Research Article

Formulation and Evaluation of Fast Dissolving Tablets of Paracetamol Using Superdisintegrants

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Received: 18-12-2019; **Revised:** 22-01-2020; **Accepted:** 28-01-2020.

ABSTRACT

The aim of present study was to carry out design, formulation and evaluation of fast dissolving tablets of paracetamol by using direct compression technique. Fast dissolving tablets of Paracetamol were prepared by direct compression machine using 3^2 factorial designs. Various concentrations Sodium starch Glycolate and Croscarmellose sodium used as a superdisintegrating agent. The prepared tablets were evaluated for weight variation, hardness, thickness, friability, disintegration time, drug content and dissolution rate study. All formulations evaluation parameters indicate that values were within permissible limit. Disintegration time for all the formulations were found to be in the range of 48-92 sec. The friability was less than 1%. F7was identified as the best formulation among all the other formulations. Optimized batch F7 showed was less disintegration time and more than 95 % drug release in 20 minutes. The results showed that with increasing the concentration of superdisintegrants the disintegration time decreases and the release of the drug increases. Thus, we are able to achieve our objective of preparing fast dissolving tablets of Paracetamol by this method.

Keywords: Fast Dissolving Tablet, Paracetamol, Direct compression, superdisintegrants.

INTRODUCTION

Fast dissolving drug delivery systems either dissolve or disintegrate generally within a minute, without water or chewing. This system has emerged as a convenient way of administering unit dose of drug in patient who may face difficulty in swallowing conventional tablets or capsules and liquid orals or syrup. Fast dissolving dosage forms include tablets, films/strips and microspheres[1].

Tablets are popular oral solid dosage forms amongst the other due to its easy administration, stability, compactness and pilfer proof in nature[2,3]. But the problem associated with solid dosage forms is the difficulty in swallowing (dysphagia) or chewing in some patients particularly pediatric and geriatric patients[4,5]. Dysphasia is a common problem associated with the tablets and capsule which results in high degree of noncompliance[6,7]. Presently, increasing attention has been paid for orally disintegrating tablets that are intended to dissolve and/or disintegrate rapidly in the mouth. Their characteristic advantages such as rapid onset of action, increased bioavailability and administration without water, anywhere, anytime lead to their suitability to geriatric and pediatric patients make these tablets popular as a dosage form of choice in the current market[8,9].

Direct compression is the most simple and economical method used in tableting. The simplicity of the direct compression process is apparent from a few steps involved in the manufacture of tablets as compared to wet granulation[10,11].

Paracetamol is the most prescribed antipyretic and analgesic drug for all age groups. Various types of paracetamol products in the form of tablets, dispersible tablets, suspensions, syrups and FDTs are available commercially. The objective of the present study is to formulate and evaluate fast dissolving tablets (FDTs) of paracetamol[12].

MATERIALS AND METHODS

Materials

Paracetamol was obtained as a gift sample from Vama Pharma, Nagpur. Croscarmellose sodium, sodium starch Glycolate and Micro crystalline cellulose was procured from Qualikems Fine Chem Pvt. Ltd. All other chemicals and reagents that were of analytical grade were used.

Preparation of Paracetamol Fast Dissolving Tablets

Fast dissolving tablets of Paracetamol were prepared by direct compression method using 3^2 factorial designs as shown in table 1.

Table 1: Factorial Design

Batch	Sodium Starch Glycolate	Croscarmellose Sodium
F1	-1	-1
F2	0	-1
F3	+1	-1
F4	-1	0
F5	0	0
F6	+1	0
F7	-1	+1
F8	0	+1
F9	+1	+1

All the ingredients (as shown in table 2) were powdered and passed through sieve number 16 separately. The drug and directly compressible excipient were mixed by adding small portion of each at a time and blending it to get a uniform mixture and kept aside. Then the other ingredients were mixed in geometrical order. Magnesium stearate and talc were added last and mixed for further two minutes and the tablets were compressed using 8-12 mm flat round punches to get tablets of 250 mg weight[13,14].

