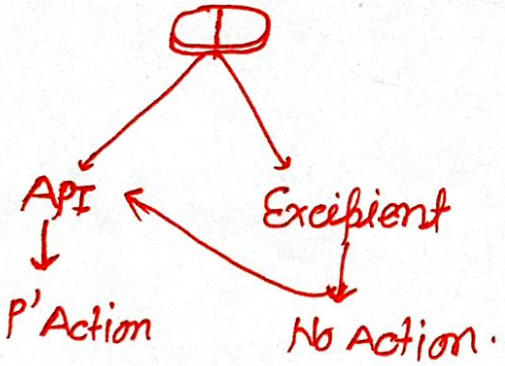
← Unit-2 →

÷ Tablet Dosage Foom ÷

Tablet ÷ → It is a solid unit dosage foom.

→ It is a conventional dosage form.

→ Tablet is a solid, unit, conventional dosage foom in which the API is compressed with the excipient. and it is available in the diff-2 shape and size.



→ The tablet is a compressed dosage form it is available in diff-2 shape and sizes basically oval Rounded and elongated.

Properties of Tablet dosage form ÷

→ It is simple dosage form

→ It is convient to use.

→ It is a accurately measured dosage foom.

→ It is Physically and chemically stable dosage foom. so they can be stand for longer time.

Advantages :-

- → Easy to take
- → It is cheapest dosage form.
- → It is easy to transport.
- → Tablet is the lightest in weight.
- → It is available in dose precision.
- → Greatest ease of swelling.
- → Can Mast the taste and colar of tablets.

DisAdvantages :-

- → It is not easy to swallow for Infant and elderly patient.
- → It is not prefer for the unconcious patient.
- ⇒ It can't give in emergency because it has later on set of action.
- ⇒ The Amorphous powder can't be convert in to the tablet form. because it has granulation difficulty.
- ⇒ The powder which are more ~~objectionable~~ they can't be convert into tablet dosage form.

:- Classification of Tablet dosage form :-

On the basis of function and and use tablet are following type -

Types of Tablet

Tablets Ingested Orally

(i) Compressed Tablets
(ii) Multiple Compressed Tablets.
(iii) Multi Layered Tablets.
(iv) Sustained Action Tablets
(v) Enteric Coated Tablets
(vi) Sugar Coated Tablets.
(vii) Film coated Tablets.
(viii) Chewable Tablets.

Tablets Used In the oral cavity

(i) Buccal Tablets.
(ii) Sub Lingual Tablets.
(iii) Lozenges And Troches.
(iv) Dental Cones.

Tablets Administered by other route

(i) Implantations Tablets.
(ii) Vaginal Tablets.

Tablets used to Prepare solution.

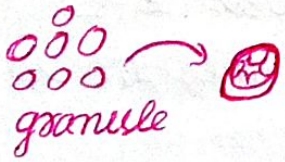
(i) Effervescence Tablets.

÷ Types of Tablet ÷

(i) Tablets Ingested orally ÷

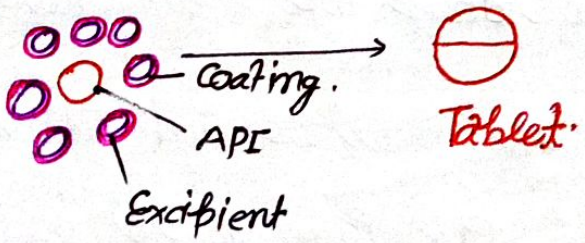
(A) → **Compressed Tablets ÷** Compressed tablet are those tablet in which the granules are compressed. and they are the uncoated.

→ And they dissociated and disintigrated in to the solvent and give quick action.

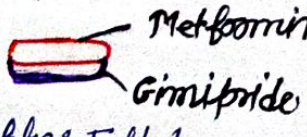


(B) **Multiple Compressed tablet ÷** The Multiple Compressed tablet taking for those tablet in which the API is incompatible with the excipient.

⇒ In this tablet the excipient compressed seperately. with API and then they mix-together.



(C) **Muti-Layered Tablet ÷** When the two different doug content are compressed and fix together. and form two are three layer This is called multiple-Layered Tablet.



