QUALITY CONTROL TESTS FOR TABLETS

By

Swarnakshi Upadhyay

Assistant Professor

School of Pharmaceutical Sciences

CSJM University, Kanpur

Introduction:

- Tablets are a solid dosage form of medicaments with or without excipients which are prepared by compression or moulding method and intended for oral administration for local and systemic effect.
- They may vary in its size shape and weight depending on the medicament and its mode of administration.

Why there is a need to perform Quality control tests for tablets?

- To ensure safety,potency,efficacy,stability,patient acceptability and patient compliance of tablet.
- To check wheather a pharmaceutical tablet satisfy certain standards to claim it to be a quality drug or not.
- To check that the quality parameters are within the acceptance limits or not.

What is Quality control?

- Quality control is a small part of QA and it is concerned with sampling,testing and documentation during manufacturing and also after completion of manufacturing.
- It is the monitoring process through which manufacturer measures actual quality performance,compares it with standards and find out the causes of deviation from standard to ensure quality product not once but every time.
- In general terms,Quality control refers to a procedure or a set of steps taken during the manufacturing of a product to ensure that it meets requirements and that the product is reproducible.

Types of Quality control tests

1.Official tests

- Weight variation test
- Drug content
- Disintegration time test
- Dissolution test

2.Unofficial tests

- Thickness
- Hardness
- Friability
- Organoleptic characters

1.ORGANOLEPTIC CHARACTERS:

Colour:

- Many pharmaceutical tablets use color as a vital means of rapid identification and consumer acceptance.
- The colour of a product must be uniform within a single tablet.Non-uniformity is referred to as 'mottling' and hence it leads to poor quality of product.

Odour:

- The presence of odor in a batch of tablets could indicate stability problems, such as the odor of acetic acid in degrading aspirin tablets.
- However, the presence of an odor could be characteristic for the drug (vitamins), added ingredients (flavoring agents) or the dosage form (film-coated tablets).

Taste:

- Taste is important in consumer acceptance of, especially, chewable tablets.

2.WEIGHT VARIATION TEST:

- According to the USP, weight variation test is run by weighing 20 tablets individually calculating the average weights and comparing the individual tablet weights to the average. The value of weight variation test is expressed in percentage. The following formula is used:

Weight Variation = (IW - AW)/AW X 100%

Where,

IW: Individual weight

AW: Average weight

Factors responsible for weight variation:

- Flow properties
- Degree of segregation

Official standards:

As per U.S.P.

Sr.No.	Average weight of tablet	% weight variation acceptable(+ or -)
1.	130 or less mg	(+ or -) 10%
2.	130-324 mg	(+ or -) 7.5%
3.	>324 mg	(+ or -) 5%

As per I.P.

Sr.No.	Average weight of tablet	% weight variation acceptable(+ or -)
1.	84 or less mg	(+ or -) 10%
2.	84-250 mg	(+ or -) 7.5%
3.	>250 mg	(+ or -) 5%

Note:

- If we are using 20 tablets,then according to U.S.P.,not more than 2 tablets show % weight variation.
- If we are taking 10 tablets,then according to U.S.P.,not more than 1 tablet show % weight variation.

3. THICKNESS TEST:

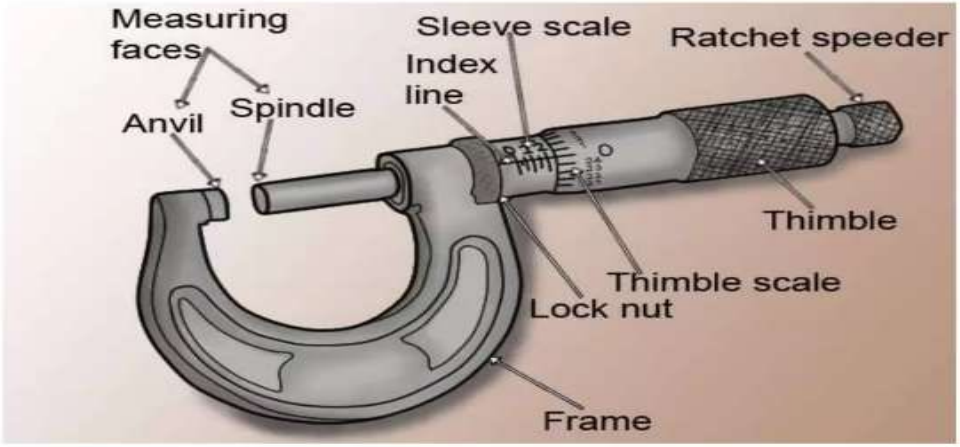
- Tablet thickness is determine by the diameter of the tablet. Micrometer and vernier caliper are used for checking tablet thickness.
- Thickness should be controlled within ± 5% variation of a standard value.
- Thickness must be controlled for consumer acceptance of the product, and to facilitate packaging.

