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# Formulation, Optimization and *In-Vitro* Evaluation of Mouth Dissolving Tablets of Carvedilol by Using Natural Superdisintegrants

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## Abstract

The purpose of the present investigation is to formulate, optimize and evaluate of mouth dissolving tablets of Carvedilol, is anti-Hypertensive drug by Direct Compression method using different concentrations of Natural superdisintegrants i.e., Guar gum, Xanthan gum and Starch as (1-6% w/w). The drug-excipient interactions were investigated by FTIR. The prepared tablets were evaluated for micromeritic properties, hardness, friability, weight variation, *in-vitro* dispersion time, wetting time, water absorption ratio, *in-vitro* disintegration and in-*vitro* drug release. All the formulations showed low weight variation with rapid disintegration time and rapid *in vitro* dissolution. Among the twelve promising formulations (F1-F12), the best formulation, F4 (Guar gum) provided short Wetting time of 57±1.25sec, water absorption ratio 16±0.85%, *in-vitro* dispersion time of 40 sec and *in vitro* disintegration of 52±1.14sec and *in-vitro* drug release i.e. 98.8% at the end of 10 min. The disintegration time was found to linearly decrease with the increase in the amount of natural superdisintegrant. It was concluded that there are no much significant changes in any values which indicated that the formulation, F4, was considered to be highly stable and mouth dissolving tablets of Carvedilol can be successfully formulated by natural superdisintegrant addition method with improved patient compliance.

**Keywords**
Mouth dissolving tablets, *in-vitro* dispersion time, wetting time, water absorption ratio.

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## INTRODUCTION

Oral routes of drug administration have wide acceptance up to 50-60% of total dosage forms. Solid dosage forms are popular because of ease of administration, accurate dosage, self-medication, pain avoidance and most importantly the patient compliance [1]. The most popular solid dosage forms are being tablets and capsules; one important

drawback of this dosage forms for some patients, is the difficulty to swallow [2]. Drinking water plays an important role in the swallowing of oral dosage forms. Often times people experience inconvenience in swallowing conventional dosage forms such as tablet when water is not available, in the case of the motion sickness (kinetosis) and sudden episodes of coughing during the common cold, allergic condition and bronchitis [3]. In certain people, the use of conventional tablets can give trouble, such as the elderly(geriatric) who are experiencing difficulties in using conventional dosage forms (solutions, suspensions, tablets, and capsules) because of hand tremors and dysphagia; and children (pediatric) who have problems in swallowing drugs because of muscular and nervous system has not fully developed. Also in patients who have trouble using conventional tablets, such as in mentally ill patients, patients who are paralyzed, patients who are unable to swallow and patients who have to avoid much water, as well as in people who experience nausea [4-6]. MDT is not only indicated for people who have swallowing difficulties, but also are ideal for active working or travelling people [7-8]. For these reasons, tablets that can rapidly dissolve or disintegrate in the oral cavity have attracted a great deal of attention. Mouth dissolving tablets are solid dosage form that disintegrates and dissolves in mouth without water within 60 seconds or less [9] and are also called as fast-dissolving tablets, melt-in mouth tablets, oro-dispersible tablets, rapimelts, porous tablets, quick dissolving etc. The faster the drug into solution, quicker the absorption and onset of clinical effect. Some drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach [10]. In such cases, bioavailability of drug is significantly greater than those observed from conventional tablets dosage form. The basic approach in development of MDT is the use of natural superdisintegrants like Xanthan gum, Guar gum Starch etc, which provide instantaneous disintegration of tablet after putting on tongue, there by release the drug in saliva. The bioavailability of some drugs may be increased due to absorption of drug in oral cavity and also due to pre-gastric absorption of saliva containing dispersed drugs that pass down into the stomach. More ever, the amount of drug that is subjected to first pass metabolism is reduced as compared to standard tablet.

Carvedilol is a non-selective beta blocker indicated in the treatment of mild to moderate congestive heart failure (CHF). It blocks beta-1 and beta-2 adrenergic receptors as well as the alpha-1 adrenergic receptors. Carvedilol is its poor bioavailability (25-35%) and short half-life (7-10 hrs). On the basis of these considerations, in the present study it was proposed to formulate an oral delivery device, in the form of mouth dissolving tablets by using direct compression technology, with the aim of rapid disintegration and a complete drug release in a short period of time.

## MATERIALS AND METHODS

### Materials

Carvedilol was a gift sample from Emco Industries Hyderabad. Guar gum, Xanthan gum and Starch were purchased from Amit Cellulose Products, Pune. Microcrystalline cellulose, Aspartame, Talc, Mannitol and Magnesium streate were purchased from SD Fine Chemicals Ltd. Mumbai. All other chemicals and solvents used were of analytical grade.

**Preparation of Carvedilol tablets by direct compression method**:

The direct compression technique was used to manufacture the tablets. The drug and the excipients were passed through #60-sieve. Weighed amount of drug and excipients except magnesium stearate were mixed in a polybag by geometric addition method for 10 minutes manually. The blend was then lubricated by further mixing with magnesium stearate (#60-sieve). All the above ingredients were subjected for drying to remove the moisture content at 40 to 45°C, the mixture was blended with flavor and the powder blend was then compressed on 10-station rotary punching machine (Remik minipress1) using flat faced punches.

**Fourier Transform Infrared Spectroscopy (FTIR)**

The FTIR spectra were obtained using KBr on a Shimadzu 8400 FTIR spectrometer (8400 series, Shimadzu). The scanning range was 400-4000 $cm^{-1}$ and the resolution was 1 $cm^{-1}$. The results are shown in Fig no. 01 to 07.