(D) **Sustained Action Tablets:** This type of Tablet is making for long duration of Action.

In this type of Tablet the API is compressed with the excipient. and they make hard tablet.

→ Because there disintigration time dissolution time is slow they gives action for prolonged time.

(E) **Enteric Coated Tablets:** Enteric Coated tablet are makes for the absorption at intestine because tablet are disintigrated in gastric HCl medium so it can't reach into the stomach.

- When we coated with the thalate it dissolue into the intestine and this is called enteric coated tablet.

(F) **Sugar Coated tablet:** Sugar Coated tablets are those tablets imwhich sugar coating is applied on the tablet to mask the bitter taste and to increase the taste.

(G) **Film Coated tablet:** Film Coated tablet are the simple tablet imwhich the tablets are coated with the Plastic sizer material.

- And to Protect from the moisture and disintegration.

(H) **Chewable Tablets:** Chewable tablet are those tablet which are used by chewing it can't be swallow.

(2) Tablets used in the oral Cavity :-

(A) **Buccal Tablet :-** The tablet which are used in buccal cavity is called buccal tablet.

(B) **Sublingual tablet :-** Sub-Lingual tablets are those tablet which are dissolve into the saliva. and they are placed below the tongue. and they directly goes into the blood from saliva.
→ And it is avoided from the first pass metabolism.

(C) **Lozenges And Troches :-** Lozenges are the tablet which are dissolve into the saliva. and for the localaction. inside the bronchi

(D) **Dental Cones :-** Dental cones are the conical tablet which are inserted into the dental cavity.

(3) Tablets Administered by other route :-

(A) **Implantations Tablets :-** Implantation tablet are the thin tablet which are release into the skin. then it goes in to the blood or systemic circulation.

(B) **Vegical Tablets :-** When the tablets are given for the local action in vegina they are called vegical tablets.

(4) Tablets Used to Prepare Solution :-

(A) **Effervescence Tablets :-** These tablets contain bicarbonates and when they dissolve in water they release CO_2 gas.

:- Ingredients And Composition of Tablets :-

API :- API are the actual drug which have different Pharmacological resporce in our body.

Excipient :- / Additives :- (A,B,C,D,D,L,F Sweet)

- Excipient are the inert pharmaceutical material which mixed with API to form a dosage form.
- Excipient have no Pharmacological Action but it helps stability in API. Excipient should be compatible with API

(A) Adhessive

(B) Binder

(C) Coloring Agent

(D) Disintigrating Agent.

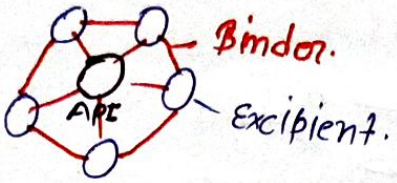
(E) Diluent / Bulking Agent.

(E) Lubricant / Glidant

(F) Flavouring Agent.

Sweet :- Sweeting Agent.

(1) **Adhesive or Binder:** Adhessive or Binder are those agent which have the binding property they bind the all excipient with the API and to each other



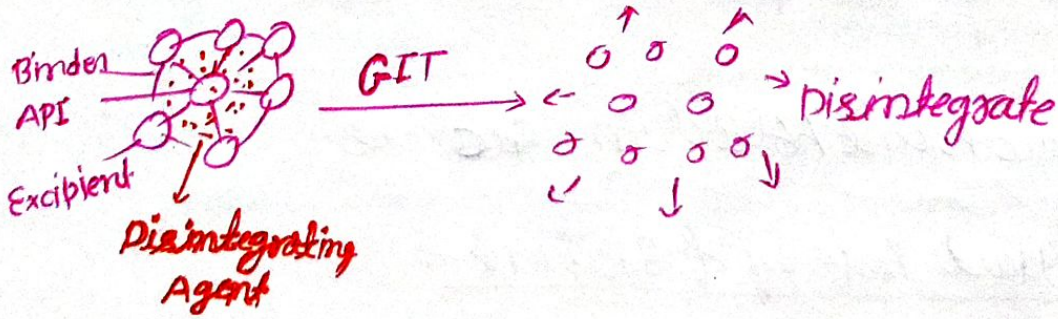
(2) **Coloring Agent:** → Coloring Agent are used to impart the color to the dossage form.

