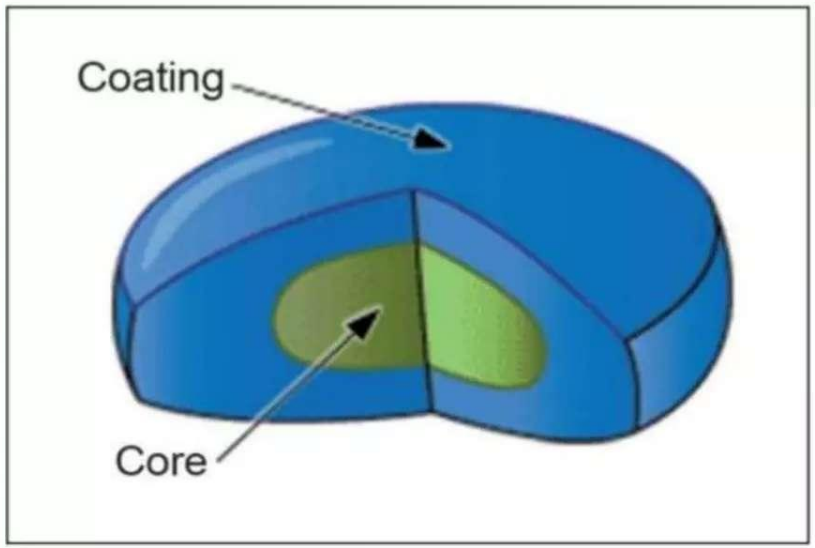
  :- layered tablets

  :- inlay tablets

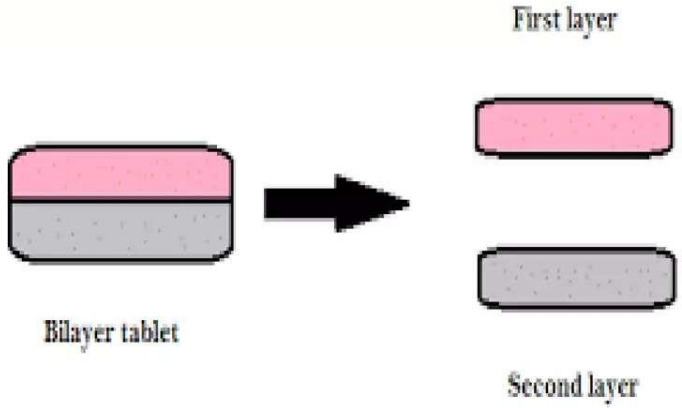
Compression coated tablets – consists of 2 parts – *internal core (the tablet)* and *surrounding coat.* These tablets are prepared by filling coat material to half, core tablet is mechanically transferred, again remaining space is filled with coat material, and finally compression force is applied.

Inlay tablets – tablet core is not completed surrounded by the coating, top surface is completely exposed. Prepared by filling the die with coating material and mechanically placing the core in the die, the compressed. Coat is displaced to form the sides.

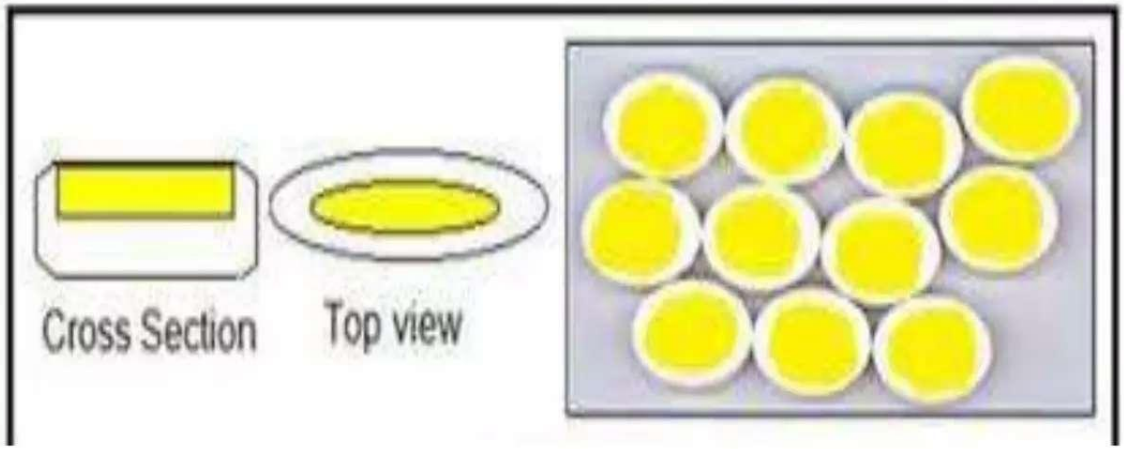
Layered tablets - consists of 2 -3 ingredients in layers. Preferred when 2 or more ingredients have to be administered simultaneously.



Compression coated tablets



Layered tablets

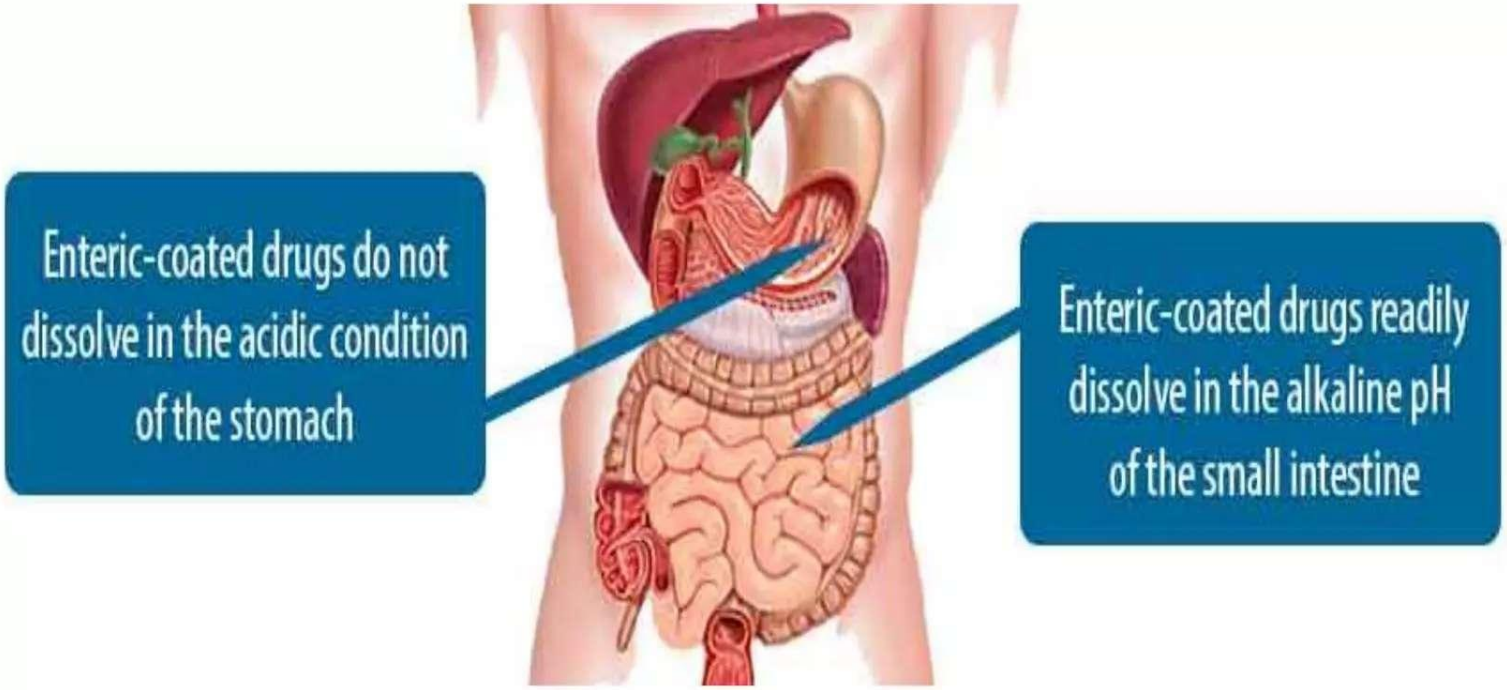


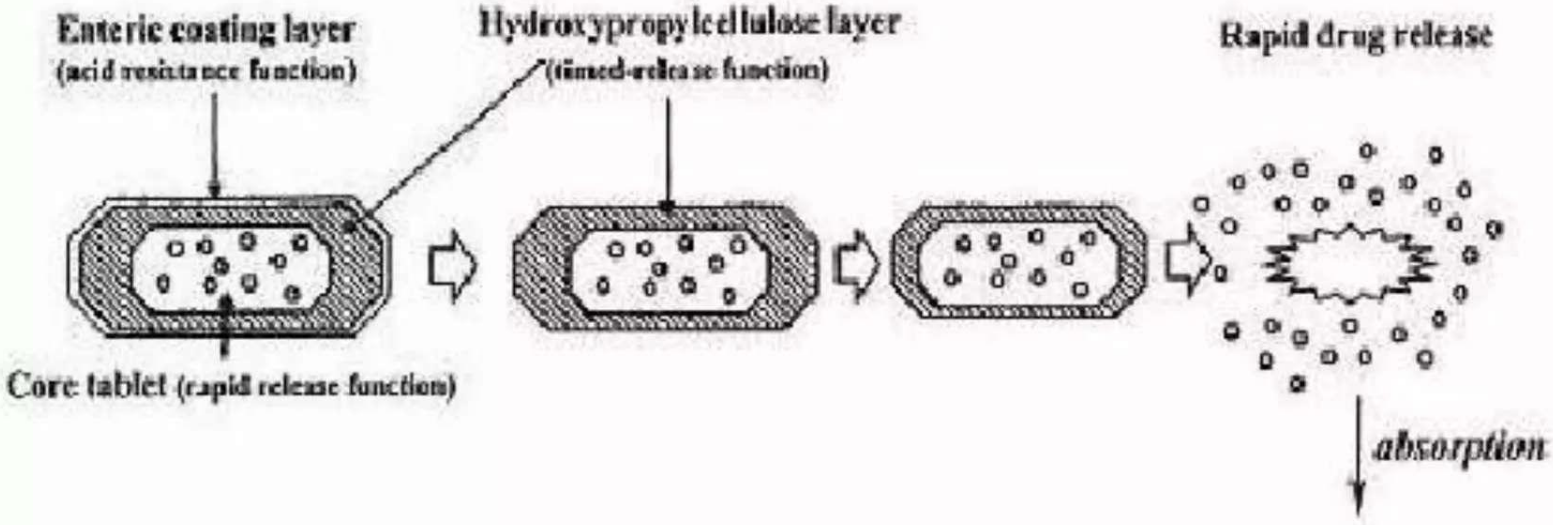
Inlay tablets

- **Enteric tablets** – formulated to prevent drug release in the stomach. Such an enteric coating is preferred when the drug gets inactivated or destroyed by gastric pH, or when drug is irritating to the gastric mucosa. Enteric coat is insoluble in the acidic pH and soluble in the alkaline pH. Such tablets are also meant for delayed release.

Enteric coating materials – polymers like Cellulose acetate phthalate, hydroxypropylmethylcellulose.

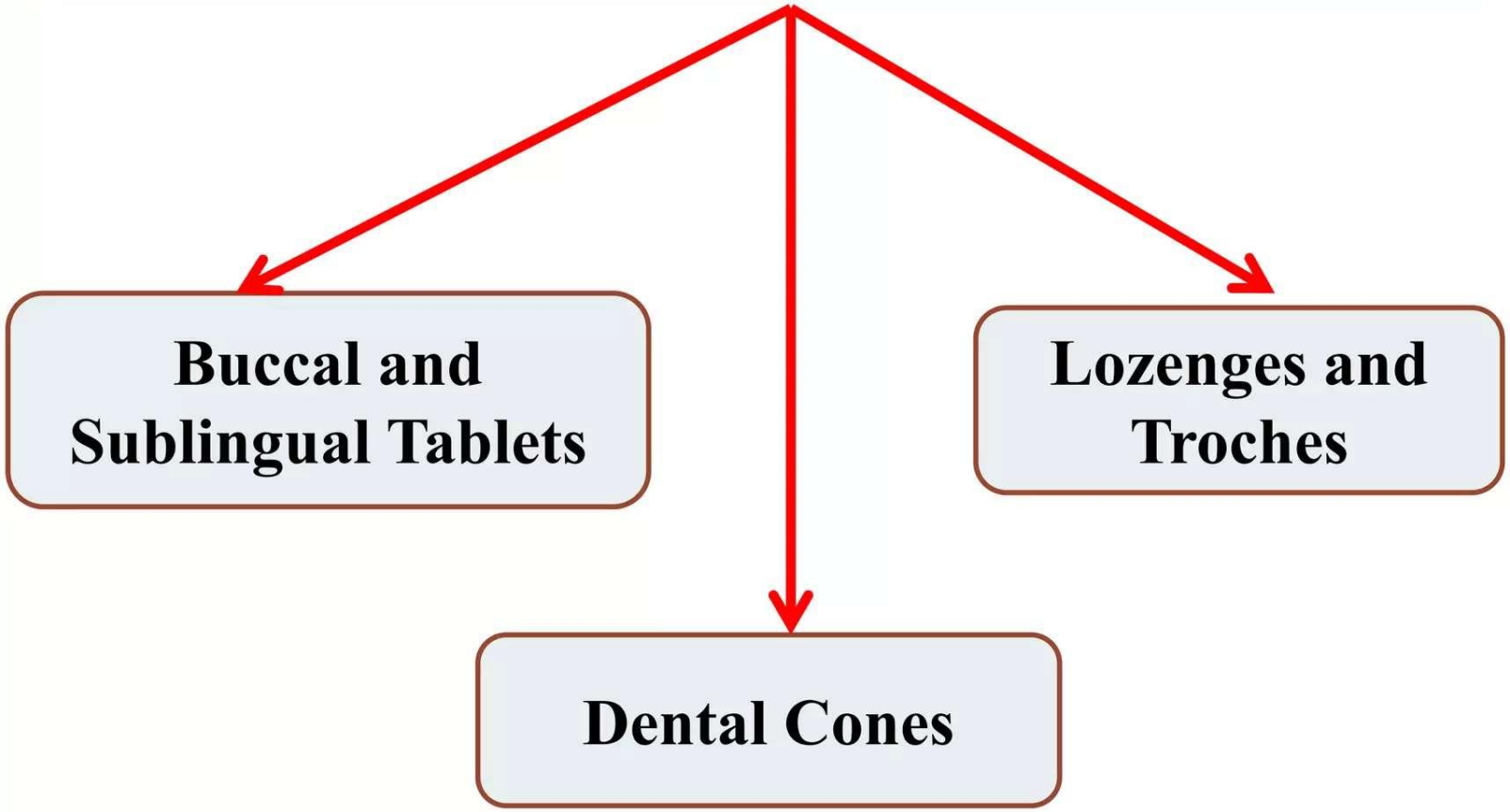
- **Sugar coated tablets** – contain concentrated sugar solution coating. Used to improve patients compliance, increase physical appearance, mask unpleasant taste, increase the stability or modify the release of the drug.


