Tablet Manufacture Cheat Sheet

by MJC3 via cheatography.com/212269/cs/46151/

The Hardness Test (Manual Tester)

1.The tablet is placed between the jaws (across its diameter), so that it is just held in place.

2.The scale is then adjusted until it reads zero.

3. The screw is then turned until the tablet breaks.

4. The breaking force is then read off the scale to one decimal place.

With this equipment, the value shown on the scale needs to be multiplied by 9.81 in order to convert it into Newtons.
One **advantage** of the manual tester is that it is obvious when the tablet has broken.

Dissolution

6 tablets from each batch are tested.

To pass the test all tablets should have more than 75% of their API dissolved within 45 minutes.

The Hardness Test (Electronic Tester)

1.The tablet is placed between the two plates

2.The machine is zeroed and the screw is turned.

3.The tablet doesn't break in quite such a spectacular way as the manual tester but cracks in two.

4. If you listen carefully then you can hear the tablet break.

The electronic display shows the breaking force in Newtons so no need for conversion.
The BP doesn't give limits for the Hardness test. These are set by the tablet manufacturers and they depend upon factors such as how hard the tablets need to be in order to withstand the company's automated packaging equipment.
Typical values would be:
Mean Breaking Force > 60.0 N
Standard Deviation < 5.0 N
Both of these criteria would need to be met in order to pass the test.

Friability

1.Take 20 tablets, put them on a sieve and clean any powders or particles from their surface using a brush.

2.Weigh the 20 Tablets collectively and record the total weight.

3.Place the tablets inside the drum of the friability tester device, close and put in place and run (the run is set to 100 cycles).

4.At the end of the run, weigh the tablets collectively again.

5.Calculate the total weight loss as percentage of the initial weight.

✓If the weight loss is **less than 1%** the tablets pass the test.
✗If the weight loss is **more than 1% or there are any cracked or broken tablets** the test fails.
✗If the test failed, it must be repeated again, if it failed the 2nd time its reported as fail.
✓If it passed the 2nd time, it has to be repeated one more time to decide if it's a pass or fail.

Uniformity of Mass

1. Weigh 20 tablets individually. Record the weight of each tablet precisely (4 decimal points).

2.Calculate the mean (average) weight of the 20 tablets.

3. The tablets should be within the following weight range:	Mean -5% < weight of the tablet< Mean + 5%

Criteria for passing the test:
No more than 2 tablets are outside this range
No tablet is more than 10% different from the mean.
Both of these criteria must be met for passing the test.

Disintegration

6 tablets from each batch are tested.

If all tablets disintegrate within 15 minutes the batch passes.

By **MJC3**
cheatography.com/mjc3/

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