

High Precision Vessels



High Precision Dissolution Vessels

Dissolution Accessories together with Takao Manufacturing Co. Ltd. has developed instrument made vessels for a wide variety of brands, in Standard and High Precision.

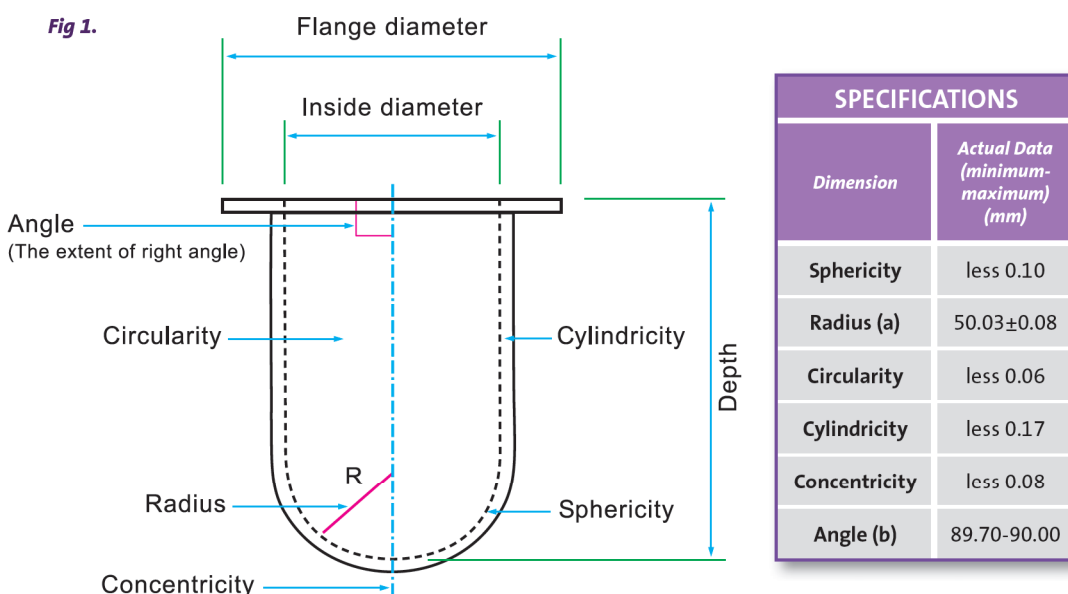
These vessels are available in most common dimensions in Clear Glass, Amber, Peak or Teflon coated.

The vessels are adapted to every brand and work without the need of any separate adapter bracket, they fit *directly* in your Dissolution instrument regardless the manufacturer! **No AccuCenter Vessel Centering is needed!**

The pharmaceutical analysts worldwide may benefit from the Takao Vessels performance, regardless of their vendor of choice.

Precision on physical dimension

Have you ever seen the vessels in which the data of physical dimensions are clearly and accurately described like this? The tolerances of actual data on physical dimensions are surprisingly narrow.



- Each value was measured by a three-dimensional coordinate measuring machine from Brown & Sharpe (PMM-C700P).
- The unit is in degree. Eight standard type vessels were subjected to this measurement.

Observations of vessel interior form

No appreciable deviation from the ideal interior shape was observed in the high precision vessel.

Conventional glass processing technology provided a large deviation of actual interior shape of the vessel from its ideal interior form. It indicated an unevenness exceeding 1.5 mm at the height of the undulations on the surface of the inside of the vessel. A large deviation was also observed for the inside cylinder. The whole inner surface was obviously found to be uneven in the vessels produced by conventional glass processing. [Fig.1]

On the other hand, an integrated glass fabrication technology gave almost the ideal interior form. The height of undulations was below 0.14 mm. No apparent deviation was observed for the inside cylinder. The entire inner surface was found to be even in the high precision vessel.

