# Inline checkweighing of packaged products in pharmaceutical manufacturing

Why system design and support considerations can help manufacturers select the correct system for use in a wider quality control regime

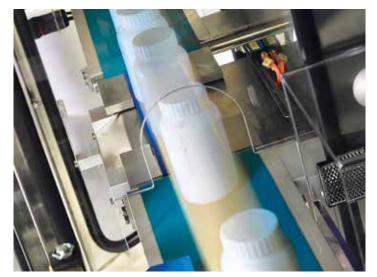
As with other packaged goods manufacturers, pharmaceutical manufacturers use inline checkweighing as a means of quality control. Weighing can help ensure consistent product quality as an intermediate or final product inspection step, identifying under or over-fills and verifying the presence of required components.

Modern pharmaceutical packaging lines can run at high speeds, processing more than 500 lightweight packages per minute (ppm). In order to successfully meet application requirements, checkweighers used in pharmaceutical packaging need to achieve high levels of dynamic weighing accuracy. In addition to weighing accuracy, it is essential that any checkweigher, and its operating software, are suited for the unique regulatory environment under which pharmaceutical plants operate. Considered product design, reliable operation and expert support can all help make the inline checkweigher a valuable tool for manufacturers.

#### High accuracy dynamic weighing

The weight of a static object can be determined with an extremely high level of accuracy using modern weighing technology. In industrial production environments, large numbers of packaged products must be weighed over a short period of time in order to meet output targets. This throughput need drives the widespread use of in-motion checkweighing systems.

In such applications weighing accuracy is not solely dependent on the ultimate accuracy of the weighing technology; it is a function of the overall system. Product handling is critical, package movement must be controlled so that packages reach the weigh table correctly spaced and orientated, and without



Plastic tablet bottles being weighed on an inline checkweighing system.

requiring excessive settling time. (A vibrating or bouncing product cannot be accurately weighed). Environmental factors, such as air drafts and external vibrations, can also introduce weighing inaccuracies.

Packaged pharmaceutical products are generally small and light, so that external influences can have a high relative effect. They can also be unstable and move at high speeds, exacerbating weighing accuracy challenges. A precision checkweigher system designed to meet these challenges will have mechanical and software features that maximize dynamic weighing accuracy.



#### System design considerations

In a production plant, air conditioning or ventilation, the movement of people or machinery, and the opening of doors can all create air drafts. As the strength of these drafts is variable they can have a measurable but inconsistent effect on weighing accuracy. To minimize interference from air drafts, a checkweigher can include a cover for the weighing section; it can be either a partial cover or a complete enclosure. For the highest accuracy applications, complete enclosures offer the best protection.



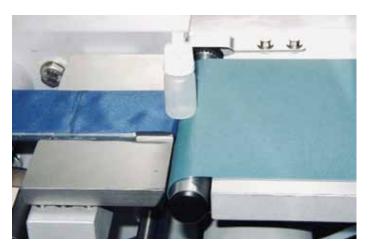
A plastic cover shields the weighing section on a pharmaceutical checkweigher.



On this checkweigher system the weighing section is fully enclosed.

One of the greatest challenges of inline checkweighing is moving products reliably and consistently onto the weighing section. Product handling is key to having the products correctly spaced, so that only one product is weighed at a time, and correctly orientated, so that the product is fully on the weigh table and each package is weighed in the same position each time.. Typical pharmaceutical applications include small tablet or capsule bottles, which are tall with a low center of gravity, and cartons containing blister packs, which are light and can move out of alignment on the conveyor belt. A supplier experienced in pharmaceutical applications can advise on the best product handling technique. For example, a worm-screw on the infeed will allow tablet bottles to be evenly spaced and stabilized, or side-belt conveyors matched to a particular carton size will ensure correct orientation of the carton.

