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# PHARM015: Observation of Solids and Voids in Sealed Lyophilized Formulations

## Introduction

Since the structure of a lyophilized formulation (cake) affects its solubility, it is important to understand the overall structure from the development stage. However, only a portion of the cake can be observed using an optical microscope, and the structure may change due to moisture absorption when the vial is opened. Using micro X-ray CT, the porosity and structure of the entire cake can be determined three-dimensionally without opening the vial. Here, we present an example of visualizing the unevenness of porosity in a cake by CT observation in a sealed condition.

## Non-destructive imaging

<b>Analysis:</b>	Formulation
<b>Use:</b>	Formulation (Dosage Form)
<b>Analyzed materials:</b>	Lyophilized Formulations
<b>Analysis software:</b>	VGSTUDIO MAX

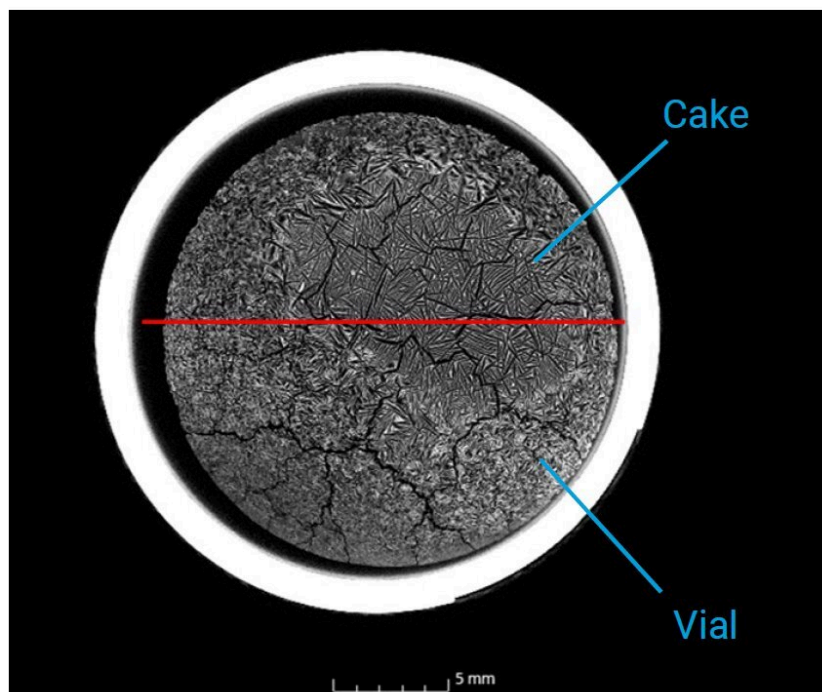


Figure 1: Cross-section image of a cake

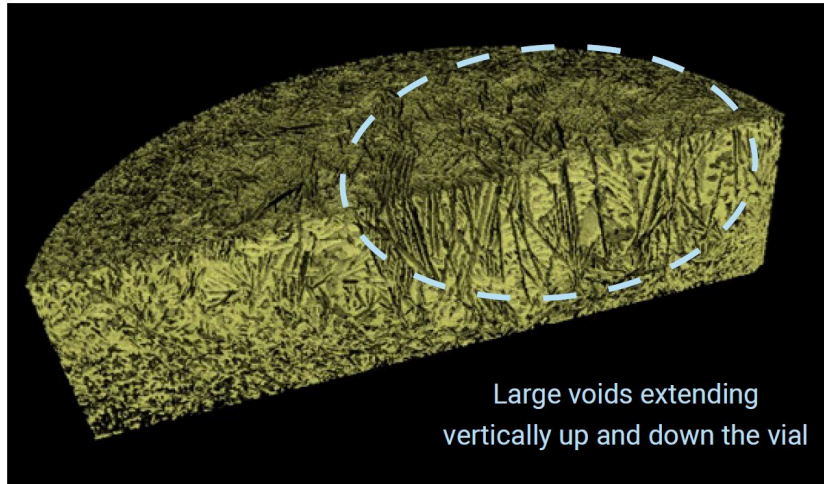


Figure 2: Three-dimensional image of a cake

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## Conclusion

The cross-sectional image in Figure 1 shows that there are variations in shape and size of the voids. Figure 2 is a three-dimensional image cut at the red line position in Figure 1, which confirms the presence of large voids extending vertically up and down the vial. Such nondestructive observation enables us to understand the internal structure formed during the formulation process and to extract factors that affect solubility and stability at an early stage.

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## Related products



### CT Lab HX

High-resolution benchtop microtomography of large samples