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Fuji Chemical Industries USA, Inc.

Fuji Spray Drying Newsletter

Vol 6: Spray Drying Utilization with Excipients

Innovation for small-molecule compounds

Spray Drying as a Tool for Development

Through the utilization of unique spray drying technology, Fuji has developed excipients used and accepted worldwide. Three excipients developed by Fuji, Fujicalin®, Neusilin® and F-MELT®, possess exceptional properties which are very useful for applications in pharmaceutical, nutraceutical, or personal care products. Fuji's excipients exhibit these exceptional attributes shown below, made possible with the development through the use of spray drying technology. We have the expertise and experience to replicate similar successful developments with our potential clients and partners.

Neusilin®

Unique mesoporous carrier for solid dispersion
High direct compressibility
Accelerates disintegration
Can act as buffering agent
Dramatically improves flowability of most powders
Competent adsorbent for liquid and SMEDDS
Adsorbs up to 300% of its weight in oil or liquid actives

F-MELT®

Ready-to-use powder matrix
Oral disintegration time less than 30 seconds
High direct compressibility and easy to use
High API loading achievable
Very flowable with little or no sticking/capping

Fujicalin®

Improves blend content uniformity even for micronized API with low loading
Exceptional flowability
Promotes rapid disintegration
High direct compressibility
High oil adsorption capability
Non-abrasive
The probiotic problem solver-significantly improves survivability during tableting & stability during storage

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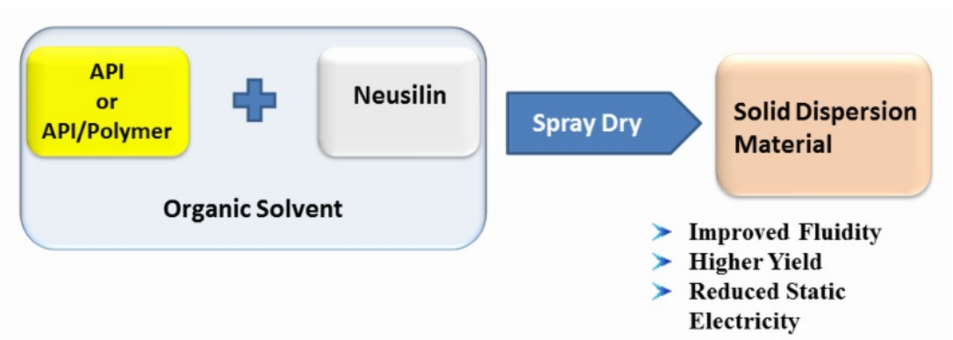
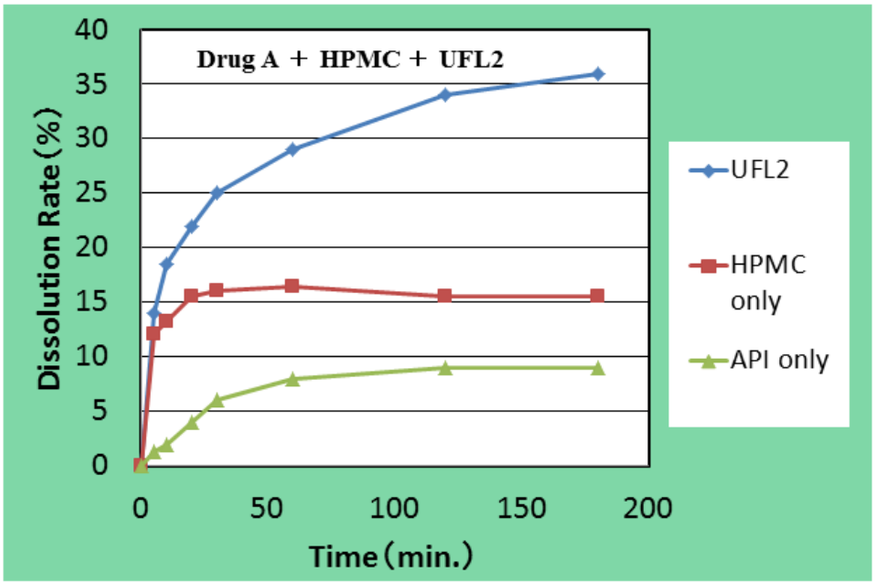
Improved Properties of the Solid Dispersion Material

