

EVALUATION OF TABLET

LAB 5

Industrial pharmacy ☐

Lec.Ashti M.H. Saeed

Assist. Lec. Marwa Malik

EVALUATION OF TABLET

DONE BY QUALITY CONTROL DEPARTMENT (Q.C.)

Role of Q.C. department (small part of quality assurance –QA-):

concerned with sampling, testing and documentation during and after completion of manufacturer.

Q.C.: set of steps taken during the manufacturing to ensure that the product meets the requirements and is reproducible. It also monitoring the product after manufacture and comparing it with standards to find out the causes of deviation from standards thus ensure the quality product not once but every time.

QUALITY CONTROL STEPS FOR TABLET

General appearance

I. Size, shape and thickness

Size and shape: can be controlled by size and shape of punches and die of tab. machine.

Tablet thickness (dimensional variation) related to:

- a) **Constant compression load:** tab. Thickness varies with tab. weight, die fill and P.S. distribution.
- b) **Constant die fill:** thickness varies with compression load.

Note: Tablet thickness controlled within $\pm 5\%$ variation, If not then problems of variation in tab thickness that restrict packaging process and a variable in fill level of the same container with a given no. of dosage units.

TABLET THICKNESS CAN BE MEASURED BY:

Micrometer: measure individual tab. thickness (so accurate information on variation between tab.).



Holding tray: measure total tab. thickness of 5-10 tab., where their total crown thickness may be measured with a sliding caliper scale.

Shape:

Shape of tab. influence the choice of tab. machine used with special slotted punches that run at lower speed or one with precompression capabilities than conventional punches that produce round tablets.



Due to

Non-uniform forces involved within tab., the more convex the tablet surface, the more likely it is to cause capping or laminating problems.

2ORGANOLEPTIC PROPERTIES (COLOR UNIFORMITY, ODOR AND TASTE)

1. Color uniformity:

To identify the product and give good impression to the consumer, while mottling (unequal distribution of the color on tab.) give bad idea to the manufacturer.

2. Odor:

Presence of odor in a batch of tab. could indicate stability problems like: odor of acetic acid in degrading aspirin tablet.

3. Taste:

It is important in chewable tab.

NON OFFICIAL TESTS:

Hardness (tablet crushing strength)

Tablet hardness: is the force required to break a tablet in a diametric compression test.

Tablets required a certain amount of strength or hardness and resistance to friability in order to:

1. Withstand mechanical shock of handling in manufacture, packaging and shipping.
2. In addition the tablets should be able to withstand reasonable abuse when in the hands of consumer.

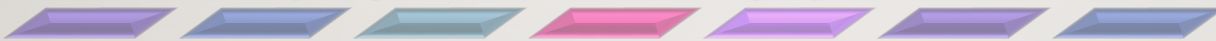
METHODS FOR HARDNESS MEASUREMENT

Unit of hardness is expressed in kg

Monsanto hardness tester (manual)



Pfizer tester (simple, low cost and rapid)



Erweka tester (electrical)



Dr. Schleuniger tester (electrical) –widely used because its fast and reproducible-





Monsanto Hardness tester



Pfizer Hardness tester

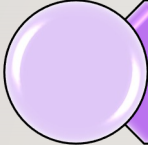
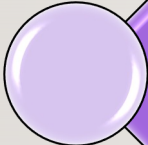
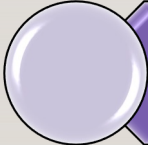


Erweka Hardness tester



Dr. Schleuniger Hardness tester

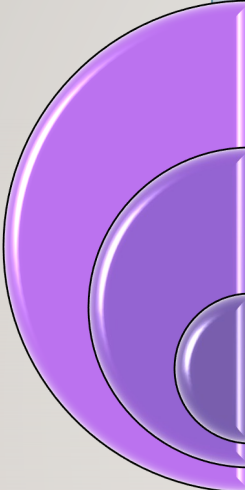
HARDNESS OF TAB LIKE ITS THICKNESS IS A FUNCTION OF:

-  (Die fill constant) then additional compression force result in more hardness and less thickness
-  (Compression force constant—fixed distance between upper and lower punches) then hardness increase with increase in die fill and decrease with lower die fill.
-  Quantity and quality of binder (good binder result in appropriate tab hardness and not hinder the release of drug from tab.).
-  Lubricant can affect tab hardness (if too high conc. or long time mixing)

HARDNESS OF DIFFERENT TYPES OF TABLET

- ❑ Ordinary tab. 4-8 kg
- ❑ Chewable tab. 3 kg to prevent harmful effect on teeth
- ❑ Lozenges (troches) and sustained release 10-20 kg

FACTORS AFFECTING FRIABILITY:

A decorative graphic on the left side of the slide, consisting of three concentric purple semi-circles of decreasing size, creating a tunnel-like effect.

Addition of large amount of fine powder to the formula.

Over drying of granules (moisture content).

Use of material that is not cohesive to the formula.

Note: Some chewable tabs. and most effervescent tab. undergo high friability loss so special stack packing that required for these types of tab.

LABORATORY FRIABILATOR TESTER:

1. **Roche friabilator**

(subject 20 tabs to the combined effect by utilizing a plastic chamber that revolves at 25RPM, dropping the tab. From a distance of 6 inches with each revolution, normally a pre-weigh tabs are placed in the friabilator which is then operated for 100 revolution (4min), the tabs are then dusted and reweighed, the friability (loss in weight) less than 0.5%-1% are acceptable).

$$W1 - W2 = W_{t. \text{ loss}}$$

$$\% \text{ of loss} = (W1 - W2) / W1 * 100\%$$

2. **Erweka friabilator** (contains plates and depends on tumbling).

:

WEIGHT VARIATION (Test Is Applied For Uncoated And Film Coated Tablets Containing 25 Mg Or More Of A Drug Substance Comprising 25% Or More, By Weight, Of The Dosage Unit).

Factors affecting wt. variation:

Segregation of the powder

Poor flow

Poor mixing

Variation in the adjustment of the upper and lower punch

Use of insufficient quantity of lubricant

