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Research Article

Formulation and Evaluation of Lisinopril Fast Dissolving Tablets Using Natural Superdisintegrants

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ABSTRACT

Fast dissolving tablets are highly accepted fast growing drug delivery system. The main objective of this study was to formulate and evaluate the fast-dissolving tablets of lisinopril using natural super disintegrants. Various formulations were prepared by direct compression using different concentrations of natural super disintegrant i.e., oats powder. The tablets were evaluated for weight variation, hardness, friability, *in vitro* disintegration time and drug release characteristics.

Hardness indicated good mechanical strength around 3-4 kg/cm^2 for all the batches. The results of *in vitro* disintegration time indicated that the tablets dispersed rapidly in mouth within 40 secs. It was concluded that super disintegrants addition technique is a useful method for preparing orally disintegrating tablets by direct Compression method.

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INTRODUCTION

Tablets are intended to be taken by orally. Because of the simplicity of self-administration, compactness, and manufacturing, tablets are the most widely used dosage type[1]. However, it can be challenging for paediatric and geriatric patients to swallow it. To overcome this problem, research teams have been focusing their efforts in recent years on developing tablets that dissolve or disintegrate easily in the mouth are defined as fast dissolving and dispersible tablets. Tablet disintegration is assumed to be the rate-limiting stage in faster drug release[2].

A dispersible tablet is a tablet that disintegrates in water or other liquid. These dispersible tablets disintegrate quickly in water or disperse immediately in the mouth. Dispersible tablets disintegrate quickly in water to form a stable suspension, making them ideal for paediatric patients17. In comparison to a standard compressed tablet, this formulation has a quicker onset of action. During the manufacturing process, the properties of the dispersible tablet, such as porosity, hardness, disintegration time, and increase in viscosity after dispersion, must be investigated because they decide the product's consistency performance. Dispersible tablets are uncoated tablets that are dissolved in water before being administered, resulting in a uniform dispersion. Bitter drugs are more acceptable to different groups of people when the tablets dispersed with a good taste and flavour. When put in water, the tablets must be able to form an adequate dispersion that is uniform and stable. The main advantage is that the absorption and onset of clinical effects are faster. They are usually made for geriatric or paediatric patients, as well as those who have trouble swallowing tablets[3, 4]. They are made up of excipients and components that are fully water soluble. Dispersible tablets dissolve quickly in water to form a stable suspension, making them ideal for paediatric patients. In comparison to a standard compressed tablet, this formulation has a quicker onset of action. During the manufacturing process, the properties of the water dispersible tablet, such as porosity, hardness, disintegration time, and increase in viscosity after dispersion, must be investigated because they decide the product's consistency performance[5, 6].

Lisinopril is a medication of the angiotensin -converting enzyme (ACE) inhibitor class used to treat high blood pressure, heart failure, and after heart attacks for high blood pressure it is usually a first line treatment[7].

It is also used to prevent kidney problems in people with diabetes mellitus. Lisinopril is taken by mouth. Full effect may take up to four weeks to occur.

MATERIAL AND METHODS:

Lisinopril, as well as other ingredients like natural super disintegrants, talc, MCC, aerosol, HPMC, lactose, magnesium stearate were taken for our research work and distilled water was used throughout the experiment.

Equipment/ Instruments:

UV-visible spectrophotometer (Shimadzu Corporation), Hot air oven, Electronic balance (Shimadzu Corporation), Tablet compression machine, Tablet hardness tester (Monsanto), Roche friabilator, linear calliper, Tablet dissolution tester USP (PLC), Tablet disintegrator (Excel enterprises), Sieve (Rolex), Glass wares (Borosilicate, India), Bulk density apparatus (Excel enterprises), were employed during the course of present research work.

Preparations of lisinopril Tablet formulation: Formulation of fast dissolving tablets containing Lisinopril with different polymers were compressed in automatic direct compression machine of Shimadzu by keeping the hardness 3.5kg/cm2 and volume 200mg for 20 tablets as given in the table no.1.

