Technical Note

2021.02

Quality Control with X-ray inspection data Part 1 of 2

Beyond contaminant detection

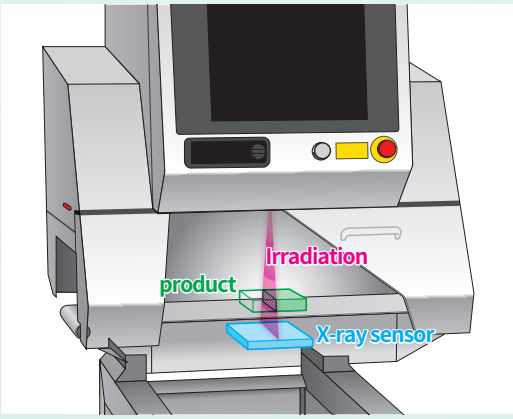
With the system's improving accuracy year after year, the inspection using X-ray Inspection systems has been introduced in a variety of industries as an effective means of contaminant detection.
For example, X-ray inspection systems are employed for sensory tests such as conventional palpation, and effectively contributing to labor saving. Manufacturers in the pharmaceutical industry have applied X-ray inspection systems to inspect the inside of the package of non-transmissive materials, which is not feasible with the conventional optical inspection system.
X-ray inspection systems of late years being incorporated to IoT system continue growing to deliver further advanced quality control.
Part 1 of 2 of this subject, you will find various usage of Anritsu's X-ray inspection system, more than detecting contaminating foreign bodies.

● The growing demand of double-sided aluminum packaging materials

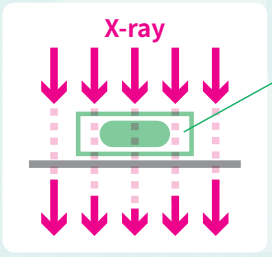
With increasing global logistics, the double-sided aluminum packaging has been up surging thanks to its excellent barrier properties. Thereby, the conventional optical inspection with cameras is unfeasible to inspect pharmaceuticals packaged in opaque materials. X-ray inspection systems fluoroscopically perceive and inspect the object inside are certainly attracting attention.

● How does X-ray inspection system function?

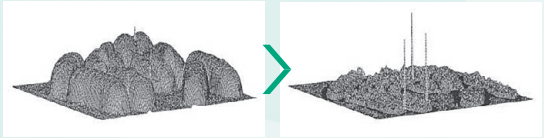
The attenuation that relatively varies to the density of the subject composition is rendered as the radiograph and enables the system to identify the contaminant. X-ray inspection system converts the detected signals of different attenuation into image with dark and bright contrast and inspects the inside of product. X-ray inspection system finds foreign bodies in drug by the difference in density of components other than they should be. Furthermore, the X-ray leaking out of the cabinet of X-ray inspection systems employed in drug production line is faint and safe to workers. Taking advantage of the feature of observing the package interior, X-ray inspection systems are feasible not only of foreign body inspection, but also of multiple inspections such as of shape and of missing product.



Schema of X-ray inspection system



The sensor that is delicate but accurate receives the X-ray emitted onto the product and converts the signals to visualize in a grayscale image.

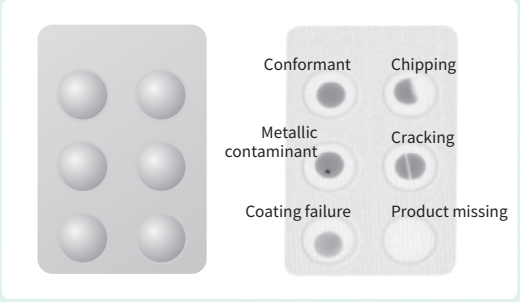


X-ray inspection system correctly spots/locates the contamination by subsequent image processing.

Anritsu's X-ray Inspection System Applications

Detecting contaminants

X-ray inspection systems detect contaminant including small pieces of metals, of glasses, of plastics and fine gravels those mixed into the product of both the content and the packaging. Generally, foreign materials impenetrable like metals are easy to detect.

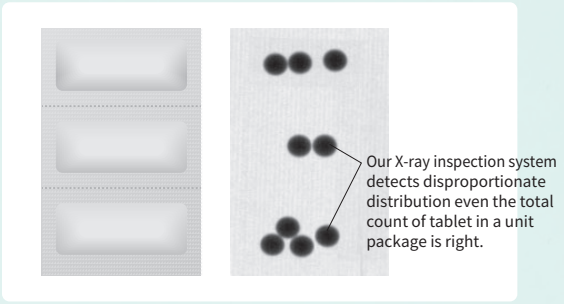


Missing product and shape detections

X-ray inspection systems detect missing product, and cracking and chipping of drugs those are invisible from outside the package. X-ray inspection systems determine the defects with the perimeter and the area of tablet, the relative mass calculated from the image contrast – which is also applied to determine the coating failure.

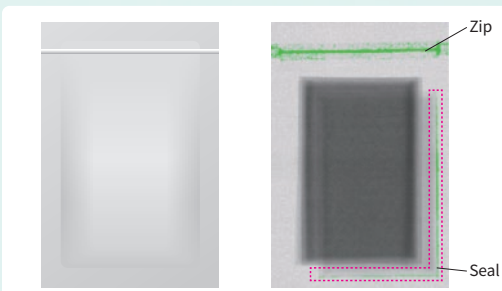
Detecting missing tablets

See case example on the right. Given that each sachet of 3 should enclose 3 tablets each; as in the image, the sum of tablets – despite of distributed 2, 3 and 4 - weigh still the same as they should have been distributed evenly 3 a sachet. Therefore, Checkweigher is not suitable for this inspection. On the other hand, X-ray Inspection Systems are feasible of detecting such defect, thanks to the image processing and the counting algorithm.



Detecting sealing defects

X-ray Inspection Systems are feasible of detecting the content caught between the seals of opaque packaging like the aluminum vapor deposited film, likewise, feasible of detecting of the content caught in the zippers.



Effective Method of Quality Control by imaging technology of Anritsu X-ray Inspection System

Anritsu X-ray Inspection System records the images of products-in-process and immediately displays in the tile view. Particularly, the immediate presentation of defective products makes it so easy to spot the imperfections as the clues of possible causes and eventually improve the quality. Furthermore, the images are copiable to the USB memory stick and reviewable on your PC.

Safety for your products

Not like on the food and alimentations, no current regulations specify the limit of X-ray irradiation on the medicines administered to human.

Anritsu has conducted the joint study to analyze the dose of the X-ray radiation on various medicines and has verified that the dose of irradiation from our system products does not compromise the quality of medicine including the medicine formula and the content of effective compounds to the pharmacological criteria.

(Drug Development and Industrial Pharmacy 2015 41:953-958: joint research, former Anritsu Industrial Solutions Co., Ltd. and Drug Delivery and Nano Pharmaceutics, Graduate School of Pharmaceutical Sciences, Nagoya City University)

Summary:

Anritsu X-ray inspection system designed and built safe in use will be one of the essential elements of your Quality Management System that supports your inspection by detecting the defects not just only of the contaminants, as well of the appearance and of the content count.
Your inquiry is all welcomed.

Can the Anritsu X-ray system inspect your product?

How precise and accurate the radiograph is?

▸▸▸ Try the sample testing at Anritsu laboratory.

Your samples sent to our laboratory will be inspected under the specified conditions and be reported the outcome including the level of detection sensitivity and the radiographs. The tested samples will be returned and available for your validation on the consequences of the irradiation.

Solutions for pharmaceutical products: https://www.anritsu.com/infivis/products/solutions-for-pharma
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