Enteric-coated drugs do not dissolve in the acidic condition of the stomach
Enteric-coated drugs readily dissolve in the alkaline pH of the small intestine

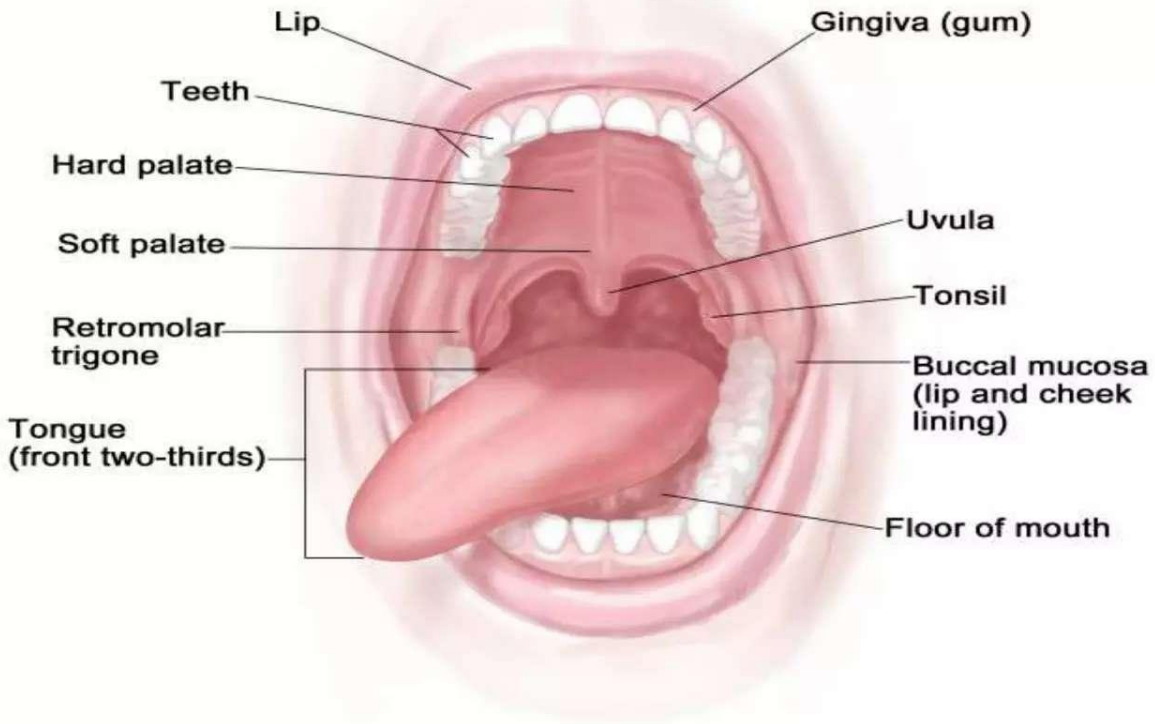

Enteric coating layer
(acid resistance function)
Hydroxypropylcellulose layer
(timed-release function)
Rapid drug release
Core tablet (rapid release function)
absorption

- **Film coated tablets** – are tablets coated with a thin layer of polymer material or a mixture of polymer materials. The coating is designed to break the core tablet at the desired location in the GIT. Film coating also protects the tablet from atmospheric effects.
- **Chewable tablets** – are chewed prior to swallowing, useful for children or adults who have difficulty with swallowing the tablet intact. Substances like mannitol, dextrose are used in the preparation along with the active ingredient. These tablets do not require any disintegrating agents. They should also have an acceptable taste and flavour.

TABLETS FOR ORAL CAVITIES



Oral cavity includes lips, cheeks, teeth, gums, floor of the mouth, bony roof of the mouth, and two thirds of the tongue.

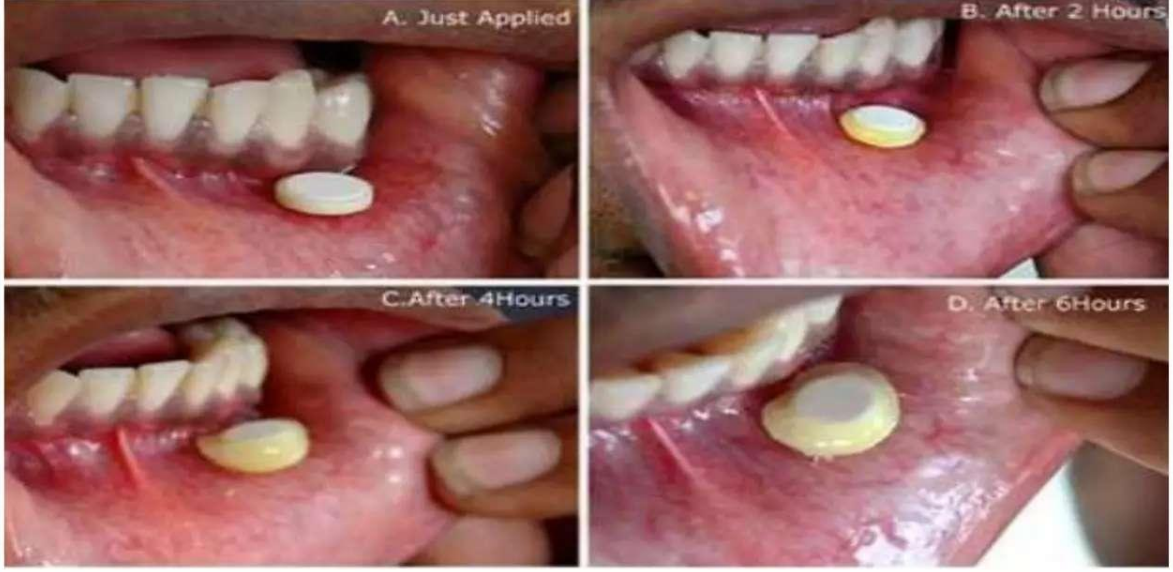


- **Buccal and Sublingual tablets** – small and flat oval tablets.

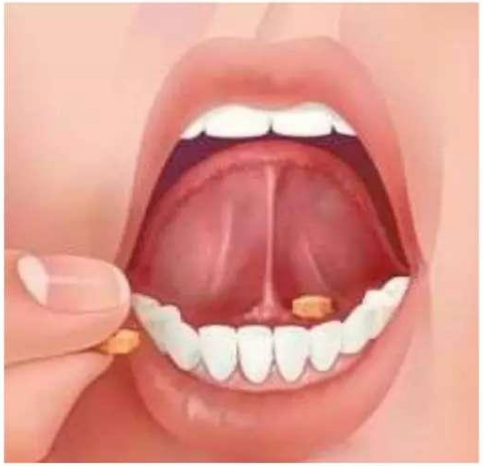
Sublingual administration – placing drug under the tongue to dissolve and absorb into the blood.

Buccal administration – placing a drug between gums and cheek to dissolve and absorb into blood

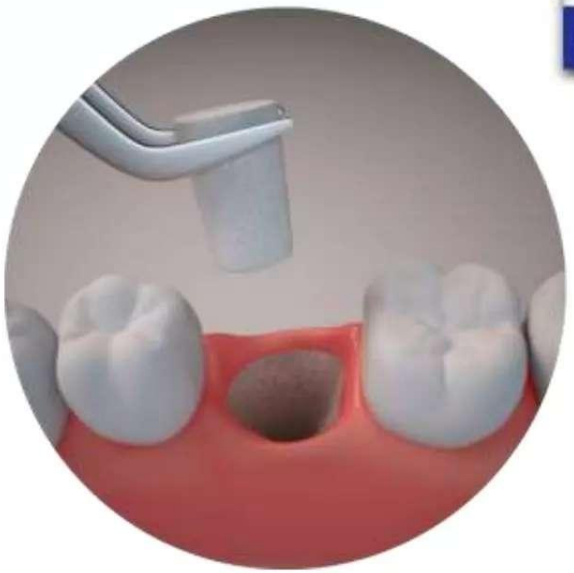
- **Lozenges and troches**– disc shaped with medicinal agents incorporated in flavoured hard candy or sugar base. Intended to be dissolved slowly in the oral cavity
- **Dental cones** - are compressed tablets which are placed in the empty sockets after tooth extraction to prevent attack of bacteria or