**Preformulation Studies**

**Bulk Density [11].**

Weighed quantity of Carvedilol (25gm) was transferred into 100 ml measuring cylinder without tapping during transfer. The volume occupied by the drug was measured. Bulk density was measured by using formula $\rho_b = m / V_b$. The values obtained are reported in the table

$\rho_b = m / V_b$

where

$\rho_b$ = bulk density

m = mass of the blend

$V_b$ = untapped volume

**Tapped density:**

25 gm of Carvedilol was taken in 100 ml measuring cylinder that was placed in Electro lab tapped density

apparatus (method USP-I). Initial volume ($V_0$) of the cylinder was noted and then the cylinder was tapped 500 times and volume was measured. Then further an additional 750 tapings were repeated. No difference was noted between the volumes of the two tapings (500 and 750). The final volume (V) was considered after completion of 750 taps. Tapped density was measured by using formula $\rho_t = m / V_t$.

**Compressibility Index: [12]**

Weighed amount of Carvedilol (25gm) was transferred to 100ml graduated cylinder and subjected to 500,750 and 1250 taps in tap density tester (Electro lab). The difference between two taps should be less than 2%. The % of compressibility index calculated using formula

**Compressibility Index = 100 * ($\rho_{tapped}$ -$\rho_{bulk}$) / $\rho_{tapped}$)**

**Hausner's ratio: [13]**

It is measurement of frictional resistance of the drug. The ideal range should be 1.2-1.5. It was the determined by the ratio of tapped density and bulk density.

**Hausners ratio = $\rho_{tapped}$ / $\rho_{bulk}$**

**Angle of repose [14]**

It is defined as the maximum angle that can be obtained between the free standing of powder heap and horizontal plane, which is given by the equation:

**$\theta = \tan^{-1} h / r$**

where $\theta$ = Angle of repose

h = Height of the pile

r = Radius of the base of the conical pile

**Procedure:** Weighed quantity of the drug was passed through a funnel kept at a height 2 cm from the base. The powder is passed till it forms a heap and touches the tip of the funnel. The radius was measured and angle of repose was calculated by using the above formula.

**Evaluation of Mouth Dissolving tablets:**

**Hardness** [15].

This test gives the indication for the tablets ability to with stand its integrity of drug with the drug release can be optimized. It was determined by placing the tablet between the anvils only one of which is movable, driven by electricity. It presses the tablet at constant load till the tablet breaks. It was recorded in KP (1kP = 1 kg). Hardness of 10 tablets determined and average hardness and range was calculated. The results are shown in Table no 05

**Thickness:**

The thickness in millimeters (mm) was measured individually for 10 preweighed tablets by using a Mitutoyo portable dial hand micrometer. The average weight, standard deviation and relative standard variation were reported. The results are shown in Table no 05.

**Friability** [16]

Friability is related to tablets ability to withstand both shocks and abrasion without crumbling during manufacturing, packing, transportation and consumer handling. Friability can be evaluated by means of friability test apparatus. Compressed tablets that loose less than 0.5% to 1.0% in weight are generally considered acceptable. Friability of the formulated tablets was determined in Roche friabilator. Ten tablets were weighed accurately and then initial weight was note down. There are introduced in the apparatus and subjected to 100 revolutions at a speed of 25 rpm for 4 min. When the drum stopped, tablets were taken and deducted and final weight was taken. % Friability was calculated by the formula.

$$\text{Friability} = \frac{\text{Initial weight (gm)} - \text{Final weight (gm)}}{\text{Initial weight (gm)}} \times 100$$

Acceptance criteria: the friability value should be less than 1.0%. The results are shown in Table no 05

**Weight variation**: [17]

Weight variation test was performed according to USP. Average weight of twenty tablets was calculated and individual weight of each tablet was taken. % deviation was calculated with respect to average weight. The maximum % deviation allowed is 5% as the tablet weight is more than 324 mg. the tablets meet the USP test if no more than two tablets are outside the% limit and if no tablet differs by more than two times the % limit. The results are shown in Table no 05.

**Content uniformity [18]**

Ten tablets of each batch were weighed and powdered. Aliquot of this powder containing Carvedilol equivalent to 6.25 mg was accurately weighed, suspended in approximately 50 ml of pH 6.8 Phosphate buffer and shaken for 15 minutes. Final volume was adjusted to 100 ml with pH 6.8 Phosphate buffer and filtered (Whatman No.1 filter paper). From this 10 ml was diluted to 100 ml. The final volume was made by taking 2 ml of above solution and diluted to 10 ml with pH 6.8 Phosphate buffer. Absorbance of this solution was recorded at 241 nm using UV/Vis spectrophotometer. The mean percentage drug content was calculated.

**Wetting Time [19]**

Five circular tissue papers were placed in a petridish of 10cm diameter. Ten milliliters of water were added to the petridish. A tablet was carefully placed on the surface of the tissue paper in the petridish at $25^0$C. The time required for water to reach the upper surface of the tablets and to completely wet them was noted as the wetting time. These measurements

were carried out in replicates of six. Wetting time was recorded using a stopwatch and results are shown in Table 06.

**Water absorption Ratio [20]**

The weight of the tablet prior to placement in the petridish was noted ($W_b$) using a Shimadzu digital balance. The wetted tablet was removed and reweighed ($W_a$). Water absorption ratio, R, was then determined according to the following equation. The results are shown in Table 06

**$R = 100 * (W_a - W_b) / W_b$**

where $W_b$ and $W_a$ were tablet weights before and after water absorption, respectively

***In-Vitro* Dispersion time [21]**

*In-vitro* dispersion time was measured by dropping a tablet in spoonful of water or in 20ml of water in a beaker. The time for the tablet to completely disintegrate into fine particles was noted. Three tablets from each batch were randomly selected and *in-vitro* dispersion time was performed.

