GUIDE TO TABLET/CAPSULE INSPECTION

Pharmaceutical labs who need to sort tablets or capsules have two options: do it by hand or use an automatic system. Has your company made the right choice?

This quick guide will give you a tour of the capabilities and the limitations of both methods.

When comparing manual inspection performed by machine operators and high-end automatic systems using the latest vision technology, do not jump to hasty conclusions: manual inspection may just be the best option for your company.

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1. MANUAL INSPECTION

If only a few batches need to be inspected in any given year, you will probably not gain much from purchasing an automatic vision system. You’d be better off purchasing a few inspection belts and pulling operators from the production line when you need to run a manual inspection.

Here is the upside:

- no large capital investment necessary
- fast start-up: no technical training necessary, start-up time is minimal
- scalable solution (to a point) adding inspection belts, adding manual inspectors or working overtime will quickly improve your output

However, if tablet/capsule sorting is a fact of life at your company or if you are occasionally hit with large batches to sort, manual inspection has a host of drawbacks:

- **only inspection of cosmetic/appearance defects**: human eyes can not check what is inside the product (content and chemical integrity, nature and concentration of the product)

- **tablet/capsule backlog**: low throughput means that it can take a few weeks to release even a single batch. A few consecutive rejected batches can quickly create an unmanageable situation. Tablet/capsule inspection becomes a bottleneck, inventory is building up and management is putting pressure on you to find a solution to the problem.

- **high variability of inspection results**: human interpretation can skew the results. *Inconsistent sorting criteria may have been applied to the same batch by various operators or by the same operator over the long duration of the sorting.* After manual inspection the batch may still not pass the AQL. That leaves you with a tough decision: sort a second time or dispose of the batch.

- **lack of validation**: because the method relies heavily on human judgement and is therefore not repeatable

- **lack of a feedback loop for production**: data is not collected and the causes of the defects can not be quantified, analysed and used to continuously improve the production process
2. AUTOMATIC INSPECTION

So is automatic inspection the panacea? Not so fast! It also has its disadvantages:

- capital investment necessary: it may take you a few months to obtain funding
- validation time: once you purchase the system you must also plan a few weeks for the full validation. Validation packages from the vendors will help you with that process, but you still need to dedicate a few weeks of your personnel time.
- time needed for initial set-up of the system, time for product changeover.

However a growing number of companies have found the benefits of automatic inspection to be greater than the drawbacks. These benefits include:

- **unique capabilities**: some of the most critical inspections those involving high cost/high margin products (bi-layer or tri-layer tablets, tablets with laser drilled holes, inspection of readability of printing or embossing, transparent partially filled capsules, etc.) can simply not be done by hand.

- **high throughput**: a batch of a million tablets/capsules can be sorted in one shift as opposed to 10-40 shifts for manual inspection

- **unmanned operation**: once production is launched and continuous feed is arranged the system runs automatically

- **high precision**: vision cameras pick up defects as small as 100 microns if necessary

- **repeatable results**: the lack of human interpretation makes for a very high repeatability of the inspection

- **IQ/OQ validation**: high repeatability allows for the system to be validated

- **defect analysis**: software provides a statistical analysis of the defective products. With this data in hand you can identify the root causes of a problem (coating issue, compression problem, printing malfunctioning, etc) and resolve the issue for future production runs.
3. SYSTEM EVALUATION

Still not sure about which option is best for you?

Doubtful about the promises made by the manufacturers of automatic sorting systems?

The best way to proceed is to evaluate the systems with real world defective tablets/capsules. A handful of defective products along with a few kilograms of good products will be sufficient for the manufacturer to tell you exactly how the system would perform if it were on your production floor.

You could then watch a live demonstration with your products and see for yourself.

This is definitely the most appropriate way to evaluate output speed, sorting capability and accuracy of the system on YOUR TABLETS/CAPSULES.

It will also help you to better define your requirements and what to focus on when looking for such system:

- is a system only based on vision the solution to your problems (inspecting only cosmetic defects), or will you also need to check the content and chemical integrity (nature and concentration) of the product, in such case Near InfraRed technology (NIR) will also be needed?

- will it be dedicated to one / a few / many different products?

- will it be mainly used for standard shapes or also for non-standard shapes?

- will it be mainly used for systematic inspection or for defective batch saving?

- what about frequency of product change over: low / medium / high?

- what about formats parts involved in product change over: cost, time for change-over

- what about easiness to do set-up: for new tablets/capsules? for tablets/capsules already recorded in system database?

Interested in going further with Tablet/Capsule inspection systems?

Please email proditec@proditec.com