Research Article

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COMPARATIVE EVALUATION OF FAST DISSOLVING TABLETS OF ACECLOFENAC PREPARED BY DIFFERENT TECHNIQUES

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ABSTRACT

Oral dosage forms are limited by first pass metabolism and gulping of tablets especially in case of paediatric and geriatrics. Fast dissolving tablets or oral dispersible tablets are novel form of oral dosage systems which disintegrates in couple of seconds so that the proportion of drug that reaches the systemic circulation is increased. Aceclofenac is poorly aqueous soluble, so it can be formulated as oral dispersible tablets, which enhances its dissolvability and ultimately its bioavailability is increased. The Main objective of the study is to develop, optimize, evaluate and compare the percentage release of acyclofenac FDT's prepared by different techniques such as direct compression, Solid dispersion and Wet granulation. The present investigation is done to select an optimum formulation which is showing good percentage release of drug and to compare the techniques that influences drug release profile. After compression of powder blend, the FDT's are evaluated for various parameters i.e. hardness, friability, wetting time, weight variation, disintegration time and in-vitro dissolution. The effect of concentration and type of superdisintegrants on in- vitro drug release profile used in formulations of fast dissolving tablets is also investigated. The investigation shows that the formulation of fast dissolving tablets containing PEG-6000 (1:1 ratio) prepared by solid dispersion technique have high percentage of drug release profile while the formulations manufactured by wet granulation technique have low percentage of drug release profile.

Keywords: Fast dissolving tablets, Solid dispersion technique, In-vitro dissolution study, Aceclofenac

INTRODUCTION

The advancement in the field of drug delivery has appeared to overcome of the shortcomings of the conventional systems. Formulations of any drug in the dosage form are aimed to achieve better results with respect to safety, efficacy and efficiency of the drug molecule. It has been found that rendering the components of a dosage form can actually lead to significant changes in the performance of drug delivery system¹.

The oral dosage forms are the most preferred medication system despite of many limitations like pre-systemic metabolism, slow onset of action and solubility problems. Although, it causes changes in various pharmacokinetic parameters related to drug response but it can be fixed by incorporating few modifications in delivery system².

One of such change which can enhance the patient compliance for oral drug delivery system is the aim of the present study. The major problem associated with the patient compliance has been reported to be the difficulty in swallowing of or the oral solid dosage forms. The population related to paediatric, geriatric and mentally ill are the most suffered subjects³. Fast dissolving tablets are also known as mouth dissolving tablets. These are the pharmaceutical preparations that disintegrate in mouth due to saliva within few seconds. This drug delivery system need not require addition of water or mastication⁴.

Altering the conventional dosage form to fast dissolving tablet can be an approach to tackle such problem. Fast dissolving tablets are the solid dosage forms which encapsulate and disintegrate rapidly, within few seconds when placed upon

tongue. The system does not require additional water to facilitate swallowing⁵.

Fast Dissolving Tablets (FDT's) disintegrate momentarily in saliva with no utilization of water. A few formulations are intended to break down in saliva quick, inside a couple of moment, are genuine FDT's. After placing in oral cavity, this tablet deteriorates quickly, releasing the medication, which disintegrates or scatters in the saliva.

MATERIALS AND METHODS

Materials collection

Aceclofenac was received as gift sample from Swiss Garnier Life Sciences, Himachal Pradesh, India. Polyethylene glycol, Acetone and Methanol were collected from Central Drug house (P) Ltd. Lactose, SSG, Sodium lauryl sulphate, Talc, Polyvinyl pyrrolidone and Microcrystalline cellulose were received from Loba chemicals Mumbai India. Magnesium Stearate was received from sd fi NE-CHEM Ltd. Mumbai India.

Preformulation studies

Preformulation studies like determination of melting point, infrared spectral analysis and physical compatibility study were performed for aceclofenac and data were compared with standards.

Formulation Development

Preparation of different formulation series of aceclofenac by direct compression method

Different batches of tablets were prepared by direct pressure strategy. Drug, diluent, superdisintegrants, surfactant and

sweetener were passed through sieve # 40 and magnesium stearate and talc were gone through sieve # 80. Obligated amount of medication and surfactant were blended first than different excipients were blended completely. The powder was compacted utilizing direct compression process⁵. The formula of different batches is indicated in Table 1.

Preparation of different formulation series of aceclofenac by solid dispersion method

It has discovered that 5-10 % w/w of fluid compound could be consolidated in PEG 6000 without huge loss of its strong properties. Thus it is conceivable to plan solid dispersion by first dissolving drug in a suitable solvent and after that the arrangement is consolidated straightforwardly into the melt of PEG (70°C) without evacuating the fluid solvent. To this solid dispersion accurately weighed remaining ingredients was added and mixed thoroughly and passed by sieve # 40 and compressed for tablets⁶. The formula of different batches is indicated in Table 2.