***In-Vitro* disintegration test [22]**

*In-vitro* disintegration time is measured by dropping a tablet in a beaker containing 50 ml of buffer pH 6.8. Three tablets from each formulation are randomly selected and *in-vitro* dispersion time is carried out.

***In-Vitro* dissolution test [23-24]**

*In-vitro* dissolution study is performed by using USP Type II Apparatus (Paddle type) at 50 rpm. Phosphate buffer pH 6.8, 900 ml is used as dissolution medium which maintained at 37±0.5°C. Withdraw aliquot of dissolution medium (5 ml) at specific time intervals and filter. Absorbance of this solution was recorded at 241 nm using UV/Vis spectrophotometer. The percentage drug release was calculated by using the standard curve

**RESULTS AND DISCUSSION:**

FT-IR spectra of Carvedilol in combination with polymers are shown in Figures 01 to 07. This indicates that there is no interaction between Carvedilol and polymers and the drug was compatible with the formulation components.

In the Preformulation studies, blended powered drug were conducted for the Angle of repose, Bulk density, Tapped density, Carr's index and Hausners ratio. From the results it is indicated that the angle of repose was low, good compressibility and found good to excellent flowability. The Angle of repose, Bulk density, tapped density, Carr's index and Hausners ratio of all formulations i.e. F1–F12 were found to be in the range of 24.64 ± 1.36 to 29.10 ± 1.25 (degree), 0.564 ± 0.005 to 0.639 ± 0.005gm/cc, 0.721 ± 0.01 to 0.854 ± 0.02gm/cc, 12.40 ± 2.02 to16.72±1.68 % and 1.13 ± 0.04 to1.31 ± 0.02 respectively. The results are shown in Table 04.

**Hardness and Friability:**

The hardness of tablets prepared by using the Natural superdisintegrants Guar gum, Xanthan gum and starch, the hardness and friability of formulations F1 to F12 were found to be in the range of 2.1±0.04 kg/cm$^2$ to 2.8±0.10 kg/cm$^2$ and 0.25 % to 0.57 % respectively. The results are shown in Table 05. From the above studies it was found that hardness and friability are within the pharmacopeia's limits.

**Thickness:**

The Thickness of tablets (F1-F12) was found to be between 3.2±0.01mm to 3.8±0.03 mm

**Weight variation:**

The Weight variation was found within the pharmacopoeial limits (148±0.2mg to 152±0.8 mg) for all the batches of the tablets. The results are shown in Table 05

**Drug content uniformity:**

The results indicated that the content of Carvedilol in all the formulations i.e. F1 toF12 were found to be in the range of 97 % to 103% which are within the Pharmacopeia limits.

**Wetting time and Water absorption ratio:**

The wetting time and water absorption ratio which are the important criteria for determining the capacity of disintegrates to swell in presence of little water or saliva. In direct compression method, by using the natural superdisintegrants (Xanthan gum) the water absorption ratio and wetting time in the formulations F1 to F4 were found to be 10 ± 0.48%, 8 ± 0.95%, 10 ± 0.35%, 16 ± 0.85% and 77 ± 0.25, 62 ± 0.87, 71 ± 0.99, 57 ± 1.25 sec. respectively. By using the natural superdisintegrants (Guar gum), the water absorption ratio and wetting time in the formulations F5 to F8 were found to be 14 ± 0.92%, 14 ± 0.95%, 9 ± 0.51%, 10 ± 0.54% and 73 ± 1.35, 66 ± 1.15, 68 ± 0.98, 75 ± 0.88 sec. respectively. By using the natural superdisintegrants (Starch), the water absorption ratio and wetting time in the formulations F9 to F12 were found to be 8 ± 0.45%, 9 ± 0.26%, 8 ± 0.56%, 9 ± 0.40% and 90±0.78, 73 ± 0.61, 66 ± 0.20, 69 ± 0.34 sec. respectively. Thus, the formulation, F4, it showed the more water absorption ratio i.e.16±0.85% and less wetting time was i.e.57±01.25 seconds, so it will take less time for disintegrating. The results are shown in Table 06.

***In- Vitro* disintegration time:**

The disintegration time of mouth dissolving tablets should be less because in a very short time it should be totally disintegrates. The *in-vitro* disintegration time in the formulations F1to F4 were found to be

117,112, 90 and 40 sec. by using the xanthan gum. The minimum and maximum *in- vitro* disintegration time was found to be 40 and 117 seconds respectively. The *in-vitro* disintegration time in the formulations F5 to F8 were found to be and 197,92, 60 and 80 sec. By using guar gum. The minimum and maximum disintegration time was found to be 60 and 197seconds respectively. The *in-vitro* disintegration time in the formulations F9 to F12 were found to be 237, 209,105and 110 sec. by using the starch. The minimum and maximum *in-vitro* disintegration time was found to be105 and 237 seconds respectively, From the above results we found the formulation, F4 was minimum *in-vitro* disintegration time of 40 sec. because with increase in concentration of natural superdisintegrants, disintegration time decreases. The results are shown in Table 06.

***In-Vitro* dispersion time:**

The dispersion in mouth is a very important consideration during the formulation of mouth dissolving tablets. The *in-vitro* dispersion time in the formulations F1 to F4 were found to be 168±1.25sec to 52±1.14sec using the natural superdisintegrants, xanthan gum. The *in-vitro* dispersion time in the formulations F5 to F8 were found to be 127±0.89sec to 73±0.54sec. using the natural superdisintegrants, Guar gum. The *in-vitro* dispersion time in the formulations F9 to F12 were found to be 177±0.68sec to 75±0.36 sec. using the natural superdisintegrants, starch. The best formulation, F4 was found to be minimum *in-vitro* dispersion time of 52±1.14 sec. The results are shown in Table 06.