Buccal Tablets

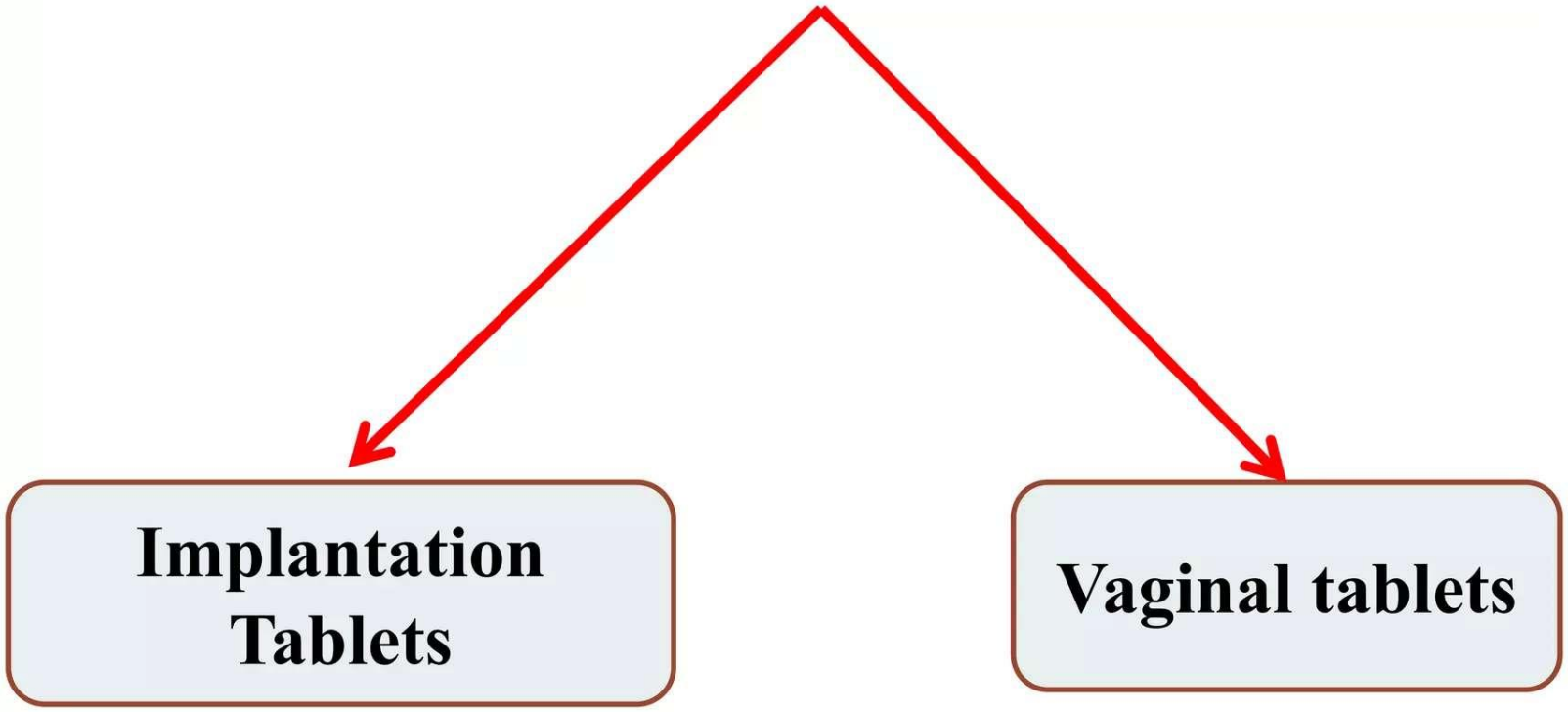


Sublingual Tablets

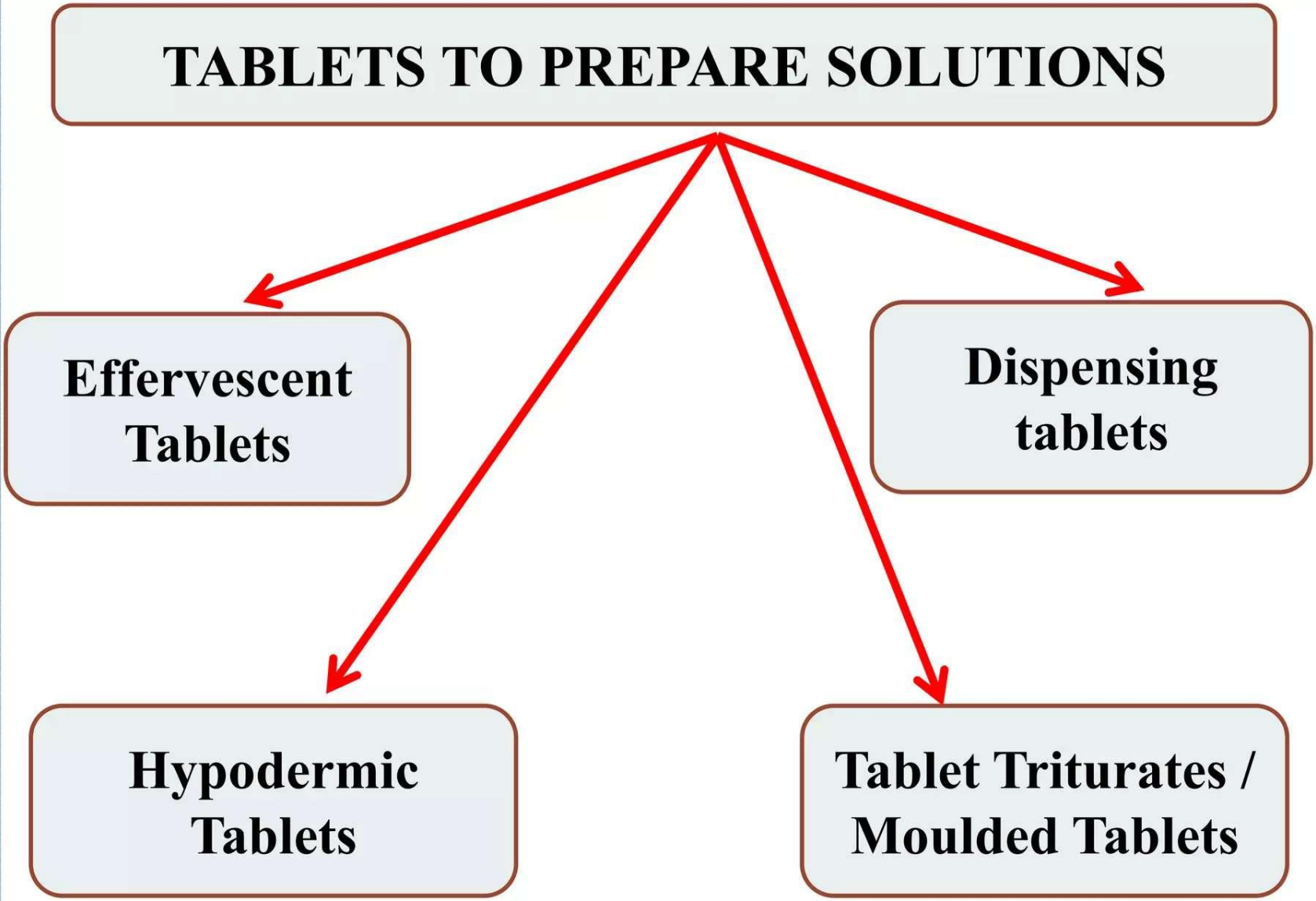


Dental Cones

TABLETS GIVEN BY OTHER ROUTES



- **Implants** – long acting sterile tablets which are designed to provide continuous release of drugs for the months or a year. Placed under the skin or inserted subcutaneously by means of minor surgical operation. Implants must be sterile. Packed individually in sterile conditions. Contains rate controlling excipients. Mainly employed to administer hormones.
- **Vaginal Tablets** – uncoated bullet shaped or ovoid tablets. They are designed to dissolve slowly in the vaginal cavity. Used to release medicaments to provide local pharmacological effect and for systematic absorption.


TABLETS TO PREPARE SOLUTIONS
Effervescent Tablets
Dispensing tablets
Hypodermic Tablets
Tablet Triturates / Moulded Tablets

- **Effervescent tablets** – uncoated tablets that contain the following – active ingredient, organic acids (eg. tartaric acid), and sodium bicarbonate. When dropped into water, tablet reacts with water releasing carbon dioxide, producing effervescence leading to disintegration.
- **Dispensing Tablets** – contain large amount of highly potent active pharmaceutical ingredients. They should be added to given volume of water. Great care should be taken in packaging and labelling. These tablets are readily dispensed into liquids.

- **Hypodermic tablets** – soft readily soluble tablets. Tablets composed with drugs that are water soluble and they are dissolved in sterile water or water for injection, and administered via parenteral routes.
- **Tablet triturates**– small cylindrical molded or compressed tablets. They usually contain a potent drug mixed with excipients like lactose, sucrose or any other suitable diluent. Prepared in special molds

Effervescent Tablets

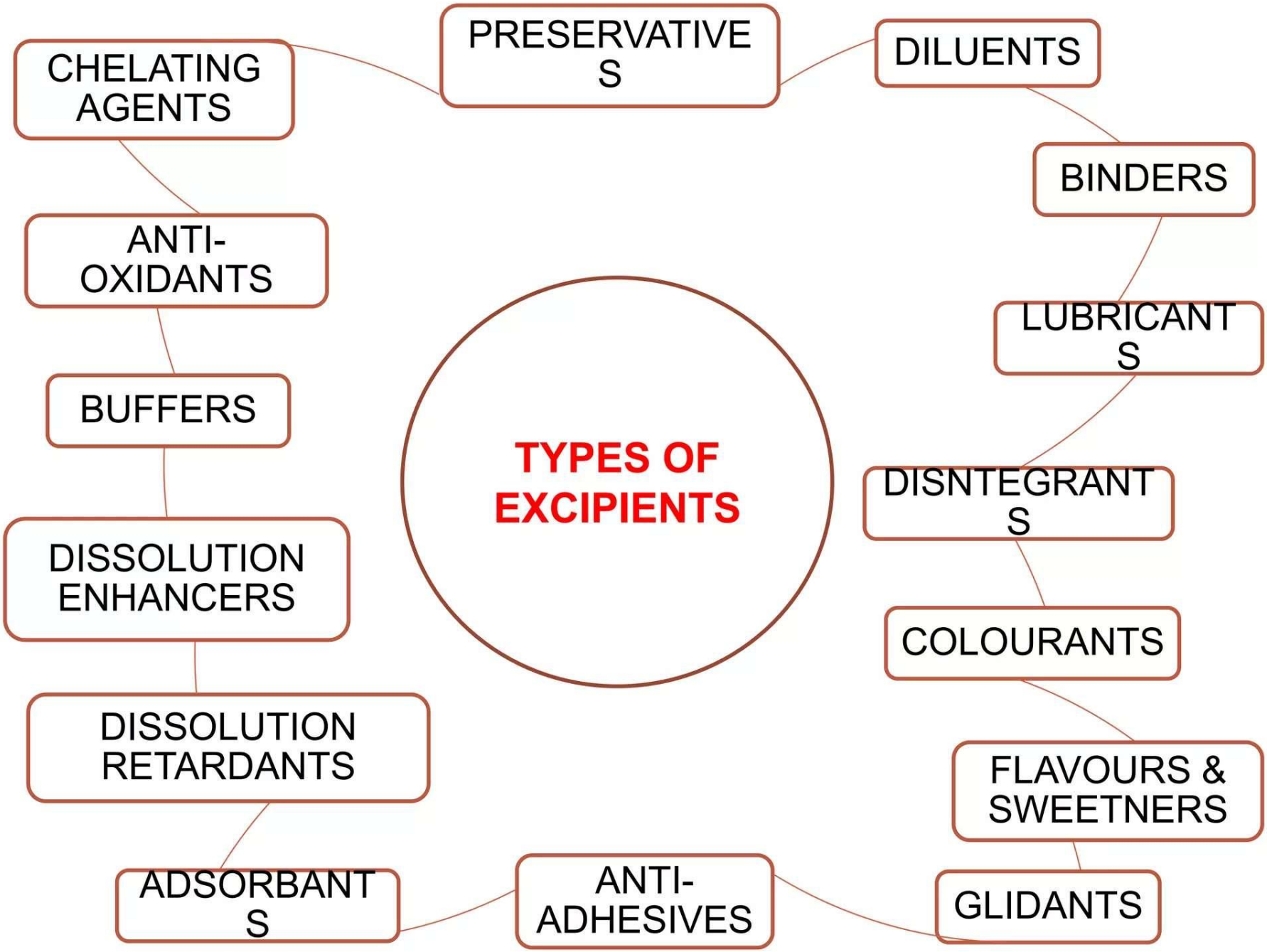
Hypodermic Tablets

Mold for Tablet Triturates

EXCIPIENTS

Pharmaceutical Excipients :- are substances other than the pharmacologically active drug or pro -drug which are included in the manufacturing process or are contained in a finished pharmaceutical dosage form.

- Helps the drug to exert its action at the required location.
- Also it keeps the drug from being released early.
- Some may help in protecting the product stability, taste better, look better, improve patients compliance and also to break into smaller pieces.


TYPES OF EXCIPIENTS
PRESERVATIVES
DILUENTS
BINDERS
LUBRICANTS
DISNTEGRANTS
COLOURANTS
FLAVOURS & SWEETNERS
GLIDANTS
ANTI-ADHESIVES
ADSORBANTS
DISSOLUTION RETARDANTS
DISSOLUTION ENHANCERS
BUFFERS
ANTI-OXIDANTS
CHELATING AGENTS

DILUENTS

- ✓Also known as **fillers or bulking agents.**
- ✓Use for making up of required bulk for a tablet.
- ✓Mostly used when dose of drug is too small to formulate as a tablet. If the dose is high, bulking agents are avoided.
- ✓Properties of an ideal diluent :- physiologically inert, non toxic, physically and chemically stable, easily available, free from microbial contamination, and does not affect the bioavailability of drug.
- ✓**Diluents can be of the following types:- lactose, spray dried lactose, mannitol, dextrose, starch, sorbitol, sucrose and microcrystalline cellulose.**

- **Lactose** – Most widely used Diluent. Available in the hydrous and anydrous form. Preferred because of pleasant taste, readily dissolvable in water, low cost and less disintegration time. One disadvantage is that it undergoes discolouration when in contact with amine drugs
- **Spray dried lactose** – can be used for direct compression due to its cohesive nature and good flow characteristics. In presence of moisture, they may undergo darkening.
- **Mannitol** – widely used as a diluent in chewable tablet. It is non-hygroscopic and non-carcinogenic. But mannitol is expensive.

- **Dextrose** – Available in the hydrous and anhydrous form. When combined in a certain amount with spray dried lactose, darkening of spray dried lactose can be avoided.
- **Starch** – very occasionally used diluent for tablet manufacturing. USP grade of starch can be used due to its free flowing nature and direct compressibility.
- **Sucrose** – suitable for direct compression.
- **Microcrystalline cellulose** – two main grades are available but they are expensive, so used in combination with other diluents.

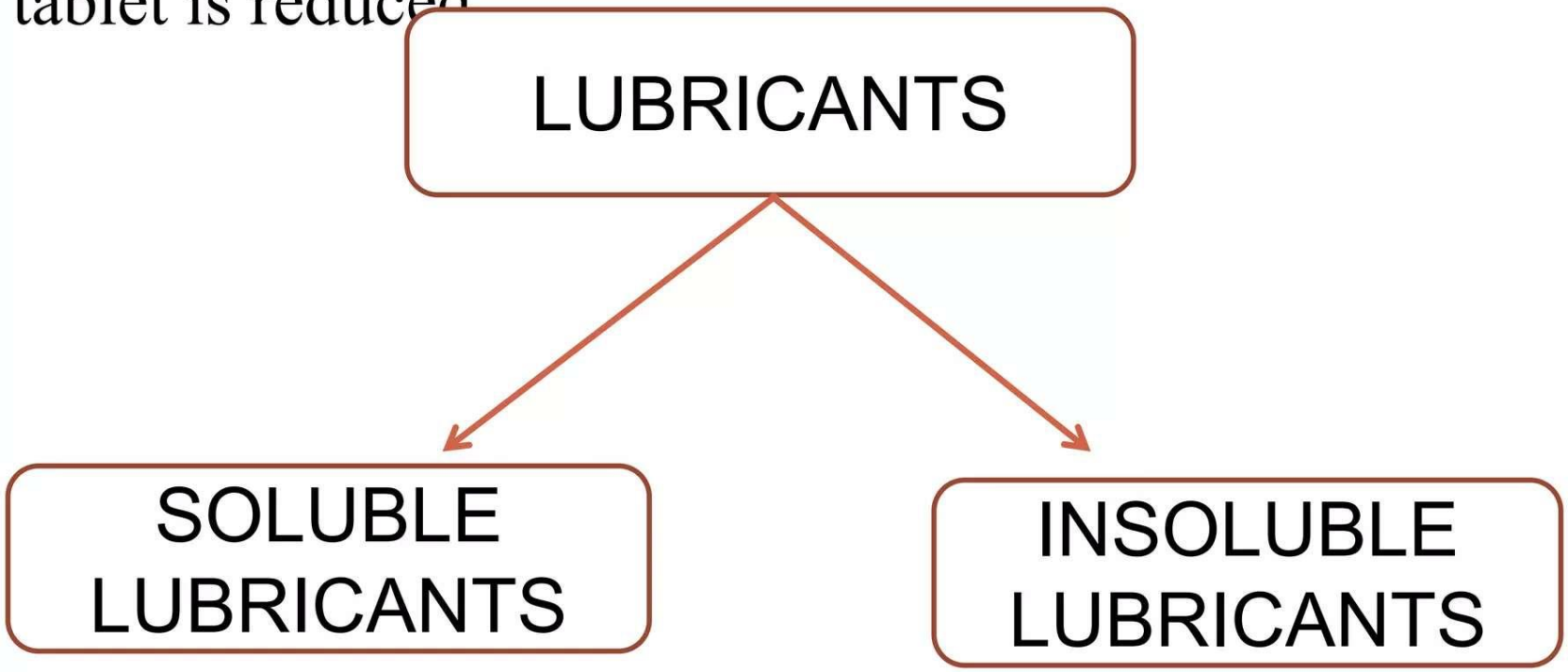
BINDERS

- ✓One of the most important excipient in tablet formulation.
- ✓Also called as Adhesives.
- ✓When mixed with powders, they are used to produce granules.
- ✓Enhance the free flowing capacity of granules of desired sized and hardness.
- ✓Selection of binder depends on the type of tablet.
- ✓For eg. lozenges require more amount of binder whereas tablets require less.
- ✓**Binders can be of the following types:- gum acacia, tragacanth, starch paste, sucrose solution, polyvinylpyrolidine, gelatin, celluose derivatives – HPMC, HEC.**

- **Gum acacia and tragacanth** – used alone in a concentration of 10-25% or in combination.
- **Gelatine** – should be prepared fresh and added in warm condition to avoid solidification.
- **Starch paste** – is prepared by dispensing starch into cold purified water, warming the mixture by continuous stirring until a translucent paste is formed.
- **Sucrose solution** – is used a wet binder which is cheap, produces hard but brittle granules. Major disadvantage is the susceptibility to microbial contamination.
- **PVP** – used in an aqueous or alcoholic solution. Suitable for moisture sensitive drugs.
- **Cellulose derivatives** – natural polymer as binder.