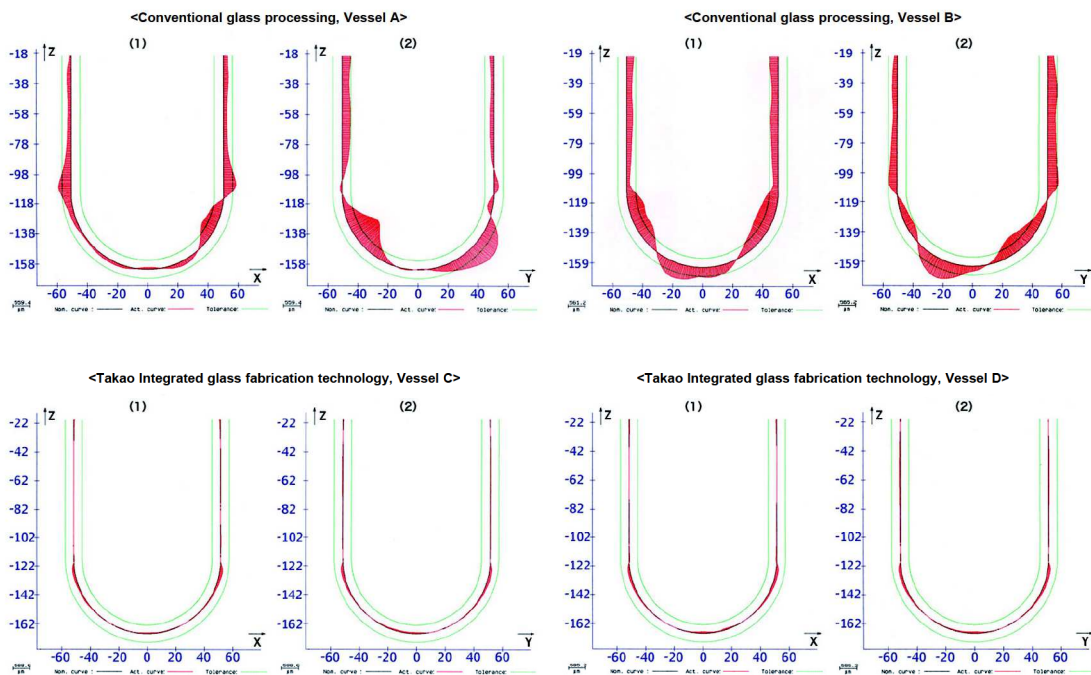


Fig.1 Comparison of deviation from the ideal interior form of the vessel between the two kinds of glass vessels manufactured by conventional glass processing and an integrated fabrication technology. The center line between the two green lines indicates the ideal interior form of the vessel. The red zone indicates the actual deviation of the interior form of the vessel from its ideal interior form. The green lines indicate the ideal interior form $\pm 0.3\text{mm}$. Each right figure (2) indicates the result of the determination at an angle of 90° from the left figure (1). Each determination was carried out by utilizing a three-dimensional coordinate measuring machine (Brown & Sharpe, PMM-C700P).

Customization of Vessels

The high precision vessels are customized to your requests. Dissolution Accessories can produce the vessel at any time changing its size, shape or thickness to fully and immediately meet your testing requirements and specifications. Dissolution Accessories provides the vessels at affordable price, in spite of its elaborate glass processing. Please contact us for more info.



Dissolution Accessories is exclusive global distributor of Takao Manufacturing Co., Ltd.

High Precision Vessels

Centering of Shaft

The exact centering can be achieved only in the use of vessels in which precise sphericity, circularity, concentricity of inner surface, vertical center, and uniform geometry are all guaranteed.

The high precision vessel of Takao ensures the vertical center.

Off center shaft is a critical factor in erroneous results. Therefore, USP, EP and JP pharmacopeia strictly specify the shaft position so that its axis is not more than 1 mm at any point from the vertical axis of the vessel. However, how should we identify the vertical axis of the vessel? When the vessel itself has some irregularity, non-uniformity or distortion of the inside vessel, the vertical axis of vessel remains vague and the essential meaning of centering of shaft will be diminished

The Effect of High Precision Vessel on Drug Dissolution Data

The variation of dissolution data can be markedly decreased by utilizing the high precision vessel.

Our data demonstrate that the range of variability in Prednisone tablet dissolution results obtained from the high precision vessel of Takao was not more than half of that obtained from vessels produced by conventional glass processing technology. [Fig. 3]

Mean dissolution data obtained from conventional vessel vary considerably from position to position in dissolution apparatus. [Fig. 2]

The range of minimum to maximum mean dissolution data in the high precision vessel was one third of that in conventional glass vessel. A similar result was presented by a Japanese pharmaceutical company at the 124th Annual Meeting of The Pharmaceutical Society of Japan on March 30, 2004, in Osaka.⁴ It was pointed out in the report that the inside bottom shapes of the vessels produced by conventional glass processing were not uniform hemispheres, resulting in much larger variation of dissolution data than those of the vessels with uniform hemisphere bottom like high precision vessel of Takao.

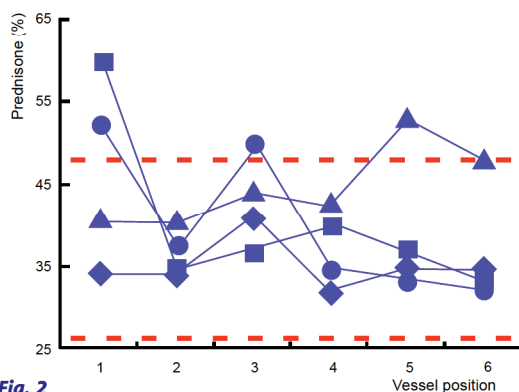


Fig. 2

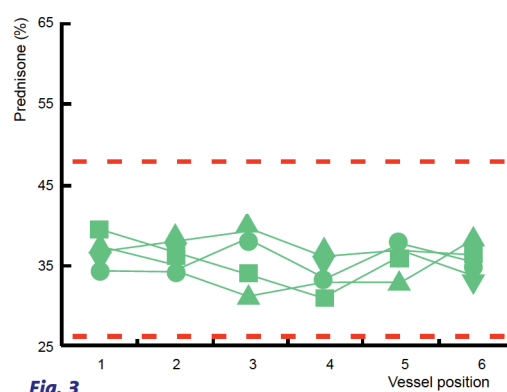


Fig. 3

Interior Form of Vessel and Dissolution Test

It has been reported that inside bottom curvature varies from one vessel to the next and irregular surfaces can occur, depending on the conventional glass processing techniques. Such non-uniformity of bottom curvature and surface irregularity cause dissolution results to differ significantly.

Dissolution testing has remarkably increased in value and significance over the last 30 or so years. It has been widely employed as an important tool in formulation development, in bioequivalence studies and in quality control. It is well known that the dissolution test involves many variables that can contribute to inaccurate results. Therefore, the current USP, EP and JP specify in detail mechanical parameters of the dissolution tester itself such as a shaft rotation speed, shaft position, wobble, distance of blade to inside bottom of vessel and the like. However, considering the vessel alone, only height and inside diameter are stated as dimensions. In addition, the tolerances of each dimension have been actually quite wide.

An innovative integrated fabrication technique developed by Takao could finally bring a solution to large variation of dissolution results. The most precise and accurate glass vessels were developed by the technology for the first time in the world.

For further reference, see:
Dissolution Technologies, 12(4) November 2005, pages 15-19.
Dissolution Technologies, 14(1) February 2007, pages 28-33.