***In-Vitro* dissolution study:**

*In-Vitro* Dissolution studies was conducted for the formulations, F1 to F4 by using natural superdisintegrants, Guar gum and percentage of drug release was found to be in the range of 94.01% to 98.8% at the end of 10 minutes. The maximum drug release was found 98.8% for the formulation, F4. For the formulation, F5 to F8, by using natural superdisintegrants, Xanthan gum and percentage of drug release was found to be in the range of 91.5% to 95.6% at the end of 10 minutes. The maximum drug release was found 95.6% for the formulation, F8. Similarly, for the formulation, F9 to F12, by using natural superdisintegrants, Starch and percentage of drug release was found to be in the range of 82.5% to 88.6% at the end of 10 minutes. The maximum drug release was found 88.6% for the formulation, F12. The results are shown in Fig. 12 to 14. From the above results for the formulations F1to F12, the maximum drug release was found to be 98.8% for the formulation, F4.

**Table No 1: Formulation of Carvedilol Mouth dissolving tablets**

| Ingredients (mg) | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 | F9 | F10 | F11 | F12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Drug | 6.25 | 6.25 | 6.25 | 6.25 | 6.25 | 6.25 | 6.25 | 6.25 | 6.25 | 6.25 | 6.25 | 6.25 |
| Guar gum | 1.5 | 3 | 6 | 9 | - | - | - | - | - | - | - | - |
| Xanthan gum | - | - | - | - | 1.5 | 3 | 6 | 9 | - | - | - | - |
| Starch | - | - | - | - | - | - | - | - | 1.5 | 3 | 6 | 9 |
| Mannitol | 90 | 85 | 78 | 64 | 90 | 85 | 78 | 64 | 90 | 85 | 78 | 64 |
| Microcrystalline cellulose | 40 | 45 | 50 | 60 | 40 | 45 | 50 | 60 | 40 | 45 | 50 | 60 |
| Talc | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 |
| Magnesium stearate | 3.5 | 3.5 | 3.5 | 3.5 | 3.5 | 3.5 | 3.5 | 3.5 | 3.5 | 3.5 | 3.5 | 3.5 |
| Aspartame | 7.5 | 7.5 | 7.5 | 7.5 | 7.5 | 7.5 | 7.5 | 7.5 | 7.5 | 7.5 | 7.5 | 7.5 |
| Pipperment oil (ml) | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Total wt (mg) | 150 | 150 | 150 | 150 | 150 | 150 | 150 | 150 | 150 | 150 | 150 | 150 |

**Table No 02: Scale of Flowability**

| Compressibility index (%) | Flow character | Hausner Ratio |
|---|---|---|
| ≤10 | Excellent | 1.00 – 1.11 |
| 11 – 15 | Good | 1.12 – 1.18 |
| 16 – 20 | Fair | 1.19 – 1.25 |
| 21 – 25 | Passable | 1.26 – 1.34 |
| 26 – 31 | Poor | 1.35 – 1.45 |
| 32 – 37 | Very poor | 1.46 – 1.59 |
| >38 | Very, very poor | >1.60 |

**Table No 03: Flow properties and corresponding angle of repose**

| Flow Property | Angle of Repose (degrees) |
|---|---|
| Excellent | 25 – 30 |
| Good | 31 – 35 |
| Fair | 36 – 40 |
| Passable | 41 – 45 |

**Table No 04: Angle of repose, Bulkdensity, Tappeddensity, Carr's index and Haunser ratio.**

| Formulation code | Angle of repose (degree) | Bulk density (gm/cc) | Tapped density (gm/cc) | Carr's index (%) | Haunser ratio |
|---|---|---|---|---|---|
| F1 | 26.96±1.42 | 0.568±0.005 | 0.810±0.01 | 15.69±1.51 | 1.31±0.02 |
| F2 | 25.50±1.32 | 0.612±0.005 | 0.762±0.01 | 14.72±1.20 | 1.31±0.03 |
| F3 | 27.30±1.50 | 0.625±0.005 | 0.745±0.02 | 13.45±1.57 | 1.14±0.02 |
| F4 | 29.10±1.25 | 0.639±0.005 | 0.736±0.02 | 14.47±1.37 | 1.19±0.04 |
| F5 | 27.10±1.36 | 0.600±0.005 | 0.794±0.01 | 16.64±1.44 | 1.26±0.02 |
| F6 | 24.79±1.48 | 0.622±0.005 | 0.745±0.02 | 12.46±1.29 | 1.24±0.04 |
| F7 | 26.22±1.67 | 0.620±0.005 | 0.736±0.01 | 12.40±2.02 | 1.15±0.03 |
| F8 | 24.64±1.36 | 0.635±0.005 | 0.721±0.02 | 12.54±1.51 | 1.21±0.03 |
| F9 | 26.47±1.56 | 0.596±0.005 | 0.758±0.02 | 16.72±1.68 | 1.13±0.04 |
| F10 | 25.35±1.42 | 0.575±0.005 | 0.765±0.01 | 13.20±1.53 | 1.20±0.04 |
| F11 | 28.23±1.23 | 0.564±0.005 | 0.854±0.02 | 15.30±2.05 | 1.16±0.03 |
| F12 | 25.03±1.35 | 0.635±0.005 | 0.735±0.02 | 12.64±1.95 | 1.21±0.03 |

