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Formulation and evaluation of fast dissolving tablets of Carvedilol

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ABSTRACT: Background: Carvedilol is a non selective beta adrenergic blocking agent with alpha-1 blocking activity and is indicated for the treatment of hypertension and mild to moderate heart failure of ischematic or cardiomyopathic origin. **Aim:** The study was aimed to develop fast dissolving tablets (FDT) of carvedilol. **Method:** The FDT of carvedilol was prepared by wet granulation method using super disintegrant croscarmellose sodium in different concentration. The drug and excipient compatibility was confirmed by FTIR study. The granules were evaluated for flow properties by determining bulk, tapped densities, Carr's Index, Hausner's ratio and angle of repose. The developed batches of tablets were evaluated for weight variation, hardness, friability, wetting time, *in vitro* dispersion time, drug content and *in vitro* dissolution studies. The optimized formulation was evaluated for stability studies at storage condition of 40±2°C/75±5% RH. **Results:** Almost all granule formulation exhibited good flow properties. Tablet formulation batch F4 was considered as the overall best formulation as it showed highest *in vitro* drug release profile of 95.52 % at the end of 40 mins and least disintegration time of 12 s. Short term stability studies revealed that the optimized FDT was stable as there no significant change in drug content was observed. The FTIR study indicated that there are no drug excipient interactions. **Conclusion:** The FDT formulation F4 containing croscarmelose 12 % could be successfully used for safe management of hypertension orally.

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Key words: Carvedilol, FDT, FTIR spectroscopy, *in vitro* drug release study.

INTRODUCTIONS:

An oral route is the most popular route of administration of dosage forms. Solid dosage forms like tablets are the most popular dosage forms existing today because of its convenience of self administration, compactness and easy manufacturing [1]. Recent advances in novel drug delivery system (NDDS) aims to enhance safety and efficacy of already used drug molecule by formulating a

convenient dosage form for administration and to achieve better patient compliance [2]. Hence the advances in NDDS for designing dosage forms like FDT for convenient to be manufactured and administered free of side effects, offering immediate release and enhance bioavailability so as to achieve better patient compliance [3,4]. Oral drug delivery systems preferably tablets are most widely used dosage forms for being compact offering uniform dose and painless delivery. But older and paediatrics patients suffer in dysphagia because physiological changes associated with those groups [5]. Generally dysphagia is observed population who are associated with a number of conditions like parkinosonism, mental disabilities, motion sickness, unconsciousness, unavailability of water etc. To avoid such problems certain innovative drug delivery systems like FDT have been developed. These are novel dosage forms which dissolve in saliva within few seconds when put on tongue. A fast-dissolving drug delivery system, in most cases, is a tablet that dissolves or disintegrants in the oral cavity without the need of water or chewing [6]. Most fast-dissolving delivery system films must include substances to mask the taste of the active ingredient. This masked active ingredient is then swallowed by the patient's saliva along with the soluble and insoluble excipients. These are also called melt-in-mouth tablets, repimelts, porous tablets, orodispersible, quick dissolving or rapid disintegrating tablets [7].The FDT are absorbed from the mouth, pharynx and oesophagus as saliva passes down into the stomach.The solution containing active ingredients is absorbed through gastrointestinal epithelium to reach the target and produce desired effect [8].

Carvedilol is an alpha and a beta adrenoreceptor-blocking agent used in the treatment of various cardiovascular disorders such as angina pectoris, cardiac arrhythmia and hypertension [10]. Carvedilol is indicated for the treatment of mild to severe chronic heart failure, Left ventricular dysfunction following myocardial infarction in clinically stable patients and hypertension. Carvedilol is a poorly water-soluble oral antihypertensive agent, with problems of variable bioavailability and bio-equivalence related to its poor water-solubility. Carvedilol was selected as a drug candidate for the formulation of FDT for the following reasons. It is chemically stable [10]. The biological $t_{1/2}$ is 7 to 10 h. In view of substantial first pas effect and its shorter plasma half life, therefore is an ideal drug candidate for FDT. In the present study FDT of carvedilol were designed using wet granulation method using various excipients and croscarmellose as natural superdisintegrants with prime objective arriving of a cost effective product.

MATERIALS AND METHODS:

Carvedilol was received as a gift sample from Maxtar Bio-Genics (Baddi)., cherlapally, H.P. Croscarmellose sodium and Aerosil were obtained as gifts from Aurobindo labs Pvt Ltd, A.P. Magnesium stearate, talc, micro crystalline cellulose,and potassium dihydrogen-o-phosphate were procured from SD fine chem. Ltd Mumbai. Sodium hydroxide and methanol were procured from Qualigens fine chemicals Mumbai.

