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محتوى المحاضرة

Every pharmaceutical dosage form preparation and production faces different possible errors and mistakes, these errors may occur during preparation of formulations, techniques… etc.

In order to ensure a proper dosage form, that give the pharmaceutical companies their qualifications and competence, a number of evaluation tests are carried out, including those for tablet dosage forms.

Evaluation of tablets:

General appearance (size, shape, color, odor, taste)

Hardness

Friability

Weight variation

Content uniformity

Disintegration

Dissolution

Hardness:

Every tablet must possess certain degree of hardness to resist mechanical shocks during handling, packaging, and shipping.

It is also known as “tablet crushing strength.”

In this test the tablet is placed between two anvils, force is applied to the anvils, and the crushing strength that just causes the tablet to break is recorded.

Some examples of hardness testers:

Monsanto Tester

Pfizer Tester

Erweka Tester

Hardness for a compressed tablet is 5 to 8 kg.

Friability:

The hardness test may not be the best measure of potential tablet behavior during handling and packaging.
The resistance to surface abrasion may be a more relevant parameter.

The friability tester is called Roche friabilator.

Roche friabilator consists of a plastic chamber that revolves at 25 rpm, dropping the tablets through a Distance of six inches in the friabilator, which is then operated for 100 revolutions.

Tablets are weighed before and after this procedure, the compressed tablets that lose less than 0.5 to 1.0 % of the tablet weight are considered acceptable.

Weight variation:

The proper weight of the tablet ensures proper amount of the drug in each tablet.

Take 20 tablets and weighed individually.

Calculate average weight and compare the individual tablet weight to the average.

The tablet passes the U.S.P. test if no more than 2 tablets are outside the percentage limit and if no tablet differs by more than 2 times the percentage limit.

Average weight (mg)	Maximum difference allowed (%)
Less than 130	10%
130-324	7.5%
More than 324	5%

Content uniformity:

It is used to confirm the proper amount of active ingredient in each tablet.

This test is applicable to tablets that contain less than 10 mg or less than 10% w/w of the active ingredient.

Disintegration test:

The U.S.P. device to test disintegration uses 6 glass tubes; open at the top and 10 mesh screen at the bottom end.

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±20C. Move the basket containing the tablets up and down through a distance of 5-6 cm at a frequency of 28 to 32 cycles per minute.

According to the test the tablet must disintegrate and all particles must pass through the 10 mesh screen in the time specified.

uncoated tablet: 5-30 min
Coated tablets: 1-2 hours

Dissolution test:

Dissolution means the amount of the drug that goes into solution per unit time under standard conditions.

This test is done by using "dissolution apparatus", the principle of this apparatus depends on immersion of tablet dosage form in dissolution

medium and stirring with variable speed motor at temperature 37±0.5ºC, then samples withdrawn at certain time intervals.