

Put it to the test

Charles Ischi, born in 1960, started out as an electronic engineer before starting his own business in 1992. Around that time he met Mr. Norbert Kraemer, an innovative German mechanical engineer who invented the first automatic tablet testing system for auto-regulation at tablet presses. By coincidence, Mr. Kraemer was looking for somebody to manage the sales of his products.

Today, Kraemer Elektronik is managed by the second generation and next year Kraemer&Ischi will celebrate 25 years of this close relationship.

EPM talks to Charles Ischi about the best approach to selecting testing equipment for oral solid dosage applications.



Q: What are the key things manufacturers should consider when selecting testing equipment for oral solid dosage applications?

A: The key thing is to ask yourself “what is the best tester functionality for this application?” At that point, factor in things like efficiency, ease of use, robustness and reliability.

Then in terms of more technical specifics, you need to analyse the data integrity of the system you’re choosing to invest in. Think about network compatibility, data export features. Good testing equipment for oral solid dosage forms should exhibit flexible interfaces for data exchange with customer data management systems.

We also think automatic data backup features as well as easy and quick data retrieval are important. Efficient Reporting Tools can help manufacturers to access historic solid dosage test data easy and quickly, when auditors are on-site and wish to inspect batch data.

Last but not least the investment into new testing equipment should be a long term decision. One of our main product strategies is the long term use and upgradeability, which often reaches 15 years and more within a product family. Due to our downward compatibility, our customers can profit from updates and upgrades on the hardware and software side and keep their testing equipment on a high quality, performance and conformity level.

Q: What are some of the common challenges experienced during testing?

A: We encounter many customers who have problems guaranteeing reliable feeding and transportation of different shapes of tablets. That’s where our solutions can really help. Similarly, it can be difficult to orientate difficult shaped tablets in the hardness test station to obtain correct and accurate test results.

Oblong shaped tablets often require a special oblong centering feature like the OZB from Ischi/Kraemer, and round, ball shaped tablets require a special, patented push-function to bring the product into the correct position.

Dusty products can pose a challenge too - many customers approach us to help them handle dusty products reliably.

Q. How has testing technology advanced over the last 20 years?

A: There are so many things! On the hardware side, we have more compact and precise weighing cells, more GMP-design. What’s more, materials in contact with the product all have to be FDA-approved now. Dust-proof testing systems provide better protection for the operators. Fully washable tablet testing systems allow the reliable and safe testing of high-potent products.

The latest state-of-the-art electronic controls allow precise control of all testing procedures. On the software side the compatibility with 21CFR-11 is a must. New features such as Authentication via Windows Active Directory Server allows a full integration with the customers user management system and provides a single point of user administration. The list goes on!

Q. Why is it important to choose good quality testing equipment for oral solid dosage applications?

A. Obviously, good quality results can only be obtained from a high quality equipment. Therefore, in order to achieve good quality results it is worth investing in reliable and good quality testing equipment, as it has a number of advantages. First, good quality testing equipment is easier to maintain. I would say that the regular calibration and verification to prove conformity is made much easier when you have well designed equipment. Second, good quality testing equipment and software can avoid human errors and human influence on test results. Using high quality equipment gives greater precision and reliability of test result data, and thus higher Data Integrity. Third, and probably one of the most important - this kind of equipment will provide you with precise and reliable results, which are demanded by official requirements and regulations such as PH-EUR and USP. Our licensed software supports this with a detailed audit trail, operator password protection and different user access levels.

