

Formulation Development and in Vitro Evaluation of Capecitabine Immediate Release Tablets

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ABSTRACT

The aim of this study is to formulate and significantly improve the bioavailability and reduce the side effects of immediate release tablets Capecitabine. The precompression blends of Capecitabine were characterized with respect to angle of repose, bulk density, tapped density, Carr's index and Hausner's ratio. The precompression blend of all the batches indicates good to fair flowability and compressibility. Immediate release tablets were prepared with various disintegrants like PEG 6000, Croscarmellose sodium and Sodium-starch glycolate at different concentration ratios and were compressed into tablets. The formulated tablets were evaluated for various quality control parameters. The tablets were passed all tests. Among all the formulations F7 formulation containing, drug and Croscarmellose sodium showed good result that is 98.12 % in 45 min. Hence from the dissolution data it was evident that F7 formulation is the better formulation.

KEYWORDS: Capecitabine, PEG 6000, Croscarmellose sodium and Sodium-starch glycolate, Immediate release Development

INTRODUCTION:

Oral route is the most convenient and extensively used for drug administration. Oral administration is the most popular route for systemic effects due to its ease of ingestion, pain avoidance, versatility and most importantly, patient compliance suitable for industrial production, improved stability and bioavailability. The concept of immediate release tablets emerged from the desire to provide patient with more conventional means of taking their medication when emergency treatment is required. Recently, immediate release tablets have gained prominence of being new drug delivery systems. The oral route of administration has so far received the maximum attention with respect to research on physiological and drug constraints as well as design and testing of product. Drug delivery systems (DDS) are a strategic tool for expanding markets/indications, extending product life cycles and generating opportunities. Most immediate release tablets are intended to disintegrate in the stomach, where the pH is acidic. Several orally disintegrating

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tablet (ODT) technologies based on direct compression. In pharmaceutical formulation includes any formulation in which the rate of release of drug from the formulation is at least 70% (preferably 80%) of active ingredient within 4 hours, such as within 3 hours, preferably 2 hours, more preferably within 1.5 hours, and especially within an hour (such as within 30 minutes) of administration. In Formulation of immediate release the commonly Superdisintegrants used are Croscarmellose, sodium, Sodium Starch glycolate and Crospovidone.¹

Oral route of administration is the most popular route for systemic effects due to its ease of ingestion, pain avoidance, versatility and most importantly, patient compliance. Also solid oral delivery systems does not need sterile conditions and are therefore, less expensive to manufacture. Patient compliance, high precision dosing, and manufacturing efficiency make tablets the solid dosage form of choice. There is

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Formulation Development of Candesartan Immediate Release Tablets Tentu Nageswara Rao, Sharadha Devi Kappari, Murthy Snvs, 2015-10-30 Oral drug delivery is the most desirable and preferred method of administering therapeutic agents for their systemic effects. In addition, the oral medication is generally considered as the first avenue investigated in the discovery and development of new drug entities and pharmaceutical formulations mainly because of patient acceptance, convenience in administration, and cost-effective manufacturing process. For many drug substances, conventional immediate release formulations provide clinically effective therapy while maintaining the required balance of pharmacokinetic and pharmacodynamic profiles with an acceptable level of safety to the patient. *Handbook of Bioequivalence Testing, Second Edition* Sarfaraz K. Niazi, 2014-10-29 As the generic pharmaceutical industry continues to grow and thrive, so does the need to conduct adequate, efficient bioequivalence studies. In recent years, there have been significant changes to the statistical models for evaluating bioequivalence. In addition, advances in the analytical technology used to detect drug and metabolite levels have made bioequivalence testing more complex. The second edition of *Handbook of Bioequivalence Testing* has been completely updated to include the most current information available, including new findings in drug delivery and dosage form design and revised worldwide regulatory requirements. New topics include: A historical perspective on generic pharmaceuticals; New guidelines governing submissions related to bioequivalency studies along with therapeutic code classifications; Models of noninferiority; Biosimilarity of large molecule drugs; Bioequivalence of complementary and alternate medicines; Bioequivalence of biosimilar therapeutic proteins and monoclonal antibodies; New FDA guidelines for bioanalytical method validation; Outsourcing and monitoring of bioequivalence studies. The cost of generic drugs is rising much faster than in the past, partly because of the increased costs required for approval, including those for bioequivalence testing. There is a dire need to re-examine the science behind this type of testing to reduce the burden of development costs, allowing companies to develop generic drugs faster and at a lower expense. The final chapter explores the future of bioequivalence testing and proposes radical changes in the process of biowaivers. It suggests how the cost of demonstrating bioequivalence can be reduced through intensive analytical investigation and proposes that regulatory agencies reduce the need for bioequivalence studies in humans. Backed by science and updated with the latest research, this book is destined to spark continued debate on the efficacy of the current bioequivalence testing paradigm.