**n=3, ±S. D**

**Table No 05: Hardness, Thickness, Friability and Weight variation**

| Formulation code | Hardness(kg/cm$^2$) | Thickness(mm) | Friability (%) | Weight variation(mg) |
|---|---|---|---|---|
| F1 | 2.6±0.02 | 3.6±0.07 | 0.30 | 151±0.4 |
| F2 | 2.8±0.10 | 3.7±0.06 | 0.22 | 148±0.6 |
| F3 | 2.1±0.04 | 3.8±0.03 | 0.57 | 149±0.4 |
| F4 | 2.6±0.06 | 3.8±0.05 | 0.41 | 152±0.6 |
| F5 | 2.5±0.06 | 3.8±0.08 | 0.26 | 148±0.2 |
| F6 | 2.8±0.05 | 3.7±0.06 | 0.422 | 149±0.8 |
| F7 | 2.4±0.07 | 3.5±0.06 | 0.38 | 150±0.2 |
| F8 | 2.6±0.05 | 3.2±0.01 | 0.35 | 152±0.8 |
| F9 | 2.4±0.03 | 3.5±0.07 | 0.26 | 150±0.6 |
| F10 | 2.6±0.02 | 3.6±0.02 | 0.42 | 151±0.4 |
| F11 | 2.5±0.16 | 3.7±0.02 | 0.35 | 148±0.6 |
| F12 | 2.2±0.10 | 3.5±0.03 | 0.32 | 151±0.8 |

**n=3, ±S. D**

**Table No 06: Wetting time, Water absorption ratio, *In-vitro* disintegration time, *In-vitro* dispersion time and drug content uniformity**

| Formulation Code | Wetting time (sec) | Water absorption ratio (%) | *In-vitro* Disintegration time (sec) | *In-vitro* Dispersion Time (sec) | Drug content uniformity (%) |
|---|---|---|---|---|---|
| F1 | 77±0.25 | 10±0.48 | 117 | 100±1.12 | 99 |
| F2 | 62±0.87 | 8±0.95 | 112 | 109±1.54 | 101 |
| F3 | 71±0.99 | 10±0.35 | 90 | 168±1.25 | 98 |
| F4 | 57±1.25 | 16±0.85 | 40 | 52±1.14 | 102 |
| F5 | 73±1.35 | 14±0.92 | 197 | 79±1.04 | 100 |
| F6 | 66±1.15 | 14±0.95 | 92 | 127±0.89 | 98 |
| F7 | 68±0.98 | 9±0.58 | 60 | 73±0.54 | 97 |
| F8 | 75±0.88 | 10±0.54 | 80 | 82±1.08 | 99 |

| | | | | | |
|---|---|---|---|---|---|
| F9 | 90±0.78 | 8±0.45 | 237 | 177±0.68 | 103 |
| F10 | 73±0.61 | 9±0.24 | 204 | 88±1.14 | 97 |
| F11 | 66±0.20 | 8±0.56 | 105 | 75±0.36 | 99 |
| F12 | 69±0.34 | 9±0.40 | 110 | 122±1.32 | 98 |