Products must transfer from the in-feed of the system to the weighing section conveyor. Here again, a system designed for a particular application will offer the best performance. For typical pharmaceutical applications, the gap between infeed and weighing conveyors should be as small as possible. This allows fast-moving products to transfer with a low risk of unbalancing and with as little vibration as possible to decrease settling time on weighing. Manufacturers can either reduce roller sizes, so that they can be placed closer together, or, on systems using a slack-belt rather than powered weigh table, take advantage of the lack of rollers on this style of weigh table to position the in-feed conveyor roller against a knife-edge which reduces the gap even further.



A plastic bottle transfers from a feed conveyor to a weighing conveyor. The system pictured utilizes a slack belt for the weighing section, eliminating a roller and allowing use of a knife edge to minimize the gap between the conveyors.

As previously mentioned, vibration during weighing causes a reduction in the accuracy of a system; some level of vibration is inevitable. In order to achieve optimal weighing accuracy the effect of such vibrations should be reduced. The checkweigher cabinet should be mechanically stable with components that minimize vibration. If a moving component can be eliminated it should be. It is important to mount the system on a level surface

and adjust it so that the belts of each conveyor section are level during operation. The system software should use algorithms that compensate for the vibration that cannot be eliminated.

#### Ease of use, reliability and support

In order for a checkweigher system to be a valuable tool, it must be easy to set up and use, highly reliable, and come with a good level of support from the equipment supplier.

Ease of set up is important during the original install or when setting up the system for new product batches. Ease of use is an ongoing need. Software should include necessary features and have a logical layout accessible through a human-machineinterface (HMI) mounted in an easy-to-access position. Modern checkweigher systems typically use touchscreen HMIs to achieve this.

Reliability should be a consideration beginning in the design; selection of high quality and durable components is key.

Any systems with moving parts require maintenance; a checkweigher is no different. Choosing a supplier with good parts availability and a strong service capability should be a key consideration in system selection. Despite manufacturers' best efforts, equipment can sometimes fail unexpectedly. Here again, a strong technical support organization and the ability to remotely diagnose issues can be key to getting a system, and the line, back into operation.

#### **Data communications**

While data from individual pieces of control equipment provides important information to plant management, combining data from equipment throughout the line or facility becomes a powerful management tool to better understand performance of the line or plant. Therefore, a checkweigher must have the necessary communications options to link to line or plant control software packages, sending information on individual package weights, batch averages, variability and instrument status.

At an operational level, the system should be equipped with visual or audible indicators so that operators can easily and quickly identify if there is a problem with a checkweigher system or the product it is inspecting. Light towers and internal lighting are best to address this need as they are readily visible whereas audible signals may not easily be heard in an operating environment.



Colored, internal lighting provides an easily visible indication of the operating status of a checkweigher system.

#### **Regulatory compliance**

Pharmaceutical production is highly regulated, patient or consumer safety is a must, and so regular audits are conducted to ensure that the plant is operating to the Good Manufacturing Practice (GMP) guidelines mandated by the U.S. Food and Drug Administration (FDA), the European Directorate for the Quality of Medicines & HealthCare (EDQM) or other regional agencies.

Therefore, checkweigher system design and software must support the wider GMP of the plant. Construction should be high quality and able to withstand regular cleaning procedures. Software should be designed compliant with 21 CFR part 11, including features such as robust data protection, password selection procedures and full audit trail traceability. The full system should be able to be qualified on installation and in operation (IQ/OQ/PQ). The system supplier should have the experience and documentation to support users throughout the qualification process.

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#### Summary

Inline checkweighing is an established quality control tool, helping manufacturers ensure consistent product output, protecting customers and brand reputation. When selecting a checkweighing system for use in a pharmaceutical manufacturing plant it is necessary to consider both the features and performance of the system, and the level of expertise and support the supplier can offer.

#### Key considerations:

- The accuracy of the system under the specific operating conditions: packaging line speed, the size, shape and weight of the product, and external environmental factors
- Design and software features, supporting qualification documentation that allows the system to be used in a regulated production environment
- The experience of the supplier and their ability to specify the correct instrument and product handling, and provide support from the order through to the end of the operational life of the equipment.



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