

Capping Threatens Product Recall

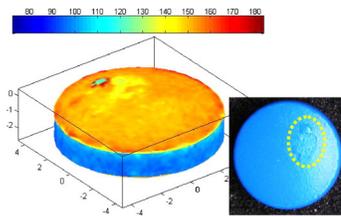


Challenge

A pharmaceutical client was at risk of a product recall due to a capping problem with a new tablet formulation.

Visual inspection at the packaging had identified that capped/laminated tablets had made it through to the packaging stage despite the tablets having met intermediate quality inspection.

Since capped/laminated tablets are unlikely to meet the correct dosage requirements for the API, the entire batch of the product would be rejected or a product recall would be possible if the product did get into circulation. The challenge faced by the client was how to accurately and cost effectively measure the thickness and integrity of the tablet prior to packaging.



Solution

The original manual inspection had not been able to consistently identify the hairline cracks and, during shipment of the tablets, some tablets separated leading to the loss of small portions of the tablet, affecting the ultimate dosage of the API. While some minor defects were allowed, these capping issues of a “critical” nature put the client at risk of a product recall.

Electronic visual inspection systems, especially Viswill TVIS-EX-CD, can be configured to check dimensions of the product quickly and then accurately identify issues that might lead to subsequent problems, such as incorrect thickness, broken products, or hairline cracks.

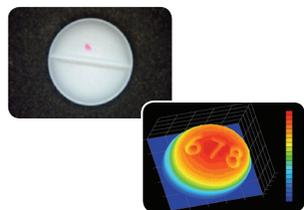
See the results on the back >>



RESULT:

Quality was *increased*.

Cost was *reduced*.



The client began using a Viswill visual inspection system and the increased accuracy of the inspections allowed them to rescue the batches and avoid the financial risk of a product recall until the root cause of the problem was determined. Ultimately, they were able to reduce their overall inspection costs while significantly increasing the quality of the inspection. More importantly, the efficacy of the drug to the ultimate user was kept intact because dosage levels were at the appropriate level.

About Visionspect

Visionspect, a division of DJA Pharma, is the industry's first contract visual inspection system, offering automated visual inspection with no capital outlay. Visionspect provides each site with Viswill (formerly Kanebo) visual inspection equipment, personnel, and expertise to visually inspect tablets and capsules. Using proven equipment and technology, Visionspect guarantees inspection results to levels that are unachievable by manual inspection, while saving clients valuable operating costs.

To find out more about how Visionspect can help you with a more cost-effective way of inspecting your products, call 630-776-2459 or email us at info@visionspect.com

