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Application News

Microfocus X-Ray CT System inspeXio™ SMX™-225CT FPD HR Plus

Example of Observing Tablet Using a Microfocus X-Ray CT System

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User Benefits

- The distribution of granules inside the tablet can be easily visualized non-destructively by CT imaging.
- The thickness of the multi-layered membrane can be analyzed without cutting and polishing the tablet, which helps in quality control of the product.

■ Introduction

Medicines are produced in a variety of forms, including powders, tablets, and capsules, depending on their intended use and purpose. Among them, tablets are widely used because they are easy to carry, store and take.

The distribution of granules and voids in a tablet affects the rate at which the active ingredient in the tablet dissolves into the bodily fluids, and is a factor that affects the efficacy and safety of the medicine. In addition, with tablets whose surfaces are coated with a membrane, the thickness of the membrane changes the organ in which the internal components are eluted, so it is important to control the thickness of the membrane in order to achieve a strong effect while reducing side effects of the medicine.

A useful tool for non-destructively observing the distribution of granules, voids and the thickness of the membrane is the Microfocus X-ray CT system. This article introduces an example of a tablet observed using the microfocus X-ray CT system, inspeXio SMX -225 CT FPD HR Plus (Fig. 1).

Fig. 1 inspeXio™ SMX™-225CT FPD HR Plus Microfocus X-Ray CT System

■ Observation of Tablet

Fig. 2 is a fluoroscopic image of the tablet. Areas that absorb fewer X-rays appear white, while areas that absorb more X-rays appear black. It can be seen that there is a multi-layered membrane on the surface of this tablet, with a small thickness layer 1 and a larger thickness layer 2 inside it.

Fig. 3 shows cross-sectional images obtained by CT. In contrast to fluoroscopic images, areas that absorb fewer X-rays are black, and areas that absorb more X-rays are white. By visualizing the membrane structure more clearly, the granules and voids inside the tablet can also be observed.

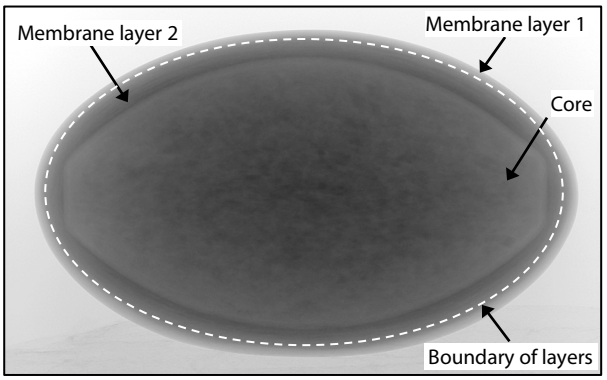
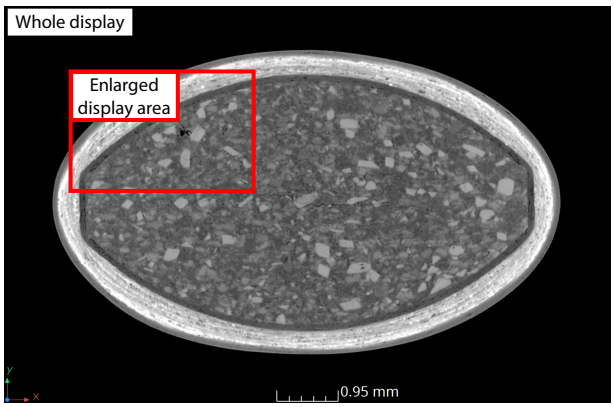


Fig. 2 Fluoroscopic Image of the Tablet



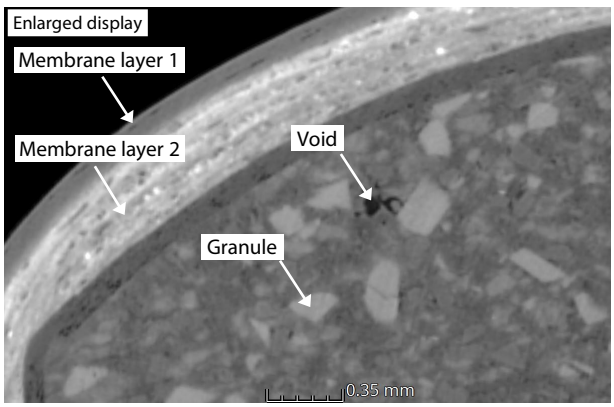


Fig. 3 Cross-Sectional Images of the Tablet (Above: Whole, Below: Enlarged)

Fig. 4 shows a three-dimensional representation created using the image analysis software VGSTUDIO MAX from the data in Fig. 3. By virtually hiding the white dashed area, the outside and inside of the tablet are observed at once. Fig. 5 also show a three-dimensional representation, but the granules inside are extracted and colored according to their volume. The smaller volume granules appear in colder colors, and the larger volume ones appear in warmer colors. This enables the size and three-dimensional distribution of the granules to be examined.

Fig. 6 is a cross-sectional image of layer 1 and layer 2 of the membrane through thickness analysis. Smaller areas are shown in colder colors, while thicker areas are shown in warmer colors. Layer 1 is about 0.1 mm, while layer 2 is 0.2 to 0.4 mm. It is assumed that the layers can be distinguished by the brightness on the cross-sectional image, but the cross-sectional image obtained by CT imaging makes it easy to analyze the membrane thickness of the entire sample.