Table 2: Composition of Fast Dissolving Tablet

Name of ingredient	Formulation Batches (Quantity in mg)								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
Paracetamol	125	125	125	125	125	125	125	125	125
Sodium starch Glycolate	2	4	6	2	4	6	2	4	6
Croscarmellose sodium	2	2	2	4	4	4	6	6	6
Talc	3	3	3	3	3	3	3	3	3
Magnesium stearate	4	4	4	4	4	4	4	4	4
Micro crystalline cellulose	114	112	110	112	110	108	110	108	106

Evaluation of oral fast dissolving tablets

Compressed tablets were then evaluated for hardness, wetting time, disintegration, friability, and drug content.

Uniformity of Weight

The uniformity of weight test is run by weighing 20 tablets individually and collectively and calculating the average weight, and comparing the individual tablet weight to the average[15].

Tablet Hardness

The hardness of prepared tablets was determined by using Monsanto hardness tester. Three tablets from each formulation batch were tested randomly, and the average reading was noted. The hardness is measured in kg/cm^2 [16].

Tablet Friability

The friability of the tablets was measured in a Roche friabilator by using 10 tablets. The percentage friability of the tablets was measured as per the following formula[17]:

$$\text{Percentage friability} = W_1 - W_2 / W_1 \times 100$$

Where,

W_1 = Initial weight of tablet.

W_2 = Final weight of tablet.

Drug Content Uniformity

Five tablets of each formulation were taken and amount of drug present in each tablet was determined. An accurately weighed quantity of powder equivalent to 10mg of Paracetamol was taken into 100 ml volumetric flask, dissolved in phosphate buffer of pH 6.8 and analyzed in UV.

Disintegration Test

The in-vitro disintegration test was performed by using disintegration test apparatus. The test is carried out for total 6 tablets and distilled water at 37°C ± 2°C was used as a disintegration media. Average value was considered as disintegration time for the tablet[18].

Dissolution Rate Study

Dissolution rate of paracetamol tablets prepared was studied in phosphate buffer of pH 6.8 (900 ml) employing eight station dissolution rate test apparatus using paddle stirrer at 50 rpm and at temperature of 37°C ± 1°C. One tablet was used in each test. Samples of dissolution fluid (5 ml) were withdrawn through a filter at different time intervals and assayed for paracetamol at257 nm.[12, 19].

RESULTS AND DISCUSSION

Evaluation of Fast Dissolving Tablet

Average weight, Thickness, Hardness, %Friability, % Drug content, Disintegration Time and dissolution studies as shown in table 3.

All formulation showed weight variation throughout in the range of 0.22 to 0.25. No significant difference in the weight of individual formulations from the average value was observed and variations were within the range. The fast dissolving tablets showed uniform thickness throughout, in the range of 2.4 to 3.4mm. The friability was below 1 % for all formulations which is an indication of good mechanical resistance of tablet. The hardness of different formulation was found to be between 3.7±0.40 to 5.2±0.36 kg/cm^2 indicating good mechanical strength. The content uniformity of the prepared paracetamol FDT was complied with IP specifications. No tablets were out of the range of 85–115% of the label claim. These results indicated that the prepared tablets had uniform distribution and proper dose of the active ingredient. All tablets disintegrated in less than 2 min.

Table 3: Post Compression Studies for Formulation of Fast Dissolving Tablets

Formulation Code	Post compression Studies					
	Avg. Wt. (g) (n=10)	Thickness (mm) (n=3)	Hardness (kg/ cm^2) (n=3)	% Friability	% Drug content	Disintegration Time (Sec)
F1	0.2375	2.50	5.2	0.96	98.1	70
F2	0.2226	2.50	4.07	0.47	98.2	52
F3	0.2436	2.4	4.05	0.54	99.8	82
F4	0.2407	3.47	4.2	0.41	86.30	60
F5	0.2479	2.99	3.9	0.13	88.38	70
F6	0.2471	3.20	4.7	0.80	86.3	92
F7	0.2443	2.83	4.8	0.81	94.4	48
F8	0.2506	3.03	4.8	0.50	96.5	51
F9	0.2484	2.79	3.7	0.87	99.8	49

Dissolution Parameter of Paracetamol tablets:

The release of the drug from the prepared fast dissolving tablets were shown in figure no. 1.

