Technical Note

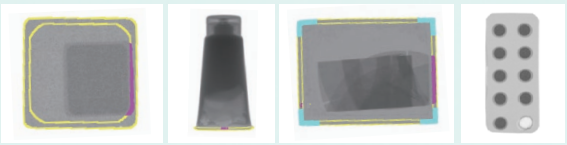
For **Pharmaceutical**

November 2018

Anritsu
envision : ensure

Effect of X-ray Inspection on Pharmaceutical Products

Cameras are commonly used for quality inspection of pharmaceutical products, but are you aware of X-ray inspection systems for the internal inspection of pharmaceutical products? X-ray inspection systems are preeminent in the inspection of non-transparent packaged drugs as shown below. However, we understand that many people are concerned about the effects of X-rays on the quality and/or physical properties of pharmaceutical products when they consider introducing such a system into their facilities. For this reason, we will discuss the effects of X-ray inspection on pharmaceutical products.



In order for pharmaceutical manufacturers to use X-ray inspection systems without concerns, Anritsu has been working with the Ozeki laboratory of Nagoya City University since 2011 and has been analyzing pharmaceutical products that have been exposed to X-rays. The analysis results have confirmed that there are no problems associated with the quality of preparations (results of tests on changes in drug content and pharmaceutical preparation testing). The test method and some of the test results are shown below.

•Test method

The three ingredients shown below were tested.

Active ingredient	Acetaminophen	Loxoprofen	Mefenamic acid
Manufacturer	Company A	Company B	CompanyC

The ingredients were tested at four different X-ray radiation doses to ascertain if there was any effect on the ingredients at any dose.

Irradiation condition	Dose given in 3 X-ray tests	Dose limit specified in the Food Sanitation Act of Japan	Radiation level that affects human blood	Excessive dose
X-ray radiation dose	0.34 mGy	100 mGy	500 mGy	300 Gy

×300! ×1,500! ×900,000!

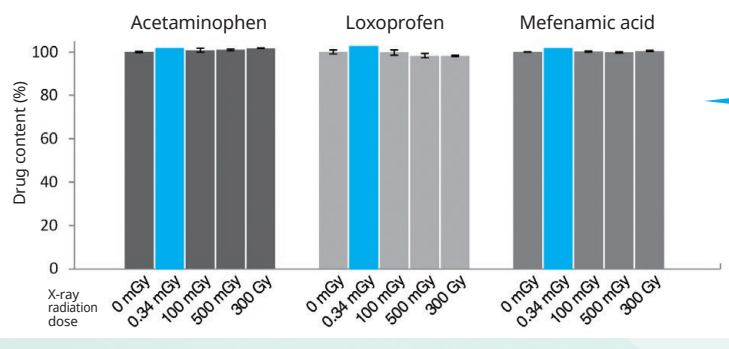
•Endpoints

To evaluate the effect on the quality of pharmaceutical products and the physical properties of preparations, we established a total of six endpoints for the pharmaceutical preparation testing; drug content test, elution test, disintegration test, hardness test, content change, and appearance/sensory test. The test method and some of the test results are shown below.

•Results

In addition to the drug content test, elution test, disintegration test, hardness test, content change, and appearance/sensory test, no adverse effects caused by X-ray inspection were found when acceleration tests (1, 3 and 6 months) and a color change test were conducted.

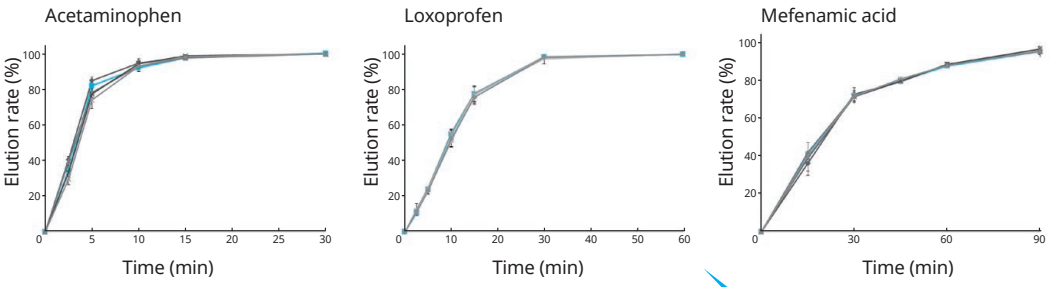
Drug content



The test results show no effect on drug content at any radiation dose.

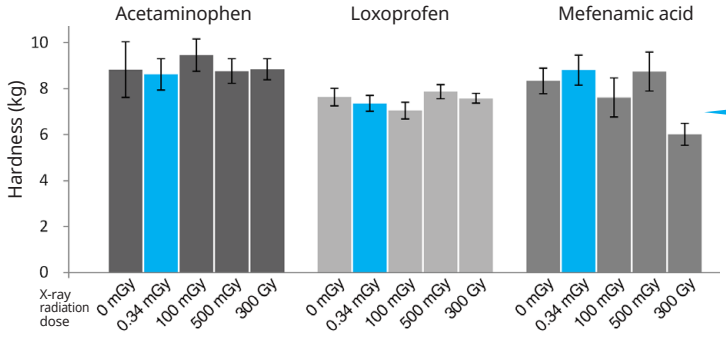
•Results (continued)

Elution test



The test results show no effect on elution rate at any irradiation duration.

Hardness test



The test results show no effect on hardness at any radiation dose.

Disintegration test

Product name	0 Gy	0.34 mGy	100 mGy	500 mGy	300 Gy
Acetaminophen	2 min 52 sec	2 min 56 sec	3 min 6 sec	3 min 10 sec	3 min 18 sec
Loxoprofen	10 min 19 sec	10 min 20 sec	10 min 29 sec	10 min 28 sec	10 min 26 sec
Mefenamic acid	3 min 39 sec	3 min 47 sec	3 min 32 sec	3 min 40 sec	3 min 54 sec

The test results show no effect on disintegration time at any radiation dose.

Reference: ANRITSU SANKI SYSTEM CO LTD (former company name), Drug Delivery Graduate School of Pharmaceutical Sciences, Nagoya City University Drug Development and Industrial Pharmacy 2015 41: 953-958

•Summary

None of the results showed changes that may affect the quality of the pharmaceutical products; therefore, we believe that X-ray inspections can be used without concern.
Use of X-rays for shape detection and foreign matter contamination inspection makes it possible to extend the inspection range to the inside of pharmaceutical products, where visual inspection is difficult, helping to establish a more advanced quality control system. Please contact us.

Would our drugs be unaffected by X-rays?

Is it really true that the ingredients aren't changed?

▸▸▸ We are accepting requests for X-ray radiation tests.

If you need an X-ray radiation test to verify the effect of X-ray radiation exposure, please contact us. We will perform X-ray radiation tests according to your use conditions such as radiation dose and irradiation duration, and report the results. However, we do not perform an impact assessment.

Anritsu products information: https://www.anritsu.com/infivis/
Contact us: https://www.anritsu.com/infivis/contact-us

References:
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