In addition, the results of analyzing the membrane thickness can be observed in the three-dimensional representation and histogram as shown in Figs. 7 and 8. In the three-dimensional representation in Fig. 7, the analysis results regarding the thickness of the membrane are displayed by layer, and the thickness of the membrane can be observed from the colors of the tablet. In the histogram in Fig. 8, the horizontal axis represents the membrane thickness and the vertical axis represents the frequency (percentage of pixels).*1 The histogram also provides statistical information, and the average thickness of layer 1 and layer 2 analyzed was calculated to be

0.009 mm and 0.034 mm, respectively. The difference in layer thickness observed qualitatively in Figs. 2 and 3 can be determined quantitatively.

*1 The number of pixels corresponding to each thickness as a percentage of the number of pixels in the analyzed layer

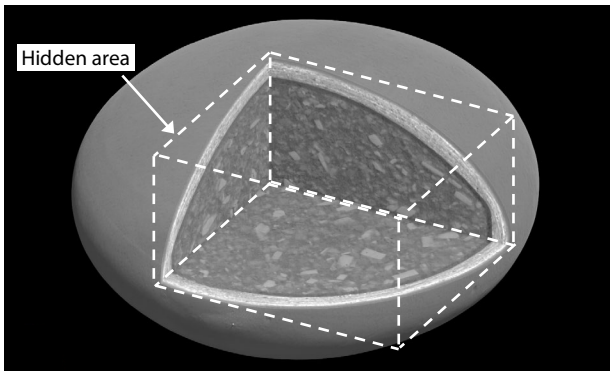


Fig. 4 Three-Dimensional Representation of the Tablet

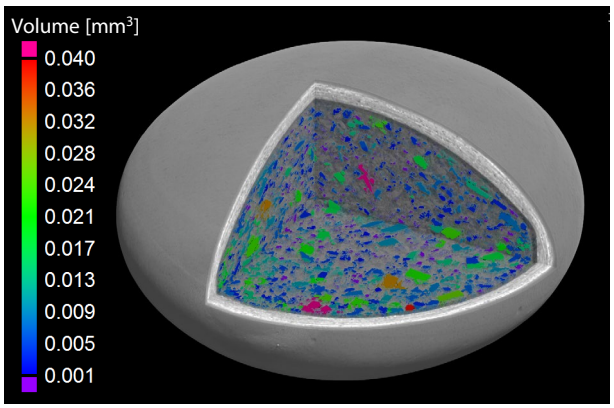


Fig. 5 Three-Dimensional Representation of Granules in the Tablet

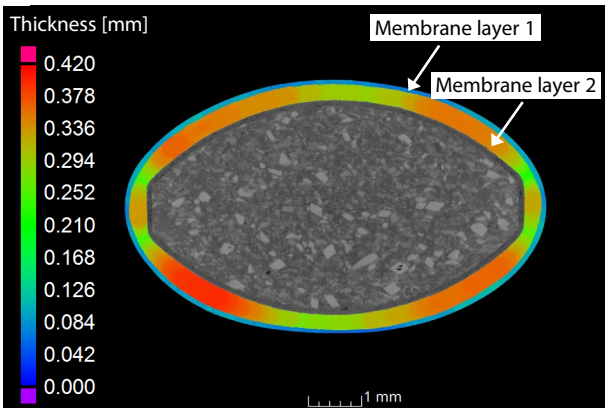


Fig. 6 Cross-Sectional Image of Volume Analysis of the Membrane

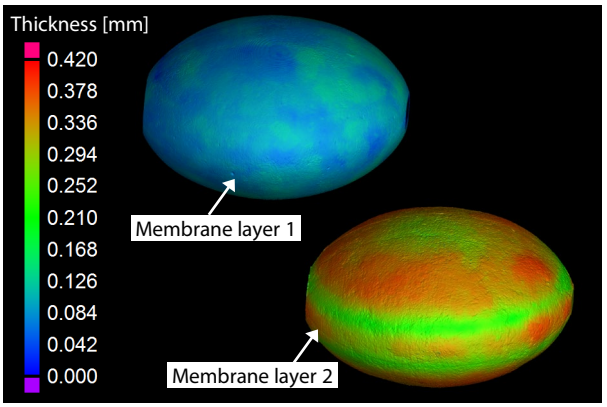


Fig. 7 Three-Dimensional Representation of Volume Analysis of the Membrane

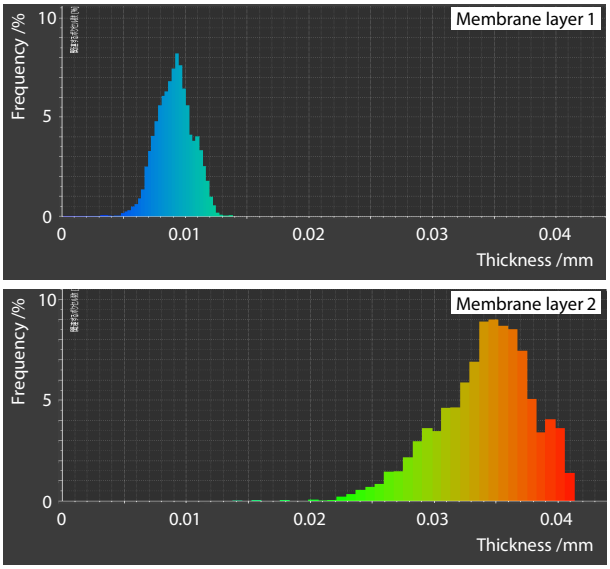


Fig. 8 Histogram of Volume Analysis of the Membrane

■ Conclusion

As demonstrated in this example, the Microfocus X-ray CT System can visualize the three-dimensional structure inside the tablet. It is useful for quality control of the product, observing the distribution of granules in the tablet, and analyzing the thickness of the membrane.

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