Charles Ischi AG
TESTING TECHNOLOGY

Press Release

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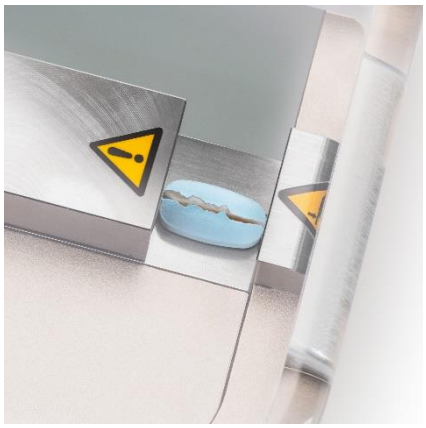
Tablet breaking force testing – constant force vs constant speed



Zuchwil, Switzerland: Charles Ischi AG - Testing Technology has issued new recommendations on one of the most debated topics in the tablet testing arena: which method is superior for assessing tablet hardness and tablet breaking force, constant speed or constant force?

Tablet breaking force testing is essential to ensure tablets are sufficiently robust to survive all manufacturing, shipping, and handling processes and has a big influence on the disintegration / dissolution time for release of the active ingredient.

Constant force vs. constant speed

Tablet testers use constant speed or constant force measurement to assess tablet breaking force. Some testers offer a choice of both methods. However, a surprising proportion of users do not appreciate the essential differences between the two methods and why they return such disparate results.

- **Constant force** involves moving the hardness tester jaw into light contact with the sample (tablet) and then increasing pressure in linear increments of 20 to 250N per second until it breaks. The correlation of time and force is the measurement that is then recorded as 'hardness' or 'breaking force'.
- **Constant speed** involves moving the test jaw into contact with the sample (tablet) and then applying the pressure to the tablet with a constant speed of 0.35 to 3.5mm per second until it breaks. The time taken to break the tablet and speed used provides the measurement of hardness.

Charles Ischi AG - OSD Testing Technology
Langfelstrasse 26 | 4528 Zuchwil | Switzerland
+41 32 621 49 23 | info@ischi.ch | www.ischi.com

Constant confusion

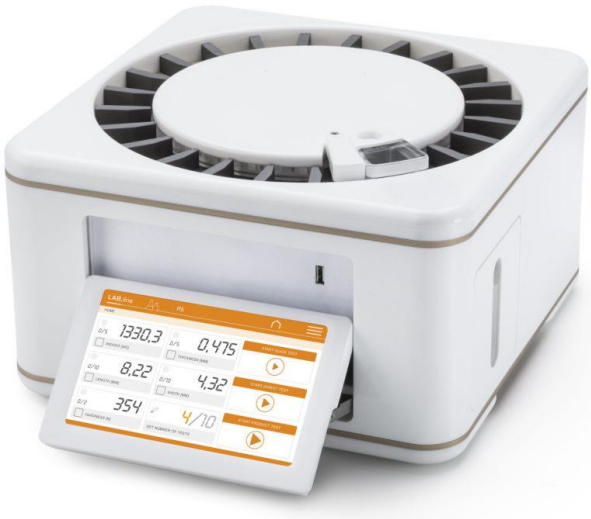
Both constant force and constant speed tests are recognized under compliance guidelines and international pharmacopeia such as USP <1217> as valid hardness testing methods. However, the different measurement results obtained from the two methods can lead to some confusion.

Latest generation testers supplied by Charles Ischi support both constant force and constant speed testing. Constant force results are in some cases higher and show a wider range, while constant speed measurements showing lower breaking force results within a much smaller range. Therefore, constant speed testing is considered to deliver more accurate results.

But variations are also found within the constant speed method. There are usually caused by significant differences in speed applied during the test.

Some testers move at high speed of 1.0-3.5mm per second along the jaw's travel from rest to tablet surface in a repeated 'hammering' movement into the tablet and cause a high impact breakage of the sample, resulting in higher values and more variation. Testers supplied by Charles Ischi are set to an ideal minimum speed of 0.35mm by default, providing a consistent and accurate tablet breaking force test.

There are many different reasons (dependent and independent from the tester) for seeing variations in testing results. The choice of the right measurement mode is one important step for reliable results.



P-Series Semi-Automated Tablet Testers support both constant speed and constant force testing

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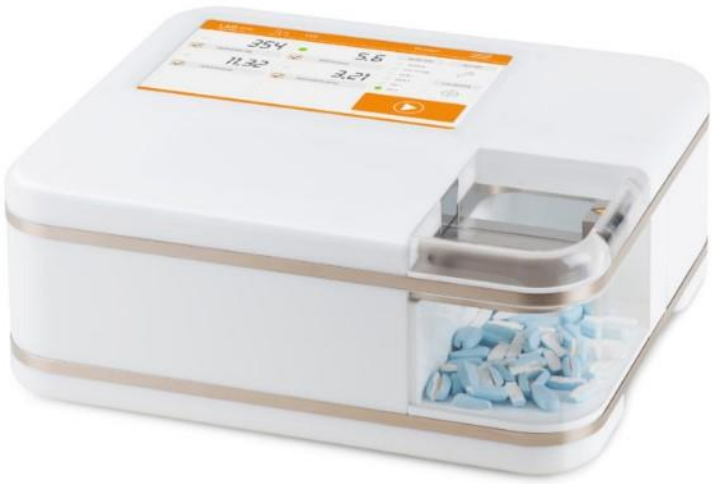
Hardness testing safeguards

Charles Ischi recommends a few basic safeguards in tablet hardness testing.

- The first is internal consistency in which method is adopted by a tablet maker or tester. Testing laboratories should not 'mix and match' but rather adopt one method and stick with it.
- To ensure uniformity, it is essential to use only stepper-motor driven hardness testers
- The majority of tablet breaking force testers used worldwide in tablet production work with constant speed at 0.35mm per second. These universal automatic tablet testing systems are usually connected to tablet presses and have become a standard platform for tableting processes. It is recommended to stick with the same method and speed for tablet break force testing.
- Finally, tablet positioning is particularly important with tablets best placed by hand or automatically between a pressing and a fixed jaw. Latest USP <1217> revisions emphasize tablet orientation and crushing surfaces that should be smooth polished and act perpendicular to tablet supporting surface to ensure uniform contact with tablet sides from top to bottom.



H-Series Advanced tablet hardness testers supports both constant speed and constant force testing

About Charles Ischi

Charles Ischi AG – Testing Technology are a Swiss-based specialist manufacturer of testing equipment for tablets and capsules and in-process control solutions for the pharmaceutical and nutraceutical industry. Supplying testing equipment, specializing

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in oral solid dosage testing technology for research, development, quality control and in-process control.

From its headquarters in Zuchwil, in the central Swiss canton of Solothurn in the heart of Europe, the company maintains an international sales and service network for Kraemer Elektronik tablet and capsule testing equipment and Charles Ischi solutions, which include a revolutionary In-Process Control (IPC) turnkey add-on solution that can upgrade in-process control tablet testing procedures in-line to all makes and model of tablet press and capsule filling machinery.

Charles Ischi has grown and developed over more than two decades by maintaining a rigorous focus on driving new technology introduction and customized solution to ensure customer satisfaction, excellent sales advice and after sales service support.

The company's key strength is a committed sales force providing support through its international sales network, with individual customer care, support for installation and qualification, training, service and repair.

Its product focus is on tablet breaking force testers, multiparameter tablet testing systems, capsule weighing systems, disintegration testers and friability testers.

Further information at: www.ischi.com

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