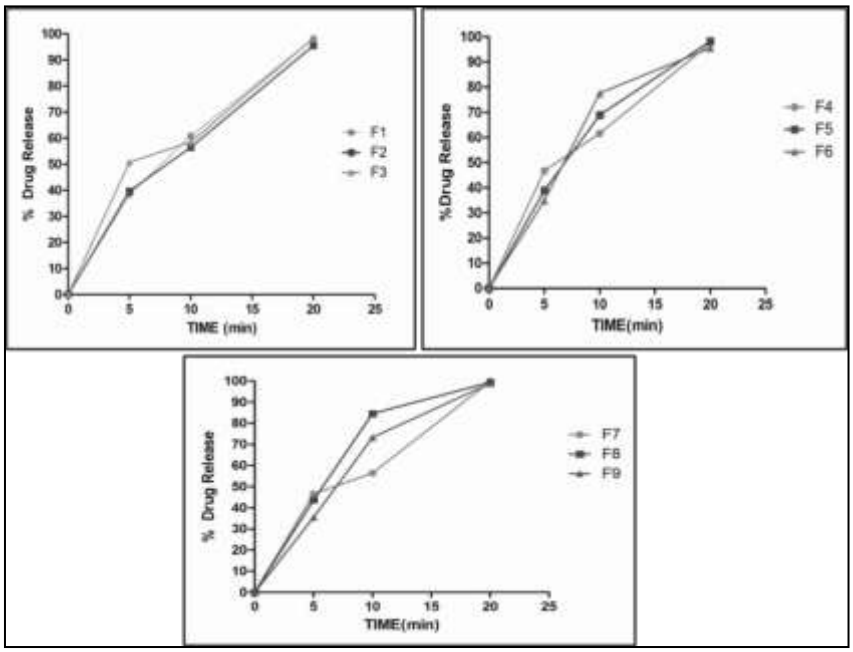

Figure 1: Percentage drug release of Formulation F1-F9

In vitro dissolution studies showed that more than 50% of the drug was released from the formulation within 10 minutes. The rapid drug dissolution might be due to easy breakdown of particle by superdisintegrant action. From in vitro dissolution data, it was observed the maximum % of paracetamol released in 20 minutes. It was also observed that, the change in concentration of both the superdisintegrants sodium starch glycolate and croscarmellose sodium had significant effect on the dissolution profile of paracetamol tablets. As the concentration of Superdisintigrants increases the rate of dissolution of tablets were also increase due to increase in hydrophilicity and swelling which in turn causes rapid disintegration. Optimized batch F 7 showed was less disintegration time and more than 95 % drug release in 20 minutes.

SUMMARY AND CONCLUSION

Many conventional solid oral dosage forms are available which releases the drug instantly to obtained fast and complete systemic drug absorption. Dysphasia is a common problem associated with the tablets and capsule which results in high degree of noncompliance. The aim of present study was formulation and in-vitro evaluation of fast dissolving tablets of paracetamol by using direct compression technique. Evaluation parameters like hardness, friability, weight variation and drug content indicate that values were within permissible limit for all formulations. Disintegration time for all the formulations were found to be in the range of 48-92 sec seconds. The friability was less than 1%. The wetting time and disintegration time were practically good for all formulations. By using different concentration of

superdisintegrant has shown better release profile. The results showed that with increasing the concentration of superdisintigrants the disintegration time decreases and the release of the drug increases. Thus, we are able to achieve our objective of preparing fast dissolving tablets of Paracetamol with the help of super disintegrating agents.

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Source of Support: Nil, **Conflict of Interest:** None.