Table 1 – Formulation of Fast Dissolving Tablets of Lisinopril

Formulation Code/ Ingredients	Lisinopril	Oat's powder	Talc	MCC	HPMC	Lactose	Aerosil	Mg. Stearate
FO1	5	2	3	65	1	115	6	3
FO2	5	3	3	65	1	114	6	3
FO3	5	4	3	65	1	113	6	3
FO4	5	5	3	65	1	112	6	3

Dissolution test of optimized Trial batch: Using a USP dissolution apparatus, the tablets were evaluated for in vitro drug release. The following criteria were used. Form II USP Dissolution Apparatus for dispersible tablets (Paddle). Distilled water is used as the medium8, 9. 900 mL of dissolution medium Paddle rotating speed is 50 rpm and the temperature is 37.0 ± 0.5 °C. 5ml sample removed at 5, 10, 15, 30, 45, and 60 minutes interval and diluted even 10 times further. The absorbance was

measured at 307 nm using UV (Shimadzu1800).

From where we found that, 96% of drug was released in 60 mins respectively.

Drug content study:

After the dissolution test, drug content test was performed for each formulation. In which first 3 tablets of each formulation was taken and triturated in mortar & pestle from where 60mg of powder was taken for each formulation and stock solution Was prepared in 50ml of volumetric flask from which 10,20,30 ppm was taken for absorbance study in uv-spectrometer.[10, 11]

Then % of drug content was found by applying formula

% of drug content = test absorbance/standard absorbance x 100

The average value for each formulation was found which are given below in the table

Friability test (F)

The crushing test may not be the best measure of potential behaviour during handling and pack-aging. The resistance to surface abrasion may be a more relevant parameter. Friability of each batch was measure in "Electro lab friabilator". Ten pre weighed tablets were rotated at 25 rpm for 4 min, the tablets were then re weighed and the percentage of weight loss was calculated[12, 13]. The friability (F) is given by the formula.

$$F = (W_{initial} - W_{final}) / W_{initial} \times 100$$

In Vitro disintegration time

In Vitro disintegration time was performed by apparatus specified in USP at 50 rpm. Phosphate buffer 3.2, 900 ml was used as disintegration medium, and the temperature of which maintained at 37±2oC and the time in second taken for complete disintegration of the tablet with no palpable mass remaining in the apparatus was measured in seconds[14, 15].

Wetting test of tablets: A Petri dish was taken where all formulation was kept. Then 2, 3 drops of colour was added to the petridish containing moistened tissue paper and observation was done by observing the colour of the tablets[16].

RESULTS AND DISCUSSION:

In the presence of natural disintegrants the matrix might be distorted resulting in higher surface area, allowing the superdisintegrants to readily pickup water & thereby rendering rapid rate of dissolution. The concentration of superdisintegrants in the formulation also affects the dissolution rate. Pre-compression parameters were found to be

within the prescribed limits and indicated good free flowing property. Batches which show best results are used for further study. Friability was found to be is less than 1 %, Drug content was found to be in the range of 98 to 100 % which is within acceptable limits. The hardness of formulations FO1 to FO4 which consists of increasing concentration of natural superdisintegrants as oats powder was found to be in the range of 3-4 kg/cm2. This shows that the more the concentration of natural superdisintegrants the minimum it attains the hardness. The Disintegration time decreases from FO1 to FO4 which consists of increasing concentration of natural superdisintegrants oats powder. This shows that the more the concentration of superdisintegrants the quicker the tablet disintegrates in phosphate buffer pH 6.8. For Wetting time and Weight variation – Both the parameters decreases from FO1 to FO4 with increase in concentration of superdisintegrants and maintaining a constant concentration of MCC. This shows that the more the concentration of superdisintegrant the minimum it attains the Wetting time and Weight variation (Table -2).

