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FORMULATION AND EVALUATION OF FAST DISSOLVING TABLETS OF RANITIDINE HCL

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ABSTRACT

The present study deals with the formulation of fast dissolving tablets by direct compression method using Ranitidine HCL. The influence of superdisintegrants on the croscarmellose sodium and sodium starch glycolate on dissolution time, wetting time etc were studied. The prepared tablets were evaluated for weight variation, *In vitro* dissolution, drug content, hardness, friability, thickness and diameter and *In vitro* dispersion time. The super disintegrants such as croscarmellose sodium and sodium starch glycolate are used in combinations with the drug and the combination containing 25mg of croscarmellose sodium and 125 mg of sodium starch glycolate showed faster dispersion time and maximum drug release in 14 min.

Key words: Ranitidine HCL, Croscarmellose sodium, Sodium starch glycolate, FDT.

INTRODUCTION

Fast dissolving Tablets are disintegrating and/or dissolve rapidly in the saliva without the need for water. Some tablets are designed to dissolve in saliva remarkably fast, within a few seconds, and are true fast-dissolving tablets. The basic approach in development of FDT is the use of superdisintegrants like cross linked carboxymethyl cellulose (croscarmellose), sodium starch glycolate (primogel, explotab), polyvinylpyrollidone (polyplasdone) etc, which provide instantaneous disintegration of tablet after putting on tongue, their by release the drug in saliva. This tablet formulation 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 <60 seconds. Stability for longer duration of time, since the drug remains in solid dosage form till it is consumed. So, it combines advantage of solid dosage form in terms of stability and liquid dosage form in terms of bioavailability[1]. FDTs are prepared by various techniques, mainly direct compression, lyophilization and moulding. The simplicity and cost effectiveness of the direct compression process have positioned this technique as an attractive alternate to traditional granulation technologies.

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Usually superdisintegrants are added to a drug formulation to facilitate the break-up or disintegration of tablet into smaller particles that can dissolve more rapidly than in absence of disintegrants[2]. Recent advances in novel drug delivery systems (NDDS) aim to enhance safety and efficacy of drug molecules by formulating a convenient dosage form for administration and to achieve better patient compliance. One such approach led to development of fast dissolving tablets3. Advantages of this drug delivery system include administration without water, convenience of administration and accurate dosing as compare to liquids, easy portability, ability to provide advantages of liquid medication in the form of solid preparation, ideal for paediatric and geriatric patients and rapid dissolution/absorption of the drug, which may produce rapid onset of action. The main reason behind developing fast dissolving tablets of ranitidine is its absorption in upper gastro intestinal tract and its instability in the intestine and colon. Ranitidine is in a class of medications called H2 blockers. These fastdissolving tablets ensure complete solubilization of tablet through surface erosion, resulting in elimination of lag time for disintegration thereby offering faster absorption and rapid onset of action[4]. Ranitidine is E)-N-[2-[[5-(dimethylamino methyl) furan-2-yl]methylsulfanyl]ethyl]-N'-methyl-2-nitro -ethene-1,1-diamine, and used in treatment of peptic ulcers. Ranitidine is a histamine H2-receptor antagonist. An H2-receptor antagonist, often shortened to H2 antagonist, is a drug used to block the action of histamine on parietal cells in the stomach, decreasing acid production by these cells. The H2 antagonists are competitive inhibitors of

histamine at the parietal cell H2 receptor. They suppress the normal secretion of acid by parietal cells and the meal-stimulated secretion of acid. The drug is 50% absorbed orally but it undergoes hepatic metabolism.

In present study an attempt has been made to formulate it as fast dissolving tablets to increase its oral bioavailability. The tablets were prepared by two methods sublimation and superdisintegrant addition using sodium starch glycolate and crosscarmellose sodium as the Superdisintegrants[5].

MATERIALS AND METHODS

Materials

Ranitidine HCL was obtained from Drugs India, Croscarmellose sodium, Sodium Starch Glycollate, mannitol, magnesium stearate and talc are of acceptable grade.

Methods

Formulation of Tablet

The fast dissolving tablets of ranitidine HCL were prepared by direct compression method. Sodium starch glycollatem, Crosscarmellose sodium are used as superdisintegrants, sodium saccharin as sweetening agent and mannitol as diluents. Formulations F1-F5 were prepared by using the two superdisintegrants in different proportions and other ingredients are maintained constant in all the formulations.

Evaluation of Tablet

All the tablets were evaluated for different parameters such as thickness, hardness, friability, uniformity of weight, disintegration time, wetting time and *in vitro* dissolution study[6].

Thickness

Thickness of tablets was determined using Vernier Caliper. Three tablets from each batch were used and an average value was calculated.

