International Journal of Pharmaceutics 417 (2011) 1–2

Contents lists available at ScienceDirect

International Journal of Pharmaceutics

journal homepage: www.elsevier.com/locate/ijpharm

Editorial

Advanced characterisation techniques

Research and development into better drug delivery systems is at the very core of many of our activities. The translational work from drug to medicine is of the utmost importance if drugs are to contribute to improved health and a higher quality of life of people. But what makes a good drug delivery system? Clearly, and perhaps most importantly, the delivery system has to help to bring the drug in the right amount and for the right time to the right place in the body. Bioavailability is thus a major concern in dosage form research and development. But to have useful delivery systems, the medicines also have to be physically and chemically stable and it has to be possible to produce them at reasonable costs and in a technically feasible and reliable way.

To achieve all this, it is paramount that we are able to characterise and understand these delivery systems as best as possible. A thorough characterisation needs to take place at all stages, from the drug to the preformulation and formulation. However, increasingly, characterisation is not restricted to the drug and dosage form itself, but encompasses the formulation and production process, as recently highlighted for example in the PAT initiative of the FDA. Moreover, many modern dosage forms undergo changes after administration, for example in many lipid formulations the delivery vehicle undergoes digestion after oral administration. Another example is the use of high energy solids, for example metastable polymorphs or amorphous forms of drugs in many delivery systems, which may undergo crystallisation or polymorphic conversion after administration. The list may be continued almost *ad infinitum* and highlights the need to also characterise delivery systems after administration.

It is therefore not surprising that a plethora of techniques are used that probe the nature of the drug and delivery systems at all levels, from the molecular level, to the colloidal and particulate level, to the bulk level. In recent years many new techniques have been developed that help us to better understand the nature of drugs and delivery systems. Other techniques that are around for longer times have been greatly improved and analytical methods now frequently include multivariate data analysis, to help understand complex mixtures qualitatively and quantitatively.

Against this background we have put together a special issue on advanced characterisation techniques. These include spectroscopic techniques, that probe the nature of drugs and delivery systems at the molecular level, and allow us for example to examine drug-excipient interactions, drug distribution, physical and chemical stability, and that can be used to monitor and control pharmaceutical production methods. FTIR, NIR and Raman spectroscopy will be highlighted in this issue (Van Eerdenbrugh and Taylor, 2011; Hédoux et al., 2011; De Beer et al., 2011) together with a comparatively new spectroscopic technique in the pharmaceutical world, terahertz spectroscopy, which probes solid materials at the particulate level (Shen, 2011).

Perhaps not as often used as they could and should be in the field of characterisation of drugs and dosage forms are the mass spectrometric techniques. In this issue two contributions on mass spectrometric techniques (ToF-SIMS and MADLI TOF MS) highlight the potential of these techniques for surface analysis (Barnes et al., 2011) and in biopharmaceutical research (Kafka et al., 2011).

Used successfully for a long time in the field of characterisation of pharmaceutical drugs and dosage forms are the thermal and diffractometric techniques, and here, two reviews on recent developments in isothermal microcalorimetry (O'Neill and Gaisford, 2011) and X-ray scattering (Dong and Boyd, 2011) and two "research reports" on amorphous (Karmwar et al., 2011) and cryo-milled materials (Bøtker et al., 2011) are included in this issue.

Within the canon of characterisation techniques, imaging techniques have gained arguable the most momentum in recent years. From classical light microscopy to electron microscopy, including cryo-TEM and environmental SEM (Kuntsche et al., 2011; Bibi et al., 2011), to spectroscopic imaging and mapping techniques, including Raman mapping (Gordon and McGoverin, 2011), nonlinear imaging techniques (Strachan et al., 2011), MRI (Mantle, 2011; Besheer et al., 2011) and EPR (Eisenächer et al., 2011), to *in vivo* imaging (Weitschies and Wilson, 2011), the reader will find reviews and research reports that indicate and highlight the exciting developments and endless possibilities these techniques offer the pharmaceutical scientist.

In the development of drugs and dosage forms the pharmaceutical scientist has to use a wide range of techniques to get a complete insight into the nature of the dosage form. In the final part of this themed issue we have included a range of characterisation techniques, that help to more completely understand delivery systems, including advancements in particle sizing (Sandler, 2011), monolayer studies that aid in the understanding of liposomal formulations (Moghaddam et al., 2011), *in vitro* lipolysis models to characterise oral lipid and surfactant based drug delivery systems (Larsen et al., 2011), new developments in taste sensing (Woertz et al., 2011), and a systems biology approach to study permeability (Khan et al., 2011).

With all these (and many other) new and advanced characterisation techniques, large amounts of data are generated, and thus an overarching problem arises, in how to handle this invaluable information. The final article in this themed issue is therefore devoted to multivariate data analysis that plays an ever increasing role in many of the above mentioned techniques (Rajalahti and Kvalheim, 2011).

0378-5173/$ – see front matter
doi:10.1016/j.ijpharm.2011.03.036

We hope that the reader of this themed issue will find the reviews and research reports as interesting as we did and that new insights may be gained that stimulate new ideas for research and development into ever more advanced drug delivery systems.

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Available online 21 March 2011