



FORMULATION AND EVALUATION OF MOUTH DISSOLVING TABLETS OF FELODIPINE

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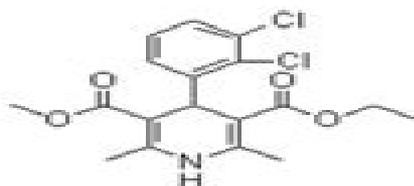
ABSTRACT

Recent advances in Novel Drug Delivery Systems (NDDS) aim to enhance safety and efficacy of drug molecule by formulating a convenient dosage form for administration and to achieve better patient compliance. One such approach is fast disintegrating/ dispersing tablet formulation. In the present work, fast disintegrating tablets of Felodipine were designed with a view to enhance patient compliance by direct compression method. In the direct compression method, croscopolvidone (2-10% w/w) was used as super-disintegrant along with microcrystalline cellulose (5-20%w/w) as disintegrant and directly compressible mannitol to enhance mouth feel. Estimation of Felodipine in the prepared tablet formulations was carried out by extracting the drug with methanol and measuring the absorbance at 260nm. The prepared formulations were further evaluated for hardness, friability, drug content uniformity, wetting time, water absorption ratio and in vitro dispersion time. Based on in vitro dispersion time (approximately 8-14 s), one promising formulation was tested for in vitro drug release pattern (in pH 6.8 phosphate buffer) and drug excipient interaction (IR spectroscopy). Among all the formulations, promising formulation (DCF) the formulation prepared by direct compression method (containing 2% w/w croscopolvidone and 15% w/w microcrystalline cellulose) emerged as the overall best formulation.

Key words: Felodipine, Directly compressible mannitol, Fast disintegrating tablets, Croscopolvidone.

INTRODUCTION

Felodipine is chemically 3-ethyl 5-methyl 4-[(2, 3-dichlorophenyl)-2, 6-dimethyl-1, 4-dihydropyridine-3,5-dicarboxylate.



Molecular formula of Felodipine is C₂₈H₃₁Cl₂N₂O₄. It is a member of dihydropyridine class of calcium channel antagonists and it blocks voltage dependent calcium channels, hence it reduces blood pressure. It is used in the treatment of hypertension. Felodipine is a member of the dihydropyridine class of calcium channel antagonists (calcium channel blockers). It reversibly competes with nitrendipine and/or other calcium channel blockers for dihydropyridine binding sites, blocks voltage-dependent Ca⁺⁺ currents in vascular smooth muscle and cultured rabbit atrial cells, and blocks potassium-induced contracture of the rat portal vein.

MATERIALS AND METHODS

Materials required

Chemicals and Drugs

Felodipine: Aarbindo-pharma limited.
Mannitol (Pearlitol SD 200): Aarbindo-pharma limited
MCC (PH 102): Aarbindo-pharma limited
MCC (PH 102): Aarbindo-pharma limited
Sodium stearyl fumarate: Aarbindo-pharma limited
Talc: SD fine chemicals.
Aspartame: Aarbindo-pharma limited
Pineapple flavor: Aarbindo-pharma limited
Potassium dihydrogen orthophosphate: SD fine chemicals.

Instruments

UV-spectrophotometer: T60 UV-Visible Spectrophotometer.
Digital Balance: BL-22004, Shimadzu.
Digital pH meter: Motex 152- R.
Dissolution apparatus: Sisco Mumbai.

IR spectroscopy: Perkin Elmer FTIR, Series model-1615 Spectrometer.

Hot air oven: Sisco, Mumbai.

Hardness tester: PDone.

Friability Test Apparatus: Sisco, Mumbai.

Tablet compression machine: Cadmach, 16 stations.

METHODS

Preparation of standard calibration curve of felodipine in methanol and phosphate buffer solution (6.8pH)

25mg of Felodipine was accurately weighed and dissolved in 25ml of water and phosphate buffer into a volumetric flask (1000 mcg/ml) respectively. 1 ml of this solution was taken and made up to 100 ml with water and phosphate buffer solution, which gives 10 mcg/ml concentrations (stock solution). From this stock solution, concentration of 10, 20, 30, 40,50mcg/ml in water and phosphate buffer solution were prepared. The absorbance of the diluted solution was measured at 260 and 264 nm respectively and a standard plot was drawn using the data obtained. The correlation coefficient was calculated by linear regression analysis. The absorbances of the above concentration are shown in table-1 and table-2.

Formulation of fast disintegrating tablets

Direct compression^{1, 2}:

Fast disintegrating tablets of Felodipine were prepared by direct compression according to the formulae given in table-3.

- All the ingredients were passed through 60 mesh sieve separately.
- The drug and MCC was mixed by small portion of both each time and blending it to get a uniform mixture and kept aside.
- Then the ingredients were weighed and mixed in geometrical order and tablets were compressed at 7 mm size to get a tablet of 120 mg weight using a Rotary Clit 10 station compression machine. The tablets were prepared according to the formulae shown in table-3.

