

Nanotechnology in Healthcare Applications

Characterization Services

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Nanoparticles have been developed for a range of applications in healthcare products from therapeutics, medical devices, drug delivery, diagnostics, disease and infection prevention. Intertek provides a comprehensive R&D or cGMP analytical capability for nanotechnology systems via its suite of relevant analytical technology.

Intertek's expertise helps our clients to accelerate the development process and support the critical stages of approval and certification for nanotechnology applications.

Turn over to read an interview with two of Intertek specialists on nanotechnology challenges

From dispersed metallic nanoparticulate systems in diagnostics applications to liposome nanoemulsions for drug delivery, Intertek is working with an increasing number of pharmaceutical or medical device clients to characterize their nanomaterial products.

Physical Characterization:

- Analysis of particle size and morphology using SEM (or TEM), light scattering techniques or disc centrifugation
- Nanoparticle interactions to aid formulation development by zeta potential measurements
- Phys-chem properties (viscosity, solubility and more)
- Surface area measurements by BET isotherm
- Crystal morphology by powder X-Ray Diffraction

Chemical Characterization:

- Organic Components e.g. by using LC-MS/MS
- Inorganic Elemental data by ICP-MS, ICP-OES, or SEM-EDX
- Chemical information: FTIR, RAMAN or NMR
- Purity and impurities
- Surface Chemistry / Surface Analysis (TOF-SIMS)

Quality

The laboratory has been inspected by the UK Medicines and Healthcare Products Regulatory Agency (MHRA) for GLP and GMP compliance and by the US Food and Drug Administration (FDA) for cGMP compliance in relation to customer's pharmaceutical manufacturing license.

Nanotechnology has delivered major advances in healthcare and has a range of applications in medicines and medical devices. According to a recent report, the worldwide market value of the nanomedicine industry was \$72.8 billion in 2011, estimated to reach \$130.9 billion by 2016.

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We catch up with two of Intertek's experts to get an update on this exciting topic:

- Dr Neil Truslove, Technology Manager
- Mike Ashton, Microscopy Team Leader

Q How do you define "nanotechnology"?

MA – The European Commission proposed a definition in 2011 — in EU legislation nanomaterials should be identified solely on the basis of the size of the particles of a material, and not on the basis of hazard or risk. Under the definition, the nanoscale range would be 1-100nm.

NT – The general consensus was that this definition was lacking and so impacted a range of current EU regulatory initiatives such as the REACH (registration, evaluation, authorisation and restriction of chemicals) regulation and legislation covering cosmetics and foods. This definition proposed by the EU would be the same as that currently used by the International Organisation of Standardisation (ISO).

Q Where have you observed application of nanotechnology in healthcare products?

NT – We have seen multiple applications of nanosystems in drug delivery systems where nanoparticulate systems enhance bioavailability or stabilise the API.

MA – We have also seen nanotech in preventative applications such as nanoparticulate antimicrobial coatings involving silver nanoparticles for wound care products or in coatings. It has been used in personal care products too for many years where for example nanoemulsions are common.

Q What are the most important aspects of characterising nanotechnology systems?

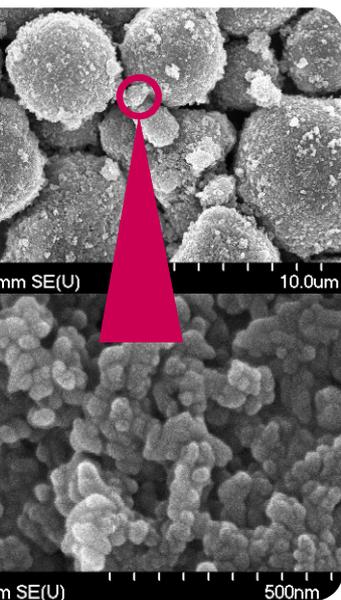
NT - Particle size is obviously a key issue and wide range of PSD technology can be applied from Laser Diffraction Techniques, Disc Centrifuge, Photocorrelation Spectroscopy (PCS). Selection of the particular method depends on the system in question.

Understanding the Zeta potential using our nanozetalyzer helps to understand interparticle interactions. It can be used to assess the effect of ingredients in a formulation e.g. dispersing agents and so aid formulation development.

MA - Particle / surface morphology is important. Bone graft materials for example are bioengineered to be mimic the structure of human bone thus assisting in the repair of a damaged tissue enhancing the interaction of cells with the implant material. SEM is a key technique for general surface characterization such as roughness but also particle size or pore size also. Complement this with surface area and porosity measurements and it reveals a huge amount of detail.

NT - Controlled release of drugs such as insulin is a hot topic as such devices can be implanted and allow continued release of a drug over the period of weeks, thus avoiding the need for regular injections. Controlled release can be studied in the laboratory using a range of imaging techniques.

MA - Where nanoemulsions are used perhaps as an encapsulation delivery system we can look at the particle size in suspension / solution using dynamic light scattering which is also excellent at investigating if these systems have a tendency to aggregate in solution. We also have a high pressure fast freezer system which in combination with cryo-electron microscopy can preserve and reveal their microstructure where conventional plunge freeze sample preparation can not



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