LUBRICANTS

✓Are intended to reduce the friction between the walls of the tablet and walls of the die cavity during the ejection of tablet. Concentration and time of mixing of a lubricant should be optimised. If the concentration is more, mechanical strength of the tablet is reduced.



- **Insoluble Lubricants** – act by inter-crossing the intermediate layer between the tablet material and the die cavity. Such lubricants are intended to act on the tablet surface or on the tablet coating surface, so added in the last stage before compression.
- E.g – Calcium or Magnesium stearate, light mineral oil, paraffins etc.
- Optimum concentration – 1-4%
- **Soluble Lubricants** – not effective as the insoluble lubricant.
- E.g – adipic acid, magnesium lauryl sulphate, sodium lauryl sulphate, polyethylene glycol 4000, 6000, 8000.

DISINTEGRANTS

- ✓**Intended to break up a tablet to smaller pieces upon administration, when it comes in contact with the gastro intestinal tract.**
- ✓Tablet disintegration is important for the further dissolution of the drug and attaining the drug bioavailability.
- ✓**Mainly used disintegrants – starch, cellulose and cellulose derivatives. Starch is mainly used due to its cheaper cost, ease of availability, and compatibility with drugs.**
- ✓Optimum concentration – 5-20%

MECHANISM OF DISINTEGRATION

- Water uptake through pores
- Acts by swelling of disintegrants
- Acts by producing gas
- Enzymatic action

Water uptake through pores

- Water uptake through the pores due to capillary action leads to disintegration.
- Hence, hydrophobicity can be a disadvantage for disintegrants using this mechanism.
- Maintenance of the porous structure of the drug is also an important factor.
- E.g – Starch and Microcrystalline cellulose

Swelling of Disintegrants

- One general problem of such disintegrants is its thickness or forming of a gelatinous mass on contact with water.
- E.g – Acacia and Tragacanth
- Optimised concentration should be used, otherwise it may lead to sticking of the powder.

Disintegrants that work due to the porous structure and by swelling are called **Superdisintegrants**

- E.g – sodium starch glycolate, sodium glycine carbonate, insoluble cationic exchange resins

Acts by producing gas

- Used when extra rapid disintegration is required.
- Main disadvantage is its stability. When in contact with the slight excess of moisture, it can initiate the reaction.
- Stringent control on the environment is required for such type of disintegrants.

Enzymatic action

- Enzymes are included to act in the presence of water.
- E. g – Amylase.

FLAVOURS & SWEETENERS

- ✓Flavours and sweeteners are added in the formulation to mask the unpleasant taste. Added in the concentration – 0.001 – 0.1 %
- ✓Dissolved in organic solvents and then the solution is sprayed on the granules just before the step of compression.
- ✓**Natural sweeteners** :- sugar, mannitol, lactose, sucrose
- ✓**Artificial sweeteners** :- saccharin, cyclamate, aspartame

COLOURANTS

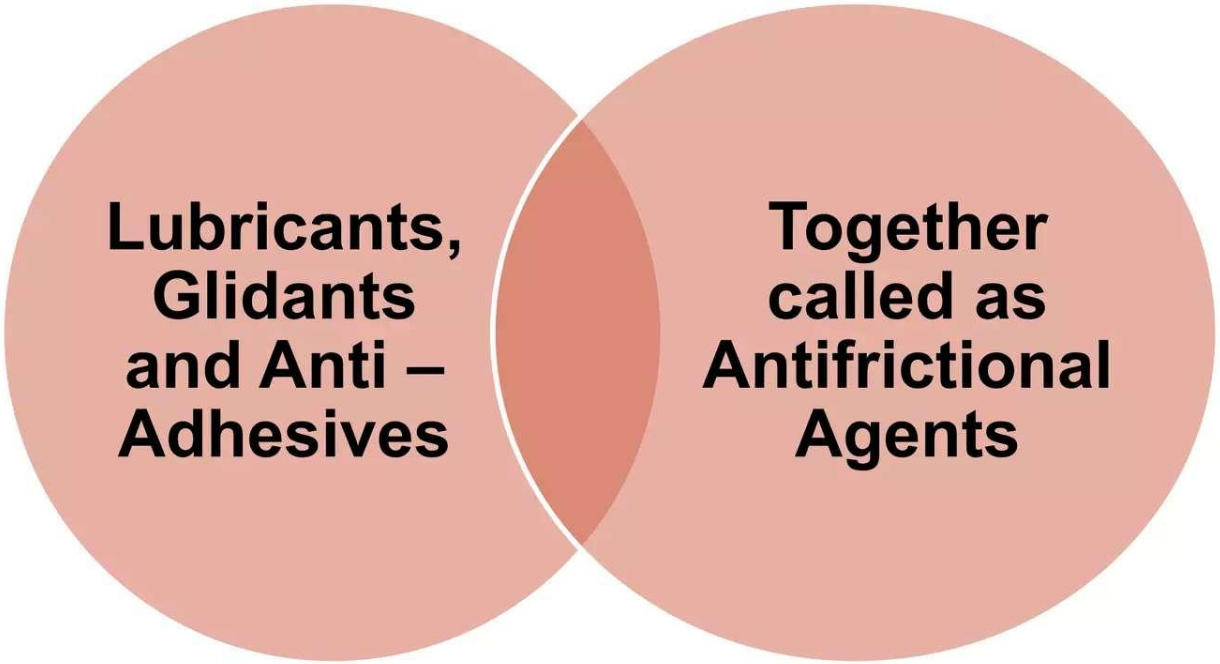
- ✓Added to the preparation to make the tablet more aesthetic.
- ✓Also used to identify the product.
- ✓All colourants used should be approved and certified by the Food and Drug Administration.
- ✓Colours are available in two forms : - lakes and dyes
- ✓E.g – Eosin Y, Sunset yellow FCF, Yellow orange, Blue green, Burnt sugar.

ANTI - ADHESIVES

- ✓Prevents sticking of the tablet material to the face of the punch or on to the die cavity.
- ✓All lubricants can be used as anti-adhesives except for water soluble lubricants.
- ✓E.g – Talc, Magnesium stearate, Colloidal silica

GLIDANTS

- ✓Used to facilitate or promote flow of granules from hopper to die cavity by reducing friction between the particles
- ✓E.g – Talc
- ✓Optimum concentration – 4-5%



ADSORBANTS

- ✓Usually agents that can retain large quantities of liquid
- ✓E.g. – anhydrous calcium phosphate, magnesium carbonate, kaolin

BUFFERS

- ✓Added to maintain a required pH.
- ✓E.g – sodium bicarbonate, sodium citrate

ANTIOXIDANTS

- ✓Added to protect drug from oxidation
- ✓Anti-oxidants undergo oxidation instead of the drug
- ✓E.g – ascorbic acid, sodium bisulphite

CHELATING AGENTS

- ✓Tend to form complexes with trace amount of heavy metal ions that can initiate oxidation by theor catalytic activity
- ✓E.g. – ethylenediamine tetraacetic acid {EDTA}, citric acid

PRESERVATIVES

- ✓Prevents the growth of microorganism that can lead to contamination
- ✓E.g – parabens like methyl paraben, propyl paraben

DISSOLUTION ENHANCERS

- ✓Alter the molecular forces between the ingredients to enhance the dissolution process leading to faster therapeutic action
- ✓E.g. – surfactants

DISSOLUTION RETARDANTS

- ✓Incorporated into tablets that are intended for controlled or delayed release.
- ✓E.g – waxy materials like stearic acid and their esters

TABLETS GRANULATION

Tablet Granulation:- **is the process in which small powder particles adhere together by forming bonds between them, resulting in the formation of large aggregates called granules. The bonds are formed either by compression or by using binding agents.**

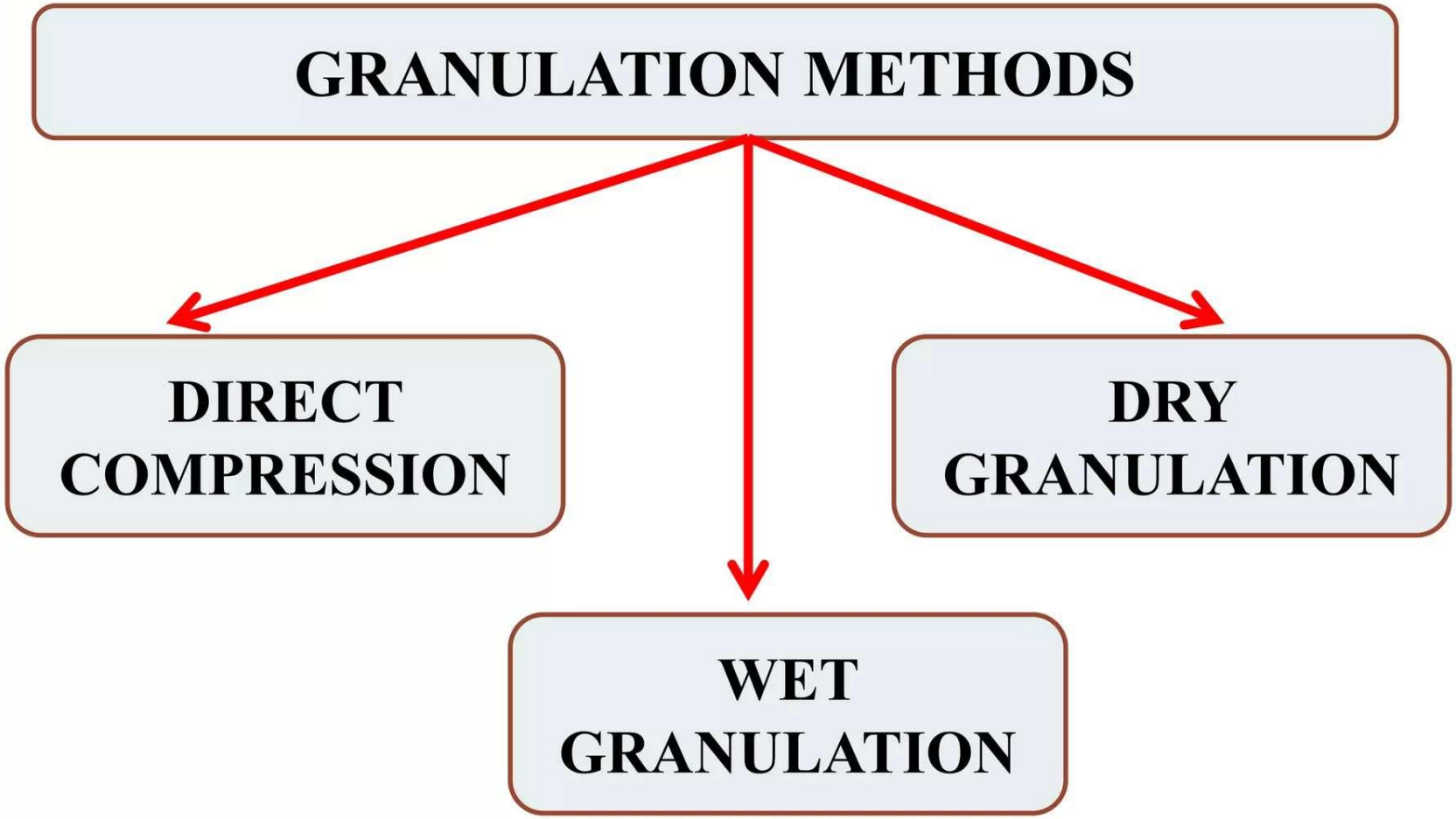
IMPORTANCE OF TABLET GRANULATION

Even though powders are present, granules are prepared due to the following reasons :-

- ✓To avoid particle separation in powders, due to their different size, shape and densities.
- ✓Enhance the flow property. Higher flow ability gives better filling of dies or containers.
- ✓Granules have higher porosity.
- ✓Improves compressibility of powders.
- ✓Materials that are hygroscopic may adhere and form a cake if stored as a powder.
- ✓Granulation of toxic materials will reduce the hazard of generation of toxic dust, which may arise during the handling of powders.

GRANULATION METHODS

Granules are used in the manufacturing of Tablets and Pellets.



