LAAN-A-ND-E008

SHIMADZU

Application News

Industrial X-ray Inspection System No.N115

X-ray CT System for Observation of Capsules

■ Introduction

Industrial X-ray CT systems have long been used for inspection and structural analysis of a wide range of manufactured products, including electronic parts, automobile parts, plastic products, etc. Recently, however, they are also proving useful for observation of the internal structures of pharmaceutical products such as tablets and granules. Here, using an X-ray CT system which allows even more detailed internal observation, we introduce image data of a granule-filled gelatin drug capsule. The images were taken using the SMX-160CTS sub-microfocus X-ray CT system (Fig. 1).

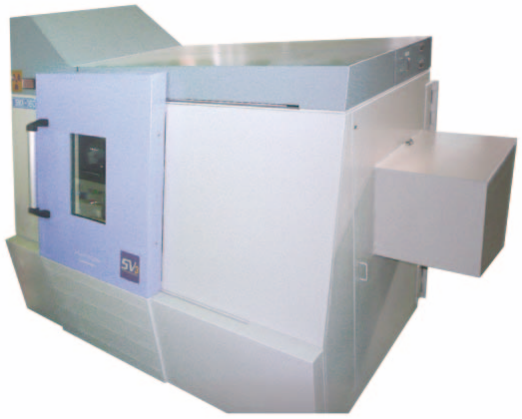

Fig. 1 Shimadzu SMX-160CTS Sub-Microfocus X-ray CT System

■ Observation of Capsule

Fig. 3 shows a fluoroscopic image of the granule-filled capsule (shown visually in Fig. 2). Because the granules inside the capsule are seen as a pile in the fluoroscopic image, there is no way to understand the positional relationships among all the granules.
Fig. 4 shows a CT image of this capsule. The image in Fig. 4 shows a longitudinal sectional image of the region near the center of the capsule, and it can clearly be seen which granule is at which position. In addition, Fig. 5 shows a three-dimensional display of this CT image, in which the granules are displayed in a more three-dimensional manner.
Observing this granule-filled capsule in a fluoroscopic CT image revealed that there were 2 kinds of granules used in this capsule, each about 1 millimeter in size. Then, each kind of granule was removed from the capsule for more detailed observation.

