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Development of fast dissolving oral film of analgesic drug markets

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The buccal mucosa has been investigated for local drug therapy and the systemic delivery of therapeutic peptides and other drugs .The tablet dosage forms are more popular but the problems associated with these dosage forms is hepatic first pass metabolism, GI toxicity and enzymatic degradation results in high incidence of non-compliance and ineffective therapy. The fast dissolving oral films overcomes the above problems. After the application of strips to the oromucosal tissue, it instantly wet by saliva, rapidly hydrates and adheres where it rapidly disintegrates and dissolves to release medicament for oromucosal absorption finally leads to quick onset of action particularly to manage pain, allergies, sleep difficulties, and central nervous system disorders. In present work fast dissolving oral films of analgesic drug was formulated by solvent casting technique using polymers like PVP K 30, HPMC, PEG and evaluated for weight variation, film thickness, content uniformity, folding endurance, tensile strength, percent elongation, in-vitro dissolution study, in-vitro drug release study, surface pH. The fast dissolving oral film was successfully formulated to achieve a safe, rapid and effective dosage form with enhanced drug dissolution and rapid analgesic activity.

Biography

Gorakh J. Dhumal doing M. Pharm (Pharmaceutics) in Shivaji University, Kolhapur. He has participated and attended many national and international conferences.

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FDA guidelines-for out of specifications (OOS)

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This guidance for industry provides the Agency's current thinking on how to evaluate out-of-specification (OOS) test results. This guidance applies to chemistry-based laboratory testing of drugs regulated by CDER. It is directed toward traditional drug testing and release methods. These laboratory tests are performed on active pharmaceutical ingredients, excipients and other components, in-process materials, and finished drug products to the extent that current good manufacturing practice (CGMP) regulations (21 CFR parts 210 and 211) and the Federal Food, Drug, and Cosmetic Act (the Act) apply. The principles in this guidance also apply to in-house testing of drug product components that are purchased by a firm. This guidance can also be used by contract firms performing production and/or laboratory testing responsibilities. Specifically, the guidance discusses how to investigate OOS test results, including the responsibilities of laboratory personnel, the laboratory phase of the investigation, additional testing that may be necessary, when to expand the investigation outside the laboratory, and the final evaluation of all test results.

Biography

G.Ravi is a student of JSS College of Pharmacy, JSS University, Mysore, Karnataka, India. He has completed his B-Pharm from JSS College of Pharmacy, Mysore during the year 2011. Presently he is pursuing M-Pharm in Pharmaceutical Quality Assurance in JSS College of Pharmacy, Mysore. He has attended various National and International Conferences. His current areas of interest are Quality Assurance, Regulatory Affairs, Quality Management Systems, GMP Auditing, analytical method development of novel drugs.

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