Drug excipient compatibility (FTIR) study:

FTIR study:

The FTIR allows identification of functional groups in various chemicals as well as incompatibilities between the drug and excipients. In this method individual samples as well as the mixture of drug and excipients were ground mixed thoroughly with potassium bromide (1:100) for 3 to 5 min in a mortar and compressed into disc by applying pressure of 10 kg/cm to form a transparent pellet in hydraulic press [11]. The pellet was kept in the sample holder and scanned from 4000 to 400 cm^{-1} in FTIR spectrophotometer (Bruker, Germany).

Table 1. Composition of carvedilol FDT.

Ingredients (mg)	F1	F 2	F 3	F 4
Carvedilol	6.25	6.25	6.25	6.25
CCS	0	4	8	12
MCC	136	132	128	124
Aerosil	1.5	1.5	1.5	1.5
Sod. saccharin	2	2	2	2
Mag. stearate	2.25	2.25	2.25	2.25
Talc	2	2	2	2
Total weight	150	150	150	150

Preparation of FDT:

The tablets were prepared by wet granulation technique [12]. Accurately weighed quantities of ingredients mentioned in Table 1 were passed through sieve no. 12 and croscarmellose sodium was passed through sieve no. 20. All the ingredients, lubricant magnesium stearate and talc (glidant) were manually blended homogenous by way of geometric dilution. The mixture was moistened

with aqueous solution and granulated with sieve no. 20 and placed in hot air oven at 60 ºC for sufficient 3 to 4 h. Then dried granules passed through sieve no.12 and blended with mgnesium stearate and talc. The homogenous mixture were placed into tablet punching machine (10 station rotary tablet machine, Clint India) getting tablet weight 150 mg each using deep concave punch.

Table 2. Scale of flowability determined by different methods [18].

Flow property	AOR (°)	CI (%)	HR
Excellent	25-30	≤10	1.00-1.11
Good	31-35	11-15	1.12-1.18
Fair	36-40	16-20	1.19-1.25
Passable	41-45	21-25	1.26-1.34
Poor	46-55	26-31	1.35-1.45
Very poor	56-65	32-37	1.46-1.59
Very very poor	> 66	> 38	>1.6

AOR – Angle of repose, CI – Carr's Index and HR – Hausner's ratio.

Pre compression evaluation of FDT granules:

***Angle of repose*:**

The angle of repose of granules blend was determined by the fixed funnel method. The accurately weighed quantity of granules was taken in a funnel. The height of funnel was adjusted in such a way that the tip of the funnel just touched the apex of the heap of the granules [13]. The granules are allowed to flow through the funnel freely onto the surface. The diameter of powder cone was measured and angle of repose was calculated using the following equation;

$\theta = \tan^{-1}(h/r)$ ……..... (1)

Where, θ is the angle of repose, h and r are the height and radius of cone in cm.

Bulk density (e_b):

Bulk density was determined by pouring the granules into a graduated cylinder. The bulk volume (V_b) and mass (m) of the granules was determined [14]. The bulk density was calculated by using the following formula;

$e_b = m/V_b$ .....(2)

Tapped density (e_t):

The measuring cylinder containing known mass of granules blend was tapped 1000 times for a fixed time. The minimum volume occupied in the cylinder (V_t) and mass of the granules (m) was measured [15]. The tapped density was measured by using the following formula;

$e_t = m/V_t$ ..... (3)

Compressibility index (Carr's index):

The percentage compressibility of granules is a direct measure of the potential powder arch and stability. The Carr's index can be calculated by the following formula [16];

Carr's index (%) $= [(e_t - e_b)/e_t] \times 100$..... (4)

Where e_t and e_b are the tapped and bulk densities of granules.

Hausner's ratio (H_R):

Hausner's ratio is used for the determination of flow properties of granules. The ratio can be calculated by the taking the ratio of tapped density to the ratio of bulk density [17].

$H_R = \frac{et}{eb}$ ……..... (5)

Evaluation of compressed FDTs:

Thickness:

The thickness of individual tablets is measured by using vernier caliper which gives the accurate measurement of thickness. It provides information of variation of thickness between tablets. Generally the unit for thickness measurement is mm. The limit of the thickness deviation of each tablet is ±5 % [19].

Hardness:

The hardness of prepared tablets was determined by using Monsanto hardness tester and measured in terms of kg/cm^2 [20]. Test was done in triplicate.