→ Diff-2 Indicators are used as the coloring agent.

→ Fox Ex- Ponceu-4-R, Sunset-Yellow

(3) **Disintegrating Agent:** Disintegrating are those agent which have Property to disintegrate the API and Exipient inside the GIT.

→ Because when tablet are not disintegrated they do not give any pharmacologeical Action.

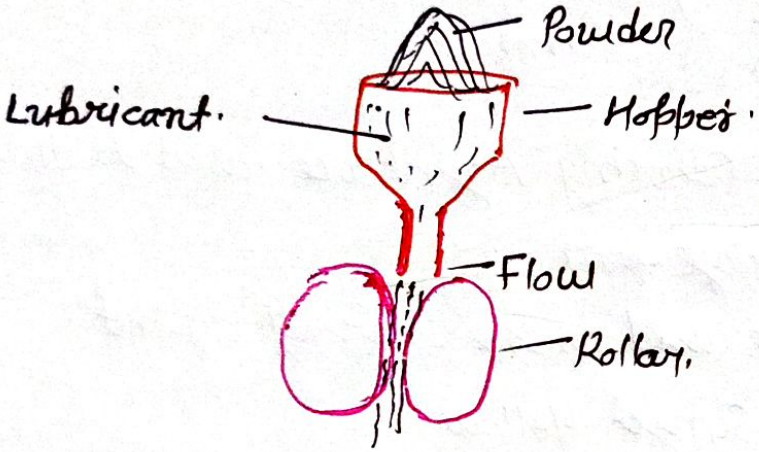


(4) **Diluent / Bulking Agent:** Diluent or Bulking Agent are the maximum part of the exipient and they make bulk. of the tablet.

* And Due to this bulking Agent it is easy to take API.

(5) **Lubricant / Glidant** Lubricant and Glidant are the excipient which is use to increase the flow property of the tablet.

→ And During the manufacturing Powder have uniform flow from the hopper.



(6) **Flavouring Agent:** Flavouring agent are Inhance the Flavour and Assence of the drug.

(7) **Sweeting Agent:** → Sweetining Agent are used to mask the bitter test of API. And Imparting the sweet taste

Ex - Saccharine, Aspartam, Sucrose

Ideal Property of Excipient:

(i) They should be chemally inert.
(ii) They should be cheap.
(iii) They should be incompatible.
(iv) They should not have any Personal Pharmacological Action.

÷ Example of Excipient ÷

A B C D D L F Sweet.

(1) Adhesives and Binders ÷

Ex ÷ Acacia, Tragacanth – Solution for 10-25 % conc.

→ Cellulose Derivatives – Methyl cellulose HPC, HPMC.

→ Gelatin – 10 – 20 % Solution.

→ Glucose – 50 % Solution.

→ Polyvinylpyrrolidone (PVP) – 20% conc.

→ Starch Paste – 10-20 % Solution

→ Sodium Algenate.

→ Sorbitol.

(2) Coloring Agent ÷

Ex ÷ → FD & C yellow 6 – Sunset yellow

→ FD & C yellow – 5 – Tartrazine.

→ FD & C Green 3 – Fast Green.

→ FD & C Blue 1 – Brilliant Blue.

→ FD & C Blue 2 – Indigo Carmine

→ D & C Red 3 – Erythrosine.

→ D & C Red 22 – Eosin Y

(3) Diluents ÷

Ex ÷ Lactose – Anhydrous and Spray dried lactose.

* Directly Compressed Starch – Sta Rx 1500.

(3) Hydrolyzed starch Emdex and Celutab.
(4) Microcrystalline cellulose - Avicel (PH 101 and PH 102)
(5) Dibasic calcium Phosphate dehydrate
(6) Calcium Sulphate dihydrate
7) Mannitol.
8) Sorbitol.
9) Sucrose - Sugartab, Di Pac, Nutab.
10) Dextrose.

(4) **Disintegrants:**

Ex: Starch - 5 - 20% of tablet weight.

