

Formulation and evaluation of anti-migraine controlled release microspheres of sumatriptan succinate

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Sumatriptan is the most commonly prescribed drug for migraine attacks. But the major problem with oral route is very low bioavailability (15%) due to pre-systemic metabolism and incomplete absorption. Hence sumatriptan is selected as model drug for colon targeted drug delivery system. The colon route has some advantage due to its large surface area, rich blood supply, avoidance of the first pass effect. The purpose for the present investigation is to formulate and evaluate microspheres for colon drug delivery system of sumatriptan succinate using solvent evaporation method. Microspheres are prepared using various natural biodegradable polymers xanthum gum and guar gum. Natural polymers particularly in the form of microspheres, have an important role in better understanding of the kinetics of drug release, more effective ways to control burst phenomena, greater understanding of drug-polymer interactions and their effect on the shelf life stability. The effect of different ratios of polymer in the preparation was identified. The drug release from the prepared system was carried out and was compared with Sumatriptan succinate tablets. Further the microspheres prepared were also tested for entrapment efficiency, swelling index, vesicle size and in-vitro analysis.

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Biopharmaceutical classification system (BCS): Regulatory applications and extensions

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The BCS is a scientific framework for classifying a drug substance based on its aqueous solubility and intestinal permeability. It allows for the prediction of in vivo pharmacokinetics of oral immediate-release (IR) drug products by classifying drug compounds into four classes based on their solubility related to dose and intestinal permeability in combination with the dissolution properties of the dosage form. BCS find applications in INDs/NDAs, ANDs and Post approval Changes. The BCS provides a regulatory tool for replacing certain bioequivalence studies with accurate in vitro dissolution tests during the process of generic drug development. BCS provides biowaivers for class I, II, and III drug for both pre and post approval phases. The proposed biowaivers includes data supporting high solubility, high permeability and data supporting rapid and similar dissolution. The drug substance for which a waiver is being requested should be highly soluble and highly permeable. A list of excipients used, the amount used, and their intended functions should be provided. Excipients used in the test product should have been used previously in FDA-approved IR solid oral dosage forms. Extension of BCS includes Quantitative BCS (QBCS) which takes DOSE-RATIO as core parameter and Biopharmaceutical drug disposition classification system (BDDCS), which includes the effect of food, routes of administration etc. in BDDCS the permeability component is replaced by metabolism component and this system increases the number of class I drugs eligible for waiver of in vivo bio-equivalence studies and provide new insight for other classes. Other extensions includes Pulmonary BCS which consider the specific biology of lungs and Six class BCS in which solubility was classified as high and low while permeability as low, intermediate or high.

Biography

Ashish Sharma is presently pursuing M. Pharmacy in Quality Assurance branch at Lachoo Memorial College of Science & Technology Pharmacy Wing, Jodhpur, India.

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