Table 3. Pre-compression parameters of FDT formulations.

FC	BD (g/ml)	AOR (°)	CI (%)	HR
F1	0.58±0.14	26±0.13	12.1±0.01	1.1±0.01
F 2	0.68±0.11	25±0.12	8.1±0.13	1.1±0.12
F 3	0.54±0.13	24±0.11	20.6±0.01	1.2 ±0.12
F 4	0.53± 0.11	29±0.09	8.6±0.11	1.1±0.11

All values are expressed as mean ± standard deviation. FC – Formulation code, BD – Bulk densities, AOR – Angle of repose, CI – Carr's Index and HR – Hausner's ratio.

Friability:

Friability of tablets was performed in a Roche friabilator. Ten tablets were initially weighed (W_0)

together and then placed in the chamber. The friabilator was operated for 100 revolutions and the tablets were subjected to the combined effects of abrasion and shock because the Plastic chamber carrying the tablets drops them at a distance of six inches with every revolution. The tablets are then dusted and reweighed (W). The percentage of friability was calculated using the following equation [21];

$$\text{Friability (\%)} = \left(1 - \frac{W_0}{W}\right) \times 100 \quad \text{..... (6)}$$

Where, W_0 and W are the weight of the tablets before and after the test respectively. The limit for percentage of friability is between 0.5 to 1 %.

Table 4. Post-compression parameters of FDT formulations.

FC	HD (kg/cm^2)	FBT (%)	DC (%)	AVW (mg)	TKN (mm)
F1	3.9±0.02	0.5±0.11	98	151±0.16	4±0.10
F2	3.8±0.01	0.5±0.01	97	150±0.15	4±0.11
F3	3.9±0.02	0.6±0.02	98	149±0.14	4±0.14
F4	3.8±0.05	0.4±0.10	99	150±0.11	4±0.13

Table 5. Post-compression parameters of FDT formulations.

FC	DT (s)	DST (s)	WT (s)	WAR (%)
F1	31±1.01	36±1.14	24±1.1	68.2±1.3
F2	22±1.05	33±1.12	20±1.02	69.5±1.8
F3	18±1.11	29±1.05	17±1.06	71.5±1.2
F4	12±1.23	20±1.02	10±1.07	47.5±1.6

All values are expressed as mean ± standard deviation. FC – Formulation code, DT – Disintegration time, DST – Dispersion time, WT – Wetting time and WAR – Water absorption ratio.

Weight Variation Test:

The weight variation test was done by weighing 20 tablets individually (Shimadzu digital balance), calculating the average weight and comparing the individual tablet weights to the average [22]. The tablets meet the USP test if not more than 2 tablets are outside the percentage limit and if no tablet differs by more than 2 times the percentage limit.

$$\text{WV (\%)} = \frac{\left(|\overline{w} - w_n|\right)}{\overline{w}} x100\% \quad \text{..... (7)}$$

Where; weights of tablets are w_1, w_2, w_3,..w_n..,w_{20}.and average weight of the tablets = $\overline{w}$.

Disintegration test:

Six tablets along disc were introduced in each tube of basket of disintegration test apparatus (Lab care instruments) [23]. The basket was positioned into a beaker containing 900 ml of distilled water and operated at 37 ± 2 ^oC. The time of disintegration of tablet was recorded. The average time and standard deviation were calculated. Three trails were performed.

Wetting time:

The wetting time of the tablets can be measured using a simple procedure. Five circular tissue papers of 10 cm diameter are placed in petridish with a 10 cm diameter [24]. Wetting time was measured by placing a tablet on a piece of tissue paper folded twice, and was placed in a small Petridish containing 6 ml of simulated saliva pH 6.8, and the time for complete wetting was measured. Five tablets from each batch were used.

Water absorption ratio:

A piece of tissue paper folded twice was placed in a small petri dish (internal diameter = 6.5cm) containing 5 ml of distilled water. A tablet was placed on the tissue paper [25]. The wetted tablet was weighed. The test was done in triplicate. The water absorption ratio (R) was determined according to the following equation,

$$\text{Water absorption ratio} = \frac{Wa - Wb}{Wa} \times 100 \quad \text{..... (8)}$$

Where, W_a is the weight of the tablets before the test and W_b is the weight of the tablet after water absorption.

Drug content:

Ten tablets from each batch of FDT formulations were taken and triturated to form powder. The powder weight equivalent to one tablet was dissolved in a 100 ml volumetric flask filled with phosphate buffer pH 6.8 using magnetic stirrer for 24 h [26]. Solution was filtered through Whatman filter paper No.1 diluted suitably and analyzed by UV-Spectrophotometer (Elico164) at λ_{max} 242 nm.

