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Novel co-processed excipients of mannitol and microcrystalline cellulose for preparing fast dissolving tablets of fexofenadine hydrochloride

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Co-processed particles of mannitol and microcrystalline cellulose were fabricated by spray drying technique to be used as a direct compression excipient in fast dissolving tablet formulation. Microcrystalline cellulose passed through sieve no.80, having a volumetric mean diameter (d_{50}) of 30.85 μm, was used to form composite particles with powdered mannitol which was previously passed through sieve no. 80, in various mixing ratios. The composite particles were evaluated for their powder and compression properties. An increase in the microcrystalline cellulose proportion imparted greater compressibility to the composite particles, but the flowability of these mixtures was decreased. Although microcrystalline cellulose and mannitol have been extensively used in the formulation of fast dissolving tablets, the non-wetting property of the hard compact central core may delay the disintegration time. Optimized co-processed formulation containing mannitol and microcrystalline cellulose in the ratio of 1.5:1 was found to have optimized powder and compressibility characteristics with fast disintegrating property (<15 s). The fast disintegration may be due to the partial amorphization and formation of submicron particles of mannitol. These results indicated that improved fast dissolving tablets could be prepared by the co-processed mixture of microcrystalline cellulose and mannitol. Finally fast dissolving tablets of Fexofenadine were prepared by blending with other excipients and compressed into tablets. Sensory study on disintegration time and mouth feel attributes ranked the present formulation based on grittiness, chalkiness and overall preference as the best.

Biography

Shobhit Sharma completed B. Pharma in 2007 from Rajiv Academy for Pharmacy, Mathura (U.P.). Presently he is M. Pharma Pharmaceutics Student in Kota College of Pharmacy, Kota (Rajasthan). Shobhit is having 4 International review articles, 2 International research articles and He is attended 2 National conferences in Delhi and in Solan (H.P.). His Research Guide is Dr. M.P. Khinchi is having 15 International Research Articles, 20 International Review Articles and he is Attended 12 National Conferences

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Generic drug user fee act – perspectives and its eminence

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As the discovery of new drugs is becoming more difficult and tedious process generics had a high bid in the market. Generic drug is a drug product that is comparable to brand/reference listed drug product in dosage form, strength, route of administration, quality and performance characteristics, and intended use. It has also been defined as a term referring to any drug marketed under its chemical name without advertising. To help FDA ensure that participants in the U.S. generic drug system comply with U.S. quality standards, and to increase the likelihood that American consumers (public) get timely access to low cost, high quality generic drugs, FDA and industry have jointly agreed to a comprehensive user fee program, Generic Drug User Fee Act. The US FDA has implemented Generic Drug User Fee Act (GDUFA) on July 9th, 2012. GDUFA is designed to build on the success of the Prescription Drug User Fee Act (PDUFA). The GDUFA law requires industry to pay user fees to supplement the costs of reviewing generic drug applications and inspecting facilities. It is designed to keep individual fee amounts as low as possible to supplement appropriated funding to ensure that consumers continue to receive the significant benefits offered by generic drugs which provided more than $824 billion dollars in savings to the nation's health care system in the last decade alone. This paper represents the aspects of GUDFA like Backlog Fee, Facility Fee, Drug Master File Fee, Abbreviated New Drug Application (ANDA) and Prior Approval Supplement (PAS) Fees.

Biography

I Sirisha K. pursuing my M.Pharm 1st year with specialization regulatory affairs in JSS College of Pharmacy, Mysore. I have pursued my B.Pharmacy in JSS College of Pharmacy, Ooty. I have attended three international conferences on "Herbal Drug Research – Present and Future Prospects", an "Indo- European Symposium on Alternative Approaches To Animal Testing" and "Trends In Pharmaceutical Sciences, Practice And Education".

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