Alzahraa university
Industrial pharmacy II (practical)

(Evaluation of tablet)

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THE CONTROL OF THE GENERAL APPEARANCE OF A TABLET INVOLVES :

I. Size & shape.
II. Organoleptic properties color & Odor…
III. Weight Variation (USP&BP).
IV. Cont. uniformity & Content Uniformity.
V. Friability .
VI. Hardness.
VII. Disintegration.
VIII. Dissolution .

I. SIZE AND SHAPE

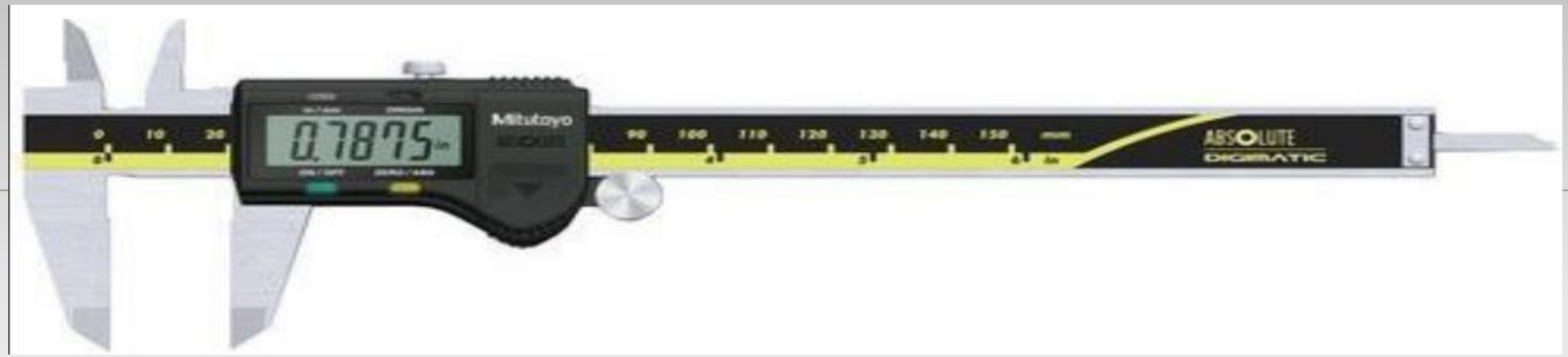
THICKNESS OF A TABLET: only dimensional variable related to the process.

a) a constant compressive load	b) a constant die fill
tablet thickness varies with changes in die fill, with particle size distribution and packing of the particle mix being compressed, and with tablet weight.	thickness varies with variations in compressive load.

MEASUREMENT OF THICKNESS

Tablet thickness should be controlled within a ±5% variation of standard value.

micrometer	sliding caliper scale	hand gauge
The crown thickness of individual tablets may be measured with a Micrometer. 1. Permits accurate measurements 2. Provides information on the variation between tablets.	(total crown thickness may be measured with a sliding caliper scale). 5 or 10 tablets in a holding tray . Adv.: more rapid than a micrometer. Disadv.: does not as readily provide information on variability between tablets.	(e.g. Vernier calliper) during production or by automated equipment.


Mitutoyo
0.7875
ABSOLUTE
DIGIMATIC


inch/mm
0.00
OFF
ON
ZERO

III. Weight Variation (USP&BP)

The quantity of fill in the die of a tablet press determines the weight of the tablet.

- USP:

Average mass	Percent deviation
130 mg or less	10
130 mg – 324 mg	7.5
More than 324	5

III. Weight Variation (USP&BP)

- BP:

Average mass	Percent deviation
80 mg or less	10
More than 80 mg and less than 250 mg	7.5
250 mg or more	5

- Procedure:

Weigh individually 20 tablets , and record the weight for each tablet. And combine the weights of 20 tablets to calculate the average weight.

