

Evaluation of Tablets; Physical Standards including Disintegration and Dissolution

Ms. Shubhashree Das

Assistant Professor

School of Pharmacy and Life Sciences

Centurion University of Technology and Management

shubhashree.das@cutm.ac.in

EVALUATION TESTS FOR TABLETS

1. Shape of tablets
2. Appearance
3. Content of active ingredient in tablets
4. Uniformity of weight
5. Disintegration test for tablets
6. Dissolution test for tablets
7. Mechanical strength
8. Friability test

Cont..

- **SHAPE OF TABLETS** : As per pharmacopoeia the shape of a tablet defined as circular with flat or convex face.
- **APPEARANCE** : check the appearance by either a relatively uniform texture. The coated tablets have a smooth surface.
- **CONTENT OF ACTIVE INGREDIENT IN TABLETS** : % of API in case of official tablets are mentioned in the individual monographs. The variation may be due to several factors such as weight, purity of API, errors in preparing granules. In that process carried out assay which are mentioned in IP for specific tablets & those are based on 20 tablets. If 20 tablets are not available at least 5 tablets should be used.

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% of API in tablets .This table stated limits are between 90% & 110% of medicaments.

Wt. of drug in each tablet	Subtract from the lower limits for sample of			Add to the upper limits for sample of		
	15	10	05	15	10	05
120 mg or less	0.2	0.7	1.6	0.3	0.8	1.8
More than 120 mg & less than 300 mg	0.2	0.5	1.2	0.3	0.6	1.5
More than 250 mg	0.1	0.2	0.8	0.2	0.4	1.0

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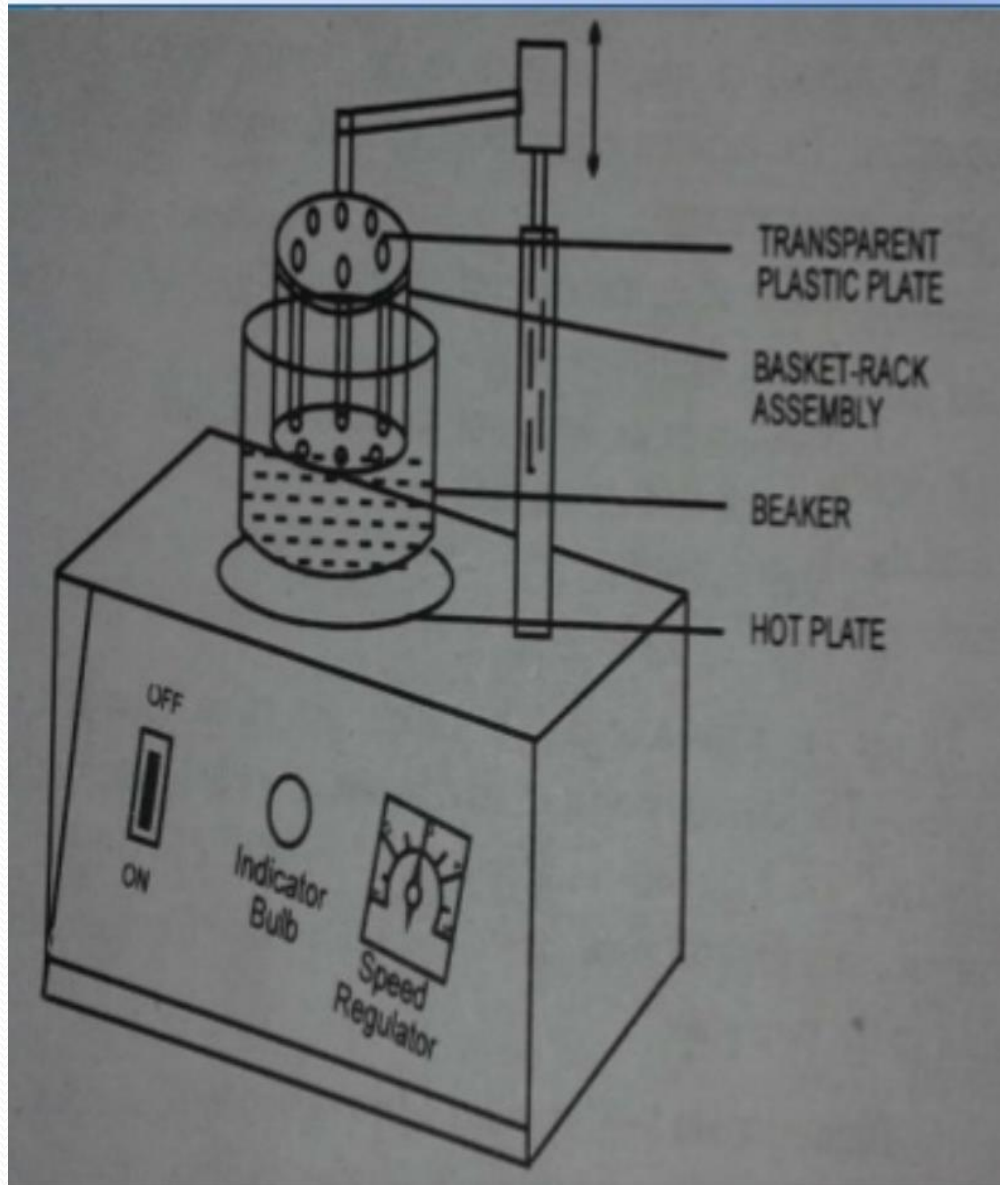
- **UNIFORMITY OF WEIGHT** : This test is used to determine the uniformity of weight of each tablet in a batch. But small variation in the weight of the individual tablet is liable to occur. Therefore a limited variation is allowed in the weight of a tablet by the pharmacopoeia.
- **wt. of 20 tablets selected randomly & determine their average weight.**
- **Not more than 2 of the individual weight may deviate from the average wt. by more than the % deviation.**

