Some Information on Tablet Hardness Testing

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This article gives some background information on tablet hardness testing, it's history, the methods used and points to look out for when comparing specifications.

History [1,2]

The first tablet hardness tester was introduced around the mid-1930s. This was a purely mechanical device and is still manufactured today. Force was applied with a screw thread and spring until the tablet fractured and the hardness was read from a sliding scale graduated in ½ kg increments. This was followed by the so-called Strong-Cobb tester, introduced around 1950. The testing force was generated by a manually operated air pump and the tablet breaking force was measured on a dial graduated in 30 arbitrary units which were designated as Strong-Cobbs. The results given by the Strong-Cobb tester were not consistent with those of the earlier tester.

Electro-mechanical tablet hardness testing machines were later introduced and have evolved into electronic test instruments such as those produced by Engineering Systems, for example the C53, shown on the right. These contain a motor drive system to generate the force and electronics to automate the test procedure, automatically detecting tablet fracture and displaying the force in a variety of units. Measurements can be printed and / or downloaded to a computer.

Why test?

Too 'soft' tablets can disintegrate in transport. Too 'hard' tablets could damage teeth. An acceptable 'hardness' is required and tablet strength testing is necessary for both, research & development of new formulations, and for quality control. The test instruments should provide accurate results and output these results in standard units. Ideally, results obtained from different manufacturer's instruments should correspond.

Tablet hardness vs. 'true' hardness

Historically, the term hardness has been used to describe tablet strength, however this is not strictly correct.
Normally, material hardness (for metals) is measured using an indentation test, such as the Vickers Hardness Test. This method is not suitable for tablet testing because tablets are relatively brittle.
When tablet hardness is referred to, it actually means - the compressive strength of the tablet.

Definition of terms

A number of terms are used in the specification of tablet hardness testers and care must be taken when making comparisons. Some commonly used terms are:

- **Resolution** – defined as 'the difference between two discrete values that can be distinguished by a measuring device' and is given by the last decimal place figure which the machine produces. For a 50 kg testing machine this might be 0.01 kg (0.1 Newtons). However, high resolution does not necessarily mean high accuracy.
- **Accuracy** – This should not be confused with resolution. Accuracy is defined as 'the degree of conformity of a measured or calculated value to its actual or specified value',

for example how close is the result given by the machine to the true breaking strength? The result could be affected by various factors:
How does the dynamic performance of the machine compare to its static calibration? i.e. does the electronic circuitry respond quickly enough to capture the true peak reading? In a perfect situation, Accuracy would be equal to Resolution.

- **Linearity** – mathematically defined as (Maximum deviation of indicated load from applied load / Maximum applied load) X 100 and expressed as a percentage. A good testing machine will have a linearity of 0.1% or better.
- **Results** – can be affected by:
  Speed of testing, geometry of the 'tablet contact points', debris in the testing area, variation in temperature, humidity, tablet age, etc.

Strength Testing Machines will never measure *accurately* to 1:50,000 but should be able to do better than 1:500 full scale reading.

Measurement units [3,4]

Most materials testing is performed using the International System of Units (SI – from Le Système International d'Unités). The Newton is the preferred unit of force as is recognised by the SI system. However the kilogram can also be used.

- **Kilogram (kg)** – The kilogramme is recognised by the SI system as the primary unit of mass.
- **Newton (N)** – The Newton is the SI unit of force and is the unit that should be used for tablet hardness testing. 9.807 Newtons = 1 kilogram.
- **Pound (lb)** – Technically a unit of mass but can also be used for force and should be written as pound force or lbf in this case. Sometimes used for tablet strength testing in North America, but it is not an SI unit. 1 kilogram = 2.204 pounds.

Some obsolete units that should no longer be used, include:

- **Kilopond (kp)** – Not to be confused with a pound. A unit of force also called a kilogram of force. Still used today in some applications, but not recognised by the SI system, making it a bad choice for modern applications. 1 kilopond = 1 kgf.
- **Strong-Cobb (SC)** – The Strong-Cobb is a legacy of the first tablet hardness testing machines (see history), it is an arbitrary unit, never recognised by the SI system. 1.4 Strong-Cobs are thought to equal about 1 kg, although this conversion factor has no scientific definition.

Test methods [5]

The standard method used for tablet hardness testing is compression testing. The tablet is placed between two jaws that crush the tablet. The machine measures the force applied to the tablet and detects when it fractures. This method is used for research & development and for quality control.
Although compressive force is applied to the tablet, tablets usually fail in a tensile manner, along the diameter of the tablet at right angles to the applied force.

Test speed

Usually, materials strength testing machines operate at constant speed. However, two methods of tablet 'hardness' testing exist, constant speed and constant force.
Constant speed testing crushes the tablet at a constant rate, the test speed being maintained electronically throughout the test by motor feedback. This is the normal method for strength testing equipment.

Constant force testing was a legacy of one of the earlier tablet testing machine designs and has been adopted by some areas within the pharmaceutical industry. The testing speed will vary throughout the test as the machine strives to apply a constant rate of force increase.

Changing the speed, especially during testing, can give varying results. Constant speed testing almost certainly gives the more consistent results.

Other test methods

3-point bend testing can be used for larger tablets i.e. washing machine tablets.
It can also be useful for research & development purposes to determine the mechanical properties of new formulations, e.g. Youngs Modulus and tensile strength. For this is it necessary to produce small rectangular beams of the new formulation.

Calibration of testing machines [6]

All items of measuring equipment require periodic calibration to ensure they remain accurate. The most accurate calibration method, for force testing machines, is by static dead weight loading. The American Society for Testing of Materials (ASTM) designation E4-07 refers to the calibration of testing machines. It suggests that calibration should be carried out with at least five different loads across the machine's full range. Calibration should be carried out at least annually, and the calibration weights themselves should be certified every five years.

Summary

Ideally, all the different varieties of testing machines would give the same results (if used on the same batch of tablets)
Machine 'accuracy' would equal Machine 'resolution'.
All pharmaceutical companies would use the same SI unit of measurement (N or kg) and the same constant (6 mm/min) test speed.
Machine calibration would be carried out with dead weights at 6 monthly intervals.

Sources

1. Remingtons Pharmaceutical Sciences. 18th ed. 1990. page 1639
   Gives a short history of Tablet Testing techniques.
2. K. Ridgway, The Pharmaceutical Journal, December 26,1970
   'Aspects of pharmaceutical engineering'. Short history and brief theory of tablet testing.
3. Russ Rowlett, 'How Many? A dictionary of units and measurements'
   http://www.unc.edu/~rowlett/units/index.html
4. The International System of Units (SI)
   Bureau International des Poids et Mesures
   http://www.bipm.fr/enus/3_SI/
5. J.E. Rees & P. J. Rue, 'Work Required to Cause Failure of Tablets in Diametrical Compression'
   Aston University, Birmingham, UK
   Drug Development & Industrial Pharmacy. 4(2) 131-156 (1978)
6. American Society for the Testing of Materials (ASTM), Designation: E4–07, 'Standard Practices for Force Verification of Testing Machines'.
   http://www.astm.org/

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