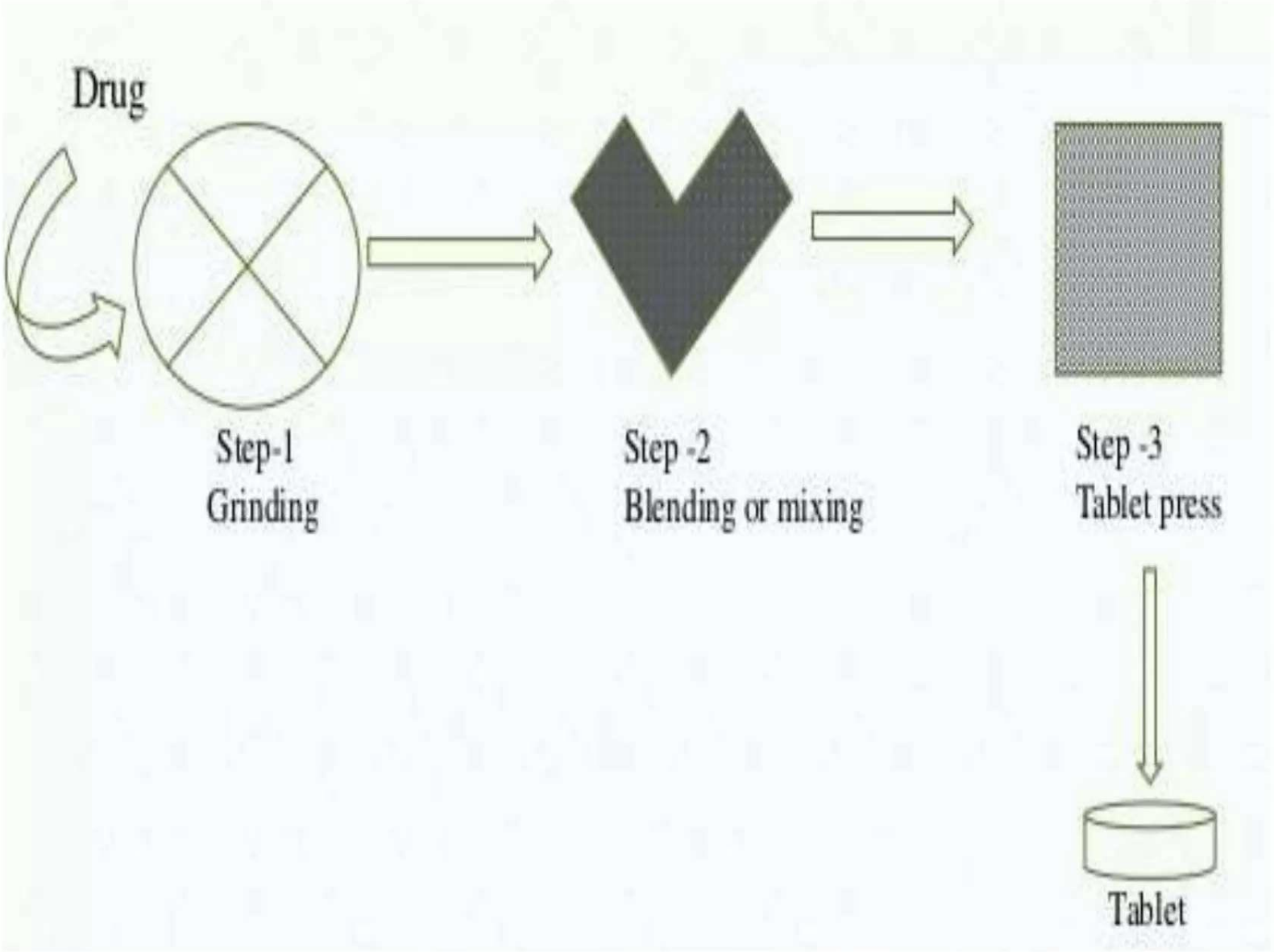
DIRECT COMPRESSION

Direct compression is a dry process where in the powdered material is compressed directly into the tablets without the physical nature of the powder being modified

Direct Compression involves the following steps:-

- ✓Weigh and grind the ingredients (active ingredients and excipients).
- ✓Mixing of active ingredients with powdered excipients including the lubricants and glidants.
- ✓Compression of mixed powders in a tablet press.
- ✓Diluent – spray dried lactose, mannitol
- ✓Disintegrants – talc
- ✓Lubricants – magnesium stearate
- ✓Glidants – talc, colloidal silica

- **Advantages** – fewer processing steps, less equipment, less expensive, no involvement of moisture and heat, faster dissolution rate, chance of transfer losses, and lesser equipment contamination.
- **Disadvantages** – selection of excipients is highly restricted due to less inherent binding property in most of the excipients, low dose of drugs will not be uniformly mixed, excipients for direct compression are expensive and they also have a problem of interaction with drug substances.


Drug
Step-1
Grinding
Step -2
Blending or mixing
Step -3
Tablet press
Tablet

WET GRANULATION

Wet or Moist granulation is the most conventional, versatile, and widely used techniques for the manufacture of compressed tablets.

This technique involves the usage of liquid to form compact masses.

Wet granulation involves the following steps:-

- ✓Weigh, sift and mix of drug substance and excipients excluding lubricants in an appropriate mixer to get uniform powder mix.
- ✓A damp mass is prepared from the powder mix using a binder solution. Insufficient binder causes poor adhesion leading to soft tablets. Excessive binder solution yields hard tablets with slower disintegration rate.

- ✓Wet granules are dried in an hot air oven at 60°C. The drying temperature and drying time are carefully observed.
- ✓Dried granules are passed through Sieve 20 to get uniform size granules.
- ✓Appropriate amount of lubricants is mixed with granules. The remaining amount of disintegrants are also added at this stage.
- ✓Mixed granules are compressed in a single or multi-punch station tablet press fitted with appropriate punches and dies.

- **Advantages** – produce more spherical granules, have better flow property, useful for low compressibility drugs, ensures better content uniformity in case of low dose drugs, improved compressibility, suitable for hydrophilic drugs.
- **Disadvantages** – several steps are involved, time, labour, energy, equipment and space required for the process is more, not suitable for hydrophobic, thermolabile and moisture sensitive materials, water used as solvent can affect the drugs stability causing hydrolysis, drying time is longer, increased length of process

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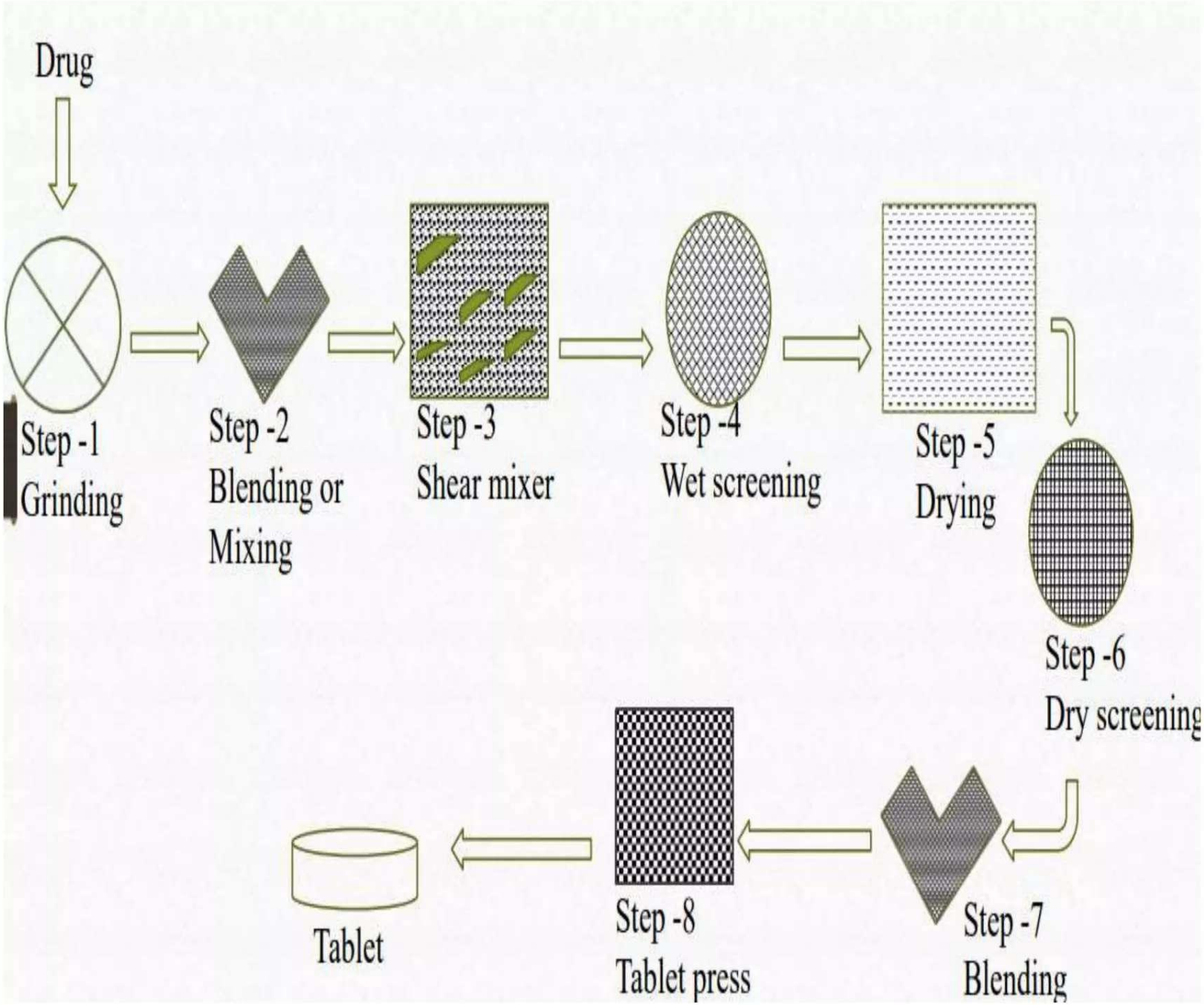

Drug
Step -1
Grinding
Step -2
Blending or
Mixing
Step -3
Shear mixer
Step -4
Wet screening
Step -5
Drying
Step -6
Dry screening
Step -7
Blending
Step -8
Tablet press
Tablet

DRY GRANULATION

Dry or Double compression is used to form granules without using a liquid solution because the product to be granulated may be sensitive to moisture and heat.

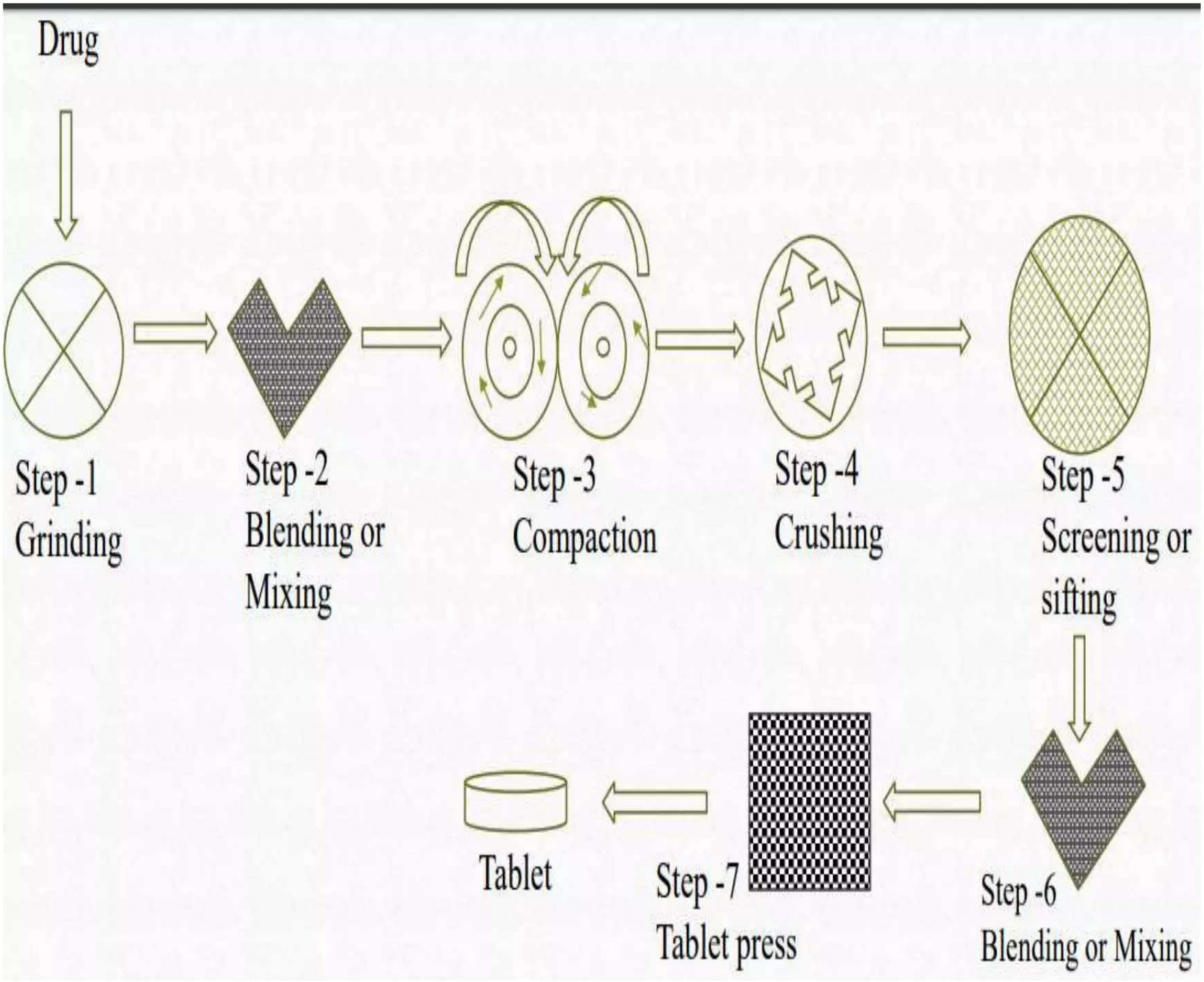
The techniques of dry granulation of powdered material can be accomplished by two methods :-

1. Slugging – formation of extra large tablets first, then broken into granules, which are again recompressed.
2. Roller compaction method – achieved by feeding powder through a set of directly opposed counter rotating rollers.

