圧力スイング造粒法を拡張した医薬品粉体の造粒

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成果の概要

In pharmaceutical granulation it is required to realize the particle design to optimize the drug dosage forms. Obtaining fine spherical granules of uniform particle size less than 500 μ m for easy handling and dispensing drug has been difficult with the conventional spray granulation which gives hard granules of mm order.

To cope with this problem, a special type of dry granulation named pressure swing granulation (PSG) has been developed by applying cyclic fluidization and compaction utilizing the spontaneous agglomerating nature of fine cohesive powders successfully producing soft and narrow size distribution of granules of 500 μ m order. However, the PSG granules' strength has been in most cases insufficient, i.e. too soft for pharmaceutical applications such as coating and tableting.

To increase the granule strength as desired, two-stage PSG granulation was conducted by introducing melt granulation. In the first stage, dry granulation of lactose and polyethylene glycol (PEG) particles was conducted in PSG at ambient temperature. Then, melt granulation was applied in the second stage at 80°C which was above the PEG melting point by introducing hot fluidizing air.

With these simple and neat processing steps, PSG in fluidized bed was made furthermore effective in producing narrow size granules less than 500 μ m with high tensile strength as in the results shown in **Fig 1 and 2**. The product granules are also smooth and spherical as depicted in the SEM image in **Fig.3**. These advantages are important to meet the current pharmaceutical industries demands.

Fig. 1 Granule size distribution of the product granules with melt granulation.

Fig. 2 Tensile strength of granules.

◇ Lactose granules

◆ Lactose and PEG-melt granulation

Fig. 3 SEM image of product granules.

Conferences

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2. Noor Fitrah Abu Bakar and Masayuki Horio, An Effective Production of Core Granules for Pharmaceutical Application. Malaysia-Japan Symposium of Advanced Technology (MJSAT) 2007, Kuala Lumpur, Malaysia.