→ Starch derivative - Primogel and Explotab (1-8%)

→ Clays - Veegum HV, bentonite 10% level in colored tablet only. cellulose.

→ Cellulose derivatives - AC - Di-Sol (Sodium Carboxy methyl Cellulose) Alginate.

→ PVP (Polyvinyl pyrrolidone, Cross-linked.

Superdisintigrate:

Ex: Crosscarmellose Cross-linked Cellulose.

→ Crosspovidone - Cross linked Povidone (Polymer

→ Sodium Starch Glycolate - cross linked starch.

→ Glidants & Lubricant

(5) **Lubricant And Glidants:**

→ **Lubricants:** Stearic Acid, Stearic Acid Salt - Stearic Acid, magnesium stearate, Talc, PEG (Polyethylene glycols) Surfactants)

→ **Glidants:** Cornstarch - 5-10% conc; Talc - 5% conc., Silica derivative - Colloidal silicas such as cab-o-sil, Syloid, Aerosil in 0.25-3% conc.

6) **Flavouring Agents:** For chewable tablet → Flavor oil are used.

7) **Sweetening Agents:**

Ex → For chewable tablet → Sugar, Mannital.

→ Saccharine (Artificial) 500 time's sweeter than sucrose.

→ Asfartame (Artificial)

Tablet Manufacturing Process

(1) Granulation ← Dry Granulation
Wet Granulation
Direct Compression.

(2) Compression.

(3) Coating ← Film Coating
Sugar Coating
Enteric Coating.

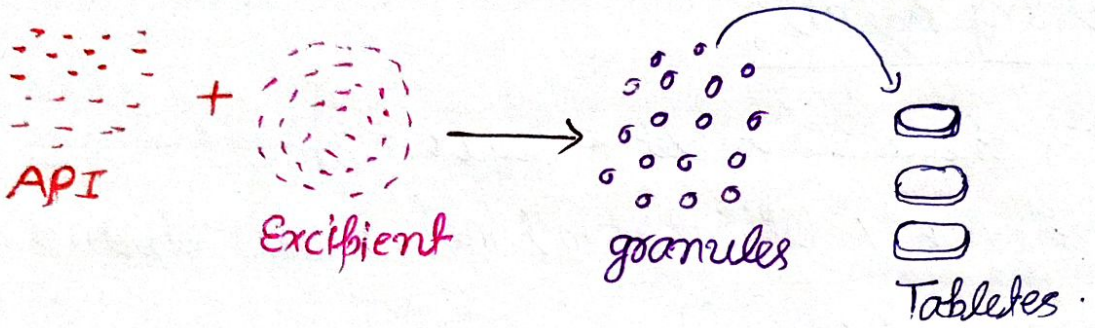
(4) Tablet Evaluation.

(5) Tablet deffect.

(1) Granulation Techniques :-

→ Granulation is the first step of tablet manufacturing process.

→ In the granulation techniques the API and the Excipients powder are mix together and converted into the granules form.



Steps of Granulation :-

(i) **Dry Granulation** :- This is simplest method and in this method the binder is use in the dry form. so it is called dry granulation method.

→ Dry Granulation Method involve following five Steps.

(A) **Screening** :- Before Starting Granulation All the API and excipient and binders are seperately screening through sieve.

(B) **Mixing** :- Now mix the API, Excipient and binder in the dry form and mix together properly with the help of propellar or Agitator.

(C) **Slugging :-** Slugging is the important part in the dry granulation method.

→ In slugging the mixed components are sent to the compression chamber. and they form the large size tablet. this tablets are called slugged tablets.

(D) **Milling :-** Now slugged large size tablet are again sent into the crusher and after the crushing they convert into the powder form or granule.

(E) **Mixing :-** Now again mix the content and sent for compression.

Advantage :- → The dry granulation method is suitable for those material who are moisture sensitive.

→ The material which are heat sensitive or thermolabile they can be use by the dry granulation method.

→ Easy and low cost.

→ Time saving process.

Disadvantage :- → In this method dusting problem appear.

→ The proper distribution of color is not possible in this method.

