View on rigaku.com

# Brand Name vs Generic Atorvastatin Tablets Comparison by X-ray CT

# About the sample: Atorvastatin tablets

Atorvastatin calcium is used to lower cholesterol and is probably best known as Lipitor, its brand name by Pfizer. Atorvastatin calcium is one of the poorly soluble drugs. The morphology of the tablets, such as particle size and uniformity of the matrix and API (Active Pharmaceutical Ingredient) mixture, affects the dissolution rate. While the content of a tablet can be analyzed chemically or by Raman spectroscopy or X-ray diffraction, these techniques do not provide much information about the morphology. X-ray CT (<u>computed tomography</u>) can image the interior of the tables nondestructively and enables morphology analysis.

#### **Analysis procedure**

- 1. In this example, brand name atorvastatin (Lipitor) and generic brand tablets that exhibited slow dissolution were scanned using a submicron-resolution CT scanner, <u>nano3DX</u>.
- 2. The CT images were compared to find the reasons for the slow dissolution of the generic tablet.

#### 1. CT scan

Brand name atorvastatin (Lipitor) and generic brand tablets were scanned to produce the 3D grayscale CT image. The gray level in CT data (left) represents the relative density. The image on the right is a 3D rendering of the CT scan with its part cut out digitally to show the internal morphology.



### Lipitor (Astellas licensed by Pfizer)

Journal of Drug Delivery Science and Technology, Volume 31, 2016, 35-40

#### 2. Image comparison

Although the Raman spectroscopy or X-ray diffraction results indicated the contents of Lipitor and the generic brand tablets were the same, the generic brand tablet took almost 15 minutes to reach 80% dissolution, while it took only 5 minutes for Lipitor.

X-ray CT images of these tablets revealed a stark difference. The Lipitor shows uniform morphology and fine particles. In contrast, the generic brand tablet exhibited heterogeneous morphology with coarse particles. Multiple massive aggregates up to several hundreds of micrometers in size were found. These aggregates are slower to dissolve compare to fine particles and explain the overall low dissolution rate of the generic brand tablet.



## Generic brand with slow dissolution

Journal of Drug Delivery Science and Technology, Volume 31, 2016, 35-40

This example demonstrates X-ray CT's capability to decipher the cause of dissolution problems that do not show any difference in traditional composition analyses. The X-ray CT images shown here were collected at Rigaku Research Laboratory (Tokyo, Japan) and published by <u>Fukami et al. (2016), J. Drug. Deliv. Sci. Technol., 31, 35-40</u>.

To learn more about micro-CT, read What is micro-CT?

# **Related products**



#### nano3DX

Ultrahigh resolution nanotomography using parallel beam g eometry