In-vitro dissolution study–Formulations FO4 shows better drug release in comparison to others (figure 1).

Table 2 - Evaluation Tests of Fast Dissolving Tablets of Lisinopril

Parameters	Weight variation (%)	Hardness (kg/cm^2)	Thickness (mm)	Friability (%)	In-vitro disintegration (sec)	Drug content (%)	Water absorption ratio(sec)	Wetting time (%)
FO1	250.4	3.5	3.82	0.59	35	99.98	56.12	2.88
FO2	252.2	3.2	3.91	0.68	28	100.21	57.32	2.53
FO3	249.6	3.3	3.84	0.58	21.89	99.67	69.56	2.24
FO4	248	3.6	3.88	0.59	13.44	100.32	78.59	1.5

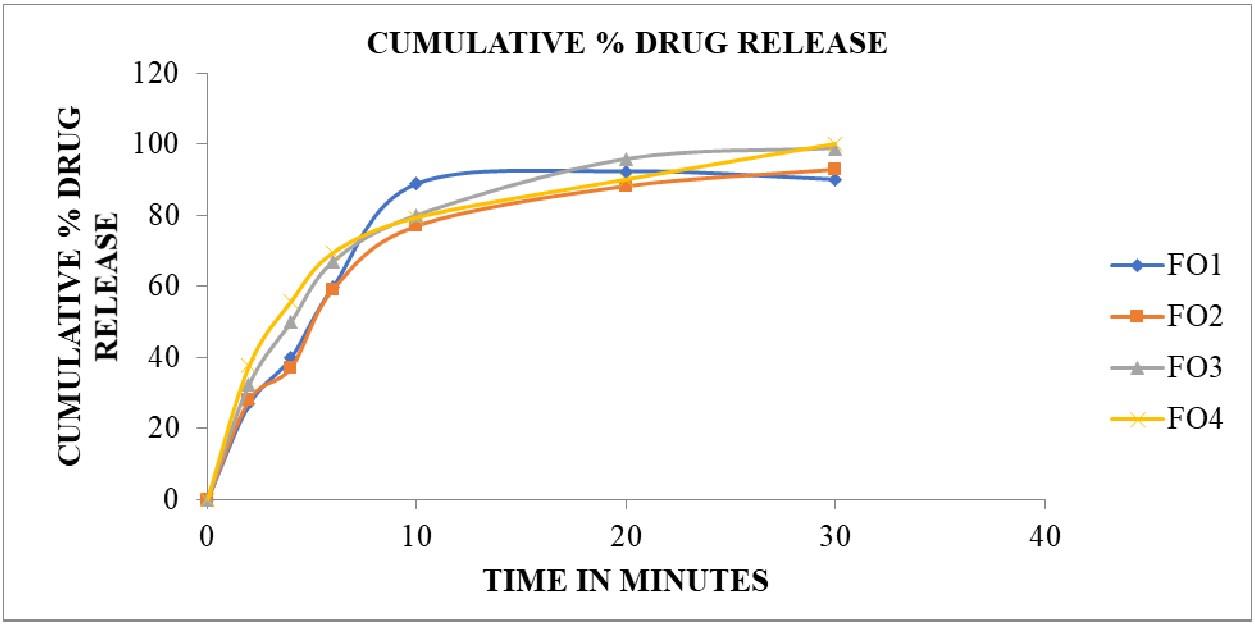

Figure 1: In-vitro dissolution study–Formulations FO1 -FO4 shows better drug release in comparison to others.

CONCLUSIONS:

Finally it is concluded that disintegrating properties of the oats powder has been studied. The isolated natural disintegrant exhibited faster drug dissolution. These formulations improve the bioavailability and effective therapy using oats powder as natural superdisintegrant. Therefore, in the years to come, there will be continued interest in natural mucilages and their modifications aimed at the development of better materials for drug delivery systems.

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