(2) Wet Granulation:-

→ In wet granulation technique the binder is use in the wet form and convert in to the solution or Slurry. in the mixture of Excipient and API.

Steps of Wet Granulation Techinque:-

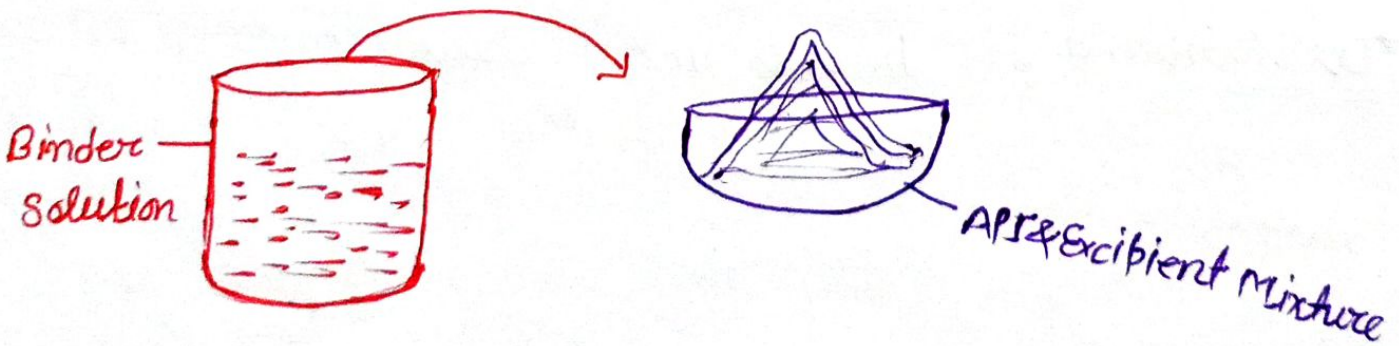
(1) **Mixing:-** In this method mix the API and Excipient

(2) **Preparation of Binder Solution** → Now Prepare the binder solution by using the appropriate solvent.

(3) **Mixing:-** Now the binder solution is added into the API and excipient mixture so they form a proper wet mixture.

4) **Drying:-** Now sent into the Tray dryer, Hot dryer for the drying.

5) **Screening:-** By the process of screening the uniform crystal can be obtained

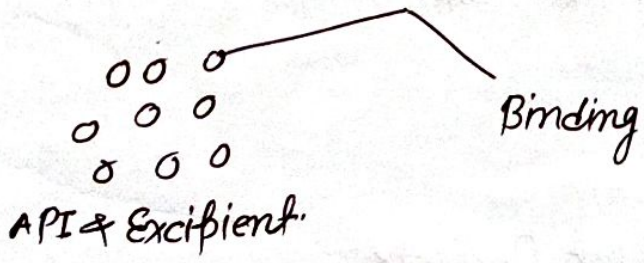


Advantage :- → Best mixing.
⇒ Improve flow Property
⇒ Improve cohesion
⇒ Reduce dust level.

Disadvantage :- → Expansive
→ Time taken
→ Loss of Material

(3) Direct Compression Method :-

In this method the use of binder is not allowed. and the particles of the excipient and API itself present in the large crystal form.

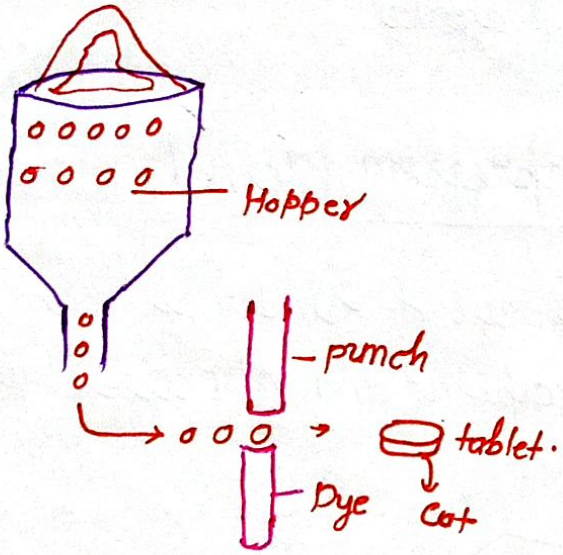


Advantage :- → Cast effective
→ Stability
→ Faster dissolution.