III. Weight Variation (USP&BP)

AW= weights of 20 tablets / 20

- Calculate upper limit and lower limit at the %deviation:

o Upper limit at % dev. = AW + (AW x % deviation)

o Lower limit at % dev. = AW - (AW x % deviation) • Then calculate the upper and lower limits at double the % deviation allowed:

o Upper limit at double % dev. = AW + (AW x 2x %dev)

o Lower limit at double % dev. = AW – (AW x 2x %dev)

Accepted Limit:

- Not more than 2 tablets (out of the 20 tablets) differ from the average weight by the % difference

listed, and No tablet differs from the average weight by double that percentage.

III. Weight Variation (USP&BP)

For example:

- We have 20 tablets with average weight=400 mg AW= 400 mg, so % deviation = 5%
- Calculate upper limit and lower limit at the %deviation:
- Upper limit = AW + (AW x % deviation)= 400 + (400 x 5%) = 400mg + 20mg = 420 mg
- Lower limit = AW - (AW x % deviation)= 400 – (400 x 5%)= 400mg–20mg= 380mg

So, the accepted weight range: 420mg to 380 mg

III. Weight Variation (USP&BP)

- Then calculate the upper and lower limits at double the % deviation allowed:

o Upper limit at double % dev. = AW + (AW x 2x %dev)= 400mg + (400 mg x 2 x 5%) = 400+40= 440 mg

o Lower limit at double % dev. = AW – (AW x 2x %dev)= 400mg - (400 mg x 2 x 5%) = 400-40= 360 mg

- So, even if we have a single tablet that is outside the 440mg-360mg range, the whole batch fails in the weight variation test.

Content Uniformity

- Randomly select 30 tablets, and assay 10 of these tablets individually.
- The batch passes the test if 9 of the 10 tablets must contain not less than 85% and not more than 115% of the labelled drug content AND the 10th tablet does not contain less than 75% and more than 125% of the labelled content.
- If these conditions are not met, we should assay the remaining 20 tablets individually and none may fall outside the 85-115% range.

IF NOT, then assay the remaining 20 tablets, And all of them should be in the weight range of

(>85mg–115mg<) .

V. Friability (BP and USP)

- Tablet's durability is determined using the friabilator. This apparatus determines the tablet's friability, or tendency to crumble, by allowing it to roll and fall within the drum.
- Resistance to loss of weight indicates the tablet's ability to withstand abrasion in handling, packaging, and shipment.

V. Friability (BP and USP)

• For tablets with a unit mass equal to or less than 650 mg, take a sample of whole tablets corresponding as near as possible to 6.5 g.

• For tablets with a unit mass of more than 650 mg, take a sample of 10 whole tablets.

• The tablets are carefully dedusted prior to testing. Accurately weigh the tablet sample, and place the tablets in the drum. Rotate the drum 100 times, and remove the tablets. Remove any loose dust from the tablets as before, and accurately weigh.

• Drum rotation: 25 ± 1 r/min. If obviously cracked , leaved, or broken tablets are present in the tablet sample after tumbling, the sample fails the test.

• If the weight loss is greater than (1%), the test is repeated twice and the mean of the 3 tests determined.

• A maximum loss of mass (obtained from a single test or from the mean of 3 tests) not greater than 1% is considered acceptable for most products.

• Procedure:

1. Weigh the tablets together.

2. Put the tablets in the friabilator and Run the instrument at 100 rounds (i.e. = 25 rpm for 4 min)

3. Weigh the tablets together.

F= 100% x (1-w/w0)

Where w0= weight of tablets before friability

w = weight of tablets after friability

4. Friability (% loss) = it must be less than or equal to 1% but

• some chewable tablets and most effervescent tablets are highly friable and require special unit packaging

VI. Hardness.

- Hardness can affect the disintegration.
- A minimum of 6 tablet samples should be tested.

Hard Tab. ⟶ not disintegrate in the Required period of time.

if the tablet hardness is too high, we first Must check its disintegration before rejecting the Batch. And if the disintegration is within limit, then The batch is accepted.