Evaluation of tablets

Weight variation^{4, 5}:

Twenty tablets were selected at random and average weight was determined. Then individual tablets were weighed and the individual weight was compared with an average weight. The results are shown in table-5.

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Formulation and Evaluation of Mouth Dissolving Tablets Reshu Gupta,2013 Oral delivery is currently the gold standard in the pharmaceutical industry where it is regarded as the safest most convenient and most economical method of drug delivery having the highest patient compliance This tablet format is designed to allow administration of an oral solid dose form in the absence of water or fluid intake Such tablets readily dissolve or disintegrate in the saliva generally within

"*Fast dissolving tablets* " Dr.G.SANDHYARANI Guggilla,2019-02-14 FORMULATION AND EVALUATION OF FAST DISSOLVING TABLETS ON RIZATRIPTON **Current Advances in Drug Delivery Through Fast**

Dissolving/Disintegrating Dosage Forms Vikas Anand Saharan,2017-05-11 Fast Dissolving Disintegrating Dosage Forms FDDFs have been commercially available since the late 1990s FDDFs were initially available as orodispersible tablets and later as orodispersible films for treating specific populations pediatrics geriatrics and psychiatric patients Granules pellets and mini tablets are among latest additions to these dosage forms which are still in the development pipeline As drug delivery systems FDDFs enable quicker onset of action immediate drug delivery and sometimes offer bioavailability benefits due to buccal sublingual absorption With time FDDF have evolved to deliver drugs in a sustained and controlled manner Their current market and application is increasing in demands with advances in age adapted dosage forms for different patients and changing regulatory requirements that warrant mandatory assessments of new drugs and drug products before commercial availability This book presents detailed information about FDDFs from their inception to recent developments Readers will learn about the technical details of various FDDF manufacturing methods formulation aspects evaluation and methods to conduct clinical studies The authors also give examples of marketed fast disintegrating dissolving drug products in US Europe Japan and India This reference is ideal for pharmacology students at all levels seeking information about this specific form of drug delivery and formulation Advances in Pharmaceutical Product Development Keerti Jain, Awesh K. Yadav,2025-03-18 This book discusses the stages involved in pharmaceutical product development including the importance requirement and effect of each stage and process It also covers prototype development for pharmaceutical formulations scale up studies optimization testing packaging and commercialization of different dosage forms for pharmaceutical products like tablets suspensions emulsions coating inhalational products sterile products and herbal formulations The book also presents advancements in tablet production and tablet coating including materials material handling granulation and granulation technologies process automation processing problems in tablet production and troubleshooting advances in equipment for coating and coating materials Further the chapter explores the advances in the formulation and development of aerosols nebulizers inhalers metered Dose Inhalers MDI and dry powder Inhalers DPIs Towards the end the book examines the challenges formulation development testing stability and regulatory guidelines in the development of herbal formulations This book provides a valuable source of information for the researcher scientists students and people working in the area

mainly focused on the challenges in pharmaceutical product development Formulation, Evaluation and Optimization of Mouth Dissolving Tablets Amita Yadav, Kamal Singh Rathore, Geeta M. Patel, 2014-08-09 Annual Report University of Poona, 2010 Indian Science Abstracts, 2011-03 **Formulation and Evaluation Mouth Dissolving Tablets of Tramadol HCL** Raja Sridhar Rao Ponugoti, Chandrashekara Rao Gonugunta, 2015-08-11 According to United States Pharmacopoeia the orodispersible tablets may be defined as solid dosage form containing medicinal substance or active ingredient which disintegrates rapidly within a matter of seconds when placed upon the tongue This means that the tablets dissolve or disintegrate in the oral cavity without use of water In this regard the tablets need to improve disintegration time dispersion time drug release studies bioavailability and patient compliance and also need to mask the bitter taste of the drug and to maintain the drug stable at accelerated condition i e 40 C 75% RH up to 6 months period as per ICH guidelines Tramadol HCl is centrally acting synthetic opioid analgesic for the treatment of moderate to severe pain and is readily soluble in water The half life of the drug is around 5.5 hours The MDT s place a major role for rapid onset of action for geriatrics pediatrics and the patients who have less access of water The drug itself having bitter taste so the present authors developed mouth dissolving tablets of tramadol HCl with the aim to mask the bitter taste of the drug to minimize the disintegration time and improve the drug release rate Journal of Scientific and Industrial Research, 2014 Chemical Abstracts, 2002 The Lancet, 1962 Genetic Engineering News, 2003 **Compendium of Pharmaceuticals and Specialties (Canada)**, 1987 Presents information supplied by manufacturers and distributors about pharmaceuticals available for use in Canada Organized by trade name Includes a section on Canadian drug regulations **Preparation and Evaluation of Mouth Dissolving Film of Metoclopramide Hcl** Dhaneshwar Kumar Vishwakarma, 2011-08 Oral drug delivery is the most widely utilized route of administration among the entire route that has been explored for the systemic delivery of drug via various pharmaceutical products of different dosage forms The conventional tablet seems to be most popular because of its ease of transportability and comparatively low manufacturing cost but poor patient compliance in case of pediatrics and geriatrics patients who experienced difficulties in swallowing in response to this mouth dissolving drugs delivery system MDDs were developed as an alternative to tablet cap syrups A variety of MDDs like mouth dissolving tablets and mouth dissolving film MDFs were commercialized MDFs evolved over the past few years from by the confection and oral care market in the form of breath strips became a novel widely accepted form by consumers It consist very thin oral strips which release active ingredients immediately after uptake into oral cavity Today MDFs are a proven accepted technology for the systemic delivery of active pharmaceuticals ingredients The Formulation and Evaluation of Orally Disintegrating Tablets Stephanie M. Chillias, 2013 Orally disintegrating tablets are a vital tool in keeping our children and elderly population healthy Their ease of use and accurate dosing allow higher patient compliance and more reliable therapeutic effects Superdisintegrants are the fundamental element contained in orally disintegrating

