Volume 4| March, 2018

Fuji Chemical Industries USA, Inc.

Fuji Spray Drying Newsletter

Vol 4: Solid Dispersion through Closed-loop Spray Drying System

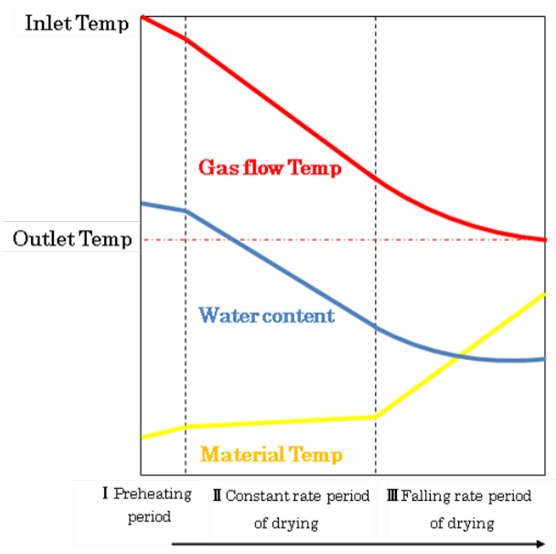
Innovation for small-molecule compounds

Solution to the Solubility Issue

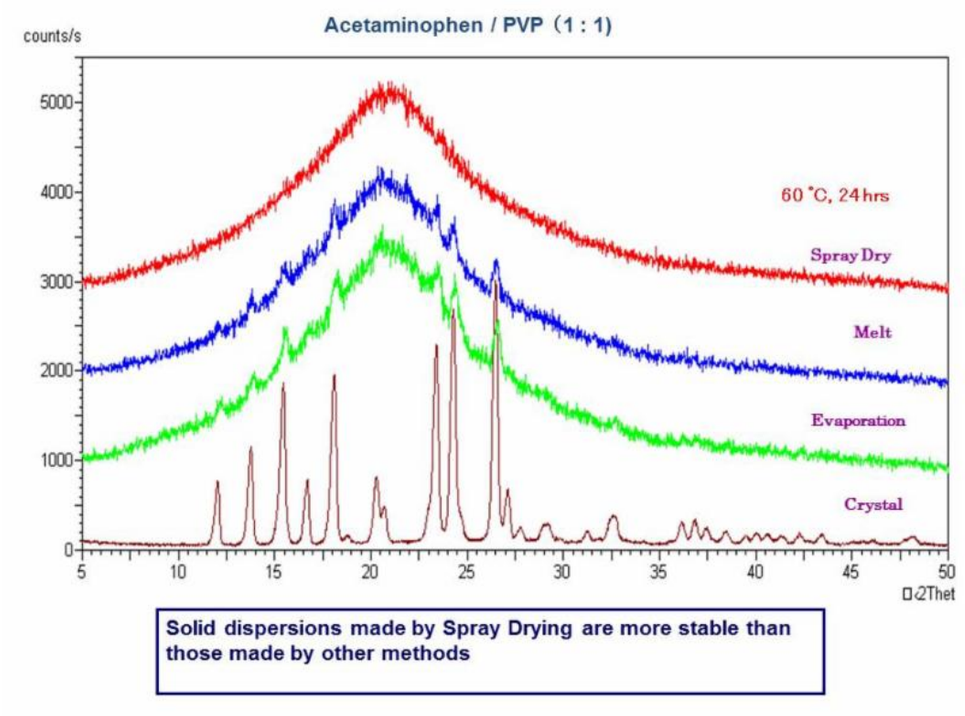
Recently in new drug development, it has become increasingly common for a promising drug candidate to run into problems due to poor solubility. At Fuji Chemical Industries, we have responded by improving the solubility of poorly soluble drugs with closed spray drying technology to make amorphous solid dispersion material. The improvement in the solubility is in large part due to the higher energy of the material as compared to its crystalline counterpart, since less external energy is required to dissolve the amorphous material. Furthermore, by utilizing the spray dried dispersion, materials with better porosity, wettability, and surface area are obtained. All of these factors contribute to improved solubility, which in turn leads to improved bioavailability.

Spray Drying Characteristics

Spray drying system works well with temperature sensitive APIs due to its drying characteristics. As you can tell from the diagram on the right, the material, which is still in the form of droplets after being sprayed from a nozzle, starts its travel inside of the spray drying chamber at very low temperature compared to the outlet temperature. As the droplets (the material) travel inside of spray drying chamber, they are dried by a flowing hot gas (usually nitrogen) losing its water content (It can be the content of other solvents.) The thermal energy in the hot gas is used to vaporized the solvent. The gas temperature therefore decreases as it flows. However, the material temperature does not increase till the water (or the solvent) content reaches down to a certain level (usually one-digit in terms of percentage.) By the time the material is collected , the droplets have turned into powder with very low solvent content. Secondary drying under a vacuumed system is conducted if necessary.

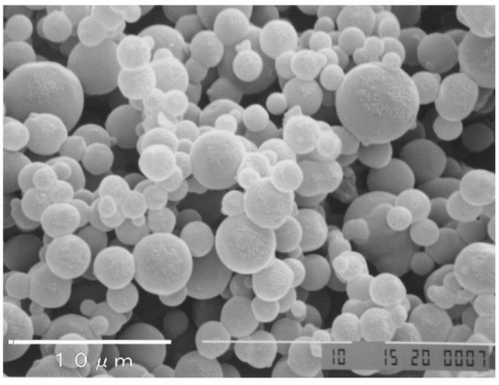


Proven Stability of the Spraying Method



The XRD data above shows comparison study results of various solid dispersion methods using PVP as the polymer to spray dry acetaminophen, subsequently stored for 24 hours at 60□C before the analysis. The solid dispersion prepared by spray dry method indicated halo pattern in contrast with solid dispersions prepared by melt method and evaporation method, which indicated slight crystalline peaks. The study demonstrates that spray drying is more stable than other methods.

Addtional Benefits



There are other advantages in employing spray drying method:

- Rapid drying– good for temperature sensitive APIs
- Reproducible product (content uniformity, particle size control,and particle uniformity)
- Short development time
- Easy to scale up
- Practical method for commercial production
- Established,continuous,and cost-efficient process

In this issue of our technical newsletter, we have shown you an outline of our technical service and GMP support. For more details, please contact our U.S. office office shown below:

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