Preparation of different formulation series of aceclofenac by wet granulation method

Tablets containing 100mg of API were prepared by wet granulation technique by using 10%w/v PVP as a binder. The accurately weighed all ingredients were mixed and triturated gently by adding binder solution. The obtained granules were dried at 60°C for complete drying and the dried powder was mixed with magnesium stearate and talc and blended. Then the powder was compressed in to tablets⁷. The formula of different batches is indicated in Table 3.

CHARACTERIZATION AND EVALUATION OF TABLETS

The tablets of different formulations prepared by direct compression, solid dispersion and wet granulation techniques were evaluated by characterizing their hardness, friability, weight variation, wetting time, in-vitro dispersion time and in-vitro dissolution study.

Hardness

The crushing strength of tablets (hardness) was measured using Monsanto hardness tester. The force required to crush the tablet was measured in Kg/cm².

Friability

The friability of a sample of 10 tablets was measured using a Roche Friabilator. 10 pre-weighed tablets were rotated at 25rpm for 4minutes. The tablets then reweighed after removal of fines and the % of weight loss was calculated using formula:

$$\% \text{ Friability} = [(W_i - W_f) \div W_i] \times 100$$

Where W_i = initial weight of tablets, W_f = final weight of tablets

Weight variation

10 tablets of each batch were selected at a random and average weight was calculated. The individual tablets were weighed and the weight was compared with an average weight.

Wetting time

The wetting time of tablets was evaluated by the use of a piece of double folded tissue paper placed in a petri dish containing 6ml of water. A pre-weighed tablet was placed on this paper and the time for complete wetting of tablet was noted as wetting time.

In vitro dispersion time

The tablet was added to 10ml of water and time required for complete dispersion was measured. Two tablets from each formulation batches were randomly selected and in vitro dispersion time was performed.

In vitro dissolution study of tablets

Preparation of standard plot of aceclofenac in phosphate buffer (pH 6.8)

Determination of the maximum wavelength: 100 mg of aceclofenac transferred into a 100 ml of volumetric flask and dissolved in 10 ml of methanol and make up the volume with pH 6.8 buffer solutions. From this solution 10 ml was taken in a 100 ml of volumetric flask and make up the volume with pH 6.8 buffer solutions to get concentration 100µg/ml. this is known as stock solution. From this solution aliquots 1ml, 2ml, 3ml, 4ml, and 5ml were pipette out into a 50ml volumetric flasks and make up the volume up to the mark with pH 6.8 buffer solutions. From the 50ml flasks sample was taken out and filled in to the cuvette of the UV apparatus. Maximum wavelength was checked from the range of 200-400nm. the highest wavelength was measured out to be 273.2nm⁸. The standard plot of aceclofenac was shown in Figure 1.

The in-vitro study of tablets was carried out using USP II dissolution apparatus (paddle method). The in-vitro dissolution media used was phosphate buffers 6.8pH. The FDT of formulation batch was dropped in to 900ml of dissolution media maintained at a temperature of $37 \pm 0.5^\circ \text{C}$ and stirred at a specified rpm i.e. 50rpm. 5ml of aliquots of dissolution medium were withdrawn at a time interval of 5, 10, 15, 20, 25, 30 minutes which was replaced with 10ml of fresh dissolution medium. The samples withdrawn were filtered and diluted and assayed at 275nm using UV- visible double beam spectrophotometer.

RESULTS AND DISCUSSION

The tablets of each formulation prepared by direct compression, solid dispersion and wet granulation techniques were evaluated. The evaluation parameters of different formulations prepared by direct compression, solid dispersion and wet granulation techniques are shown in table 4, 5 and 6 respectively.

The hardness of the fast dissolving tablets prepared by three different techniques was found within 3.12 to 4.7 kg/cm². Percentage of friability for all the formulations was less than 1 %. All the FDT tablets passed weight variation test. The wetting time for all the formulations was rapid and the values obtained lies between 93-193 sec.

The in-vitro dispersion time of the aceclofenac tablets prepared by different techniques were found to be between 78.9-148 sec. Hence it is concluded that tablets of each formulation show fast disintegration. The evaluation parameters of the formulation F3 of direct compression, F2 of solid dispersion and F1 of wet granulation technique were compared, which is indicated in Table 7.

Figure 2, 3 and 4 show the dissolution profiles of different formulations prepared by direct compression, solid dispersion and wet granulation technique respectively. From the figure 2, it was observed that formulation F3 prepared by direct compression has the better drug release profile, as compared to other formulations of same technique. Similarly formulation F2 of solid dispersion and F1 of wet granulation technique showed better drug release profile as shown in the Figure 3 and Figure 4 respectively.

