

Tablet Production: Increasing Efficiency of Physical Testing Processes

A closer look at physical testing in QC and IPC – and how efficient processes effectively save time and money.

Clearly defined quality standards and strict control of these standards are vital in Pharmaceutical manufacturing. Despite the importance of quality control, QC managers are often confronted with statements like “Production makes money, quality control costs money”. While it is obvious that no pharmaceutical-grade product can be sold without having implemented a system of constant quality control according to regulatory requirements, physical testing processes have often remained labor-intensive and time-consuming. This article illustrates possibilities of how efficiency increases can be realized in quality control to effectively reduce overall manufacturing costs.

INEFFICIENT PROCESSES

Pharmaceutical manufacturing is increasingly competitive, and the ability to guarantee consistent quality, reduce direct manufacturing costs and immediately evaluate test results can be paramount in maintaining a competitive edge. Despite this cost pressure, physical tests are often performed manually – including recording of measured results. Especially manually calculated reports make the entire process slow, laced with opportunities for error and very time-consuming. Typical consequences are specification input errors, avoidable production stoppages, waste production and long product release processes.

STREAMLINING PHYSICAL TESTING PROCESSES: WHERE TO START?

There are many approaches to increasing the efficiency of physical testing processes – from implementing relatively simple measures to investing in complex integrated systems. In order to find the best solution for individual testing needs (in line with available budgets), a short analysis of how tests are performed today provides a basis to start from. This article takes a closer look at specific physical tests performed in IPQC at a customer (see table 1) – and how the tablet testing process had been improved.

Table 1: Physical tests (of tablets)

- | |
|-----------------------|
| • Weight |
| • Thickness |
| • Diameter |
| • Hardness |
| • Disintegration time |
| • Friability |

CASE STUDY: A “TRADITIONAL” SCENARIO

In each compression room, operators used a standard balance and a caliper to quickly check the quality of produced tablets. Measured results were not recorded – mainly because this was the responsibility of the IPQC department, but also because the caliper measurements were highly inconsistent from operator to operator. Tablets

were collected at regular intervals and handed over to the IPQC lab for testing. The staff in the laboratory then performed weight measurements on a standard balance, thickness measuring using a stand-alone thickness gauge and hardness measuring using a very basic tablet hardness tester. In addition, friability tests were performed and disintegration time was recorded by visually inspecting tablets during tests performed on a simple disintegration tester. All measured results were recorded manually in special printed test report forms by the laboratory staff and were then handed over to the supervisor for evaluation. In case measured results were not within specifications, the supervisor had to immediately alert production to take corrective actions.

When the company launched a new product and purchased a new high-performance tablet press to allow for higher volumes, the IPQC capacities needed to be increased accordingly. Instead of simply adding more staff and purchasing the same type of equipment, management decided to first analyze current quality control processes. They quickly discovered, that their current process took very long until evaluated results were available to take corrective measures and that their entire process was highly inefficient (see table 2). As a consequence, the company looked at available options to improve efficiency of their physical testing process.

Table 2: Problems of “traditional” process

- “Time-to-evaluated-result” takes too long
- Inconsistent disintegration time recordings
- Very labor-intensive report creation
- Specification input errors

COMBINING MEASUREMENTS

The easiest solution to increase efficiency is to combine several measurements in one single report. Advanced tablet hardness testers like the Dr. Schleuniger® Pharmatron “MultiTest 50” (see Figure 1) allow programming up to 100 products including nominal values and limits for weight, thickness, width, diameter/length and hardness – eliminating specification input errors and providing evaluated data in report form.

Manual recording of results is no longer necessary, making the entire process much faster (see table 3). Reports can be either directly printed on an Ethernet LAN printer (to save bench space) and/or stored electronically on a central PC for further evaluation if needed.



Figure 1: MultiTest 50, Tablet hardness tester to combine weight, thickness, width, diameter and hardness measurements in a single report

Table 3: Time savings by combining measurements*

Measuring & Recording	Individual	Combined
Weight measuring	100s	100s
Recording of weight	60s	–
Thickness measuring	80s	60s
Recording of thickness	60s	–
Width measuring	80s	60s
Recording of width	60s	–
Diameter/Length measuring	80s	60s
Recording of diameter/length	60s	–
Hardness measuring	100s	60-100s
Recording of hardness	60s	–
Report creation	5 min.	–
TOTAL	17 min.	6 min.