***In vitro* dissolution studies:**

The release rate of FDT were determined using United States Pharmacopeia (USP) dissolution testing apparatus type 2 (paddle method) [27-30] .The dissolution test was performed using 900 ml of Phosphate buffer pH 6.8, at 37 ± 0.5 ^0C and 50 rpm. In specified time intervals an aliquot of 5 ml samples of the solution were withdrawn from the dissolution apparatus and with replacement of

fresh fluid to dissolution medium. The samples were filtered through filter paper of 0.45 µm. Absorbance of these solutions were measured at λ_{max} 242 nm using a UV/Visible Spectrophotometer (Elico164). The drug release was plotted against time to determine the release profile of various batches.

In vitro dispersion time:

This test is performed to ensure disintegration of tablets in the salivary fluid, if it is to be used as an FDT. *In vitro* dispersion time was measured by dropping a tablet in a measuring cylinder containing 6ml of simulated salivary fluid of pH 6.8 [31,32]. Three tablets from each formulation were randomly selected and *in vitro* dispersion time was measured.

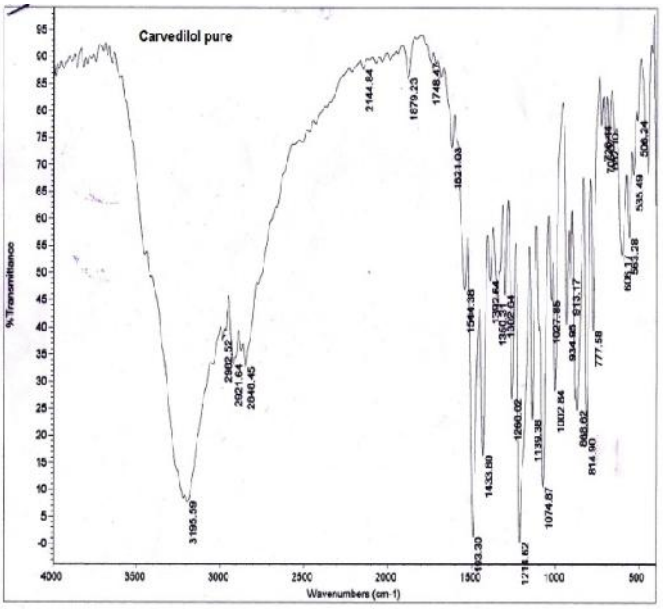

Fig 1. FTIR spectrum of carvedilol pure drug.

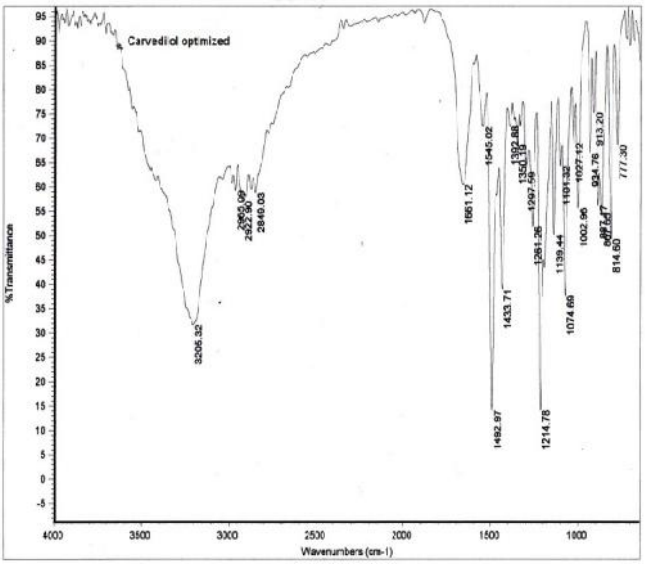

Fig 2. FTIR spectrum of optimized formulation (F4).

Stability studies:

The purpose of stability study is to provide evidence on the quality of a drug substance or drug product which varies with time under the influence of a variety of environmental factors such as temperature, humidity and light. The formulation was subjected to accelerated stability studies as per ICH (The International Conference of Harmonization) guidelines. The packed tablets in air tight container were placed in stability chambers (Thermo lab scientific equipment Pvt.Ltd. Mumbai, India) maintained at 40±2ºC/75±5% RH for 3 months [33-35]. Tablets were periodically removed and evaluated for physical characteristics, drug content, *in vitro* drug release etc.