Table 1: Formulations of aceclofenac FDT by direct compression technique

Ingredients	Batches coded Quantity (mg)		
	F1	F2	F3
Aceclofenac	100	100	100
Sodium starch glycolate	55	66	77
Microcrystalline cellulose	50	50	50
Talc	10	10	10
Magnesium stearate	5	5	5
Sodium lauryl sulphate	5	5	5
Lactose monohydrate	325	314	303
Total	550	550	550

Table 2: Formulations of aceclofenac FDT by solid dispersion technique

Ingredients	Batches coded Quantity (mg)		
	F1	F2	F3
Aceclofenac	100	100	100
Poly ethylene glycol-6000	0	100	200
Sodium starch glycolate	52	54	56
Microcrystalline cellulose	50	50	50
Talc	10	10	10
Magnesium stearate	5	5	5
Sodium lauryl sulphate	5	5	5
Lactose monohydrate	328	226	124
Total	550	550	550

Table 3: Formulations of aceclofenac FDT by wet granulation technique

Ingredients	Batches coded Quantity (mg)		
	F1	F2	F3
Aceclofenac	100	100	100
Sodium starch glycolate	52	54	56
Microcrystalline cellulose	50	50	50
Talc	10	10	10
Magnesium stearate	5	5	5
Sodium lauryl sulphate	5	5	5
Lactose monohydrate	328	326	324
Total	550	550	550

Table 4: Results of formulation series of aceclofenac by direct compression method

Parameters	Formulations		
	F1	F2	F3
Hardness(kg/cm ²)	3.52	3.54	3.56
Friability(%)	0.857	0.556	0.723
Weight variation	Pass	Pass	Pass
Wetting time(sec)	193	181	165
In vitro dispersion time(sec)	137	122	118

Table 5: Results of formulation series of aceclofenac by solid dispersion technique

Parameters	Formulations		
	F1	F2	F3
Hardness(kg/cm ²)	3.22	3.18	3.12
Friability(%)	0.551	0.632	0.618
Weight variation	Pass	Pass	Pass
Wetting time(sec)	154	93	117
In vitro dispersion time(sec)	103.7	78.9	84.4

Table 6: Results of formulation series of aceclofenac by wet granulation method

Parameters	Formulations		
	F1	F2	F3
Hardness(kg/cm ²)	4.1	4.5	4.7
Friability(%)	0.447	0.683	0.722
Weight variation	Pass	Pass	Pass
Wetting time(sec)	145	159	147
In vitro dispersion time(sec)	123	138	148

Table 7: Results of formulation series of aceclofenac by direct compression, solid dispersion and wet granulation technique

Parameters	Formulations		
	F3 of direct compression	F2 of solid dispersion	F1 of wet granulation
Hardness(kg/cm ²)	3.56	3.18	4.1
Friability(%)	0.723	0.632	0.447
Weight variation	Pass	Pass	Pass
Wetting time(sec)	165	93	145
In vitro dispersion time(sec)	118	78.9	123

Table 8: Percentage release of aceclofenac from formulated tablets by wet granulation, direct compression and solid dispersion techniques

No	Time (min)	F1 of wet granulation	F3 of direct compression	F2 of solid dispersion
1	5	16.11	21.68	26.22
2	10	27.58	27.24	35.8
3	15	33.67	34.36	49.17
4	20	49.13	46.51	60.36
5	25	52.5	58.81	64.61
6	30	63.8	68.14	74.14

Figure 1: Standard plot of aceclofenac using phosphate buffer of pH 6.8

Series1- (F1), Series2-(F2), Series3-(F3).
Figure 2: Comparison of cumulative % release of different formulation prepared by direct compression method

Series1- (F1), Series2-(F2), Series3-(F3).
Figure 3: Comparison of cumulative % release of different formulation prepared by solid dispersion technique

Series1- (F2), Series2-(F1), Series3-(F3).
Figure 4: Comparison of cumulative % release of different formulation prepared by wet granulation technique

Figure 5: Comparison of % release of aceclofenac by three different techniques
Series1-Direct compression (F3), Series2-solid dispersion (F2), Series3-wet granulation (F1)

Regarding with the evaluation of in-vitro dissolution of formulations, the results of release profile of aceclofenac prepared by three different techniques are shown in Table 8. It showed that formulation F2 prepared by solid dispersion technique released 74.14% of aceclofenac, formulation F3 of direct compression released 68.14% and formulation F1 of wet granulation technique released 63.8% of aceclofenac within 30 minutes. The comparative release profile of aceclofenac prepared by three different techniques has shown in Figure 5.

CONCLUSION

The present investigation was done to select an optimum formulation which is showing good percentage release of drug than other formulations and comparison of the techniques about their drug release profile. The effect of concentration and type of superdisintegrants on in-vitro drug release, used in formulations of fast dissolving tablets was also investigated. From the present study it was found that the fast dissolving tablets prepared by solid dispersion technique showed better drug release profile, as compared to other techniques. Therefore it was concluded that the formulation F3 of aceclofenac fast dissolving tablets containing PEG-6000(1:1 ratio) prepared by solid dispersion technique showed higher in-vitro drug release and tablets prepared by wet granulation technique showed lower in-vitro drug release.

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