Dry granulation involves the following steps:-

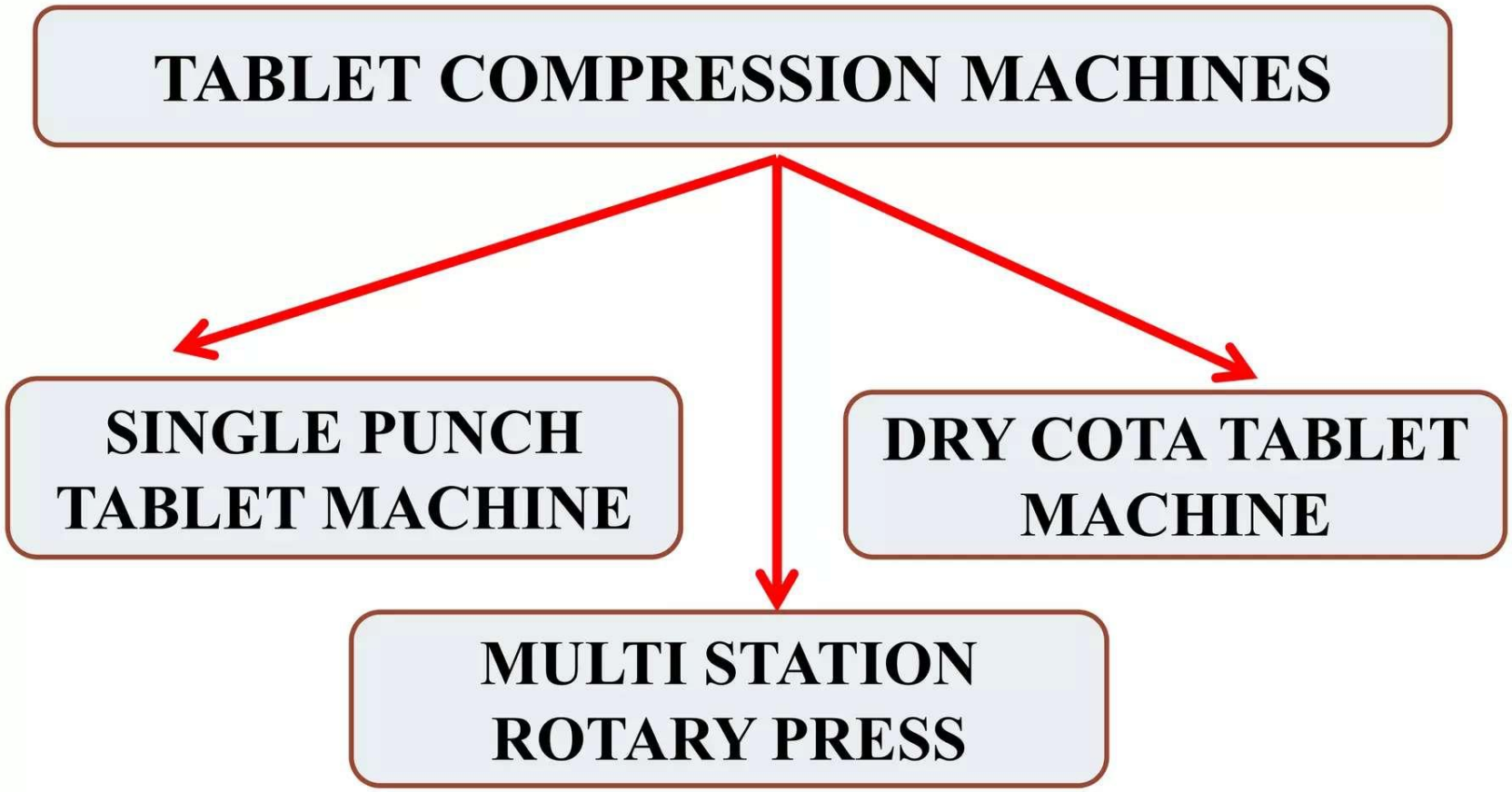
- ✓Appropriate quantities of ingredients and excipients are weighed on an analytical balance.
- ✓Ingredients are mixed in a powder mixer until a uniform powder mix is achieved. The half quantity of lubricant is added at this stage to enhance powder flow and to prevent sticking of powder to die.
- ✓Mixed ingredients are compressed into flat large tablets called slug. This is called **pre-compression or slugging.**
- ✓**Slugs** are broken into smaller pieces using an appropriate miller. Milled slugs are sieved to produce uniform granules.
- ✓After sieving, remaining lubricants and excipients are incorporated into granules and mixed to form a uniform blend.
- ✓Mixed uniform blend of granules are compressed into tablet using the tablet press.

- **Advantages** – requires less equipment and minimum floor space, suitable for moisture and heat sensitive materials, no alteration in drug morphology during formulation, shows better disintegration as dry binder has lesser adhesive effect.
- **Disadvantages** – process generates dust which can cause cross contamination, separation of components may occur after mixing, flowability of powder decreases .


Drug
Step -1
Grinding
Step -2
Blending or
Mixing
Step -3
Compaction
Step -4
Crushing
Step -5
Screening or
sifting
Step -6
Blending or Mixing
Step -7
Tablet press
Tablet

TABLET COMPRESSION MACHINES

Dried granules are compressed into tablet using machines known as Tablet Compression machines or Tablet Press.



✓**Tablet presses are designed with following basic components.**

✓**Hopper** – holds an feed granules to be compressed.

✓**Dies** - define size and shape of tablet

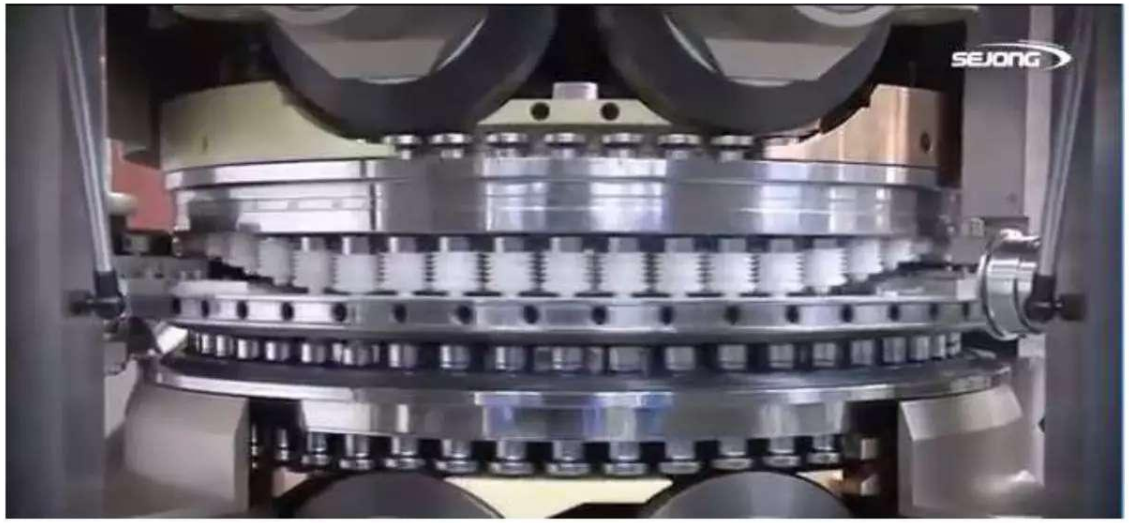
✓**Punches** – compresses granules within the dies.

✓**Cam Tracts** – guides the movement of punches

✓**Feeding Mechanism** – moving mechanism of the granules from the hopper to the dies.

HOPPER

PUNCHES & DIES

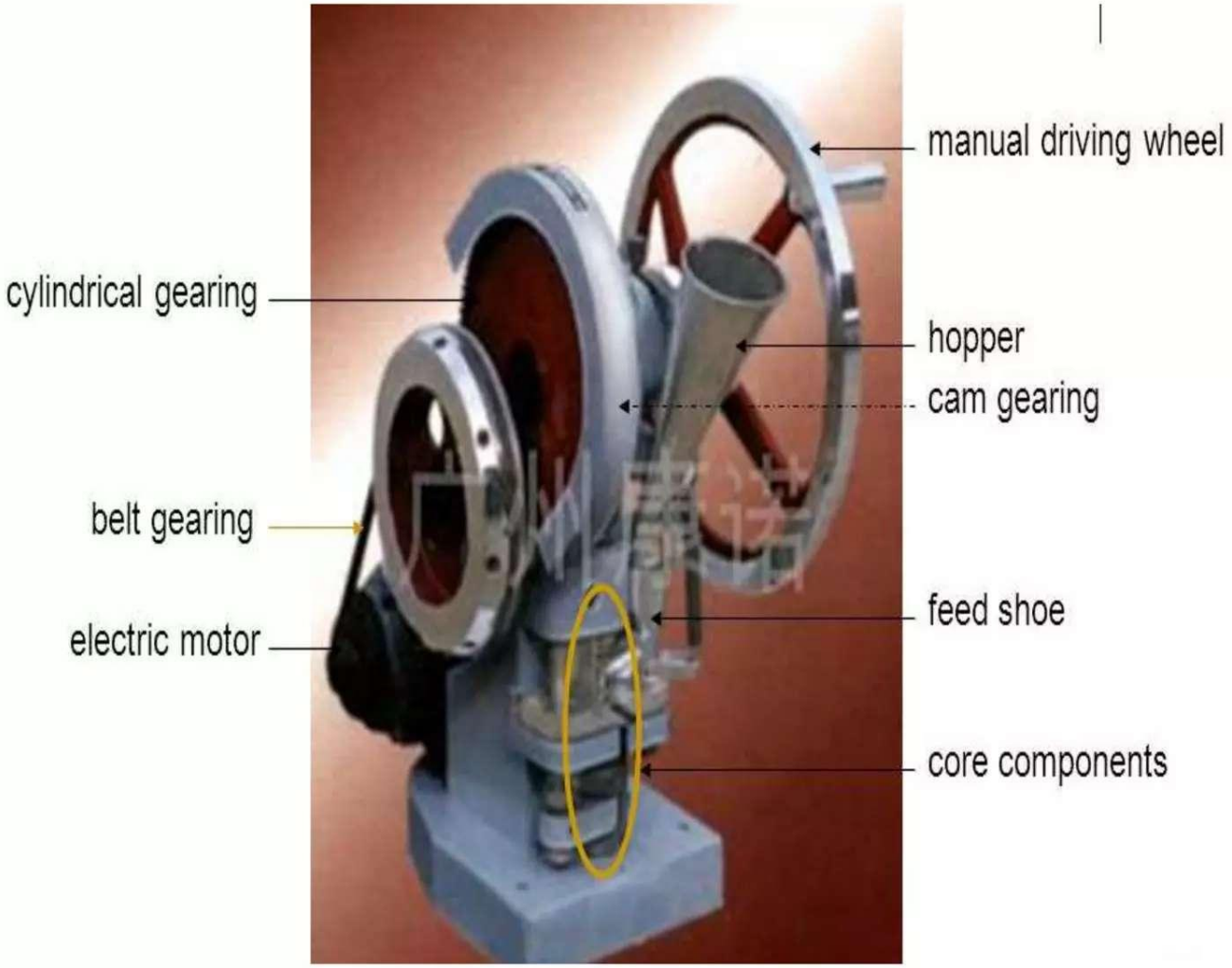


CAM TRACT

SINGLE PUNCH TABLET MACHINE

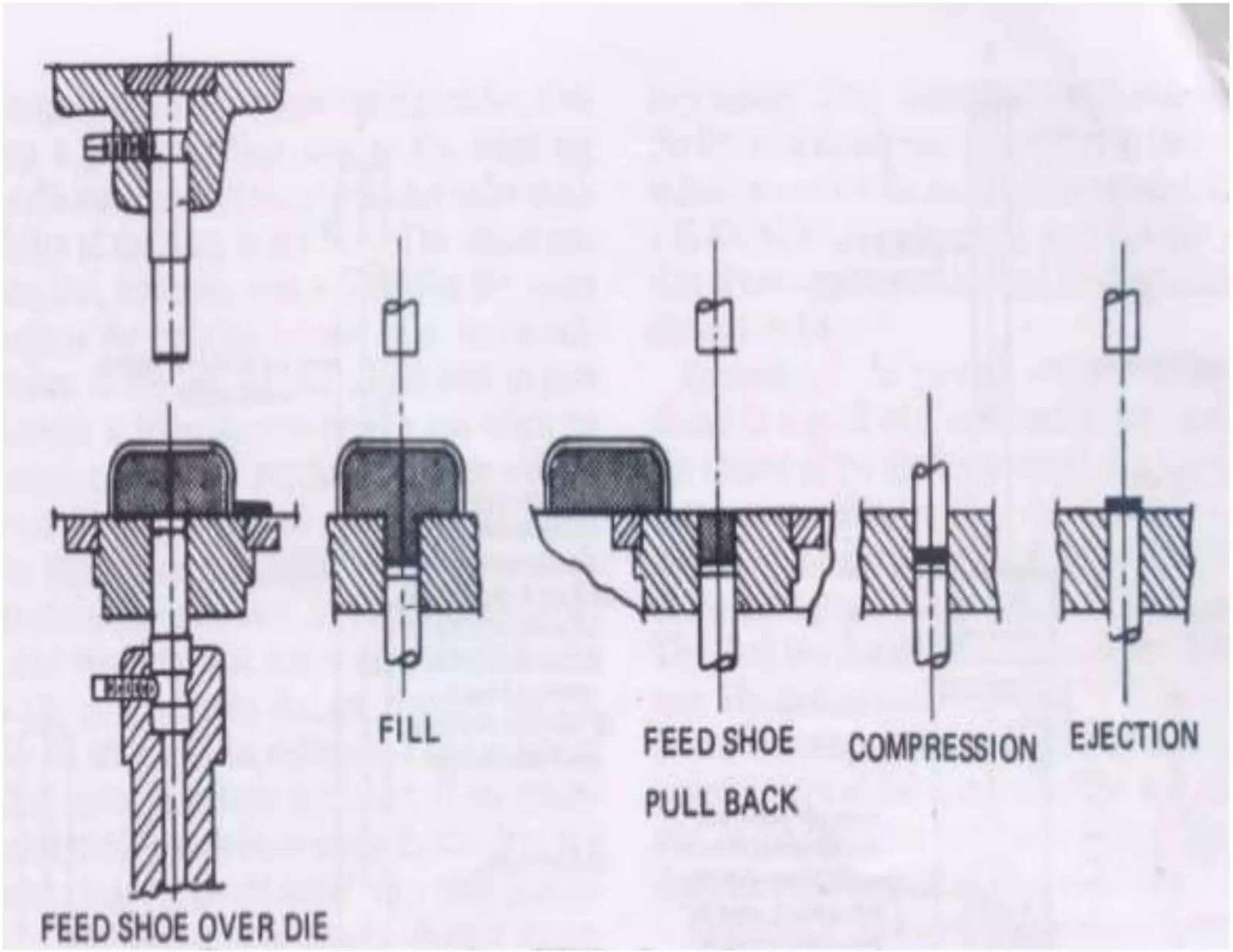
Also called as **ECCENTRIC PRESS**. **Ideal for Small Scale Productions.** This tablet press includes a Die and a pair of Upper and Lower Punch, along with the basic components. Also the machine has two more components :-

- ✓Capacity Regulator – adjusts lower punch to allow the required quantity of granules by the die.
- ✓Ejection Regulator – facilitates ejection of tablet from die cavity after compression.


manual driving wheel
cylindrical gearing
hopper
cam gearing
belt gearing
feed shoe
electric motor
core components

WORKING OF SINGLE PUNCH STATION

- ✓The upper punch moves up and lower punch moves down to create a cavity in the die.
- ✓Feed or granules from the hopper fall into the dies.
- ✓Upper punch moves down - compresses the granules into tablets
- ✓Upper punch moves up, lower punch also moves up – eject the compressed tablet.
- ✓Whole process repeats again and again, until granules finishes.
- ✓Output – 200 tablets per minute
- ✓Uses high pressure to compress tablet to reduce weight variation between tablets.