One of the excipients mentioned above, Neusilin, is an ideal excipients for use in combination with our spray drying technology. Neusilin is used as a base material to improve the powder property of the solid dispersion material.This is accomplished by making use of the Neusilin's unique properties such as fluidity enhancement, which reduces the adhesion loss for improving the yield, and its ability to lower the static electricity.



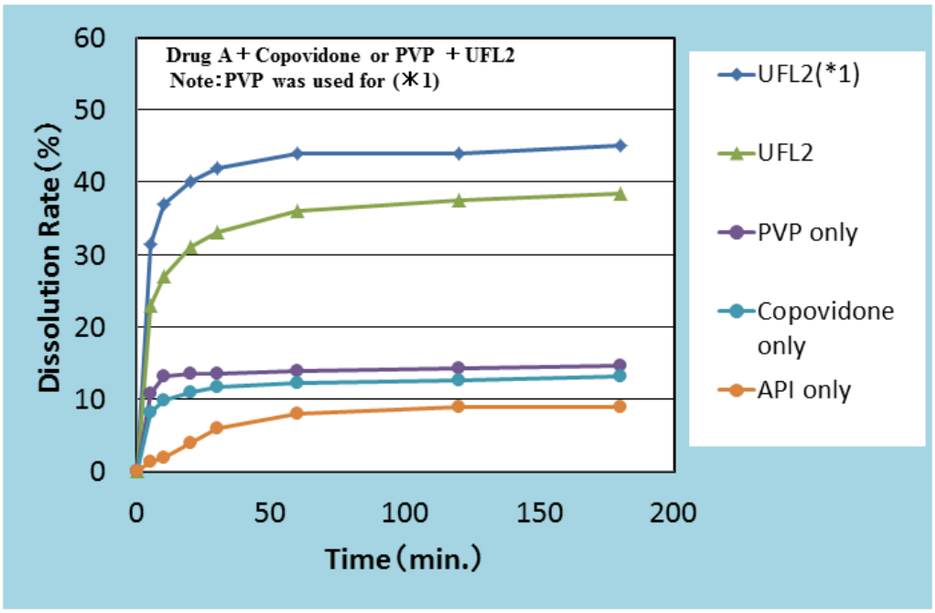
Dissolution Results of the Solid Dispersion Material with HPMC



Drug A : HPMC : UFL2 = 2 : 1 : 0.5
Drug A : HPMC = 1 : 1 （Drug and Polymer only）
Dissolution Medium : Water (37 ˚C)

The study was conducted to assess the Neusilin®'s efficacy to improve the dissolution property of the solid dispersion material. Drug A and the polymer (HPMC) were spray dried with UFL2, one of the Neusilin® grade with neutral acidity and low water content. As you can see in the data above, the study indicates that solid dispersion material produced by spray drying Drug A with UFL2 has the highest efficacy in terms of dissolution rates. The study demonstrates improved dissolution property through the combined utilization of spray drying technology and excipients.

Dissolution Results of the Solid Dispersion Material with PVP or Copovidone



Drug A : Polymer : UFL2 = 2 : 1 : 0.5
Drug A : Polymer = 1 : 1 （Drug and Polymer only）
Dissolution Medium : Water (37˚C)

Similar results were obtained for the solid dispersion material produced by spray drying Drug A with different polymers, either Copovidone or PVP. In the graph above, "UFL2 (*1)" indicates solid dispersion material produced by spray drying Drug A and UFL2 with PVP. Likewise, "UFL 2" indicates solid dispersion material produced by spray drying Drug A and UFL2 with Copovidone.

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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