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Clay, nano-clay and their composites as an excipient for the extended release of drugs

Monika Datta
University of Delhi, India

In recent years, a naturally occurring clay mineral Montmorillonite (Mt) has attracted the great interest of researchers. The advantageous characteristic physicochemical properties of Mt make it an ideal drug delivery vehicle. It could effectively protect unstable bioactive molecules against harsh biological conditions and release them in an extended/controlled manner, which finally contribute to enhanced efficacy. Montmorillonite (Mt), belonging to the smectite group of clay mineral is supposed to be a promising drug delivery vehicle due to its biocompatibility, low toxicity, the ability of interaction with drugs by various mechanisms, enhanced adsorption and mucoadhesion capabilities and extended-release characteristics. Mt belongs to the GRAS list of FDA as an excipient material. Our research group has been successful in developing Mt and its composites (organo-Mt, Mt-Polymer nanocomposites and Mt- polymer microbeads) as an extended release carrier for various categories of drug (Anti-hypertension, Anti-inflammatory, Anti-depression, Antibiotic, Anti-cancer, Anti-diabetes etc. 1-5). One of the most important drawbacks associated with the commercially available selected drugs includes fluctuation in the concentration of the drug in plasma which results in a concentration of the drug sometimes below the MEC (Minimum Effective Concentration) and above the MTC (Maximum Toxic Concentration) due to multiple dosing. Therefore, there is a strong need for the development of an extended release drug delivery vehicle to minimize the need for multiple dosing. Drugs were incorporated via ion exchange, adsorption and emulsion solvent evaporation techniques. The drug encapsulation efficiency and drug loading capacity in the synthesized products were estimated with the help of HPLC/UV-Visible spectrometric techniques. In all the synthesized samples, physical status of Mt and drug, their particle size and surface morphology have been evaluated with the appropriate analytical techniques. *In vitro* release profile of the drugs from Mt, organo Mt, and Mt– polymer nanocomposites have been investigated in the simulated gastric and intestinal fluids. Results have been compared with the drug incorporated polymer nanoparticles and commercially available formulations. Thus, by tuning multiple parameters at the same time, a broad spectrum of functionalities have been developed that can be used for engineering extended release drug delivery vehicles with a reduction in multiple dosing frequencies and improved patient compliance.