Factors affecting thickness:

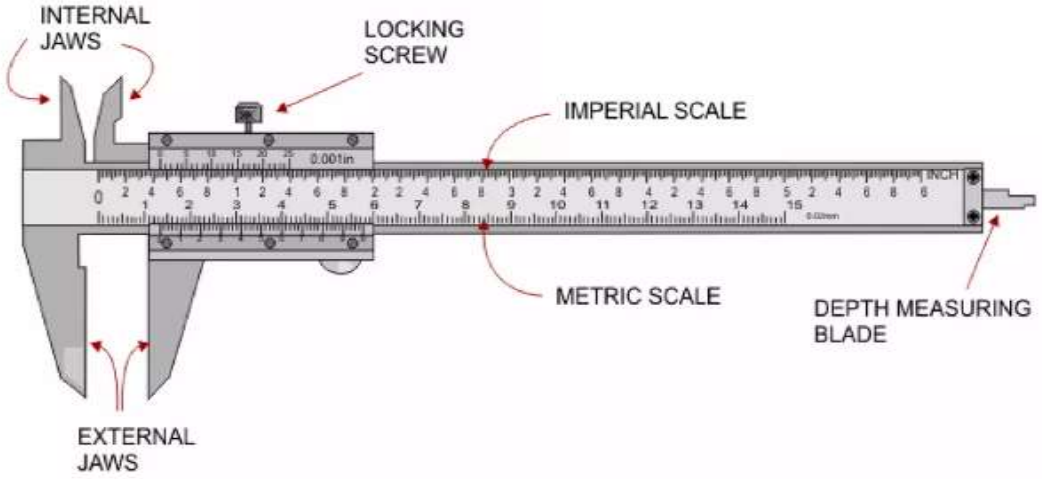
- ➢ Size and size distribution
- ➢ Compression force

Equipments used in this test:

A. Micrometer: Here,put the tablet between two anvils and read it's thickness by scale. It is measured in micrometer(mm).



B. Vernier caliper: Here, tablet is put between two jaws of vernier caliper and measure thickness of tablet by reading scale.It is measured in centimeter(cm).



Note:

- As per official standard,tablet thickness variation alloted upto (+ or -) 5% of standard value.

4.HARDNESS TEST:

- This test is also known as **"Crushing Strength Test".**
- Tablets require a certain amount of strength, or hardness to withstand mechanical shocks of handling in manufacture, packaging and shipping
- Tablet hardness has been defined as the force required to break a tablet in a diametric compression test.

Factors affecting hardness:

- Concentration of binder
- Moisture content
- Compression force

Equipments used in this test:

(a)Monsanto hardness tester
(b)Pfizer hardness tester
(c)Strong cobb hardness tester
(d)Erweka hardness tester

- Out of the above equipments,Monsanto hardness tester and Pfizer are commonly used to determine hardness of tablet.

(a)Monsanto hardness tester:

Here,tablet is put between moving jaw and fixed jaw. Moving jaw is moved and pressure is applied on tablet by means of screw knob.The point where tablet get break down,it is recorded by means of scale.The hardness is measured in Kg/cm^2.

