Expert Registry

Dr. Malaykumar D. Shah

Assistant Professor in Nanocarriers in Drug Delivery,

(Pharmaceutical Technology & Nanomedicine),

Institute of Research & Development,

Gujarat Forensic Sciences University,

Sector 18A, FSL Campus,

Gandhinagar, Gujarat, 382007.

Phone: 079- 65735508, +91-992-466-4111

Email – malay2512@yahoo.co.in, malayds2512@gmail.com

SUMMARY OF RESEARCH INTERESTS

My research expertise is in the development of nanoparticulate delivery systems (Polymeric & Lipidic) with emphasis on drugs having poor bioavailability. Current projects being pursued include development of lipid based formulation and ocular transit studies on various antibacterial drugs. I have researched in a wide variety of nanocarriers and conventional dosage forms, including the PLGA based nanoparticles, Carbon Nanotube based drug delivery, Lipidic Nanoparticles, Transdermal Patch, In Situ Gel etc. The potential of SLN in various classes of drug delivery systems have been an abiding interest over last 4 years.

Recent studies includes: In silico solubility parameter approach for the screening of excipients; development of lipidic nanoparticle for the delivery of highly hydrophilic drug molecules; Statistical designing and optimization of lipidic nanoparticles; carbon nanotube based drug delivery system; carbon nanotubes as an adsorbents in preparation of diltiazem HCl microspheres. These CNTs based study is the first of its kind in India, provided unique opportunities to explore the potential of CNTs.

Other research interests include: Preformulation and formulation study of parenteral dosage forms, tablets, emulsion and suspension.

Expertise in instrumentation like HPLC, SEM, Malvern Zetasizer, FTIR, Raman, Homogenizer, UV-Visible Spectrophotometer, Release study. Excellent knowledge in training and handling statistical data analysis and exposure of wide variety of softwares like Design Expert, Origin, Minitab, Systat, Cambridge Chembio Office, Graphpad, Molecular Modeling Pro.

Key Areas

- Preformulation Studies
- Formulation Development – NDDS, Nanomedicine, Nanocarrier Drug Delivery System, Biomolecules Drug Delivery & Parenteral Formulation (Area of Research covers Polymeric and Lipidic Materials)
- Statistical Formulation Optimization

- Analytical Studies and Interpretations
- In Silico QSPR Studies

Key Research Achievements

- Carbon nanotube based drug delivery system was first time reported in India for which I was awarded best research paper prize in 2007.
- One of the very few publications reporting the potential of carbon nanotubes for the hydrophilic as well as hydrophobic molecules in drug delivery.
- Success of In Silico solubility parameter approach was reported in a very few studies for the prescreening study of lipids and solvents for the development of SLN.
- By considering the excipients compatibility studies with drug succefully reported the loading of the hydrophilic drug molecule in lipidic nanoparticles.

Publications List

- Malay Shah, Namdeo Jadhav, Y.K. Agrawal. Carbon Nanotube as adsorbent for floating microsphere of Diltiazem Hydrochloride. Fullerenes Nanotubes and Carbon Nanostructures. 17:5, 528 — 547, 2009.
- Malay Shah, Y.K. Agrawal. High throughput screening: An *in Silico* Solubility Parameter Approach for lipids and solvents in SLN preparations. Pharmaceutical Development & Technology, Online November 22, 2011.
- Malay Shah, Y.K. Agrawal. Ciprofloxacin Hydrochloride Loaded Glyceryl Monostearate Nanoparticle: Factorial Design of Lutrol F68 and Phospholipon 90G. Journal of Microencapsulation, Online January 18, 2012.
- Malay Shah, Y.K. Agrawal. Development of Ciprofloxacin HCl based Solid Lipid Nanoparticles using Ouzo Effect: An Experimental Optimization and Comparative Study. Journal of Dispersion Science & Technology – Online January 20, 2012.
- Malay Shah, Y.K. Agrawal. Calixarene: A New Architecture in the Pharmaceuticals. Journal of Scientific and Industrial Research. 71, 21-26, 2012.
- Malay Shah, Y.K. Agrawal. Carbon Nanotube: A Novel Carrier for Sustained Release Formulation. (Accepted in Fullerenes Nanotubes and Carbon

Nanostructures, Taylor&Francis).

