University of Tikrit
College of Pharmacy
Department of Pharmaceutics

Practical Industrial Pharmacy II

Lab 4

Evaluation of Tablets

Part 1

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The Quality Control Requirements of Different Pharmacopea

- **B.P:**
- Weight variation
- Content uniformity
- Disintegration test
- Labelling

- **USP:**
- Bulk density, Tapped density(powder flow)
- Disintegration
- Dissolution
- Friability
- Uniformity of dosage form
- Labelling of active ingredients

Official and Non-official Test

Tablets are evaluated by a variety of methods:

- **Official test**
- Weight variation
- Content uniformity
- Disintegration test
- Dissolution test

- **Non-official test**
- Hardness test
- Friability
- Thickness

Tablet Hardness Test

- Tablets must be hard enough to withstand mechanical stress during packaging, shipment, and handling by the patient.

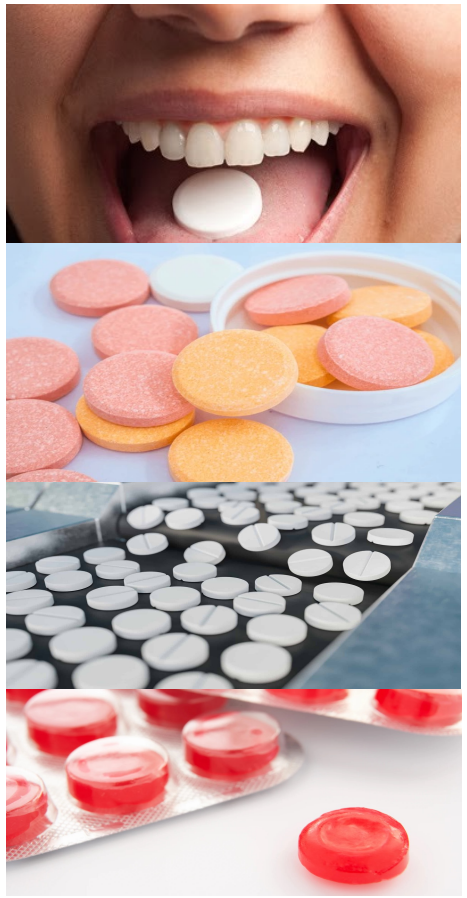
- The principle of hardness measurement involves subjecting the tablet to an increasing load until the tablet breaks or fractures. The load is applied along the radial axis of the tablet.

- Several terms were used to define hardness like: crushing strength (radial or axial), resistance of tablet for bending or breaking, resistance to cracking force, resistance to impact force and resistance to attrition and abrasion.

Tablet Hardness Test

The required hardness of the tablet depends on the desired site of disintegration as following:

- **For orodispersible tablet** (disintegrates in the oral cavity): the accepted hardness is usually below 3 kg.
- **For chewable tablet:** the accepted hardness is 3 kg.
- **For oral uncoated (ordinary) tablet** (disintegrates in the GIT): the accepted hardness is usually (4 – 8 or 10) kg.
- **For lozenges or sustained release tablet** (disintegrates slowly): the accepted hardness range is (10 – 20) kg.

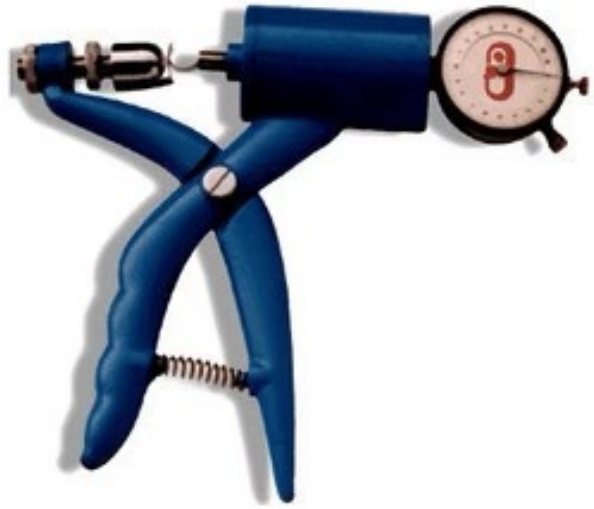


Tablet Hardness Test

Apparatuses used as hardness testers are:

