Addendum

Recent Patents Filed in the Field of MSNs for Biomedical Applications

Ever since its first publication, modifications in terms of synthesis aiming to control the particle size and pore volume has led to the filing of several patents on MSNs. Owing to its versatile nature of loading therapeutic agents, both hydrophilic and hydrophobic, patents filed on MSNs mainly include investigating them for biomedical applications, biosensors, imaging and as adsorbents of different drugs for solubility and bioavailability enhancement.

A review of the some recent patents related with the sustained/targated drug delivery applications of MSNs is presented here.

Applications and tools based on silica particles coated with biological or synthetic molecules (U.S. 20170172935A1); Inventor:- Huseyin Avni Oktem, veli Cengiz Ozalp, Frank J. Hernandez, Luiza I. Hernandez developed mesoporous silica nanoparticles (MSNs) loaded with cargo antibiotics and their surface coated with a polymer to prevent premature release of the drug. The formulation was designed such that, the cargo will be released only in response with the stimuli.

Lipid bilayer coated mesoporous silica nanoparticles with a high loading capacity for one or more anticancer agents (U.S. 20160008283A1) Inventor:- Andre E. Nel Jeffrey I. ZinkHuan Meng developed phospholipid bilayer coated MSN loaded with gemcitabine (GEM) for the treatment of human pancreatic ductal adenocarcinoma (PDAC). The MSNs were synthesized and loaded with GEM. The delivery system showed enhanced uptake in tumours showing a significant reduction in tumour volume. The MSNs were coated with PEI/PEG and it prolong the circulation time of the Gemcitabine.

Hcd formulation for cancer treatment. (U.S. patent 20160243236A1) Inventor: Ching-Feng Weng, Yi-Chen Chia, Chia-Hung Lee, T. Varadharajan developed copper modified mesoporous silica nanoparticles for improving the efficacy of a natural molecule, 16-hydroxy-cleroda-3,13-dine-15,16-olide (HCD) for the treatment of cancer and in in vitro release the drug shows the sustained release.

Mesoporous Silica Nanoparticles for Biomedical Applications. (U.S. Patent 20100255103A1), Inventor: Liong, M.; Lu, J.; Tamanoi, F.; Zink, J.I.; Nel, A. developed mesoporous silica nanoparticles to carry water-insoluble drugs like camptothecin (CPT) and paclitaxel (PCL) for the treatment of pancreatic carcinoma.

Nanostructured Material Formulated with Bone Cement for Effective Antibiotic Delivery. (U.S. Patent 9155814B2), Inventor:- Shou-Cang, S.; Kiong, N.W.; Chia, L.;

Tan, R. Loaded antibiotic drugs gentamicin, vancomycin and anti-inflammatory indomethacin, ibuprofen into the MSNs. Formulate MSN based bone cement, the drug was loaded into the MSNs and polyacrylate was added to form a mixture to which monomer, methyl methacrylate was added and polymerized to form the bone cement. This current invention can be used as an alternative to treat osteomyelitis, augmentation of the bone crew and bone-implant interface during joint replacement surgery, as bone filler and bone graft substitute.

Current Regulatory Perspective with MSNs

A key point during the planning of the clinical trials of nanoparticles that should be dealing with the regulation agencies, such as the American Food and Drug Administration (FDA) and European Medicines Agency (EMA). Nowadays there is a lack of specific requirements for nanomedicines from those agencies, and the evaluation process follows the same path as for small-molecules drugs. This means that every novel nanocarrier for drug delivery has to follow a complete evaluation process, even if the transported drug (Active Pharmaceutical Ingredient) alone has been already accepted for clinical use. This supposes a bottleneck for the translation of novel nanomedicine, with only 5% of the initial nanomedicines initially evaluated succeeding in the market authorization.

It is expected that in the near future the regulatory agencies might develop specific requirements for nanomedicine to accelerate the translation from the lab to the clinic.

As per concern about the mesoporous silica nanoparticles as per the US-FDA use of the amorphous silica (Key material in the Mesoporous silica nanoparticles) in drug delivery is Generally regarded as safe (GRAS) and recently, use of these mesoporous silica nanoparticles was seen in the form of FDA's approval to conduct stage I human clinical trial for Cornell dots (C dots). C dots are core-shell mesoporous silica nanoparticles containing fluorescent molecules within the silica core surrounded with silica shell which is further coated with polyethylene glycol (PEG). This marked an important step towards the acceptance of silica nanoparticles.

Efforts are to be made by researchers like us to bridge the gap between the preclinical and clinical use of MSNs to achieve marked progress and fulfil the regulatory requirements in this subject. So if a careful assessment during the production and in vitro evaluation along with studies to ascertain the biosafety of MSNs is performed, these novel designs can be a vital breakthrough in the future for clinical applications to the patients.