1. **Tablet thickness:**

* The thickness of individual tablets may be measured with a micrometer.
* Thickness should be controlled within ± 5% variation of a standard value.
* Thickness must be controlled for consumer acceptance of the product, and to facilitate packaging.

1. **HARDNESS (CRUSHING STRENGTH):**

Carry out the test on the batch of tablets provided using Erweka hardness tester. Calculate the mean crushing strength of 10 tablets (taken randomly).

N.B., a crushing strength of **4-8 Kg** for uncoated tablets is acceptable

1. **friability test:**

**Method:**

1. Select 20 tablets randomly, dedust and weigh (WO).
2. Place the tablets in the Roche friabilator drum, switch on the apparatus adjusting the timer at 4 min. and the speed at 25 rpm.
3. At the end of this operation, remove the tablets from the friabilator, dedust and reweigh (W). (Any tablet that breaks up should be rejected before reweighing).
4. friability is expressed as a percentage loss in weight: i.e.,

***% loss = ***

**N.B.,** if the value of friability (% loss) is less than or equal to 1%, the batch is accepted.

1. **DISINTEGRATION TEST:**

**Method:**

1. Place one tablet in each of the six tubes of the basket (tablets are selected randomly).
2. Position the basket rack in 1- L beaker containing distilled water (as the disintegration medium) maintained at 37 oC.
3. Start the apparatus (to move the basket assembly containing the tablets), and record the time required for all of the six tablets to break into particles and to pass to the disintegration medium.

**Limit:**

* + The tablets should disintegrate within 30 minutes (uncoated tablets).
  + If one tablet fails to disintegrate within 30 minutes, the disintegration test is repeated on 12 additional tablets. Not less than 16 out oh the total 18 tablets tested disintegrate completely within 30 minutes.

1. **WEIGHT VARIATION TEST:**

**Method:**

1. Select 20 tablets randomly from the batch provided, then weigh the tablets individually.
2. Weigh the 20 tablets together and calculate the average weight (W).
3. Compare the average weight calculated to the previous table to determine the maximum % difference allowed.
4. calculate the upper and lower limits at the % difference allowed:

Upper limit = W + [(%/100) (W)]

Lower limit = W – [(%/100) (W)]

1. Furthermore, calculate the upper and lower limits at double the % difference allowed:

Upper limit = W + [(2x %/100) (W)]

Lower limit = W – [(2x % /100) (W)]

1. Compare the individual weights of tablets to the upper and lower limits calculated at the % difference allowed and at double that percentage.
2. Comment on the results.

**Limit:**

For the batch to be accepted:

1. Not more than 2 tablets (out of the 20 tablets) differ from the average weight by the % difference listed, and
2. No tablet differs from the average weight by double that percentage.
3. ***Table: Weight variation tolerances for uncoated tablets:***

|  |  |
| --- | --- |
| Average weight of tablets (mg) | Maximum % difference allowed |
| 130 or less | ± 10 |
| 130 – 324 | ± 7.5 |
| More than 324 | ± 5 |