- **Monsanto or Pfizer hardness tester**

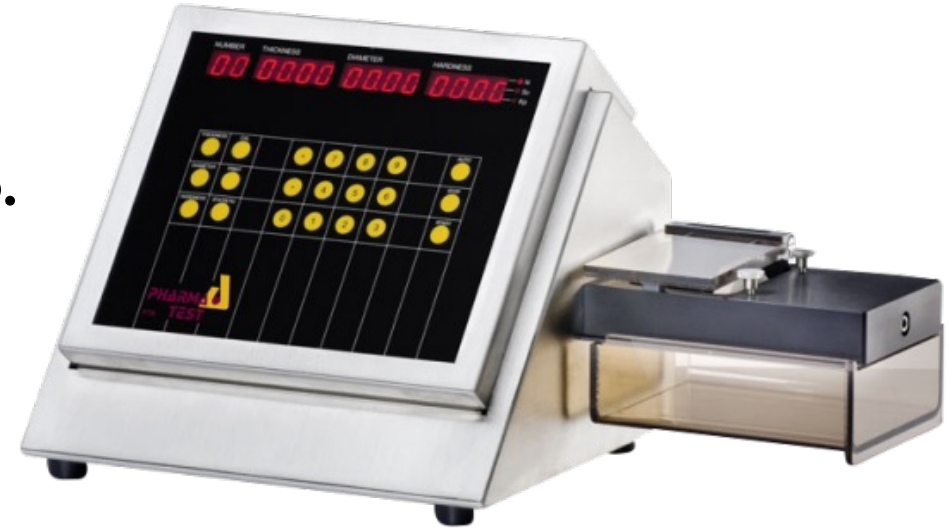
(manual hardness tester)



- **Erweka or Pharma test**

(electrical hardness tester)

- It's measure the thickness and diameter also.



What affects the tablet hardness?

- **The binder** (quality and quantity), in addition to other physicochemical properties of other contents.

Ex: Gelatin solution give tablets greater hardness than starch paste.

- **Compression force,** there is a direct relationship between hardness and log compression force.

↑ force of compression ⟶ ↑ hardness.

- **Amount of granules in the die at the moment of compression.**

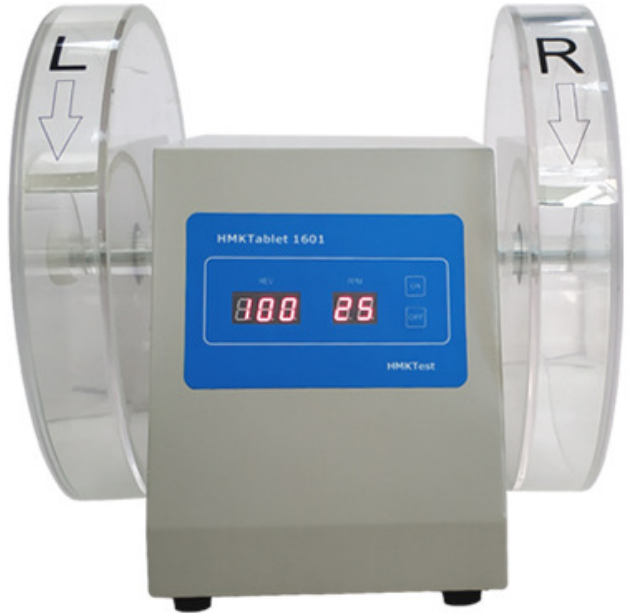
↑ amount ⟶ ↑ hardness.

- **Distance between lower and upper punches.**

↓ distance ⟶ ↑ hardness.

Friability Test

- This test is designed to measure the ability of the tablet to withstand handling and transportation.
- Sometimes we may get tablet of good hardness but it still friable.
- Certain amount of drug powder may be found at the bottom of drug container.
- Machine used to study the friability is **Friabilator** which has a plastic chamber that revolves at 25 rpm.



Friability Test

- Friability is expressed as a the percentage loss in tablets weight.
- **Factors affecting tablet friability:**

➢ **Adhesiveness and cohesiveness** of the binder or any other constituent.

- Bad adhesiveness or cohesiveness ⟶ friable tablets.

➢**Moisture** (H_2O is an adhesive agent).

- So, over drying ⟶ water loss ⟶ friable tablets.

➢**Addition of large quantity of fine powder (lubricant)** to the granules before compression ⟶ friable tablets.

Weight Variation Test

- The total weight of a tablet is determined by the depth of the die cavity, the bulk density of granules or powder, and the uniformity of particulate flow.

- Tablets are required to meet a weight variation test where the active ingredient comprises a major portion of the tablet and where control of weight may be presumed to be an adequate control of drug content uniformity.