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Uniformity weight of tablets

Sr.No.	Average weight of a tablet deviation	Percentage
1.	80 mg or less	10
2.	More than 80 mg & less than 250 mg	7.5
3.	250 mg or more	5

DISINTEGRATION TEST FOR TABLETS



DISINTEGRATION TEST FOR TABLETS

- Tablet disintegration test apparatus use for compressed tablets but not use for lozenges tablets.
- Pharmacopoeia specified limit for 15 mint.
- The assembly should be raised & lowered betw. 28 to 32 times per minute in the liquid at 37°C.
- The tablets are kept immersed in the liquid within tube.
- A cylindrical disc is made of transparent plastic having thickness of 9.5 mm & diameter of 20.7 mm.
- The assembly is suspended in the liquid medium in a 1000ml beaker.

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• DISINTEGRATION METHOD FOR UNCOATED TABLETS:

- ✓ Place one tablet in each of the 6 tubes of the basket.
- ✓ Then maintained temp. of water at 37°C .
- ✓ After completion of 15 mins or the specified time in the individual monograph.
- ✓ Observe the tablets .
- ✓ If, one or two tablets are not disintegrate then again repeat the test on 12 additional tablets & observe the tablets .
- ✓ The tablets passes the test if not less than 16 of the 18 tablets tested get disintegrated.

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• DISINTEGRATION METHOD FOR COATED TABLETS:

