

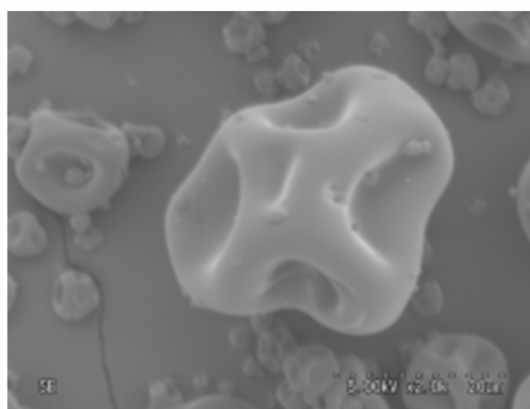
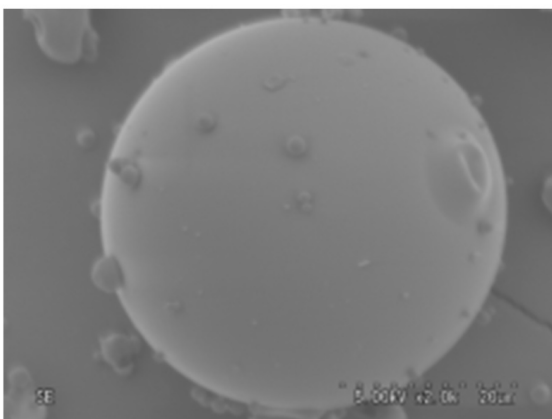
Fuji Spray Drying Newsletter

Vol 8: Sprayed Dried Solid Dispersion Development: Process Parameter Setting

Process parameter of the solid dispersion has significant effect on the quality of the solid dispersion product (particle size/shape, etc.). Therefore, before the pilot manufacturing is performed for the purpose of toxicity test or investigational drug manufacture, a study for appropriate operating condition is conducted, and optimum spray drying process parameter is determined. If the client requests for the specific process parameter, we will manufacture accordingly. Even without the detailed process parameter specifications, if the client could provide us with the desired product quality, we can propose and conduct the study for the spray drying process parameter which will enable us to obtain the target product attributes/quality. The explanation for the 3 critical process parameters are provided in the following sections below.

Chamber Outlet Temperature

Chamber outlet temperature depends on the solvent of the feed solution and its feed flow rate. Higher the chamber outlet temperature, lower the residual solvent amount, and spherical particle is typically obtained as a result. On the other hand, low chamber outlet temperature leads to high residual solvent amount, and particles with ragged surface are typically obtained.

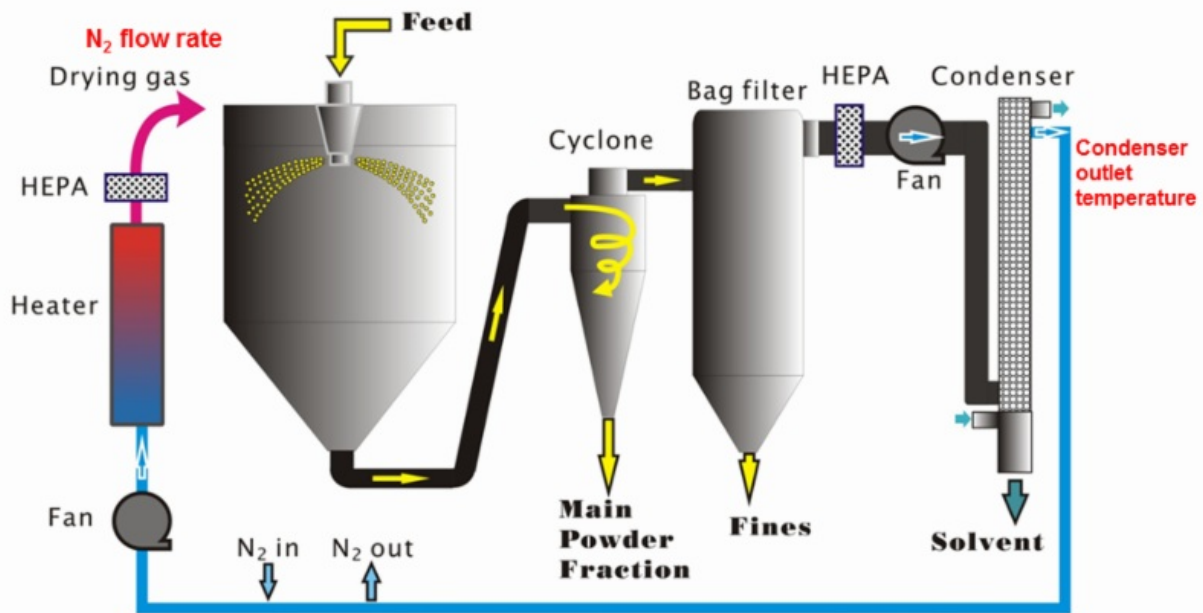


Feed Flow Rate

Lower the feed flow rate, smaller the particle size, and residual solvent amount is consequently lower. Higher the feed flow rate, larger the particle size, and residual solvent amount is higher as a result. In addition, if the feed flow rate is increased, productivity will also increase during the commercial manufacturing, since the same amount of feed solution is sprayed in shorter time.

Nitrogen Flow Rate of the Two Fluid Nozzle

Higher the nitrogen flow rate of the two fluid nozzle, smaller the particle size since the feed solution droplet size is smaller. Conversely, lower nitrogen flow rate of the two fluid nozzle results in larger particle size.



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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Meet us at the following upcoming events!

ChemOutsourcing
 Sept. 17 – 19
 Long Branch, NJ
 Booth#:27

Contract Pharma
 Sept. 27 – 28
 New Brunswick, NJ
 Booth#: TBD

AAPS
 Nov. 4 – 7
 Washington D.C.
 Booth #: 2514

CPhI Worldwide
 Oct. 9-11
 Madrid, Spain
 Booth #: 10A80
 (Contract Manufacturing)
 8H81 (Excipient)