Weight Variation Test

- **Factors affecting weight variation test:**

- **Flow rate,** (size distribution in the die). If the amount of granules or powder reach the die from time to time is not constant ⟶ weight variation.
- **Amount of lubricant added also affect weight variation.**

- **The difference in the length of the lower punches** (as in rotating tablet machine).

Content Uniformity Test

- Weight variation is not a adequate indication of content uniformity where the drug substance comprises a relatively minor portion of the tablet, or where the tablet is sugar-coated.

- Thus, the Pharmacopoeias generally require that coated tablets and tablets containing 50 mg or less of active ingredient, comprising less than 50 % by weight of the tablet, pass a content uniformity test.

- In the content uniformity test, individual tablets are assayed for actual drug content.
- Each drug formulation has its own accepted content uniformity test.

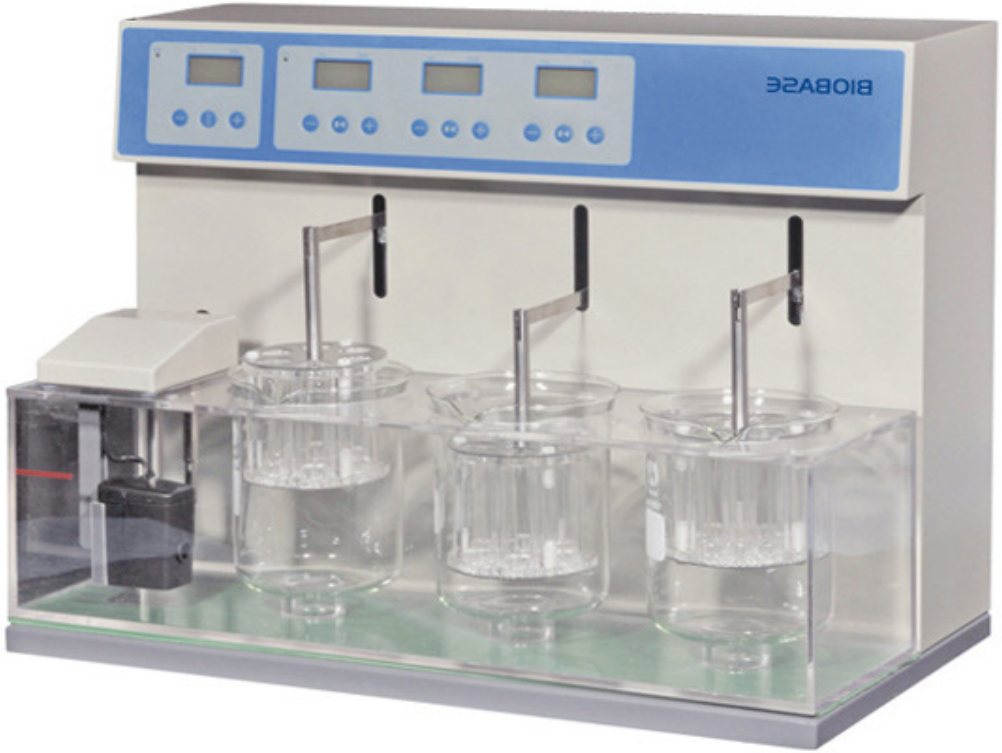
Disintegration Time Test

- Except for chewable and some extended release tablets, disintegration is an essential attribute of oral tablets.
- **Disintegration is the time required for a tablet to rupture into small non palpable particles.**
- It does not imply complete solution of the tablet or even its active constituents.
- The accepted disintegration time for each formulation is stated in their individual monograph.
- For medications with poor water solubility, the results of dissolution test will be more acceptable.

The USP disintegration test apparatus:

- Uses different numbers of glass tubes that are 3 inches long, open at the top.
- The bottom end of the basket rack assembly is covered with a 10 mesh screen (2 mm opening).

- The basket rack is immersed in a suitable liquid in a 1 liter beaker and the basket moves up and down about 30 strokes/ min.
- The temperature is adjusted at (37 ± 2) °C.
- The disintegration media could be water, buffer or artificial (simulated) gastric juice which has a pH = 1.2.



Factors affecting tablet disintegration time:

- **Contents**, especially quantity and quality of disintegrant and binder.
- **Hardness**, amount of binder and the compressing force.

- According to the USP, the accepted disintegration time is for an uncoated tablet is (5 – 30) minutes.
- According to BP, disintegration time for uncoated tablet should be not more than 15 minutes.
- For coated tablets, it could take more than 2 hours.

Thank You