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Formulation and evaluation of pH-sensitive nanoparticles for intestinal - site specific drug delivery system

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The objective of this study was to develop a novel pH sensitive nanoparticulate system for Intestinal- site specific drug delivery based on natural gums for the Intestinal ulcer application. Esomeprazole magnesium was used as a model drug. Guar gum is used as the polymer for preparation of pH sensitive nanoparticles. Thus formulated nanoparticles are dispersed in a Capsule. The size distribution of the prepared nanoparticles is measured. FT-IR and DSC were made to examine the compatibility between the drug and the polymer. The morphology of the nanoparticles is examined by SEM. Drug content of prepared nanoparticles is performed and the *In-vitro* dissolution of nanoparticles is evaluated.

Biography

VNSK Varma has done Bachelors in Pharmacy at NGSMIPS, Mangalore. He is presently pursuing M. Pharmacy in Pharmaceutics stream at JSS college of Pharmacy, JSS University Mysore. He has participated in several international conferences and seminars and made poster presentation in various international &conferences and seminars.

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Process analytical technology-Current scenario

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Process Analytical Technology (PAT) has been gaining momentum in the biopharmaceutical community due to the potential for continuous real time quality assurance resulting in improved operational control and compliance. Implementing a PAT analytical scheme allows us to meet two of the key goals that have been outlined for PAT: "variability is managed by the process" and "product quality attributes can be accurately and reliably predicted over the design space established for materials used, process parameters, manufacturing, environmental, and other conditions" The term "Process Analytical Technologies (PAT)" has been used to describe "a system for designing and controlling manufacturing through timely measurements (i.e. during processing) of critical quality and performance attributes for raw and in-process materials and also processes with the goal of ensuring final product quality". The PAT initiative focuses on building quality into the product and manufacturing processes, as well as continuous process material at critical stages of manufacturing. It provides platform for continuous manufacturing and real-time release of the product and the possibility of replacing the conventional validation batches. PAT provides increased information on the process continuous learning and identification of sources of variability increased information understanding of process variable effecting critical product parameters. PAT tool can be implemented in both the lab and the plant, with laboratory PAT focused more on the design of a quality process and with plant PAT focused on the monitoring and control of the process.

Process analytical technology (PAT) refers to a series of tools used to ensure that quality is built into products while at the same time improving the understanding of processes, increasing efficiency, and decreasing costs. The PAT toolkit contains process analyzers, multivariate analysis tools, process control tools, and continuous improvement/knowledge management/ information technology systems. The integration and implementation of these tools is complex, and has resulted in uncertainty with respect to both regulation and validation. The paucity of staff knowledgeable in this area may complicate adoption. Studies to quantitate the benefits resulting from the adoption of PAT within the pharmaceutical industry would be a valuable addition to the qualitative studies that are currently available.

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