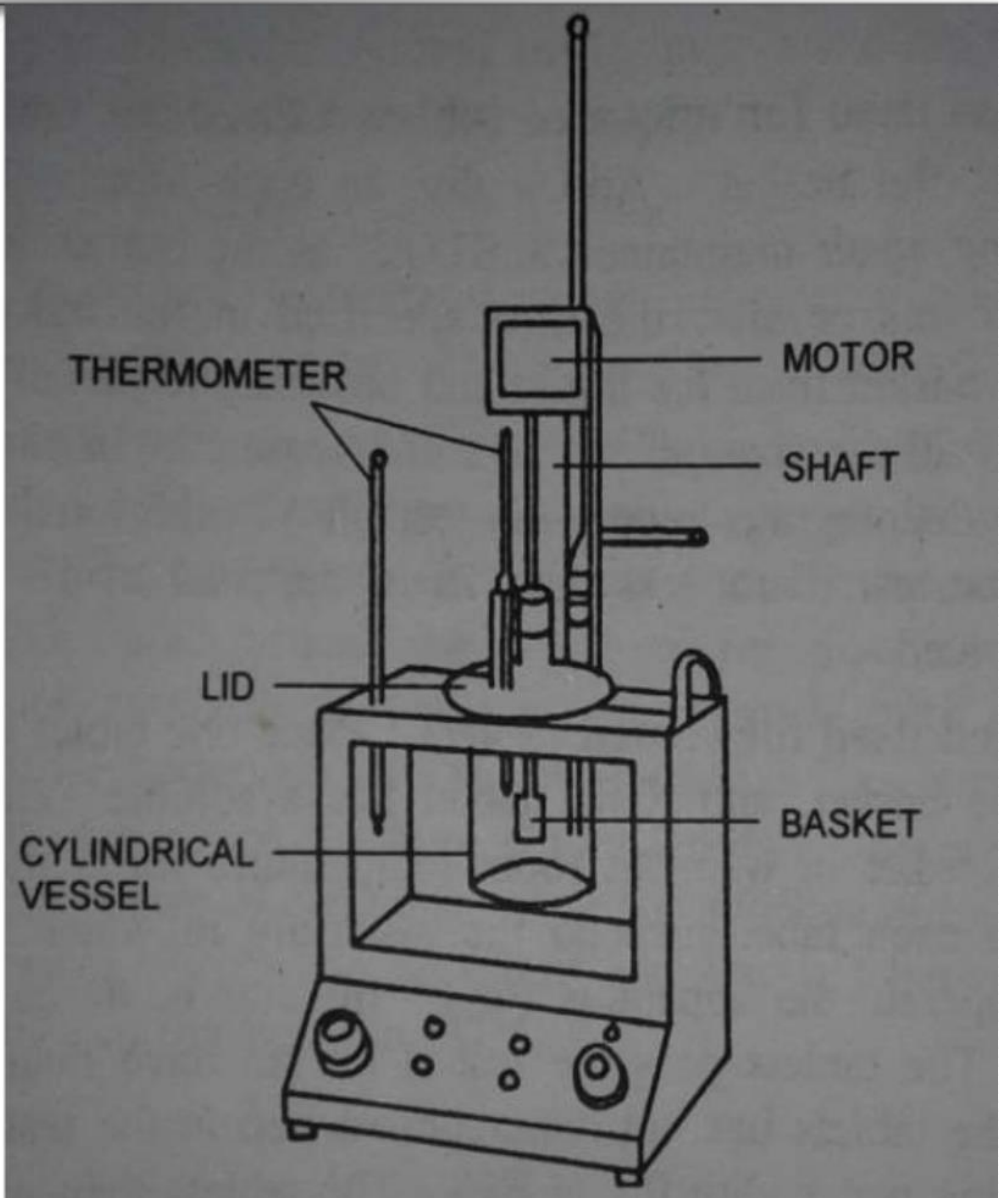
- Place one tablet in each of the 6 tubes of the basket.
- If the tablet has a soluble external coating, immerse the basket in water at room temp. for 5 mint.
- Then add disc to each tube & suspend the assembly in water at temp. 37°C . & operate for 60 mint. or as per monograph.
- If any case tablet has not disintegrate then replace the water with 0.1 N HCl & again add 6 tablets.
- The test is repeated on 12 additional tablets if one or two tablets still to fail disintegrate.
- The tablets passes the test if not less than 16 of the 18 tablets tested get disintegrated.

Cont..

● DISINTEGRATION METHOD FOR ENTERIC-COATED TABLETS:

- ✓ Place one tablet in each of the 6 tubes of the basket.
- ✓ If the tablet has a soluble external coating, immerse the basket in water at room temp. for 5 mint.
- ✓ Then operate apparatus without disc in 0.1N HCl for two hours at 37°C.
- ✓ If no any tablet show to disintegrate or crack then add a disc & operate the apparatus using phosphate buffer pH 6.8 at 37°C. For 60 mints.
- ✓ Then observe the tablets.
- ✓ The test is repeated on 12 additional tablets if one or two tablets still to fail disintegrate.
- ✓ The tablets passes the test if not less than 16 of the 18 tablets tested get disintegrated.

