

Fuji Spray Drying Newsletter

Vol 7: Spray-Dried Solid Dispersion Development: Formulation Study

Amorphization is a technology which can greatly improve the solubility of the API. However, there are many clients with no experience in working with them. At Fuji, we provide the formulation study service of the spray-dried solid dispersion. Qualified specialists with years of knowledge and experience will be in charge of the formulation study. There are 2 approaches to formulation study depending on the API amount that you can provide for us.

If you are able to provide approximately 0.5 g of API to us, we will conduct the formulation study by evaporation method. We will prepare several types of solid dispersion materials, selected from countless combinations of factors such as solvent and polymer types, various API/polymer ratio, solid component concentration, and inorganic excipients like Neusilin® or Fujicalin®. Prepared solid dispersion materials are subsequently vacuum dried, and simplified dissolution test will be conducted for evaluations.

If you are able to provide approximately 2 g of API to us, the formulation study can actually be conducted using the bench-top scale spray dryer. As with evaporation method, several types of solid dispersion materials, selected out of countless combination of aforementioned factors, will be prepared and subsequently vacuum dried. Since sample amount obtained will be larger in comparison with the evaporation method, we can also conduct XRPD, PSD test, residual solvent test, DSC, and SEM as required in addition to the simplified dissolution test. Furthermore, we can also perform assay using HPLC/UPLC and analysis for related substances, provided that the analytical method is shared with us.

Common Polymers and Solvents Normally Used for Formulation Study

Polymers		Solvents	
HPMC	HPMCP	Methanol	Dichloromethane
HPC	HPMCP	Ethanol	Tetrahydrofuran
PVP	Methacrylic Acid Copolymer	Acetone	Water
PVP VA	-----		

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

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