FEED SHOE OVER DIE
FILL
FEED SHOE
PULL BACK
COMPRESSION
EJECTION

MULTI STATION ROTARY PRESS

Multistation rotary presses are termed as "rotary" because the head that holds the die, upper and lower punches in place – Rotates.

As the head rotates, the punches are guided up and down by fixed cam tracts.

The portion of the head that hold the upper punches are called **upper turrets**, and the portion that hold the lower punches are called **lower turrets**. The portion holding the dies are called **die table**.

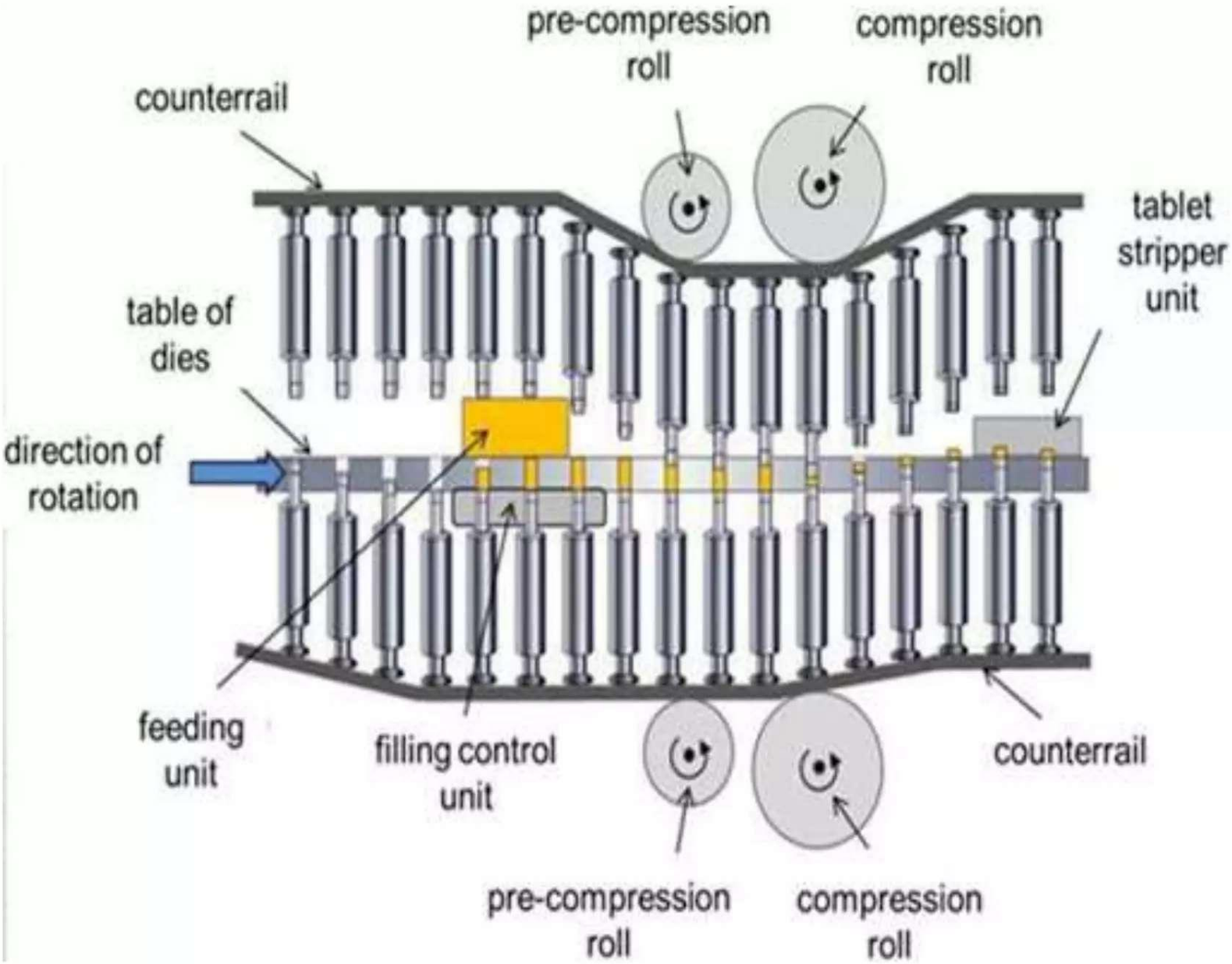
Along with the basic components, additional components are,

- **Ejection cam** – facilitates ejection of tablet from die
- **Take off blades** – helps to push tablet to a discharge chute, which is collected in a container.

WORKING OF MULTISTATION ROTARY PRESS

- ✓The powder or granules are placed in the hopper.
- ✓Material is fed into several dies simultaneously.
- ✓Machine removes excess of powder to avoid any form of inconsistencies.
- ✓Desired volume and weight of powder is compressed to tablets.
- ✓Upper and lower punch exert a predetermined amount of pressure that compresses the tablet.
- ✓As the head revolves, dies get filled with granules flowing from the hopper.
- ✓Granules are compressed when the upper and lower punch comes close together.

- ✓The upper cam pull the upper punches back to the initial position and the lower punches are lifted up to eject processed tablets out of the die cavity.
- ✓Scraper will remove the tablet from compression machine.
- ✓This is then considered, as the end of one compression cycle of the tablet compression machine
- ✓**Output – 1200 tablets / minute.**
- ✓**Used for large scale production.**


pre-compression roll
compression roll
counterrail
tablet stripper unit
table of dies
direction of rotation
feeding unit
filling control unit
counterrail
pre-compression roll
compression roll

DRY COTA TABLET MACHINE

Here, two rotary machines work simultaneously, therefore, core tablet is prepared in one machine, and then transferred to the another machine for compress coating.

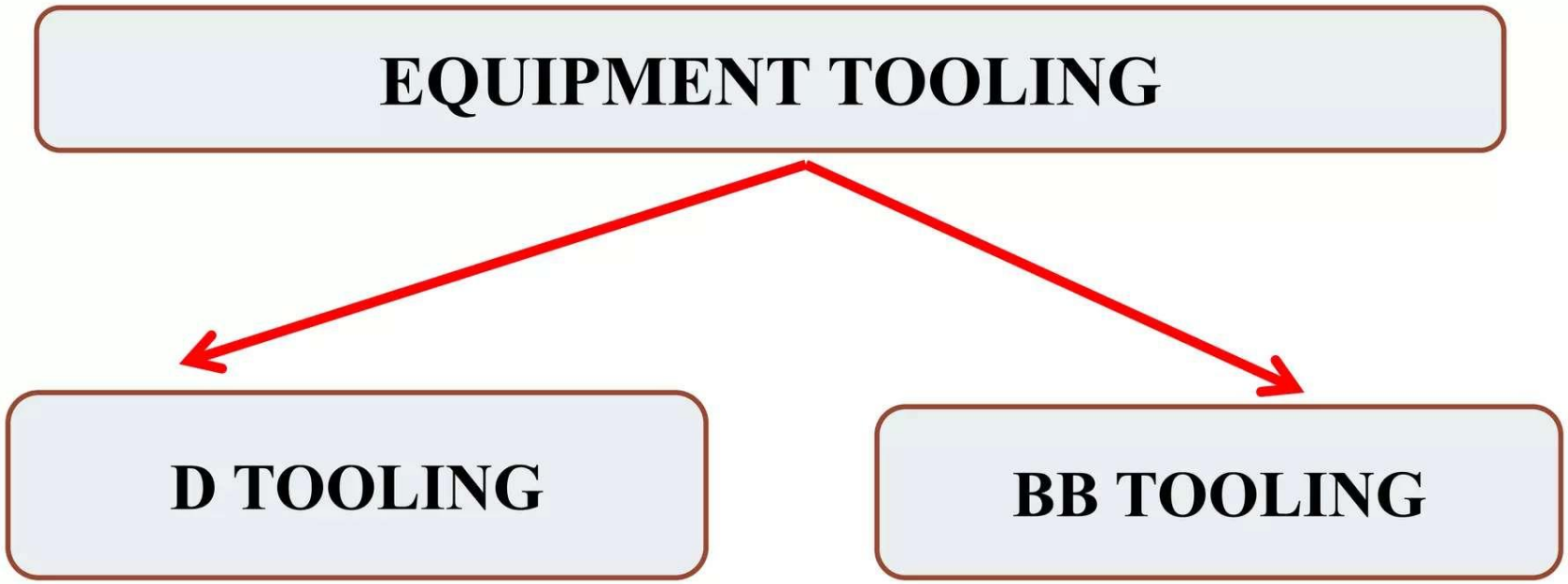
- Preferred for multicompressed, multicoloured and press coated tablets
- Allow manufacture to manufacture a wide variety of tablet shapes.

EQUIPMENT TOOLING

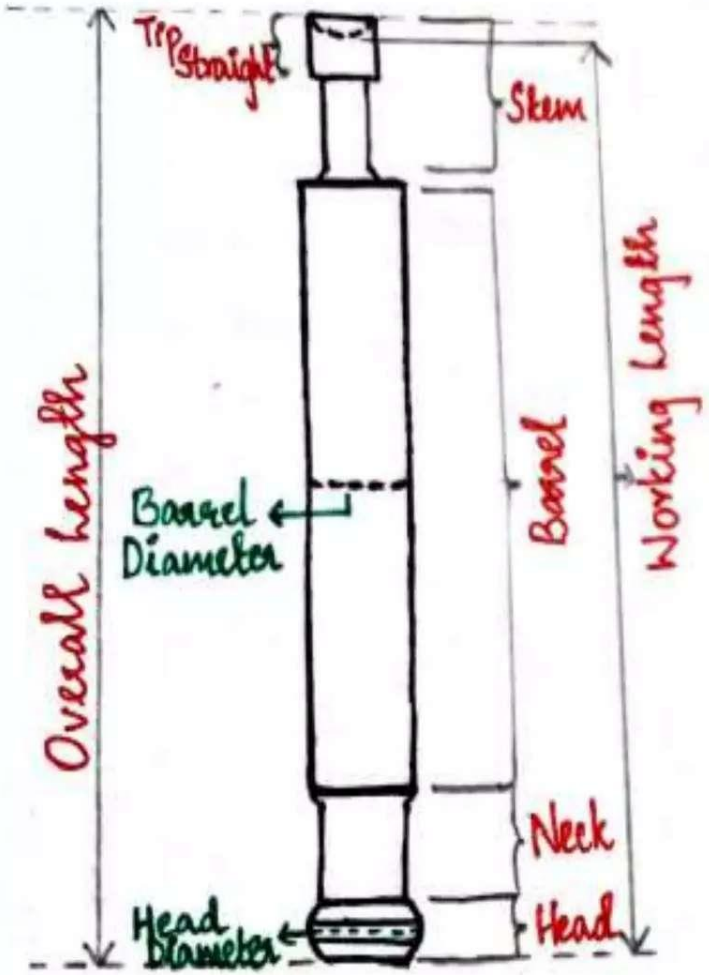
Equipment tooling:- **The size and the shape of a tablet, and certain identification markings are determined by the equipment tooling or compression machine tooling.**

- **Each tooling set consists of die and upper and lower punches.**
- **Tooling must meet the requirements to satisfy the needs of dosage uniformity, product efficiency and aesthetic appearance.**

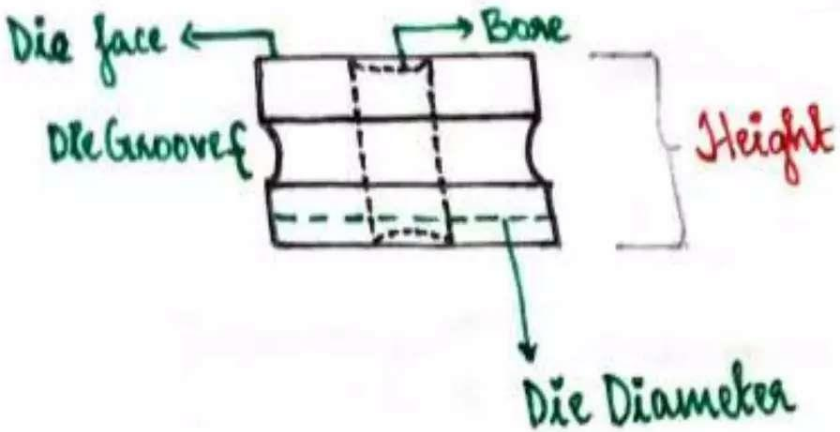
Basically, there are two types of equipment tooling or compression machine tooling.



EQUIPMENT TOOLING



PUNCH BODY



DIE

PARAMETERS	D TOOLING	BB TOOLING
Compression force exerted by the machine on the tools	10 tonnes	6.5 tonnes
Barrel diameter of the Punch	1 inch	0.75 inch
Head diameter of the Punch	1.25 inch	1 inch
Length of the Punch	5.25 inch	5.25 inch
Die Diameter	0.945 inch	1.18 inch

Several types of steel are normally used for the manufacture of compression machine tools. Steel differs in toughness to withstand the compressing forces and wear resistance. Therefore, selection of the steel must be based on experience and accumulated history of the product to be manufactured.