RESULTS AND DISCUSSION:

FTIR study:

Carvedilol showed characteristic peaks (Fig 1). at 3195.59 cm^{-1} (O-H stretching), 2982.52 cm^{-1} (Amine stretching), 1621.03 cm^{-1} (N-H bending vibrations) and 1260.02 (O-H bending and C-O stretching) cm^{-1} and 1027.85 cm^{-1} (alkyl aryl ether bending vibration) and the optimized batch F4 showed the similar characteristic absorption band without any significant change in the wave number of drug indicating no chemical interaction between drug and excipients (Fig 2).

Pre-compression parameters of FDT formulations:

The bulk density of pre-compression granules is reported to be in the range of 0.53 ± 0.11 to 0.68±0.11 gm/ml, tapped density in the range of 0.58±0.14 to 0.74±0.09 gm/ml, angle of repose in the ranges from 24.0±0.11 to 29.0±0.09°, the Carr's index values were in the range of 8.1±0.13 to 20.58±0.01 %, and the Hausner's ratio was in the range between 1.08±0.12 to 1.2 ±0.125. All values are obtained in acceptable ranges as given in Table 3. The result showed that all granules exhibited excellent to good flow properties.

Post-compression parameters of FDT formulations:

The post compression parameters such as hardness, weight variation, drug content uniformity, friability and thickness values are given in Table 4. All values are obtained in acceptable ranges as per I.P. The hardness of all FDTs was comparatively good. All FDTs were passed for friability as their value was less than 1 %. All FDT formulations obtained satisfactory drug content. The drug content was maximum (99.45 ± 0.04 %) for FDT formulation F4. The average weight and thickness for all FDT formulations were uniform. The other

parameters such as wetting time, disintegration time and *in vitro* dispersion time values are given in Table 5. The maximum (31 ± 1.01 s) and minimum (12 ± 1.23 s) disintegration time was achieved by FDT formulation F1 and F4. The maximum (36± 1.14 s) and minimum (20± 1.02 s) dispersion time was achieved by FDT formulation F1 and F4. The FDT formulation F1 and F4 exhibited maximum (24 ± 1.1 s) and minimum (10 ± 1.07 s) wetting time. The FDT formulation F2 and F4 exhibited maximum (69.50 ± 1.8 %) and minimum (47.48 ± 1.6 %) water absorption ratio. *In vitro* drug release studies were performed in pH 6.8 phosphate buffer, on the above promising formulation (F4) gives maximum amount of drug release comparing to other formulations.

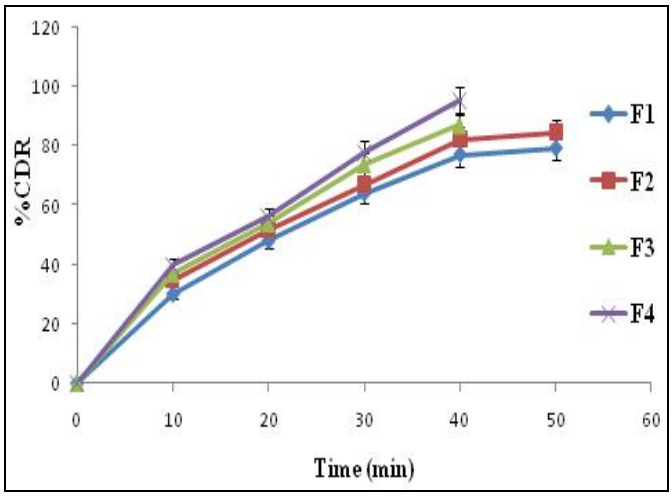

Fig 3. Comparative *in vitro* drug release study of carvedilol batches.

The percentage cumulative drug release (% CDR) of F4 was best giving 95.52 % in 40 min comparing to other batches F1 (79.2 %) in 50 min, F2 (84.6 %) in 50 min and F3 (87.19 %) in 50 min. The dissolution profiles of the above formulations are depicted in Fig 3. Short-term stability studies on the above promising FDT formulation (at 40±2^{o} / 75±5% RH for 3 month) have shown no significant changes in physical appearance, drug content and *in vitro* dispersion time, thus the formulation was fund to be stable.

CONCLUSION:

The study clearly demonstrates that FDT of carvedilol could be successfully prepared by wet granulation method using superdisintigrants. From the developed formulations, the release of carvedilol was best in F4 formulation, From the FTIR study, it was confirmed that the drug and excipients in the formulations were compatible with each other. Hence the availability of various technologies and the manifold advantages of FDT will surely enhance the patient compliance providing rapid onset of action.

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