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Formulation and *In-vitro* evaluation of gastroretentive drug delivery system containing metronidazole

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In recent years scientific and technological advancements have been made in the research and development of rate-controlled oral drug delivery systems for prolongation of the gastric residence times. The challenge to develop efficient gastroretentive dosage forms began following the discovery of Helicobacter pylori by Warren and Marshall. Helicobacter pylori lives deep within the gastric mucus layer and prolonged local application of drug is needed for sufficient to diffuse to the bacteria. Gastroretentive floating beads have a potential for enhancing the bioavailability and controlled delivery of drugs. The present study involves development of metronidazole floating beads in order to increase the gastric retention time for the eradication of Helicobacter pylori. The beads were prepared by ionotropic gelation technique, using polymers solution such as sodium alginate and then dipping the dispersion into a solution of calcium chloride. Calcium alginate beads were formed. These beads were evaluated for entrapment efficiency, buoyancy, swelling and in vitro drug release. The prepared beads exhibited prolonged drug release in gastric medium and hence could be utilized for sustained delivery of drugs.

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Basics of patent term extension

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Patent is an exclusive legal right to protect the invention from any unauthorized commercial use. As per TRIPS agreement the term of patent is 20 years from the date of filing the patent application. However, the effective patent term is usually less than 20 years because patents are often obtained before products are actually marketed. Patent term extension means extending the term of an enforceable pharmaceutical patent beyond 20 years by the law under certain circumstances. Although there are no internationally agreed standards for patent term extension, a number of countries like US, Australia, Japan and many member states of the European Union provide patent term extension for pharmaceuticals. In US, patent term extension is granted as per 35 USC 156 under the Drug Price Competition and Patent Term Restoration Act, 1984 (the Hatch–Waxman Act) to compensate the delays caused by US FDA in regulatory approvals of human drug products, including antibiotics and biologics, medical devices, food additives, and color additives. Under 35 USC 154, patent term can be adjusted for any delays caused by USPTO during the prosecution of the patent application. In Europe, patent term extension can be obtained for medicinal products by means of a supplementary protection certificate (SPC) under European Community Regulation No. 469/2009. Provisions of patent term extension cause profound impact on pharmaceutical industry. On the one hand it encourages the development of new drugs through the incentives it provides to the patent owners and on the other hand it also delays the entry of cost effective generic versions of new drugs in the market. The patent owner shall be aware of the requirements and limitations of such extensions, and the time limit to apply for the same.

Biography

Mr. Tarun Sharma is presently pursuing M. Pharmacy in Pharmaceutical Management & Regulatory Affairs branch at Lachoo Memorial College of Science & Technology, Pharmacy Wing, Jodhpur, India.