÷ Compression Techniques ÷

- After the granulation technique the processing of tablet is done under the compressor:

→ In this compression technique when the powder flow from hopper and comes b/w the dye and punches then after compression it gives the tablets.



÷ Tablet Deffects ÷

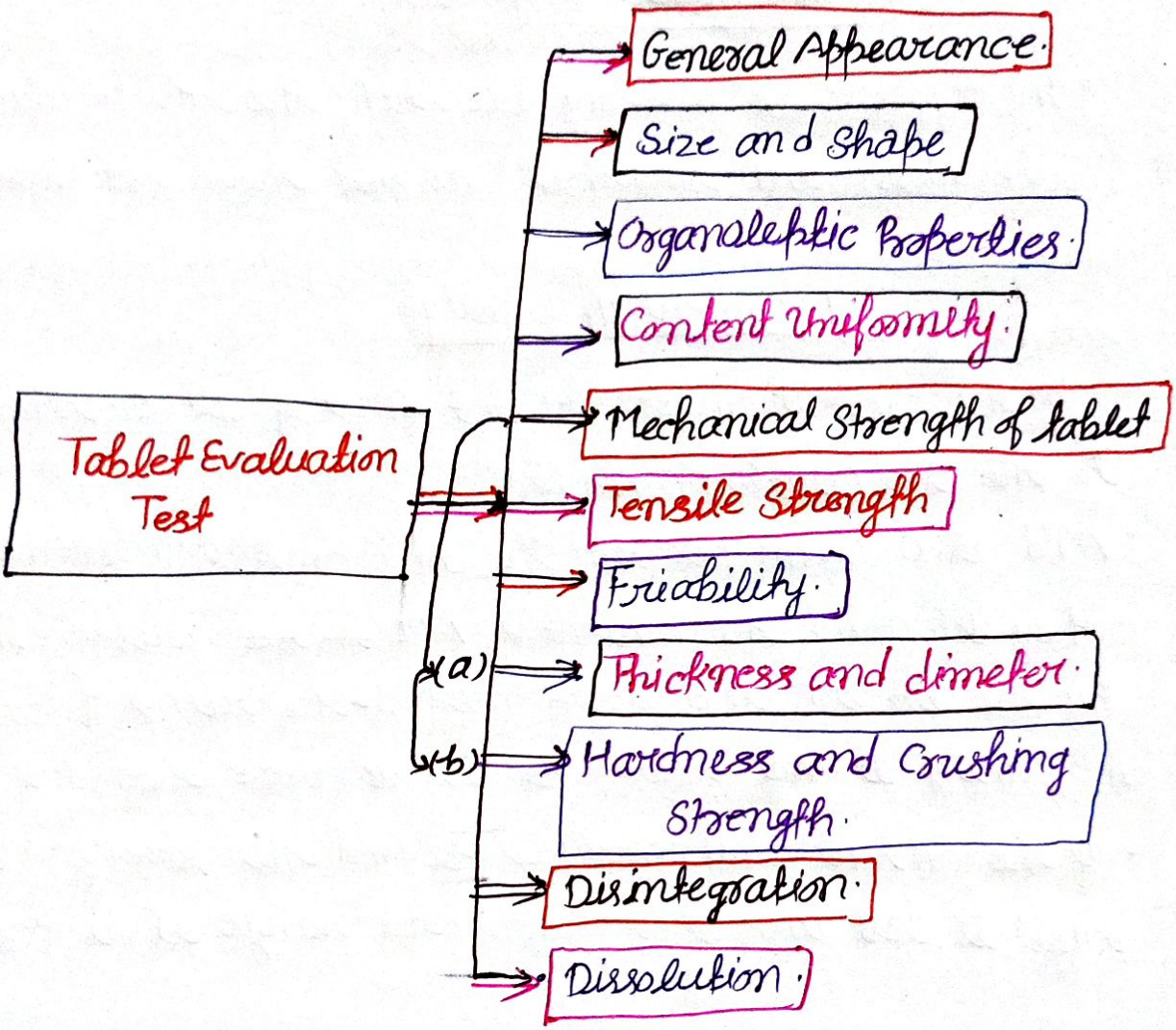
Tab Processing deffects ÷

Deffects / Problem	Causes	Remedy
→ Capping and Lamination	→ Granulation too dry → compression too hard → Damaged upper punches	→ Increase moisture content. → Reduce compression pressure → Replace the tools which are damaged.