* measuring 20 tablet samples

SEMI-AUTOMATIC MEASURING

To increase the number of possible tests without requiring additional personnel, semi-automatic testing can be a cost-effective alternative. Tablet samples are placed in a feeder carousel by the operator and all further testing of weight, thickness, width, diameter/length and hardness is done automatically. Investing in a semi-automatic tablet tester combines the benefits of comprehensive reporting with reduced labor costs per test. The time needed for an operator to prepare samples is significantly less than the actual testing time (see table 4).

Table 4: Labor time / Testing time comparison*

Measuring & Recording	Labor time	Testing time
Individual (not combined)	17 min.	17 min.
Combined	6 min.	6 min.
Semi-automatic	60s	3 min.

* measuring 20 tablet samples

In certain cases it can even be advisable to use two semi-automatic testers for performing parallel tests as opposed to sequentially testing with one fully automatic system, where additional feeding & emptying processes need to be considered.



Figure 2: SmartTest 50, Semi-automatic testing system to perform all measurements without operator

AUTOMATIC MEASURING

If one tester is to be shared by an entire team, a fully automatic tablet testing system offers highest comfort at almost zero labor costs. An undefined number of tablets are simply filled in a feeder and testing proceeds automatically until the set sample size has been reached. By using a multi-magazine feeder, several different products / batches can be loaded concurrently. Additionally, new tests can be setup anytime, so that operators don't have to wait until the currently running test has been completed.



Figure 3: AutoTest 4, Fully automatic testing system to perform tests of various products / batches

FULLY AUTOMATIC IN-PROCESS CONTROL

To minimize the time span between a test and taking corrective actions on a tablet press if needed, modern automatic testers can be fully integrated with high-performance tablet presses from different manufacturers. Samples are diverted automatically to the tester at regular time intervals and measured results are immediately transferred online to the tablet press. Using advanced algorithms, the software of the tablet press can automatically adjust production

parameters based on measured results. Often referred to as “lightly attended operation”, no operator is permanently needed in the compression room – neither for controlling the tablet press, nor for performing tests. One operator can in fact supervise production in several compression rooms. In case of limit violations, alarms are triggered to alert the operator and the press can even stop automatically to prevent waste production.

EFFICIENT DISINTEGRATION TESTING

A frequent problem in evaluating manually recorded disintegration times is the repeatability of test results. Often varying disintegration times are not related to inconsistencies in the product, but rather are caused by different operator judgments when visually checking whether tablets have completely disintegrated or not. An automatic tester with proven detection principle will reliably detect disintegration times for both tablets and capsules – and eliminate manual tasks associated with recording results and report creation (see Figure 4).



Figure 4: DisiTest 50, Bath-less disintegration tester to automatically record disintegration times

While standard automatic disintegration testers may provide repeatable results, they only marginally reduce testing times and labor costs (see Table 5). Significant productivity increases can be achieved by reducing the time needed to heat the test medium (solvent) to the required temperature. The “DisiTest 50” from Dr. Schleuniger® Pharmatron uses innovative induction heating and thereby reduces heating times from 15-20 minutes to only 3-5 minutes. Once a test has been setup, baskets lower themselves automatically when the required test medium temperature is reached – making additional manual verification of beaker temperature prior to starting a test obsolete. Without a conventional water bath and featuring self-centering quick-change baskets, the tester also sustainably reduces cleaning times and energy costs (only 50W power consumption instead of 1’100W or more).

Table 5: Labor time / Total time comparison*

Measuring & Recording	Labor time	Total time
Manual disintegration tester (with water bath)	7 min.	40 min.
Automatic disintegration tester (with water bath)	2 min.	35 min.
Automatic disintegration tester (with induction heating –no water bath)	–	14 min.

* for 1 test (10 minutes max. testing time), incl. heating and report creation; cleaning times not considered

SUMMARY

Whether your focus is on reducing costs or increasing capacities (or both), efficient physical testing processes save time and money – providing you with an increasingly important competitive edge in today’s challenging environment. Various alternative solutions allow you to tailor processes to your individual needs in order to maximize your return on investment.