- Malay Shah, Y.K. Agrawal. M Solid Lipid Nanoparticles of Water Soluble Drug Ciprofloxacin HCl: Binary Mixture Lipid of Triglycerides and PEG100 Glyceryl Stearate. (Communicated to IJPS)
- Malay Shah, Y.K. Agrawal. Solid Lipid Nanoparticle: A New Vision in Ocular Drug Delivery. (In Pipeline).
- Solid Lipid Nanoparticles in the Delivery of Ketoconazole topically. (Under Development)
- Malay D. Shah, Karthik Nair, Pramod Shirote, Neela M. Bhatia, and Namdeo R. Jadhav. Methods of Carbon Nanotube and Nanohorn Synthesis: A Review. Pharma info.net August 2007.

Journal Reviewer

Journal of Nanoparticle Research

Acta Pharmaceutica

International Journal of Nanomedicine

Summary of Current Research Projects

Nanoparticle in Ocular Drug Delivery Research Project

Ocular drug delivery is a one of the challenging site of drug administration due to critical and pharmacokinetically specific environment exists in the eye. The anatomy, physiology and biochemistry of the eye render this organ exquisitely impervious to foreign substances. All the conventional ocular dosage forms administered topically, periocularly or systematically are having profound pain of poor bioavailability. Certain conditions like glaucoma, macular degeneration and AMD are treated by intravitreal and other invasive routes where repeated administration put the patient at high risk of endophthalmitis, cataracts, vitreous hemorrhages, and retinal detachment. In a path of continuous advancement to the conventional ocular therapy, we have started developing nanoparticles to improve the ocular bioavailability of the drugs. The potential of nanoparticle for the ocular delivery of various therapeutic agents are required to be recognized. Nanoparticulate drug delivery system seems to be ready to deliver a

solution to the challenges posed by conventional ocular drug delivery. The long-term goal of this research is the development of a commercially viable novel nanoparticle production process that improves the formulators control over robust particle size, stability, high drug loading, superior targeted and controlled release capabilities, with high potential benefits in treating ocular diseases. The present research is focused on ophthalmic dosage form directed towards improving the topical route of administration, primarily to increase the amount of drug at the site of absorption and to increase its duration of contact with the target site.

Solid Lipid Nanoparticle Development

Since the 1990s, lipid nanoparticles (SLN and NLC) have been an interesting carrier system for the delivery of cosmetics, neutraceuticals and pharmaceutical actives and involved a number of researchers throughout the world with the advantage of being prepared with physiological lipids. A solid lipidic matrix of SLN is expected to provide better physical and chemical stability than that of liposome and emulsion system. Lipid nanoparticles represent as a fascinating carrier and have the perspective to be introduced to the market in a number of products from cosmetics, neutraceuticals and pharmaceutical area. However, despite the perceived advantages and numerous researches, the commercialization of solid lipid nanoparticle technology has proved extremely difficult. Physical instability, characterized by particle growth, and drug burst release have led to call the SLN testimonies into question. Given the solid nature of the lipid, particle size growth represents a potentially lethal complication. Commercialization has been impeded by the lack of a large-scale, economically efficient production process. Currently available technologies do not provide the necessary particle size control, long-term stability, drug loading capability, and reproducibility to fully realize the potential previously demonstrated in laboratory settings. The primary objective of this research effort is to enable solid lipid nanoparticle technology to move beyond its current stability, release, and cost limitations. We at our laboratory developing an improved production process required to realize the full technological and economic potential of solid lipid nanoparticle technology. We are investigating solid lipid nanoparticle synthesis and the resulting effects on stability, drug loading, drug release, and efficacy.

Carbon Nanotube based Drug Delivery

Within the family of carbon, carbon nanotube is emerging as an alternative and efficient tool for transportation and translocation of therapeutic molecules. CNTS possess various novel properties that make them useful in the field of pharmaceuticals. Their unique surface area, stiffness, strength and resilience have led to much excitement in the field of pharmacy. Nanotubes possess the unique feature of being able to enter a living cell without causing its death or without inflicting other damage. Apparently they behave like miniature needles and pass through the cell membrane. Due to this fact, they can be used to deliver small organic drug molecules into the cells, as well as various peptides, proteins, and nucleic acids. Therapeutic and diagnostic agents can be encapsulated, covalently attached, or adsorbed on the surface of carbon nanotube. In our laboratory we have successfully demonstrated that CNTs can be used as strong adsorbents in a number of applications in pharmaceutical sciences. We have reported sustainability of MWCNTs in designing of extended release drug delivery systems using drugs like candesartan cilexetil, diclofenac sodium and diltiazem hydrochloride with distinct solubility profile. However, in the preparation of adsorbates certain factors like homogeneity, temperature, interactions and energy related with adsorption and release of drug, wide distribution of the nanotubes diameters, toxicological study etc are under consideration.