DISSOLUTION TEST FOR TABLETS



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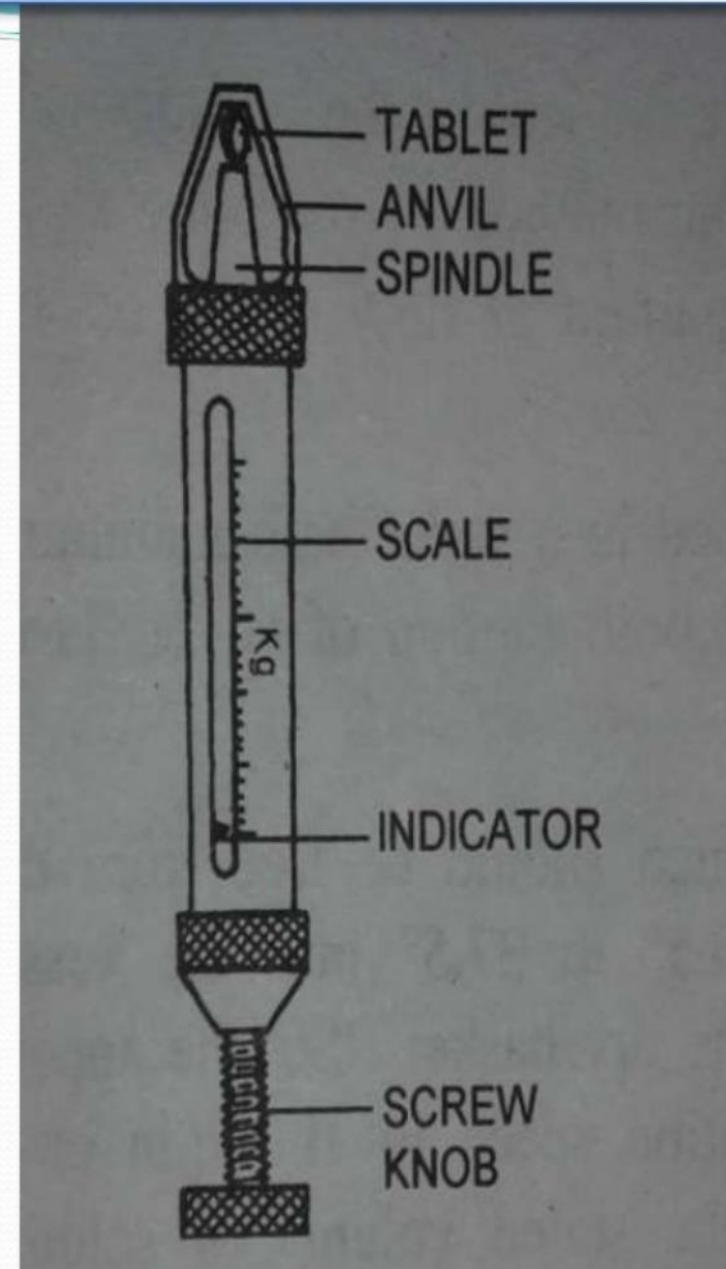
- Place the 1000ml water or specific solvent mentioned in the monograph into the vessel & those solvent which was previously warmed at 36.5 or 37.5°C.
- Place the specified number of tablets in the dry basket.
- Then start the motor & adjust the rotation speed to 100 rpm or as per monograph.
- Withdraw the stated volume of solution from the vessel after 45 mins or as per monograph.
- Then determine the active ingredient present in the solution by the method given in the monograph.
- Repeat the complete operation 4 times.
- The tablet pass the test if the amount of active ingredient in solution is not less than 70% of the stated amount.