**n=3, ±S. D**

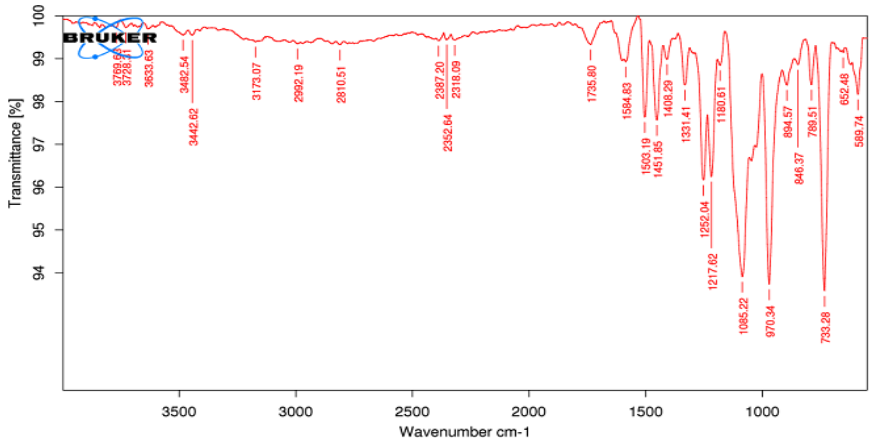


**Figure 01: FT-IR spectrum of pure Carvedilol**

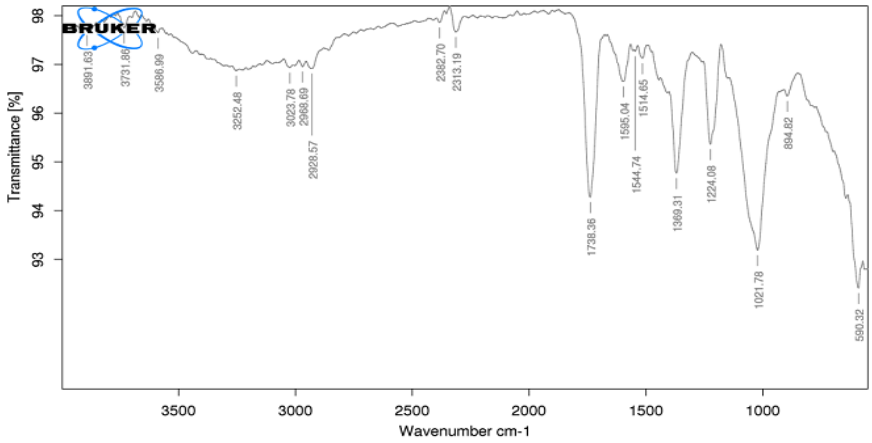


**Figure 02: FT-IR spectrum of Xathan gum**

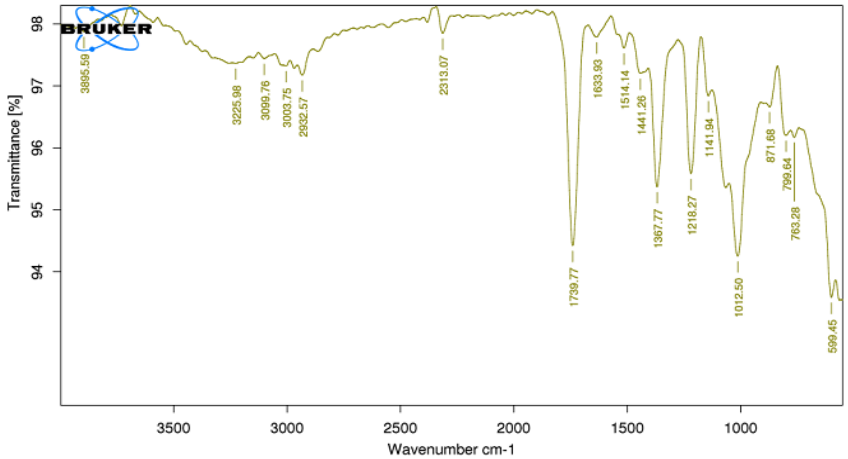


**Figure 03: FT-IR spectrum of Guar gum**

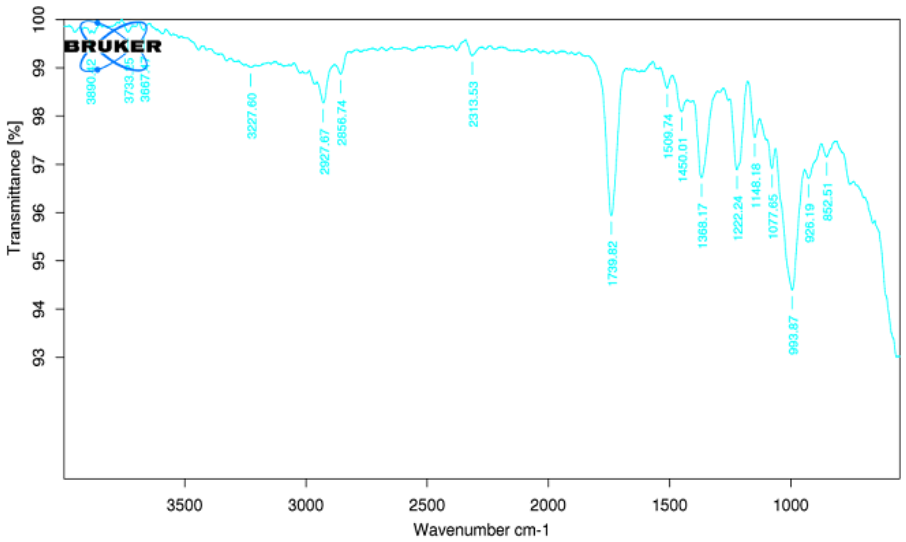


**Figure 04: FT-IR spectrum of Starch**

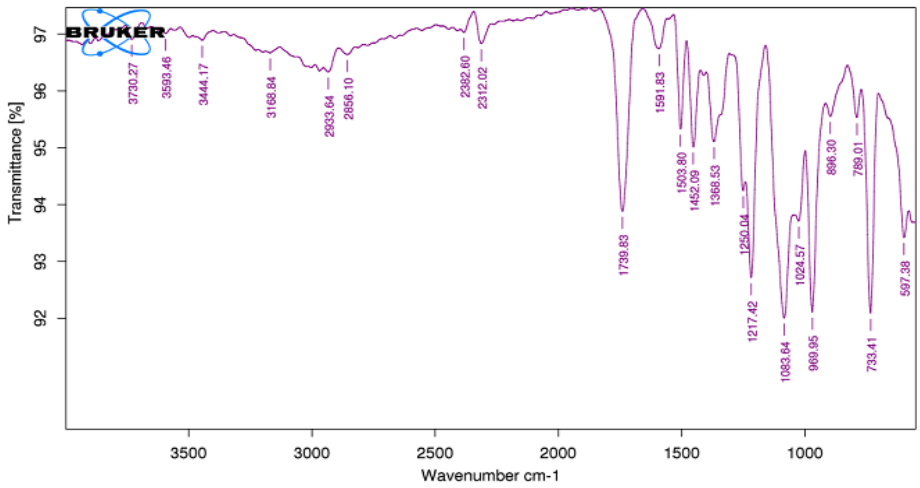