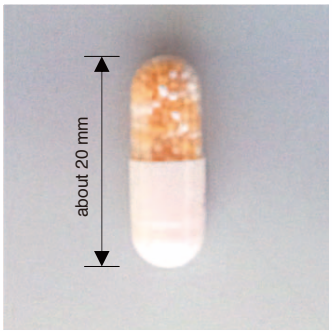

Fig. 2 Photograph of Capsule

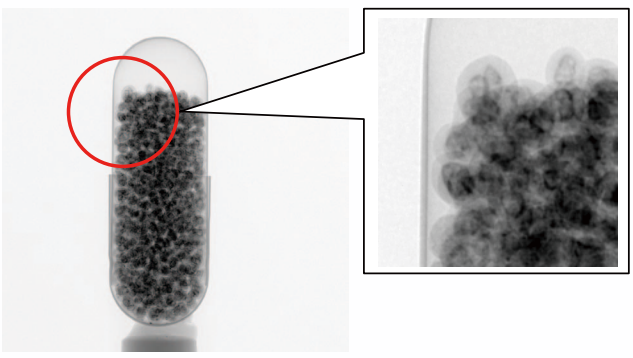

Fig. 3 Fluoroscopic Image of Capsule

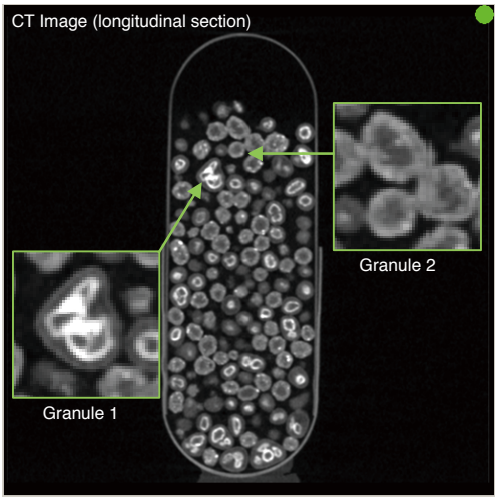

Fig. 4 CT Sectional Image of Capsule

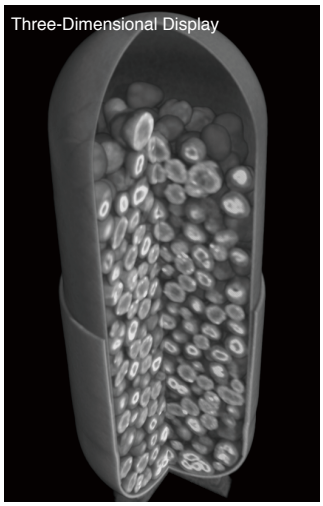

Fig. 5 Three-Dimensional Image of Capsule

■ Observation of Granule (1)

Fig. 6 shows a transparent image, a CT image, and a three-dimensional image of granule type 1.
Granule type 1 has a 3-layer construction with an outer low-density drug substance (Fig. 6 (1)) and a slightly higher density drug substance middle layer (Fig. 6 (2)), which acts as a coating that encloses a separate granule (Fig. 6 (3)). In addition, by generating a magnified CT image, it can be observed that voids exist near the border between drug substances (1) and (2) (Fig. 6 (1), (2)).

