

Benefits of Solid Dispersion by Fuji Chemical Industry's CSD Technology

According to several independent reports, nearly 40% of NCEs launched in US market during the last decade are poorly-water soluble APIs and that percentage continues to rise. Consequently, many pharmaceutical companies spend a lot of time and effort to improve solubility and increase bioavailability while trying to keep the successful dosage form in mind. If on the other hand, outsourcing is an option, consider the solid dispersion technique by Closed-cycle Spray Drying (CSD) offered by Fuji Chemical Industry. Since 1999, our business offers attractive "problem solving" services such as the development and manufacture of amorphous API solid dispersions by CSD.

Our Expertise and Experience

Since 1999, Fuji began the large scale solid dispersion manufacturing by CSD technology. It was not an overnight transformation, but rather a natural progression after 40 years of custom spray drying services for pharmaceuticals. We believe this was part of the foundation for our success as well as know-how to achieve solid dispersion proprietary technology and quality of support. To date, we have solved issues at various stages of solid dispersions such as formulation, process development and scale-up. At the time of writing, we've completed roughly 30 projects covering the following:

- ✓ Higher API load in formulations
- ✓ Preparation of a stable solid dispersion
- ✓ Minimizing particle size and bulk density changes accompanying with scale-up
- ✓ Solving post-spray-drying process problems

Working with You from Bench to Scale



Successful examples of Fuji Solid Dispersion Technology by CSD

Increase of apparent solubility of API, the specific feature of solid dispersion, is the driving force to enhance bioavailability. Fig 1 shows the apparent solubility of the indomethacin/PVP solid dispersion increased approximately 6 times compared to that of physical mixture. Furthermore, this super saturation status is maintained for a long time. Fuji designed solid dispersion also shows improved bioavailability when compared to micronized API as indicated by the plasma concentration of the API in rats (Fig2).

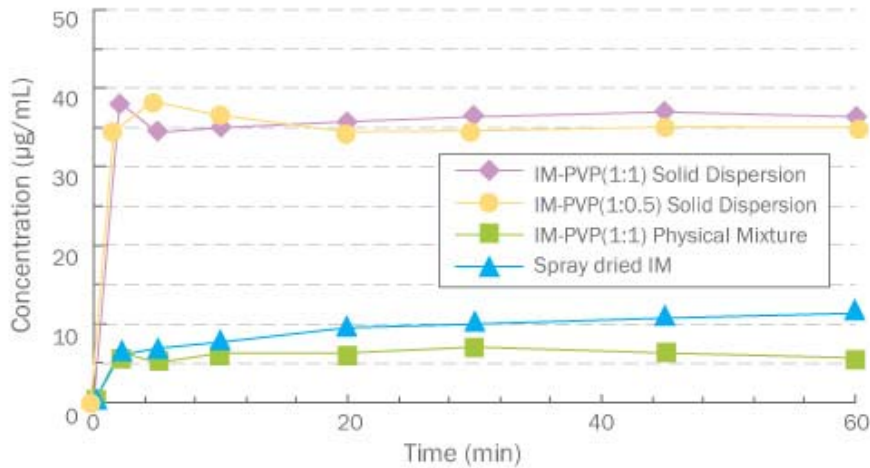


Fig. 1. Dissolution profile of Indomethacin

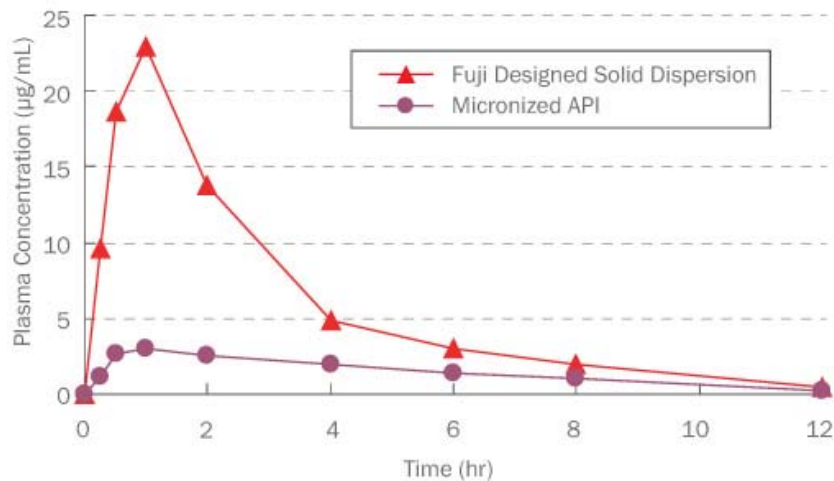


Fig. 2. Fuji designed solid dispersion improves bioavailability when compared to micronized API