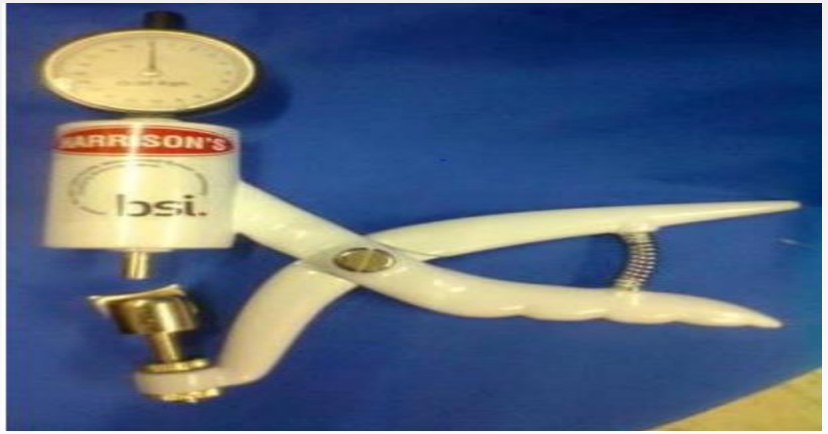
Factors : Compression force, (more binder >> more hardness) ,(wet granulation gives more hardness than direct method, slugging method gives the best hardness).

Limits: Oral tablet (4-10 kg) ,Chewable tablet (3Kg) , S.R. (10-20 Kg).

USP:

1. Monsanto hardness tester was based on compressing tablets between two jaws via a spring gauge and screw.
2. Pfizer hardness tester, the vertically mounted tablet was squeezed in a device.
3. Strong Cobb hardness tester, the breaking load was applied through the action of a small hydraulic pump.

- Problems associated with these devices were related to operator variability.



USP:

strain gauge-based load cells for force measurements, and electronic signal processing.

Convert kg to Newtons

- One kilogram is equal to 9.81 Newtons.
- To convert Newtons to kilograms, divide by 9.81.
- Ex: To convert 20 Newtons to Kg
- 20/9.81 = 2.04 kg

VII. Disintegration.

The time required for a group of tablets to disintegrate into particles which will pass through 10 mesh screen.

Liquids used in disintegration: Water , Simulated gastric fluid, Simulated intestinal fluid.

A) Basket-rack assembly for normal-size tablets :

1. Place 1 tablet in each of the 6 tubes of the basket.
2. at 37 ± 2 °C.
3. If 1 or 2 tablets fail to disintegrate, repeat the test ON another 12 tablets.

✓The batch is accepted if not less than 16 of the 18 tablets tested have disintegrated.

VII. Disintegration.

B)Basket-rack assembly for large-size tablets (BP only):

To pass the test, all the 6 tablets must have disintegrated.

Time:

uncoated tablets :not more than 30 minutes according to USP (to BP 15 minutes).

coated tablets: up to 2 hours.

S.L : up to 3 min, but 2 minutes for nitroglycerine S.L. and to up to 4 hours for buccal tablets.

Enteric-coated: similar except , simulated gastric fluid for 1 hour, after which no sign of disintegration , cracking, or softening must be seen.

VIII . Dissolution (BP and USP):