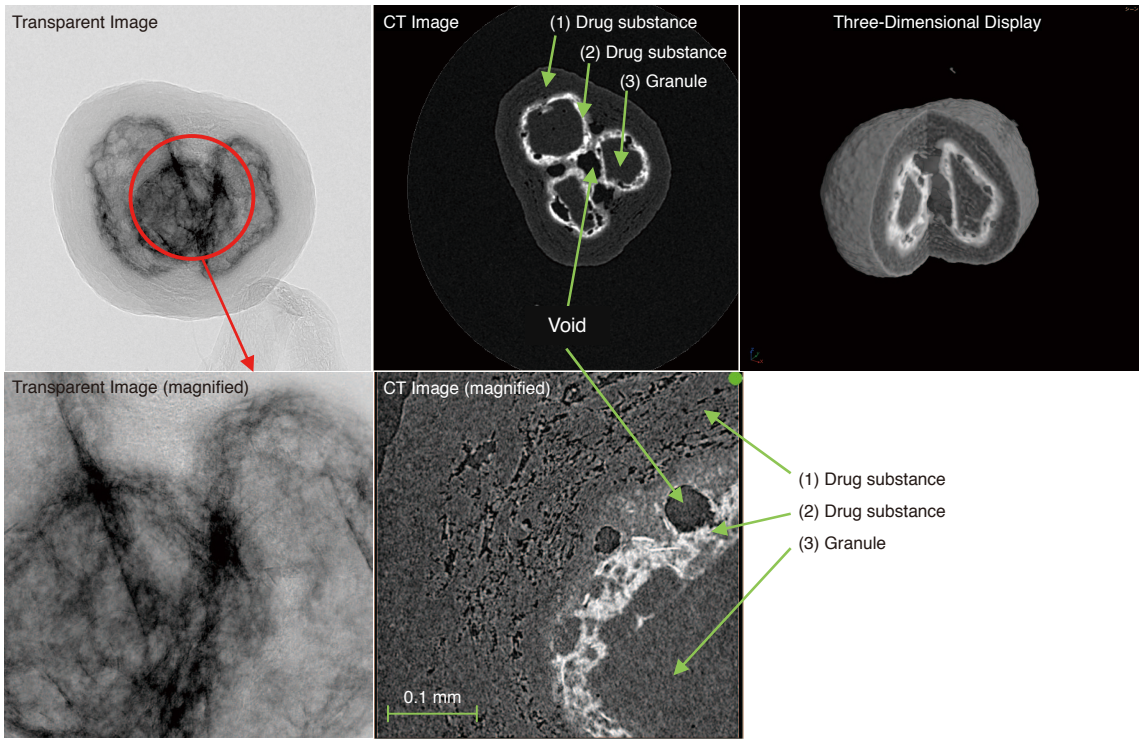

Fig. 6 Observation Images of Granules (1)
Upper: Overall image of Granule 1
(from left) Transparent image / CT image / Three-dimensional image
Lower: Magnification image of Granule 1
(from left) Transparent image / CT image

■ Observation of Granule (2)

Fig. 7 shows a transparent image, a CT image, and a three-dimensional image of granule type 2.
Granule type 2 is observed to consist of a low density drug substance granule (Fig. 7 (1)) coated with a higher density drug substance (Fig. 7 (2). In addition, it can be seen that there are voids inside the granule similar to those observed in granule type 1.

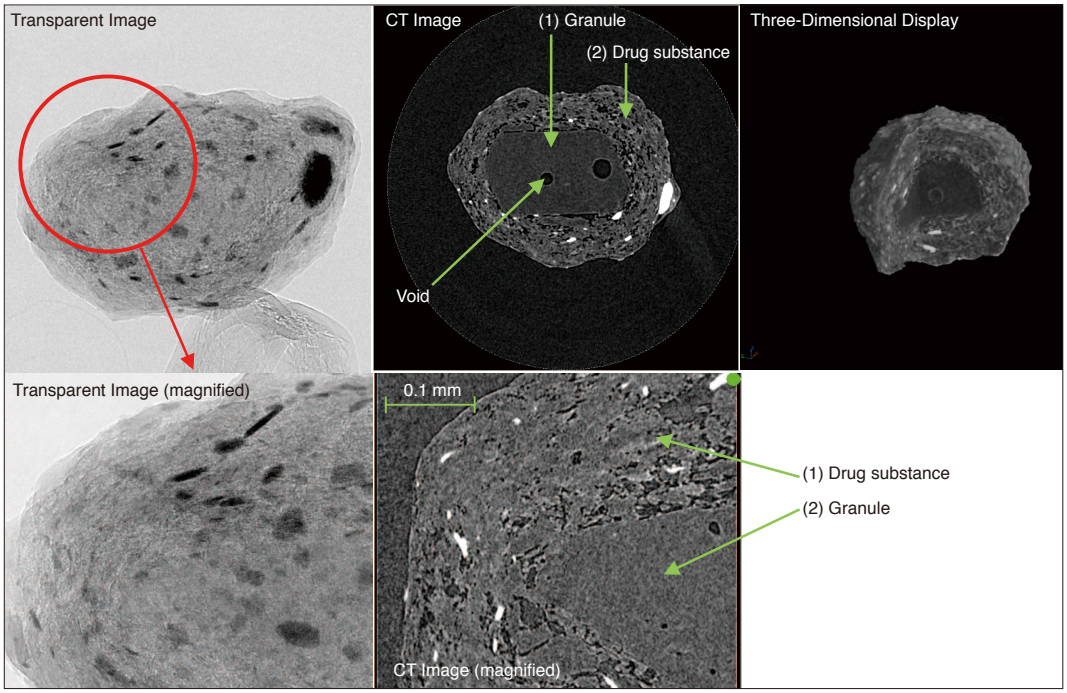

Fig. 7 Observation Images of Granules (2)
Upper: Overall image of Granule 2
(from left) Transparent image / CT image / Three-dimensional image
Lower: Magnification image of Granule 2
(from left) Transparent image / CT image

In this way, by using the SMX-160CTS sub-microfocus X-ray source, a single granule from a capsule down to the internal micro features of that granule can now be observed in a short time without the need to carry out complex fabrication or processing.

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