

## Development of a Novel High Speed Kneading Granulator and Its High Performance in Producing of Multi-Functional Granules

Prof. Satoru Watano

*Department of Chemical Engineering, Osaka Prefecture University, Japan*

E-mail: watano@chemeng.osakafu-u.ac.jp

### **Abstract**

Most of the new drug developed recently in the pharmaceutical industries indicates water-insoluble property. Also, formulation including high content of the water-insoluble drug should be sometimes designed, because of its low bio-availability. When such formulation is used for wet granulation by high shear mixer and etc., undesirable results such as 1) large adhesion of drug onto inside vessel wall 2) granules with wide size distribution, and 3) long time operation and large labor cost, are expected. So, there is a great demand for efficient granulation of such formulation containing water-insoluble drug.

In this study, we have developed a novel "high speed kneading granulator" which can produce wide varieties of granules in an extremely short operating time. This granulator composes of a bottom vessel, and kneading and chopper blades that are both placed in an upper vessel. Each blade rotates independently (top drive) drafting different trajectory, so that the mixing performance is very good and the dead space is extremely small. Due to the high speed revolution of the kneading blade, binder liquid is quickly dispersed into powder materials, forming wet mass with uniform dispersion of the binder liquid. Owing to the high speed rotation of the chopper blade, granules with uniform size distribution can be produced from the wet mass. This unique granulation mechanism realizes high efficient and high speed granulation of any kinds of materials including high content of water insoluble active ingredient. So far, we have shown that the developed granulator could produce soft granules for tableting, spherical well-compacted granules for coating core, fine granules with high content of water-insoluble drug and oral rapidly disintegrating tablets having good disintegrative property, enough tablet hardness, and constituent granules with median diameter of 100-200 microns.

**Key words:** high speed kneading granulation, water-insoluble drug