**Figure 05: FT-IR spectrum of physical mixture of Carvedilol and Guar gum**

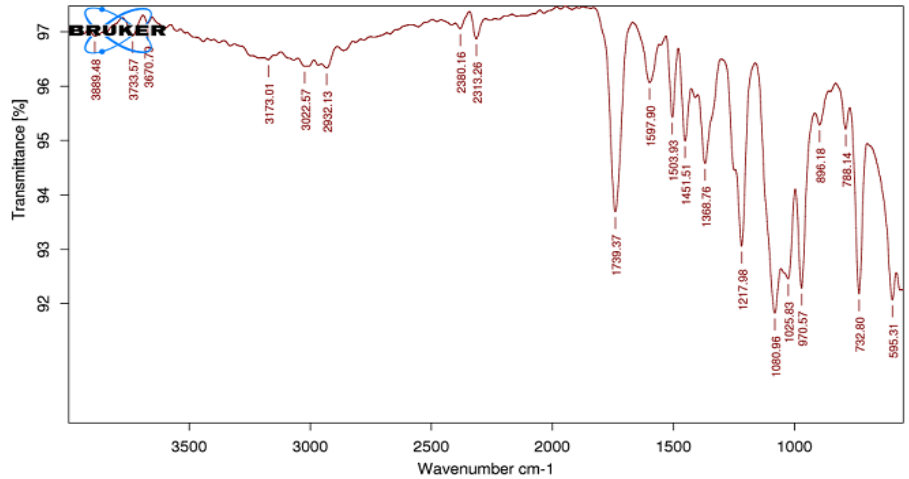


**Figure 06: FT-IR spectrum of physical mixture of Carvedilol and Xanthan gum**

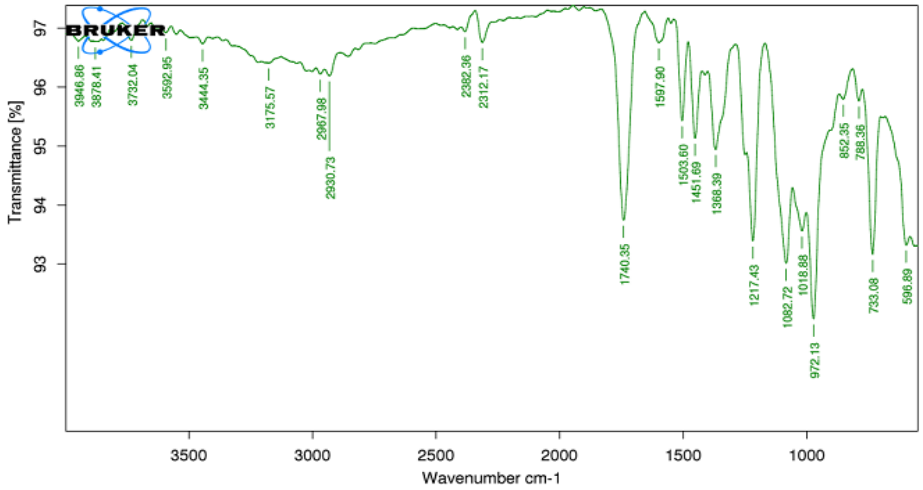


**Figure 07**: **FT-IR spectrum of physical mixture of Carvedilol and Starch**

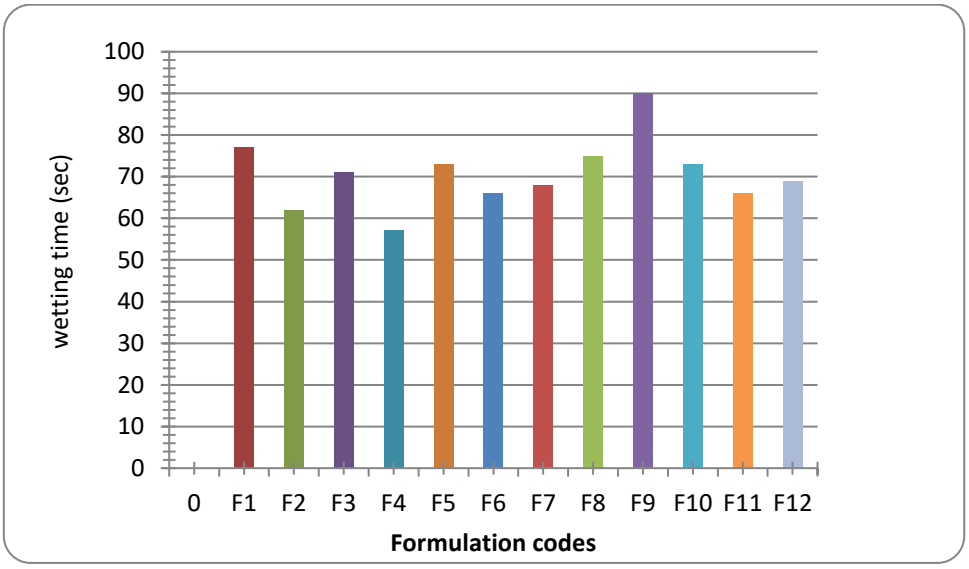


