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Editorial

Theme Issue "Granulation"

Granulation is a size enlargement of particles, which for many reasons is frequently necessary in the production of solid dosage forms. Thus, the particle size distribution is one of the most important properties for the evaluation of the resulting granules. Granulation processes were established and have been widely used in the pharmaceutical industry for a long time. However, there are still a number of issues, which are of practical and scientific interest. Although a lot of work has been done during the past decades to clarify the mechanisms of granule growth and to predict granule properties we are still not able to understand the processes, the materials used and their interactions completely. Further work is necessary to provide a better insight into the mechanisms and to allow the development of robust processes for the production of high quality products with designed properties.

I would like to thank Robert Gurny who encouraged me to prepare a theme issue 'Granulation' for *EJPB*. During the planning of this issue I intended to include topics such as modelling of a granulation process, dry granulation, melt granulation, on-line control, substrate-binder interactions, extrusion, fluid-bed granulation, high shear mixer and drying in single pot systems. Well-known scientists in the field agreed to prepare contributions for the theme issue. However, some of the intended topics could not be included, mainly due to the strict time schedule of preparation. Nevertheless, this volume presents some of the current research in the field along with reviews on important aspects and perspectives of granulation. Pharmaceutical sciences and industrial practice are addressed.

Granulation in high shear mixers and fluid-bed equipment are the most common processes, which is reflected in the content of the theme issue. Topics like scale-up and end point control which are of vital importance for the industry are covered in the first two reviews. A further review paper

introduces a (semi) continuous granulation process summarising a series of papers about a concept which has been developed some years ago.

An industrial study is related to the scale-up of a granulation process with respect to the particle size distribution from a small scale high shear mixer to production equipment. Dry granulation and melt granulation have the advantage of being solvent free processes. Two papers deal with melt granulation in high shear mixers. The first one demonstrates the use of DOE in the development process and the second paper describes the mechanisms of granulation particularly at low impeller speeds. The modelling of a fluid-bed granulation by the population balance approach is the subject of the paper from Abberger. The modelling should allow the prediction of the granule size distribution resulting from a specific process. Another approach to achieve the desired size distribution is the use of an on-line control. The implementation of image analysis during high shear granulation for this purpose is described in the paper from Watano et al.. Usually, granules are prepared for tableting purposes. In the paper from Johansson and Alderborn, the tablet forming ability of granules with respect to their shape and porosity is studied. One step beyond granulation is the concept of a continuous single step granulation/ tableting process by the use of extrusion. A granulation process is used for the shaping of tablets, which opens new innovative possibilities.

I would like to thank all the colleagues who spent their time in writing or reviewing the contributions for the theme issue. The results clearly demonstrate that granulation is an area of growing interest in pharmaceutics.

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