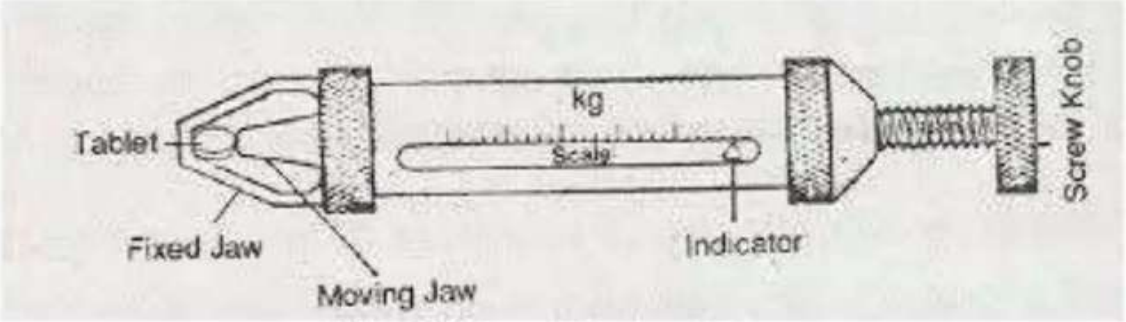
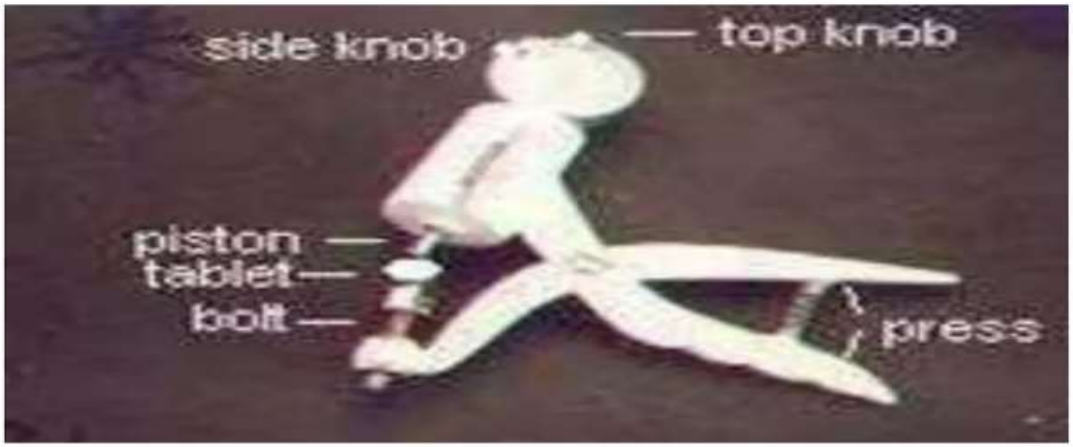


Fig. 17 Monsanto hardness tester

(b) Pfizer hardness tester:



The Pfizer tester compresses tablet between a holding anvil and a piston connected to a force-reading gauge when its plier-like handles are gripped. The point where tablet gets break down,it is noted by reading gauze.

Official standards for Hardness:

- 5-8 kg/cm^2 for standard compressed tablet except Effervescent tablet,Dispersible tablet,Orodispersible tablet,Chewable tablet,etc.
- More than 8-12 kg/cm^2 for Sustain released tablet and controlled release tablet.

5.FRIABILITY TEST:

- "FRIABILITY is the phenomenon where the surface of the tablet is damage or shown a site of damage due to mechanical shock."
- **PURPOSE**: To evaluate the ability of the tablets to withstand the breakage during the transportation and handling.
- Friability testing is a method, which is employed to determine physical strength of uncoated tablets upon exposure to mechanical shock and attrition. In simple words, friability test tells how much mechanical stress tablets are able to withstand during their manufacturing, distribution and handling by the customer.
- It means **Surface Erosion** by certain mechanical shock and lost of material from intact tablet.

Equipment used in this test:

Roche friabilator tester is most commonly used for determining % friability of tablet.

Procedure:

1.Take 20 tablets and take initial weight of it and put it into friabilator.
2.Now rotate the drum at 25 rpm per min or 100 rpm for 4 mins.
3.During this,tablet gets dropped on plastic from 6 inches, it will pass through mechanical shocks.
4.After 4 minutes,calculate final weight of tablets and that of % friability.

% Friability can be calculated by following formula-

$$\% \text{ Friability} = W1 - W2/W1 \times 100$$

Where,

W1 = weight of tablets before testing

W2 = weight of tablets after testing.

Standards for friability:

- % Friability should be upto **0.5 to 1%** for all standard compressed tablets.
- For effervescent,chewable,WHISKERING,orodispersible tablets % friability should be greater than 1.