tablets and are responsible for their unique ability to quickly disintegrate and dissolve on the surface of the tongue without the use of any additional liquid In order to determine the most effective type and optimal amount of superdisintegrants for orally disintegrating tablets manufactured by direct compression the following tablet parameters were tested based on the standard USP 30 methods hardness thickness friability disintegration time and wetting time Four superdisintegrants were tested namely Kollidon CL SF Primojel Ac Di Sol and Polyplasdone XL and the most efficient superdisintegrant was selected based on the above mentioned studies Polyplasdone XL outperformed the other superdisintegrants in nearly all the concentrations and all of the testing parameters The ideal concentration was 5% Polyplasdone XL for the orally disintegrating tablets before the API diphenhydramine HCl was added Various concentrations were analyzed using the aforementioned parameters and 10% Polyplasdone XL was selected for the final formulation Tablets were tested over eight weeks of accelerated stability testing at various temperatures to determine percent of diphenhydramine HCl released in dissolution disintegration time wetting time hardness thickness and weight variation The tablets remained stable and within the acceptable range of drug release 90% 110% at the three temperatures analyzed Additionally tablets were analyzed at different levels of relative humidity for percent weight change and change in hardness The final formulation of diphenhydramine HCl tablets was stable between 3 40 C and at 33% relative humidity or less for eight weeks

Taste Masking and Formulation of Ondansetron Mouth Dissolving Tablets Poudel Bhupendra Kumar, Subdei Shyam Raj, Thapa Panna, 2015-11-23 The present work is an attempt to design mouth dissolving tablets of Ondansetron hydrochloride Drug Resin Complex was formulated by direct compression into mouth dissolving tablet using microcrystalline cellulose PH 102 as diluent and croscarmallose sodium and sodium starch glycolate as superdisintegrants while aspartame was used as sweetening agent to enhance palatability Taste masking was done by using polacrilex resin Tulsion 335 The prepared formulation can be useful for patients who have swallowing difficulty

Oncology, 2005 *Formulation And Evaluation Of Nebivolol Hcl Fast Dissolving Tablets* Vanitha Kondi, 2015-06-16 The objective of the present study was the formulation and evaluation of Nebivolol Hcl fast dissolving tablet by solid dispersions Fast dissolving tablets are novel types of tablets that dissolve disintegrate disperse in saliva within few seconds without water The major category of Nebivolol Hcl is in the treatment of hypertension adrenergic beta antagonist and vasodilator It is a poorly soluble and require enhancement of solubility and dissolution rate in its formulation development

Formulation and Evaluation of Fast Dissolving Tablet of Thiabendazole Pareek Ashish Kumar, 2015-11-30 Fast Dissolving Tablets of Thiabendazole is designed for Providing the better and effective treatment against Helminthiasis Fast Dissolving Tablet of Thiabendazole is designed with the aim to enhance the bioavailability of the dosage form Helminthiasis infection is very common in urban areas and particularly in the childrens that are playing in soil so the Fast dissolving tablet of Thiabendazole provide cidal action by inhibiting the enzyme fumarate reductase so it provide a safest action and effective treatment

Drug Delivery to the

Oral Cavity Tapash K. Ghosh, William R. Pfister, 2005-02-28 With contributions from recognized authorities in industry academia and government this reference presents the state of the art in the testing formulation and clinical evaluation of intraoral drug delivery products summarizing intraoral dosage forms in various stages of research as well as products currently on the market

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