MECHANICAL STRENGTH

- The pharmacopoeia has not fixed any standards for the mechanical strength or hardness of tablets.
- The following devices are commonly used by manufacturers
 - Monsanto hardness tester
 - Pfizer tablet hardness tester

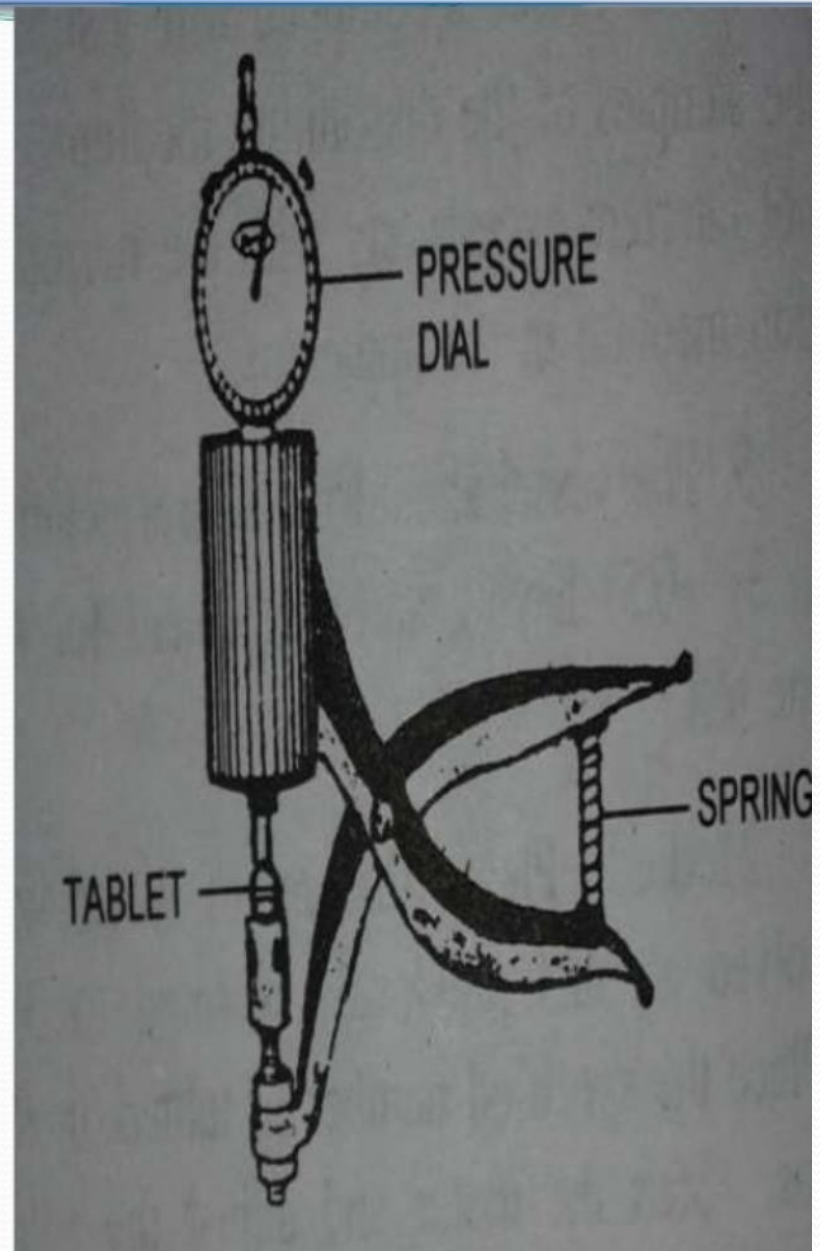
MONSANTO HARDNESS TESTER

- Designed by Monsanto chemicals Co. Ltd.
- The reading unit Kg/Sq cm.
- Tested tablet placed in between spindle & anvil.
- Then adjust to zero reading.
- Then apply the pressure as clockwise till the tablet break.
- Then noted the reading.
- That reading indicates the pressure which is needed to break the tablet.

