

Controlled Release – Relevant Capabilities in ICI Measurement Science Group

Controlled release is the provision of an active component of a formulation or structure to a target medium or location at the required time. It can involve protection of the active until it reaches the medium in which it must be released, or perhaps controlled diffusion or dissolution to enable a long-term “bleed” of the active component into the environment in which it can act. The kinetics of various processes, physical and chemical, can be vital to the release rate and ultimately the efficiency of the total formulation package. Highly ingenious, as well as much simpler, methods have been devised to incorporate actives in formulations and to ensure appropriate and consistent rates of release.

Measurement Science Group is able to monitor and probe many aspects of these often complex structures and has much to offer companies that are seeking to prove and improve the effectiveness of new delivery packages. It works for clients in the pharmaceutical, medical and agrochemical sectors as well as for those in the personal care and foods arenas, in addition to its traditional heartland of the chemicals, polymers and plastics industries. Its high-level capability includes instrumentation and expertise appropriate to characterisation and problem-solving in the controlled release area.

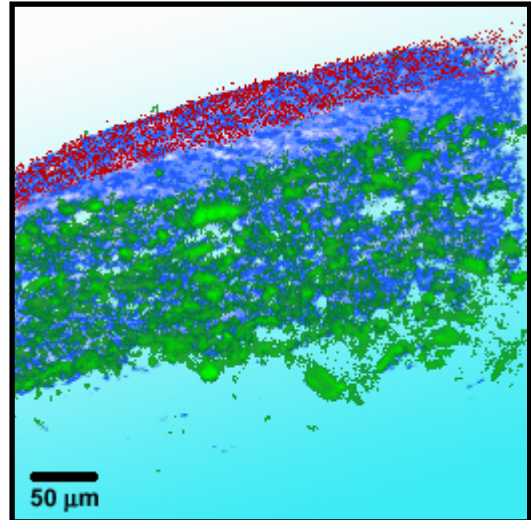
Activities within Measurement Science Group which are relevant to controlled release and delivery are described below.

Physical and Chemical imaging

Surface Analysis techniques (**SIMS** and **XPS**) allow for the identification and location of ingredients and contaminants (organic or inorganic) with sub-micron spatial resolution in 2- and 3-dimensions. Quantitative analysis can be carried out at a point, along a linescan or through a depth profile.

Similarly, imaging using complementary techniques, **Infra-red** or **Raman spectroscopy**, can also probe the distribution of key components.

Analytical Electron Microscopy (**SEM** and **TEM**) can also show the distribution of suitable elements as well



as the size and shape of the solid systems being examined.

Applications include:

- Identification of coating structures
- Thickness measurements
- Distribution of actives
- Contamination
- Degradation studies

as well as

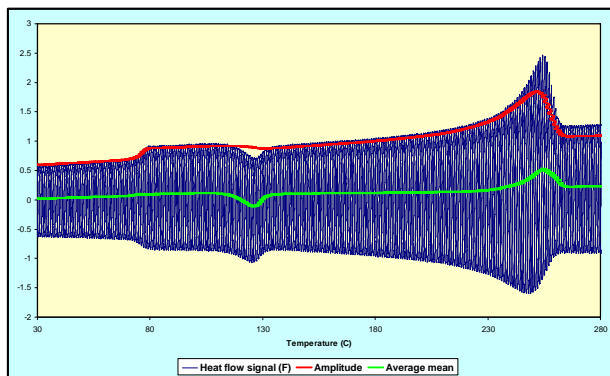
- Resolution of packaging issues
- Patent policing and protection
- Surface engineering for Biocompatibility and Quality Control

The size, distribution of sizes and shape of components provide important information about the make-up and consistency of formulations for controlled release. Measurement Science Group is highly experienced in measuring particle sizes by a variety of means, obtaining distributions of sizes by **light scattering** or by **image analysis** of optical or electron micrographs.

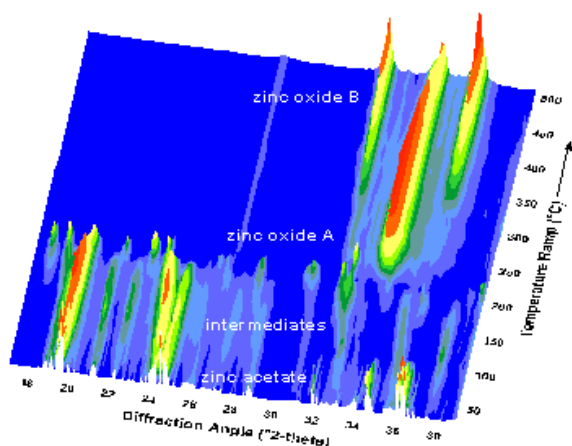
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Polymer Science & Characterisation

Polymer Science is involved in the optimisation of polymer properties for new drug delivery systems.



X-Ray diffraction can be used for the investigation of polymorphic transformations and crystallinity.



Chemical Identification, Chromatographic separations and quantification

Techniques that permit chemical deformation may be applied to competitive analysis and in patent protection issues.

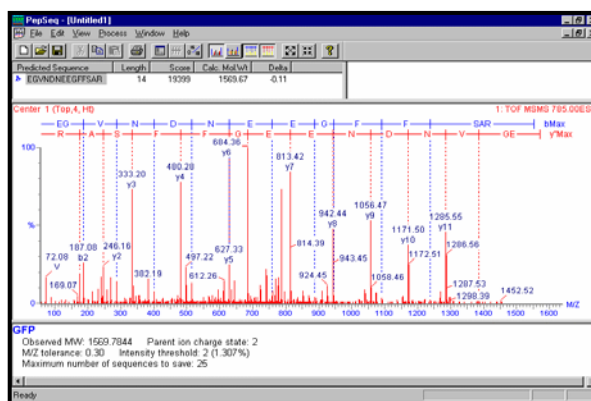
Complex mixture analysis is important in both the early stages of formulation and in production analysis and control. We have a fully integrated Spectroscopy and Separation Science team, with state-of-the-art equipment. Capabilities of particular relevance to the

pharmaceuticals industry and controlled release mechanisms include:

- High performance MALDI
- High sensitivity LC-MS
- LC-NMR & GPC-NMR

for use in:

- quantification of drugs (assays)
- protein characterisation
- investigation of metabolic pathways



Additionally, high-sensitivity accurate mass spectrometry and tandem mass spectrometry provide excellent means of unknown species identification.

Kinetic studies

Rate of release must be measured to prove efficacy. The concentration of active released can be determined by GC, LC or other chromatographic techniques or by vibrational spectroscopy and identification of ingredients proven by mass spectrometry or NMR.

If there is any interest in the above capabilities, please address your enquiries to Allan Stewart or Isla Mathieson at the following.

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