Hardness

The crushed strength of the tablets was measured using a Monsanto hardness tester. There tablets of each formulation batch were tested randomly and the average value was noted.[7]

Friability

Twenty tablets were weighed and placed in a Roche friabilator and the equipment was rotated at 25 rpm for 4 min. the tablets were taken out, dedusted and reweighed. The percentage friability of the tablets was calculated by using the following formula-

Percentage friability = Initial – final weight / Initial weight × 100.

Weight variation

Twenty tablets were randomly selected after compression and the average weight was determined. None of the tablets deviated from the average weight by more than±7.5%.

Drug content

Twenty tablets were weighed and powdered by using mortar and pestle. And amount of the powder equivalent to 300 mg of ranitidine was dissolved in 100 ml of phosphate buffer pH 6.2, filtered, diluted suitably and analyzed for drug content at 285 nm using UV-Visible spectrophotometer.[8]

Wetting time

A piece of tissue paper folded twice was placed in small petridish containing 6 ml of simulated saliva pH, a tablet was put on the paper and time for complete wetting is measured. Three trials for each batch were performed and the values were noted. [9]

Disintegration Test

Disintegration time is considered to one of the important criteria in selecting the best formulation. Place one tablet into each tube and suspend the assembly into the 1000ml beaker containing medium maintained at 37^0c±0.5^0c and operate it. Disintegration time was recorded when all the fragments of the disintegrated tablet passed through the screen of the basket.

Dissolution test

Dissolution test was carried out in 900 ml of pH 6.2 phosphate buffer in dissolution apparatus USP II at 50 rpm. An aliquot of dissolution medium was withdrawn at regular interval and absorbance was measured at 285 nm. An equal volume of phosphate buffer was added. [10]

Table 1: Composition of formulations F1-F5

Ingredients (mg)	F1	F2	F3	F4	F5
Ranitidne HCL	300	300	300	300	300
Crosscarmellose sodium	75	50	25	100	125
Sodium starch glycollate	75	100	125	50	25
Mannitol	40	40	40	40	40
Talc	2.5	2.5	2.5	2.5	2.5
Sodium saccharin	5	5	5	5	5
Magnesium stearate	2.5	2.5	2.5	2.5	2.5

RESULTS AND DISCUSSION

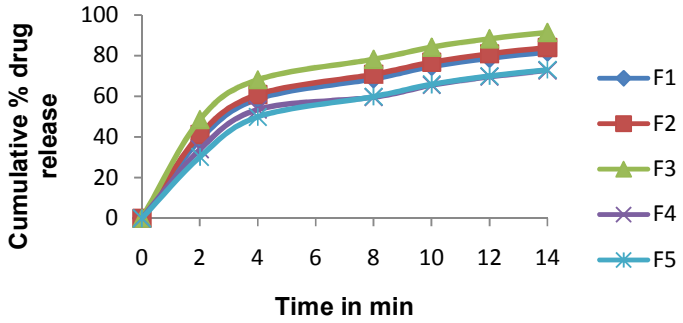
The tablets were prepared by direct compression method. The comparative results of all the evaluation parameters are listed in table 2. The drug content was found to be within range of 95.4 to 97.6 indicating uniform distribution of the drug in all the formulations. The hardness of the tablets was found to be 2.9±0.15 to 3.2±0.20 indicating good mechanical strength with an ability to withstand physical and mechanical conditions while handling operation. Friability of all formulations was found less than 1% indicating good mechanical resistance.

Table 2: Evaluation data of formulations (F1-F5)

Parameters	F1	F2	F3	F4	F5
Friability	0.64±0.11	0.8±0.20	0.46±0.18	0.68±0.16	0.92±0.17
Drug content (%)	95.4±0.11	95.5	97.6	96.1	96.0
Hardness	3.1±0.26	3.0±0.30	3.0±0.11	2.9±0.15	3.2±0.20
In vitro dispersion time	39	34	29	42	46
Weight variation	495.5	498.5	497	494.5	496.5

Table 3: Dissolution studies of formulations (F1-F5)

Time (sec)	F1	F2	F3	F4	F5
0	0	0	0	0	0
2	38.6	41.2	48.56	33.89	30.26
4	58.6	60.8	68.16	53.49	49.86
8	68.56	70.76	78.12	59.49	59.82
10	74.56	76.76	84.12	65.49	65.82
12	78.63	80.83	88.19	69.56	69.89
14	81.73	83.93	91.29	72.66	72.99



CONCLUSION

In the present work, efforts have been made to prepare and evaluate fast dissolving tablets of ranitidine HCL using various polymers. Release profile of F3 was found to have maximum release at the end of 14 min. The super disintegrants were also found to be compatible with the other excipients of the formulation as well as with drug, which is evident from the drug content values. Comparison of all formulation of Ranitidine HCL revealed the fact that the developed formulation F3 showed comparable release characteristics, thus it may have fair clinical efficacy.

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