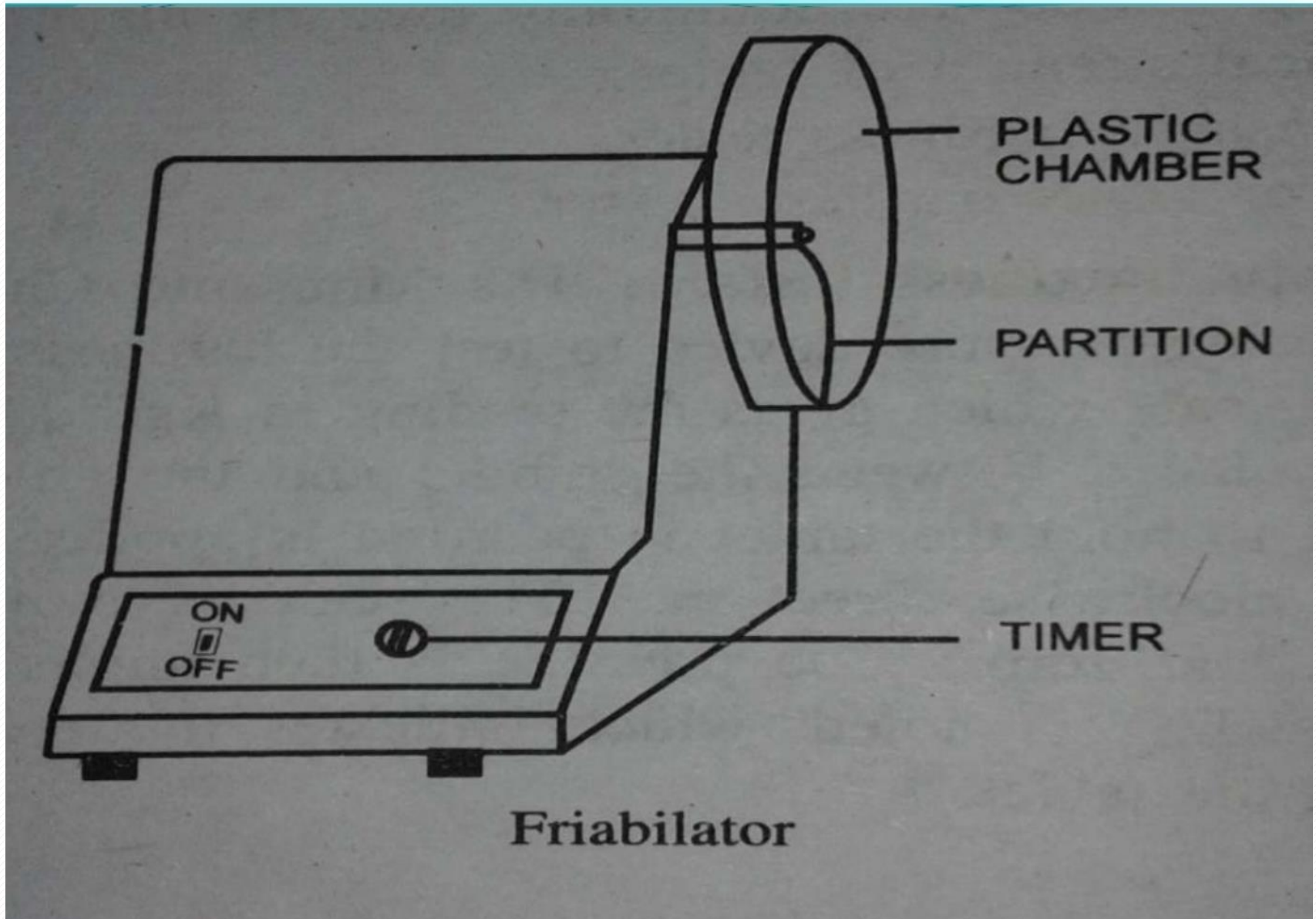


PFIZER TABLET HARDNESS TESTER

- It is based on principle of plier.
- This tester is a plier fitted with a pressure dial.
- The tablet is placed between the jaw of the plier & pressure is applied by pressing the handle with hand unit until the tablet breaks.
- The reading of the dial indicates the pressure needed to break the tablet.



FRIABILITY TEST



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- Friability test is performed to evaluate the ability of the tablet to withstand wear and tear in packing, handling and transporting.
- This apparatus consist of a plastic chamber, which is divided into two parts & it revolves at a speed of 25 rpm.
- 20 tablets are weighed & placed in the plastic chamber.
- The chamber is rotated for 4 mint or 100 revolutions.
- During each revolution the tablet falls from a distance of 6 inch.
- The tablets are removed for the chamber after 100 revolutions & weighed.
- Loss in weight indicates the friability.
- The tablet are considered to be good quality if the loss in weight is less than 0.8%.



Thank you!