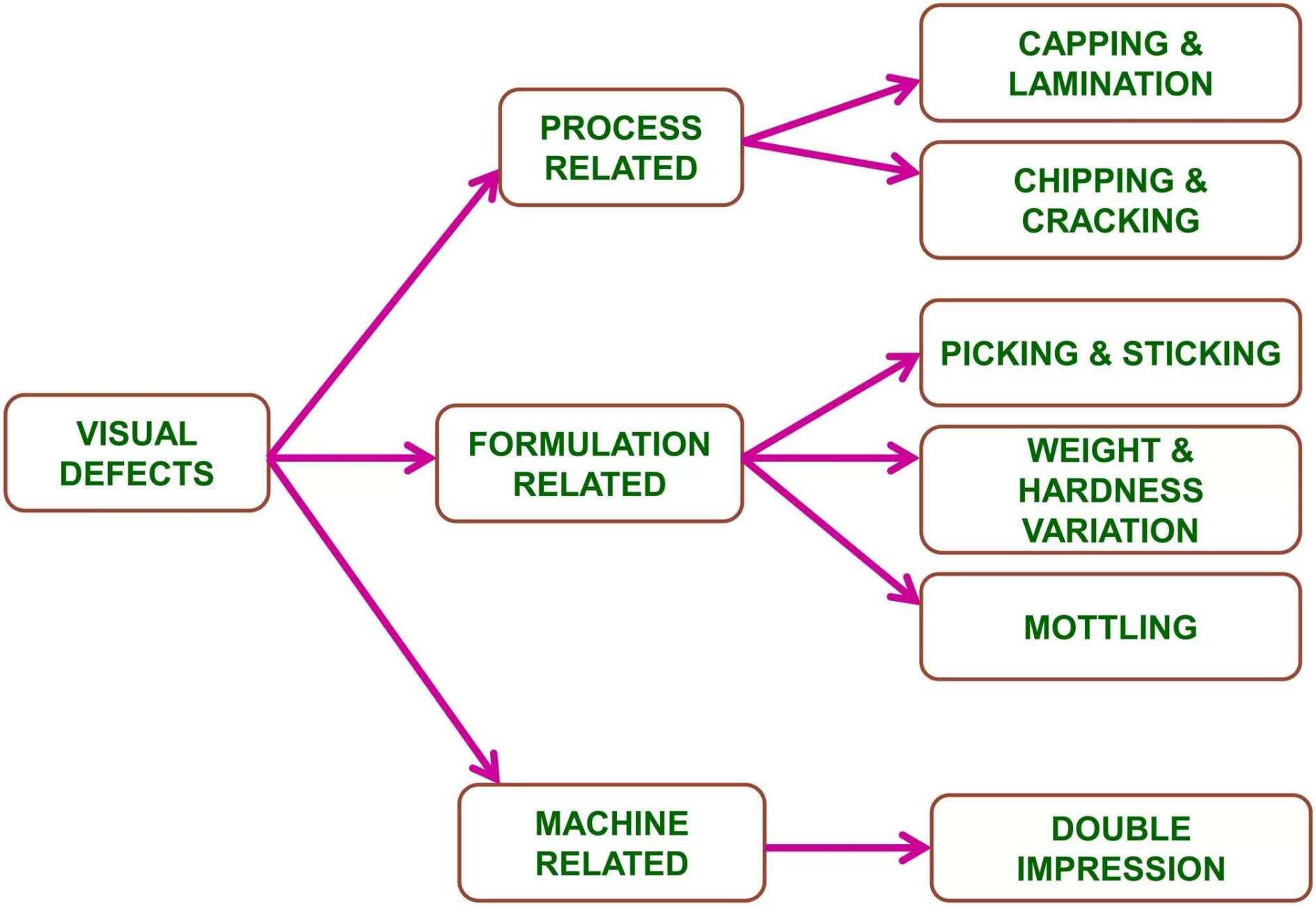
- ✓**Improper storage and handling can readily result in damage and lead to the complete replacement of the whole set of punches and dies.**
- ✓**Punch tips are delicate and susceptible to damage, if they come in contact with each other or with the dies, or due to improper handling while insertion and removal of the punches and dies.**
- ✓**To avoid tooling damage, calculate the load or pressure to be applied before the production starts.**

COMPRESSION & PROCESSING PROBLEMS

An ideal tablet should be free from any visual or functional defect. Number of problems can be encountered during the tablet manufacture process.

✓**Visual defects :-** due to inadequate fines or moisture in granules or faulty machine settings. They can be further due to the following factors :- formulation design, tabletting process, machine related, or others.

✓**Functional defects :-** due to a faulty formulation calculation.


VISUAL DEFECTS
PROCESS RELATED
CAPPING & LAMINATION
CHIPPING & CRACKING
FORMULATION RELATED
PICKING & STICKING
WEIGHT & HARDNESS VARIATION
MOTTLING
MACHINE RELATED
DOUBLE IMPRESSION

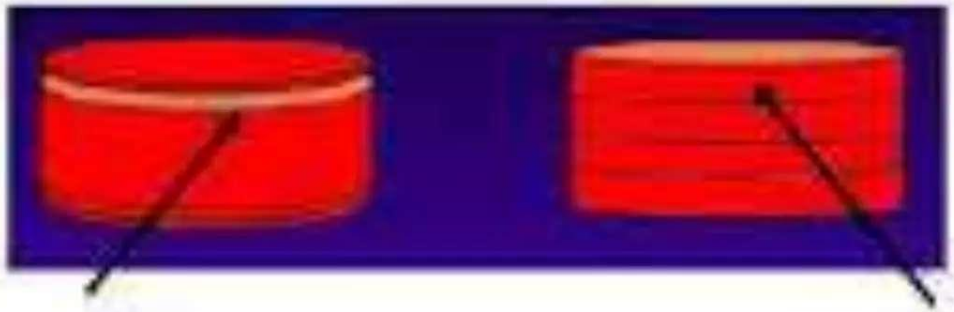
1. CAPPING & LAMINATION

1. Capping – partial or complete separation of top or bottom crown of the tablet from the main body of the tablet
2. Lamination – separation of the tablet into 2 or more distinct layers.

Capping & lamination occurs due to the following reasons:-

- ✓ **Presence of excess fine powders** will lead to entrapment of air in the tablet during compression . This air has a tendency to come out leading to cappig and lamination. Quantity of fine incorporated should be optimised to correct the problem

- ✓**Worn out punches and dies** also cause capping and lamination. Hence, replacement of the punches are required. Chromium plated dies can be used to correct the problem.
- ✓**High pressure** also an be used, which can be optimised before the production starts.
- ✓**Insufficient or improper lubricant** can cause this problem, hence the amount of lubricant used can be optimised or the type of lubricant can be changed.
- ✓**Addition of oily or waxy materials** can cause capping and lamination, that can be corrected by the usage of adsorbents or absorbents.
- ✓**Over drying of granules** are also a major reason for capping and lamination to occur. This can be overcome by the addition of optimum level of moisture.



Capping

Lamination

Good tablet

2. PICKING

Picking – material gets off from the tablet surface and adheres to the face of the punch.

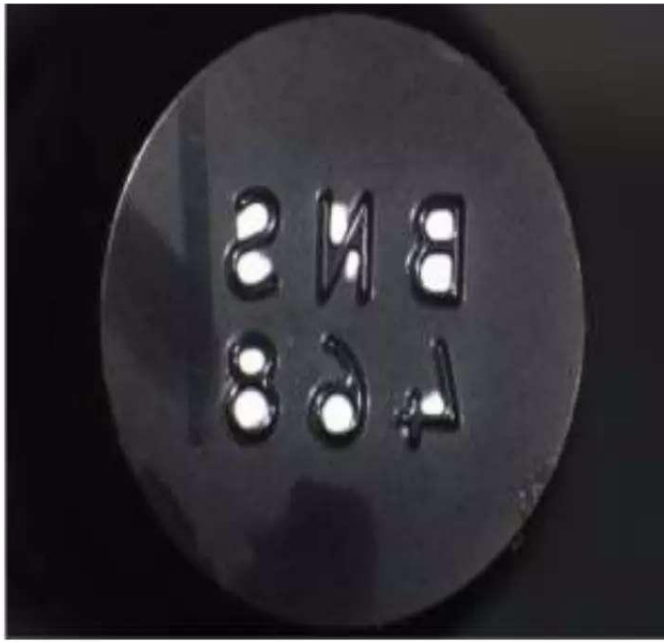
Reasons :-

- ✓ When punches have letters with sharp edges like A, B, M, W etc.
- ✓ When granules are improperly dried.
- ✓ When materials have low melting point.

Corrections :-

- ✓ punches that have sharp edged letters can be corrected by modifying the design of letters.
- ✓ When using low melting point materials, punches should be polished with colloidal silica


BMS
1668


BMS
1668

3. STICKING

Sticking – material gets off from the tablet surface and adheres to the die wall.

Reasons :-

- ✓ Presence of excess moisture.
- ✓ Improper lubrication of granules.
- ✓ Fast compression process.

Corrections :-

- ✓ Proper drying of granules.
- ✓ The amount of lubricant used can be optimised or the type of lubricant can be changed.
- ✓ Speed of the compression process should be optimised
- ✓ Dies should be polished with colloidal silica

4. MOTTLING

Mottling :- is a defect that occurs with coloured tablets.

- ✓ Mottling occurs due to the uneven distribution of the colour on the surface of the coloured tablets.

Reasons :-

- ✓ Migration of the dye on the tablet surface during the process of drying
- ✓ Decomposition of active ingredient or excipients improper mixing of colour binder solution

Corrections :-

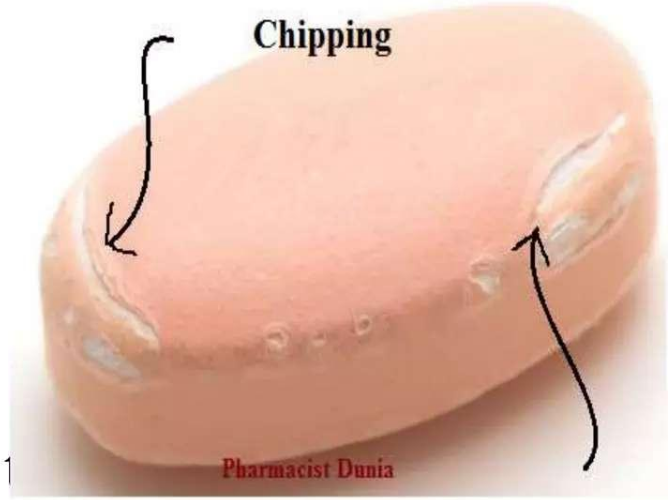
- ✓ Change the solvent system and decrease of temperature while drying.
- ✓ Incorporating dry colour excipients and fine powdered adhesives during mixing step of ingredients. Then the granulating liquid is added to prepare granules.

5. CHIPPING

Chipping :- is a defect where the film on the edges of the tablet is chipped or dented.

Reasons :-

- ✓ Dry granules
- ✓ Addition of large amount of binder
- ✓ Worn out edges of the punch



Corrections :-

- ✓ Addition of hygroscopic substances t moisten the granules.
- ✓ Polishing of edges of punch.
- ✓ Optimisation of the amount of binder.

6. CRACKING

Cracking :- is a defect where upper and lower central surface of tablets gets cracked.

Reasons :-

- ✓ Dry granules
- ✓ Size of granules are too large, air can get entrapped between the cavities, and during compression cracking occurs.
- ✓ Deep concave shaped punches

Cracking

Corrections :-

- ✓ Addition of right amount of binder moistening the granules.
- ✓ Reduce granules size or add fines.

7. DOUBLE IMPRESSION

Double impression – is a defect where the shape of the monogram or other engravings appears stamped twice on the tablet.

Reasons :-

- ✓ Due to the free rotation of the lower punch. The lower punch moves slightly upward before the ejection of a tablet and makes new impression on the bottom of the tablet

Corrections :-

- ✓ Control the free rotation of any punches

8. WEIGHT VARIATION

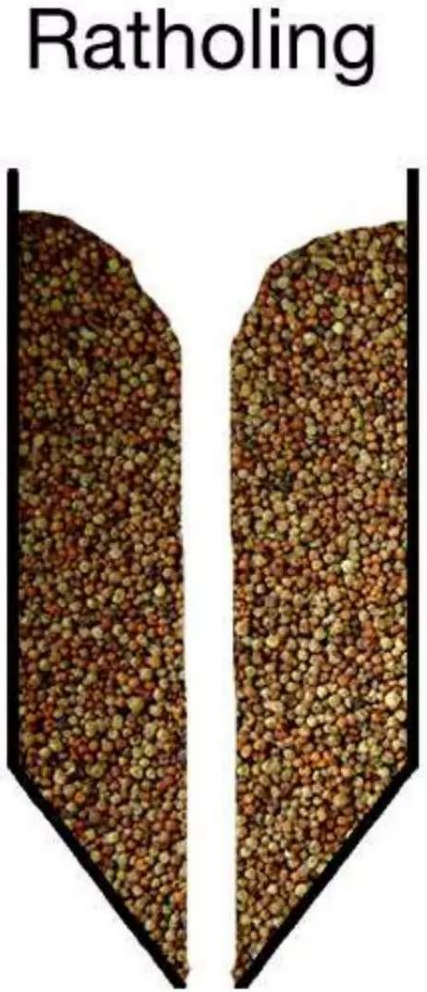
Weight variation– occurs when tablets compressed do not have uniform weight .

Reasons :-

- ✓ When granules are not in uniform size. This changes the filling of granules in the die. Large size or too small size granules changes can hence cause weight variation.
- ✓ Poor flow of granules from the hopper to the die. Rat holing, where the powder gets deposited over the inner walls of the hopper, this obstructs the flow of powder from the hopper to die.

Corrections :-

- ✓ Addition of vibrator to the hopper to improve the flow of powder.



9. HARDNESS VARIATION

Hardness variation– occurs when tablets compressed do not have uniform hardness.

Reasons :-

- ✓ No uniform weight
- ✓ Incorrect space between the upper and lower punch at the time of compression

Corrections :-

- ✓ Maintain the weight of the tablet.
- ✓ Optimum gap between the upper and lower punch should be maintained.


Thank you!!!