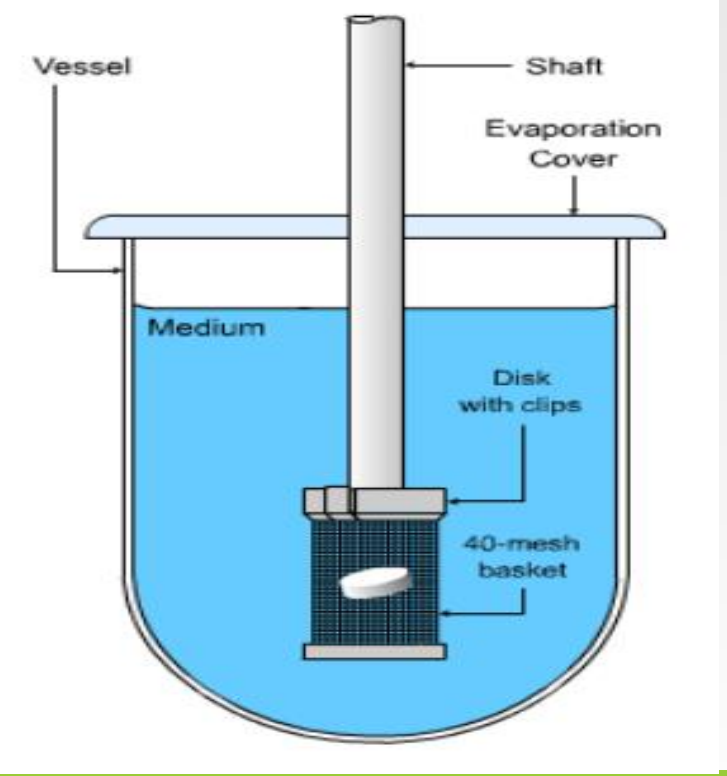
• Tablet disintegration is the important first step to the dissolution of the drug in a tablet.

referred to as in-vivo in-vitro correlation(IVIVC). mainly for immediate-release solid oral dosage forms.

A) Apparatus 1 (Basket apparatus):

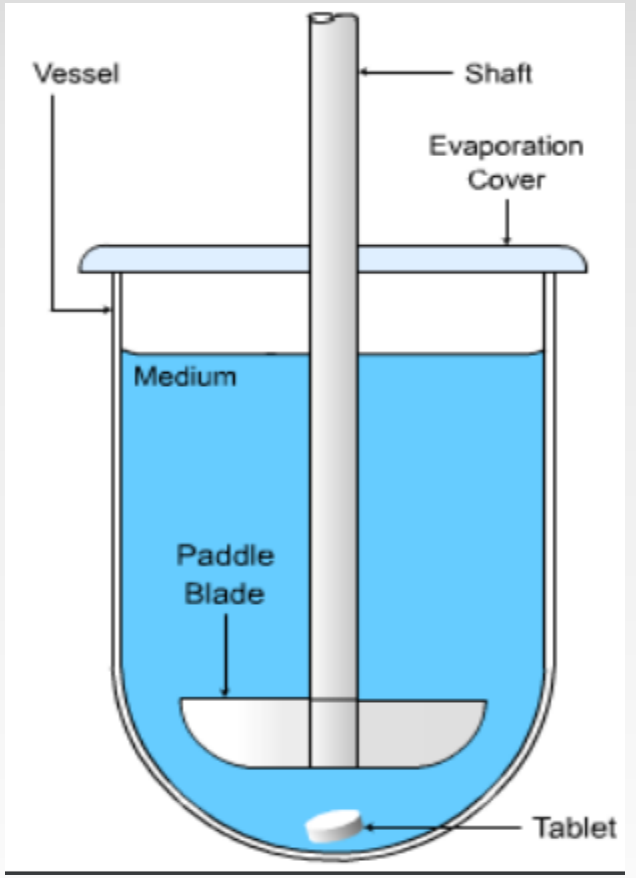
- The vessel: a water-bath capacity of 1 liter maintained at 37±0.5 °C.
- Drive shaft.
- Cylindrical basket .
- Motor (A speed-regulating device is used that allows the

shaft rotation speed to be selected and maintained at a specified rate).



VIII . Dissolution (BP and USP):

B) Apparatus 2 (Paddle apparatus):Identical to apparatus 1, except that a paddle is used as the stirring element. A small piece of non-reactive material (small wire helix) may be attached to tablets and capsules that would otherwise float.



Procedure:

• In each test, a volume of the dissolution medium (as stated in the individual monograph) is placed in the vessel and the temperature is set to 37°C ±0.5°C.

• Then, the stirrer is rotated at the speed specified.

• At stated intervals, samples of the medium are withdrawn for chemical analysis of the proportion of drug dissolved.

• The tablet or capsule must meet the stated monograph requirement for rate of dissolution, for example, “not less than 85% of the labelled amount is dissolved in 30 minutes.


THANKS YOU