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Development and optimization of pH responsive crosslinked polymeric microparticulate system for solubility enhancement of Rosuvastatin calcium (RST)

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Statement of the Problem: Low solubility in water as well as biological media leads to poor bioavailability that reflects sub-therapeutic response even at low doses. Rosuvastatin calcium (RST) is a synthetic lipid lowering agent of statin group that is widely used for the treatment of hyperlipidemia. It belongs to BCS-II and has crystalline nature. It presents solubility issues and poor bioavailability i.e. 20% with gastric media leading to patient non-compliance. These properties lead towards high cost of product as well as wastage of pharmaceutical resources.

Methodology & Theoretical Orientation: Aqueous free radical polymerization technique was adapted to prepare polymeric microparticles. Resultant lyophilized products were characterized for entrapment efficiency, FTIR, thermal analysis i.e. DSC & TGA, SEM, TEM, sol-gel fraction, PXRD, zeta size and zeta potential, swelling behavior, solubility studies, dissolution studies and pharmacokinetic evaluation. Release data was subjected to kinetic models to find out best fit model and mechanism of release of RST from micro-particles.

Findings: A highly stable, biocompatible and non-toxic polymeric network containing methacrylic acid as monomer was successfully developed. pH dependent swelling and ultimate higher drug release (85.74%) was seen at basic pH. 9.59 folds increased solubility of RST was proved when compared to the pure drug. Amorphous nature of RST within the microparticles was confirmed by PXRD. Compatibility among ingredients was confirmed by FTIR studies.

Conclusion & Significance: RST loaded hydrogel microparticles were prepared and optimized successfully to improve solubility. At pH 6.8 a marked increase in solubility of RST was seen. A rapid release and improved bioavailability of RST was offered by this newly prepared polymeric carrier system. These cheaper, non-toxic and biocompatible matrices can be used for solubility enhancement of other hydrophobic drugs.

Biography

Sajid Bashir has expertise in solubility and bioavailability enhancement of hydrophobic drugs and has devotedly enhanced solubility of various drugs by utilizing various techniques including the introduction of hydrogel microparticles in solubility enhancement in his Doctorate degree. Currently, he is working on nanocomposite hydrogels.

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