	→ Machine RPM too fast → Excessive Lubrication → Less binder in granules → Entrapped air in granule	Reduce Machine speed. → Reduce or change the lubricant. → Increase binder concentration. → Improve granulation by using tapered dies.
2. Chipping -	→ Damaged Punches of dies → Compression to ~~fast~~ → Faulty machine testing → Less binder. → Compression too soft.	→ Replace the damaged punches or dyes. → Reduce compression speed. → Reduce the speed increase binder → Increase the compression pressure.
3. Sticking Picking, Filming	→ Compression too soft. → Uneven granulation. → High moisture content → High relative humidity → Improper lubrication. → Damage of upper punch	→ Increase compression pressure → Improve Granulation → Reduce maisture content in granulation. → use dehumidifier. → Improve lubrication → Polish the punches → Buffering the punches with lubricants.
4) Non Uniform Weight.	→ Machine RPM Too fast → Non-Uniform granules. → Restricted free flow of granules → Granules sticking to lower punches.	→ Reduce Machine speed → Provide Unifarm granules → Add glidant to Improve the flow properties → Improve lubricant

4) Dissolution	→ Large Granules → Tablets too hard → Excess lubricants	→ Reduce Granules size → Reduce tablet hardness → Reduce compression hardness.
5) Black Mark on tablets	→ Improper feed frame setting → Excessive moisture → Over sized granules. → Granules having black particles prior to compression → Lubricants, grease or oil may be contaminating the powder	→ Improve feed frame setting → Avoid excessive moisture → Reduce Granules size → Avoid contamination with oil or grease
6) Delayed Disintegration	→ Compression to hard → Over Granulation → Excess blending times with lubricants or glidants	→ Reduce the compression pressure → Improve the granulation → Reduce the blending time of lubricant

÷ Evaluation of Tablet ÷



(1) General Appearance ÷

- After the processing of tablet the General Appearance properties like - color, shape, size and weight is compaired with the original standered tablet. this is called general Appearance tablet.

÷ (2) Size And Shape ÷

Measured by ÷ → Micrometer
→ sliding caliper Scale

- Tablet thickness should be controlled within ± 5% variation of standered value

→ More likely to cause capping problem.

(3) Organoleptic Properties:

→ In organoleptic property we study the tablets - Colour, Taste, Odour and smoothness as per their standered tablet.

(4) Content Uniformity:

→ In the content uniformity test first of all 20 tablet sample is sent to the Q.C (Quality Controle)

→ And Q.C Person perform the drug content uniformity test.

→ They determine the content of API ~~in the~~ presence in the drug by the titration and assay method & the reange of content uniformity. it not should be less or more than the ± 10%

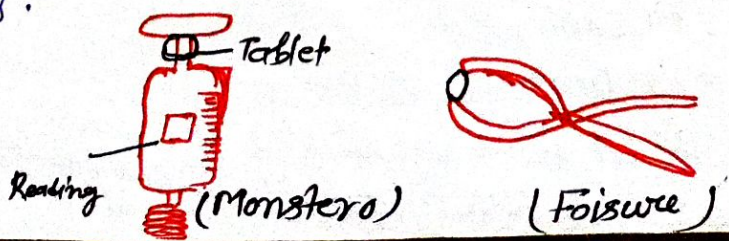
→ If the content uniformity is beyond this strength then tablet is fail and it is within the range it is pass.

:5) Mechanical Strength of tablet:

(A) Hardness test: Hardness testing is perform to determine the tensile strength of the tablet.

→ That how much pressure and how much strength it can be beared.

→ It is usually measured with the "Monsfero" and Foisure apparatus.



→ It is always taken in the form of kg.