6. DISINTEGRATION TEST:

- Disintegration is a process in which tablets are break up into granules or smaller particles.
- The time it takes a tablet to disintegrate is measured in a device described in the USP/NF.So, disintegration test is a measure of the time required for a group of tablets to break up into particles under a given set of conditions.
- This test is essential for tablets intended for administration by mouth, except those intended to be chewed before being swallowed or those that should dissolve slowly in the mouth, e.g., lozenges, glyceryl trinitrate, or effervescent tablets. Also, disintegration does not apply to some types of sustained-release tablets.

Disintegration time: Time required for breaking of tablet into small particles under influence of disintegrating fluid.

- Disintegrating fluid may be either simulated gastric fluid or simulated intestinal fluid.

Equipment used in this test:

Disintegration test apparatus is commonly used.

Apparatus construction:

- Two batches of six tablets can be simultaneously tested with this instrument.
- The USP device to test disintegration uses 6 glass tubes that are 3 inches long,open at the top,and held against a 10-mesh screen at the bottom end of basket rack assembly.Each glass tube has percolated sieve (no.10) at the bottom.

Procedure:

- 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°C±2°C ,such that tablets remain 2.5 cm below the surface of liquid on their upward movement and descend not closer than 2.5 cm from the bottom of beaker.
- A standard motor-driven is used to move the basket assembly containing the tablets up and down through a distance of 5-6 cm at frequency of 28-32 cycles per minute.Thus, in this way,note the time required to complete disappearance of tablet from glass tube.

Official standards:

Sr.No.	Types	I.P.	B.P.	U.S.P.
1.	Standard compressed tablet(Uncoated)	15 mins	15 mins	5 mins
2.	Sugar coated tablet	60 mins	30 mins	---
3.	Film coated tablet	30 mins	30 mins	---
4.	Enteric coated tablet	1 hr.	1-2 hrs	2 hrs
5.	Effervescent tablet or dispersible tablet	<3 mins	<3 mins	<3 mins
6.	Orodispersible tablet	<1 min	<1 min	<1 min

Note:

- The disintegration time is not for buccal,sublingual and chewable tablets.Beacuse they are directly absorbed.
- No disintegration time for sustained release and controlled release tablets.

7.DISSOLUTION TEST:

- The administration of drugs via oral dosage forms is one of the most common and effective means of delivering treatments to patients. When a dosage form is swallowed, the rate at which it releases the active ingredient is critical to ensure that the drug is delivered properly. The rate at which the drug is released is called the **dissolution rate.**
- Several dissolution apparatuses exist. In (USP) ,there are four dissolution apparatuses standardized and specified. They are:

(A)USP Dissolution Apparatus 1 – Basket (37 ° C)

(B)USP Dissolution Apparatus 2 – Paddle (37° C)

(C)USP Dissolution Apparatus 3 – Reciprocating Cylinder(37 ° C)

(D)USP Dissolution Apparatus 4 – Flow-Through Cell (37 ° C)

- According to I.P.,

➢ Type I : Paddle type apparatus

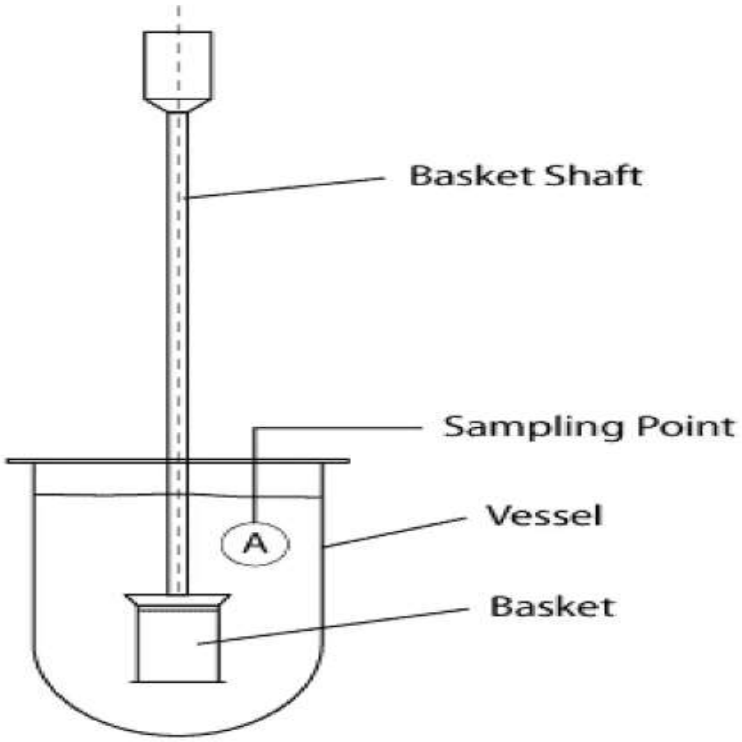
➢ Type II : Basket type apparatus

Equipments used in this test:

[1] Rotating basket apparatus:

Assembly consists of:

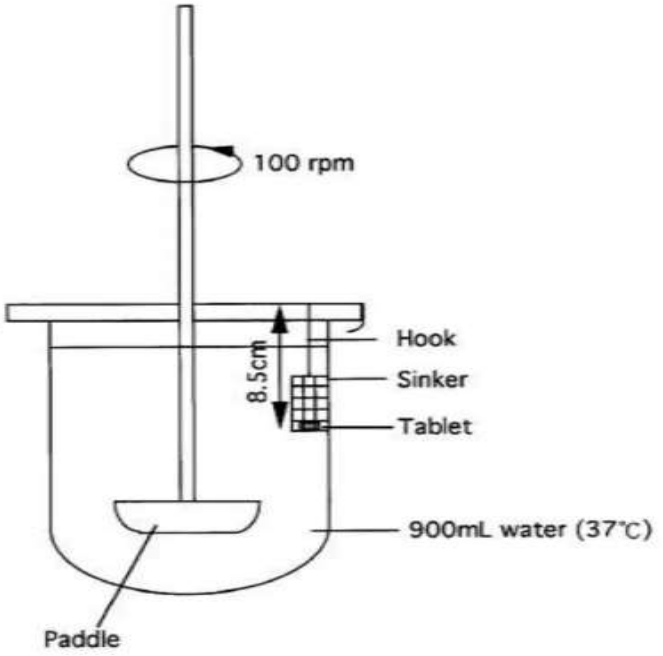
- A covered vessel
- Metallic drive shaft
- Cylindrical basket
- Motor
- Sample port
- Water bath holding temperature $37 \circ C \pm 0.5 \circ C$
- Acidic media or alkaline media

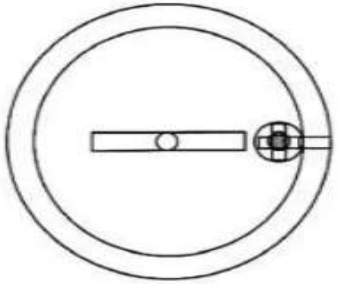


[2]Rotating paddle apparatus:

Assembly consists of:

- A covered vessel
- Metallic drive shaft
- Stainless steel paddle
- Motor
- Sinker to prevent floating of tablet
- Water bath holding tempe -rature at 37◦C ± 0.5◦C
- Acidic media or alkaline media





Standards:

Sr.No.	Stages	No. of units	Acceptance criteria
1.	S_1	6 tablets	All units '6' not less than Q + 5%
2.	S_2	6 tablets	Average of 12 tablets equal to or not > Q and Q-15%
3.	S_3	12 tablets	Average of 24 tablets is equal to or not >Q and Q-25%

Where,
Q=% drug dissolved

Note: 75% of drug should be dissolved within 45 mins as per U.S.P.

8.CONTENT UNIFORMITY TEST:

- Content uniformity test was developed to ensure content consistency of active drug substances .

Factors affecting drug content:

- ➢ Tablet weight variation.
- ➢ Uneven distribution of the drug in the powder or granules
- ➢ Segregation of the powder mixture or granulation during formulation processes
- By the USP method, 30 tablets are randomly selected, 10 of these tablets are assayed individually according to the method described in the individual monograph.
- Unless otherwise stated in the monograph, the requirements for content uniformity are met if the amount of active ingredient in nine (9) of the ten (10) tablets lies within the range of 85% to 115% of the label claim.

- The tenth tablet may not contain less than 75% or more than 125% of the labelled drug content. If one or more dosage units do not meet these criteria, the remaining 20 tablets are assayed individually and none may fall outside of the 85% to 115% range for the batch to be accepted.

Conclusion:

- Quality control of tablets involves various tests which require keen attention.
- To ensure that established product quality standards are met, these tests must be performed during production (in process control)and verified after the production of each batch.