Drug Discovery and Evaluation: Methods in Clinical Pharmacology H. Gerhard Vogel, Jochen Maas, Alexander Gebauer, 2010-12-15 Drug Discovery and Evaluation has become a more and more difficult, expensive, and time-consuming process. The effect of a new compound has to be detected by *in vitro* and *in vivo* methods of pharmacology. The activity spectrum and the potency compared to existing drugs have to be determined. As these processes can be divided up stepwise, we have designed a book series *Drug Discovery and Evaluation* in the form of a recommendation document. The methods to detect drug targets are described in the first

volume of this series Pharmacological Assays comprising classical methods as well as new technologies Before going to market the most suitable compound has to be selected by pharmacokinetic studies and experiments in toxicology These preclinical methods are described in the second volume Safety and Pharmacokinetic Assays Only then are first studies in human beings allowed Special rules are established for Phase I studies Clinical pharmacokinetics are performed in parallel with human studies on tolerability and therapeutic effects Special studies according to various populations and different therapeutic indications are necessary These items are covered in the third volume Methods in Clinical Pharmacology Pharmaceutical Preformulation and Formulation Mark Gibson, 2016-04-19 Pharmaceutical Preformulation and Formulation A Practical Guide from Candidate Drug Selection to Commercial Dosage Form reflects the mounting pressure on pharmaceutical companies to accelerate the new drug development and launch process as well as the shift from developing small molecules to the growth of biopharmaceuticals The book meets the need for advanced information for drug preformulation and formulation and addresses the current trends in the continually evolving pharmaceutical industry Topics include Candidate drug selection Drug discovery and development Preformulation predictions and drug selections Product design to commercial dosage form Biopharmaceutical support in formulation Development The book is ideal for practitioners working in the pharmaceutical arena including R D scientists technicians and managers as well as for undergraduate and postgraduate courses in industrial pharmacy and pharmaceutical technology *American Journal of Veterinary Research*, 2015 Volumes for 1956 include selected papers from the proceedings of the American Veterinary Medical Association **Immediate Action Plan on Economic Development and Prosperity, 2012**, 2012 Poorly Soluble Drugs Gregory K. Webster, Robert G. Bell, J. Derek Jackson, 2017-01-06 This book is the first text to provide a comprehensive assessment of the application of fundamental principles of dissolution and drug release testing to poorly soluble compounds and formulations Such drug products are vis vis their physical and chemical properties inherently incompatible with aqueous dissolution However dissolution methods are required for product development and selection as well as for the fulfillment of regulatory obligations with respect to biopharmaceutical assessment and product quality understanding The percentage of poorly soluble drugs defined in classes 2 and 4 of the Biopharmaceutics Classification System BCS has significantly increased in the modern pharmaceutical development pipeline This book provides a thorough exposition of general method development strategies for such drugs including instrumentation and media selection the use of compendial and non compendial techniques in product development and phase appropriate approaches to dissolution development Emerging topics in the field of dissolution are also discussed including biorelevant and biphasic dissolution the use of enzymes in dissolution testing dissolution of suspensions and drug release of non oral products Of particular interest to the industrial pharmaceutical professional a brief overview of the formulation and solubilization techniques employed in the development of BCS class 2 and 4 drugs to overcome solubility challenges is provided and is complemented by a collection of chapters that survey the approaches and considerations in

developing dissolution methodologies for enabling drug delivery technologies including nanosuspensions lipid based formulations and stabilized amorphous drug formulations [Encyclopedia of Analytical Science](#), 2019-04-02 The third edition of the Encyclopedia of Analytical Science Ten Volume Set is a definitive collection of articles covering the latest technologies in application areas such as medicine environmental science food science and geology Meticulously organized clearly written and fully interdisciplinary the Encyclopedia of Analytical Science Ten Volume Set provides foundational knowledge across the scope of modern analytical chemistry linking fundamental topics with the latest methodologies Articles will cover three broad areas analytical techniques e.g mass spectrometry liquid chromatography atomic spectrometry areas of application e.g forensic environmental and clinical and analytes e.g arsenic nucleic acids and polycyclic aromatic hydrocarbons providing a one stop resource for analytical scientists Offers readers a one stop resource with access to information across the entire scope of modern analytical science Presents articles split into three broad areas analytical techniques areas of application and and analytes creating an ideal resource for students researchers and professionals Provides concise and accessible information that is ideal for non specialists and readers from undergraduate levels and higher [National Programme to Rehabilitate and Develop Cambodia](#) Cambodia, 1994 **The Interstate Oil & Gas Compact & Committee Bulletin**, 1990 [Pharmaceutical Science : Its Past and Its Future](#), 1985 *Formulation, Development & Evaluation of Multi-compartment Dosage Form* Naisarg Pujara, Ramesh Parmar, 2013 In the present study formulation of multi compartment dosage form containing soft gelatin capsule of Nifedipine granules of Losartan potassium and fast disintegrating tablet of Hydrochlorothiazide was designed to achieve immediate release of drug from the dosage form to increase therapeutic efficacy and to improve patient compliance in case of hypertension Triple combination of antihypertensive drugs induces superior reduction in blood pressure as compared to conventional dosage form The basic aim of this work is to produce immediate release action of drug from the hard gelatin capsule containing soft gelatin capsule of Nifedipine granules of Losartan potassium and fast disintegrating tablet of Hydrochlorothiazide Soft gelatin capsule was prepared by encapsulation method using propylene glycol and PEG 400 as solubilizing agents The granules were prepared by wet granulation method using PVP K30 as binder The fast disintegrating tablets were prepared by direct compression method using croscarmellose sodium and crospovidone as super disintegrating agents Multi compartment dosage form was considered as optimized formulation for immediate release of antihypertensive drugs **International Human Resource Management** Helen De Cieri, 2017-05-15 Since the late 1970s scholars and practitioners of international management have paid increasing attention to the impact of globalisation on the management of human resources across national boundaries This collection of important articles and essays provides a comprehensive review and critique of developments and future directions in International Human Resource Management Focusing on three major developments or approaches Cross Cultural Management Comparative HRM and Strategic HRM the volume explores challenges and opportunities facing

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