(6) Friability :-

→ The Friability test is official in usp but not in BP and IP.

→ Friability tester is known as the "Roche friabilator"

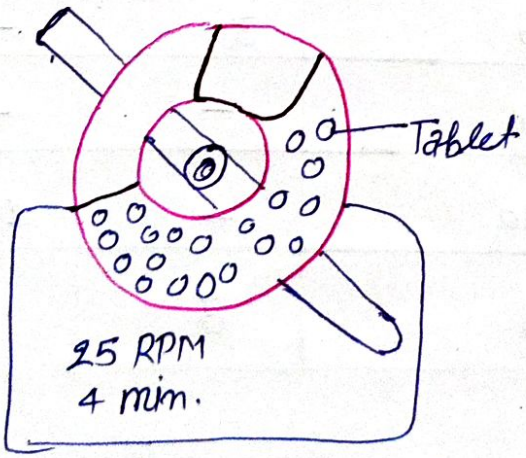
→ Tablet hardness is not an absolute indicator of strength since some formulation when compressed into very hard tablets.

→ **Procedure :-** → Pre weighed tablet sample placed in friabilator
→ Operated 100 revolution (25 rpm for 4 min)

→ Dropping tablets a distance 6 inch.

→ Tablet are then dusted and reweighed

→ Conventional compressed tablet that lose less than 0.5 to 1% of their weight are generally acceptable.



(Roche Friabilator.)

$$\text{Friability Test} = \frac{\text{Initial Weight}}{\text{Final Weight}} \times 100$$

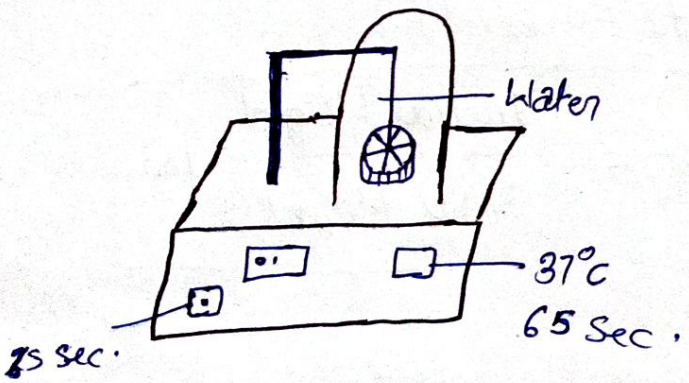
(T) Disintegration Test:-

→ It is the time required for the tablet to break in to particles.

→ The disintegration test is a measure only of the time required under a given set of conditions for a group of tablets to disintegrate into particles.

→ When any tablet is paure inside the hot water in disintegration apparatus then the time duration in which the tablet is disintegrated this is called disintegration time.

	Disintegration Time (min)		
Type of Tablet	IP	BP	USP
Un Coated	15	15	5
Coated	60	30	—
Film	30	—	—
(Enteric) Enteric	120	—	1+2 hr
Dispersible	3	3	3



(8) Dissolution:-

→ Dissolution is the process by which a solid solute enters a solution.

→ Pharmaceutically it may be defiant as the amount of drug substance that goes into solution per unit time under standardized conditions of liquid / solid interface, temperature and solvent composition.

⇒ Dissolution kinetics is imp. in determining the bioavailability of a drug.

⇒ The motor is adjusted to turn at the specified speed, and samples of fluid are withdrawn at intervals to determine the amount of drug in solution.

→ For Example- For methyldopa tablets the dissolution test calls for a medium of 900ml of 0.1 N HCl apparatus 2 turning at 50 RPM & time limit of 20 min.

→ The accepted amount dissolved in 20 min is not less than 80 % of the labeled amount of methyldopa.

⇒ It is carried out in -

(i) USP dissolution apparatus type 1 (Basket type.

(ii) USP dissolution apparatus type -(ii) (Paddle type

→ In general, a single tablet is placed in a small wire mesh basket fastened to the bottom of the shaft connected to a variable speed motor.

→ The basket is immersed in the dissolution medium (as specified in the monograph) contained in a flask. The flask is maintained at constant temperature of 37°c ± 5°c by a constant temperature bath.