

## Research Article

# Formulation Development and Evaluation of Fast Disintegrating Tablets of Salbutamol Sulphate, Cetirizine Hydrochloride in Combined Pharmaceutical Dosage Form: A New Era in Novel Drug Delivery for Pediatrics and Geriatrics

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The objective of the present study was to prepare the fast disintegrating tablet of Salbutamol Sulphate, Cetirizine Hydrochloride in combined tablet dosage form for respiratory disorders such as bronchitis, asthma, and coughing for pediatrics and geriatrics. The tablets were prepared by direct compression technique. Superdisintegrant such as Sodium Starch Glycolate was optimized as 4% on the basis of least disintegration time. Different binders such as MCC and PVP K-30 were optimized along with optimized superdisintegrant concentration. 1% MCC was selected as optimum binder concentration on the basis of least disintegration time. The tablets were evaluated for hardness, friability, weight variation, wetting time, disintegration time, and drug content uniformity. Optimized formulation was further evaluated by *in vitro* dissolution test, drug-excipient compatibility, and accelerated stability study. Percent weight variation and content uniformity were within the acceptable limit. The friability was less than 1%. The wetting time and disintegration time were practically good for all formulations. FTER studies and accelerated stability study showed that there was no interaction between the drug and excipients. It was concluded that, by employing commonly available pharmaceutical excipients such as superdisintegrants, hydrophilic and swellable excipients and proper filler, a fast disintegrating tablet of Salbutamol Sulphate, Cetirizine Hydrochloride in combined tablet dosage form, were formulated successfully with desired characteristics.

## 1. Introduction

Fast disintegrating tablets (FDTs) have received ever-increasing demand during the last decade, and the field has become a rapidly growing area in the pharmaceutical industry. Recent advancements in novel drug delivery system (NDDS) aim to enhance safety and efficacy of drug molecule by formulating a convenient dosage form for administration in order to achieve better patient compliance. One such approach is "fast disintegrating tablet." Many patients find it difficult to swallow tablets and hard gelatin capsules that results in high incidence of noncompliance and ineffective therapy [1, 2]. Fast disintegrating drug delivery systems

(FDDDS) are a new generation of formulations which combine the advantages of both liquid and conventional tablet formulations and, at the same time, offer added advantages over both traditional dosage forms. They provide the convenience of a tablet formulation and also allow the ease of swallowing provided by a liquid formulation [3]. The concept of fast dissolving/disintegrating tablets emerged from the desire to provide patients with more conventional means of taking their medication when drinking water is not available and in certain cases such as motion sickness, sudden episodes of allergic attacks, or coughing. Particularly these types of difficulty are faced by pediatric and geriatric patients [4]. Recent developments in technology have

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sciences Drug Development Chris Rundfeldt,2011-12-07 This book represents a case study based overview of many different aspects of drug development ranging from target identification and characterization to chemical optimization for efficacy and safety as well as bioproduction of natural products utilizing for example lichen In the last section special aspects of the formal drug development process are discussed Since drug development is a highly complex multidisciplinary process case studies are an excellent tool to obtain insight in this field While each chapter gives specific insight and may be read as an independent source of information the whole book represents a unique collection of different facets giving insight in the complexity of drug development *Pharmaceutical Drug Product Development and Process Optimization* Sarwar Beg,Majed Al Robaian,Mahfoozur Rahman,Syed Sarim Imam,Nabil Alruwaili,Sunil Kumar Panda,2020-05-01

Pharmaceutical manufacturers are constantly facing quality crises of drug products leading to an escalating number of product recalls and rejects Due to the involvement of multiple factors the goal of achieving consistent product quality is always a great challenge for pharmaceutical scientists This volume addresses this challenge by using the Quality by Design QbD concept which was instituted to focus on the systematic development of drug products with predefined objectives to provide enhanced product and process understanding This volume presents and discusses the vital precepts underlying the efficient effective and cost effective development of pharmaceutical drug products It focuses on the adoption of systematic quality principles of pharmaceutical development which is imperative in achieving continuous improvement in end product quality and also leads to reducing cost time and effort while meeting regulatory requirements The volume covers the important new advances in the development of solid oral dosage forms modified release oral dosage forms parenteral dosage forms semisolid dosage forms transdermal drug delivery systems inhalational dosage forms ocular drug delivery systems nanopharmaceutical products and nanoparticles for oral delivery PHARMACOGNOSY- I: A TEXTBOOK ,2025-06-17

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disease conditions Regulatory agencies have raised the bar for the development and manufacture of antibody based products expecting to see the use of Quality by Design QbD elements demonstrating an in depth understanding of product and process based on sound science Drug delivery systems have become an increasingly important part of the therapy and most biopharmaceuticals for self administration are being marketed as combination products A survey of the market indicates that there is a strong need for a new book that will provide one stop shopping for the latest information and knowledge of the scientific and engineering advances made over the last few years in the area of biopharmaceutical product development The new book entitled Development of Biopharmaceutical Drug Device Products is a reference text for scientists and engineers in the biopharmaceutical industry academia or regulatory agencies With insightful chapters from experts in the field this new book reviews first principles covers recent technological advancements and provides case studies and regulatory strategies relating to the development and manufacture of antibody based products It covers topics such as the importance of early preformulation studies during drug discovery to influence molecular selection for development formulation strategies for new modalities and the analytical techniques used to characterize them It also addresses important considerations for later stage development such as the development of robust formulations and processes including process engineering and modeling of manufacturing unit operations the design of analytical comparability studies and characterization of primary containers pre filled syringes and vials Finally the latter half of the book reviews key considerations to ensure the development and approval of a patient centered delivery system design This involves the evolving regulatory framework with perspectives from both the US and EU industry experts the role of international standards design control risk management human factors and its importance in the product development and regulatory approval process as well as review of the risk based approach to bridging between devices used in clinical trials and the to be marketed device Finally case studies are provided throughout The typical readership would have biology and or engineering degrees and would include researchers scientific leaders industry specialists and technology developers working in the biopharmaceutical field

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