**Fig .08: Wetting time of Formulations**

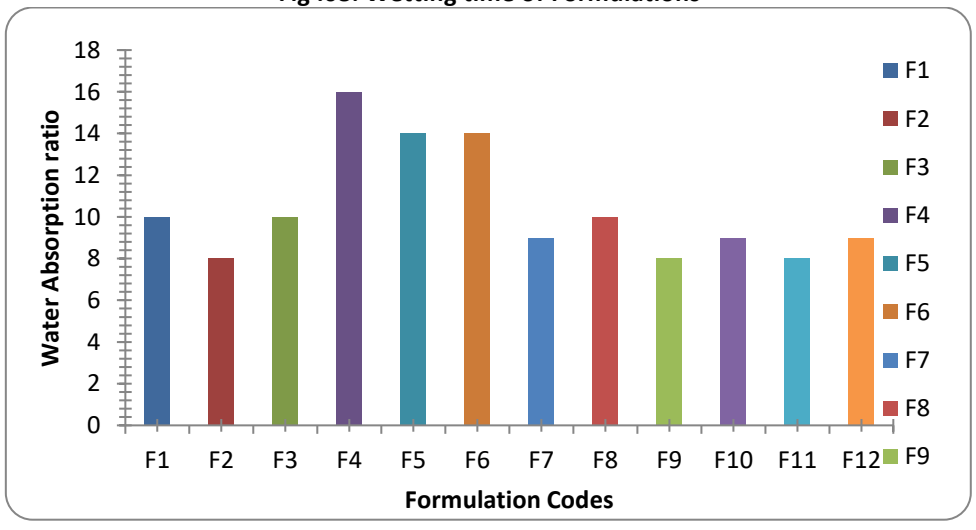


**Fig 09: Water absorption ratio of formulations**

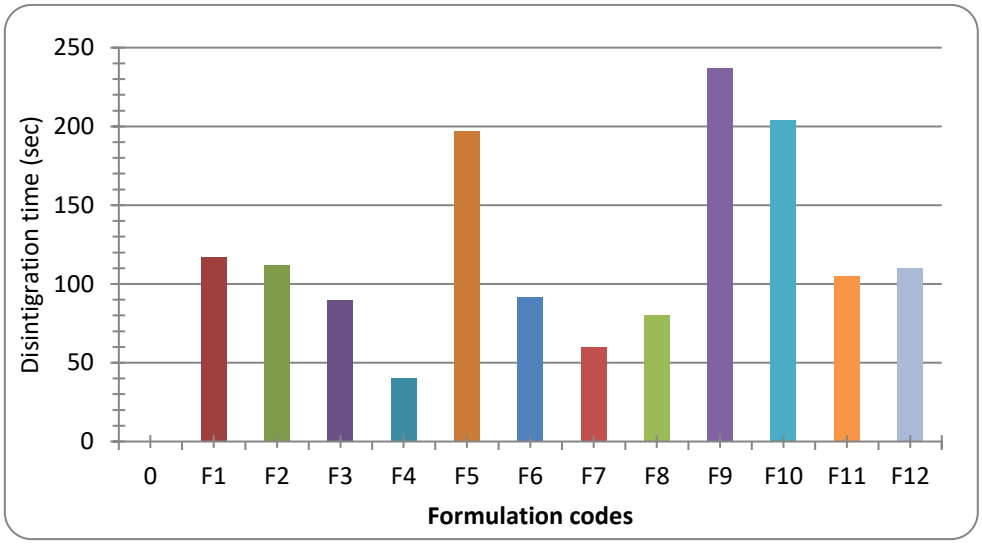


**Fig 10: *In-Vitro* Disintegration time of Formulations**

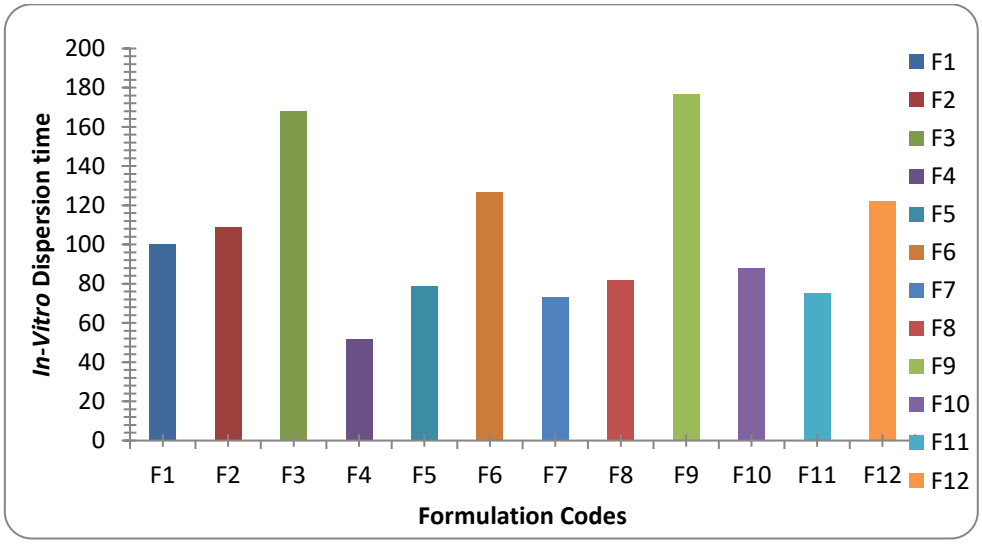


**Fig 11: *In-Vitro* Dispersion time of Formulations**

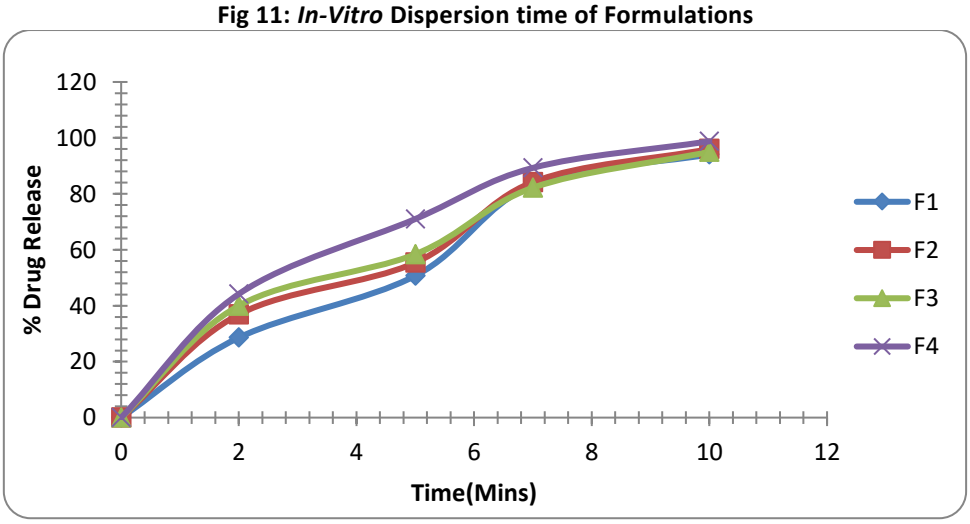


**Fig 12: Comparision of *In-vitro* Dissolution profle of F1-F4**

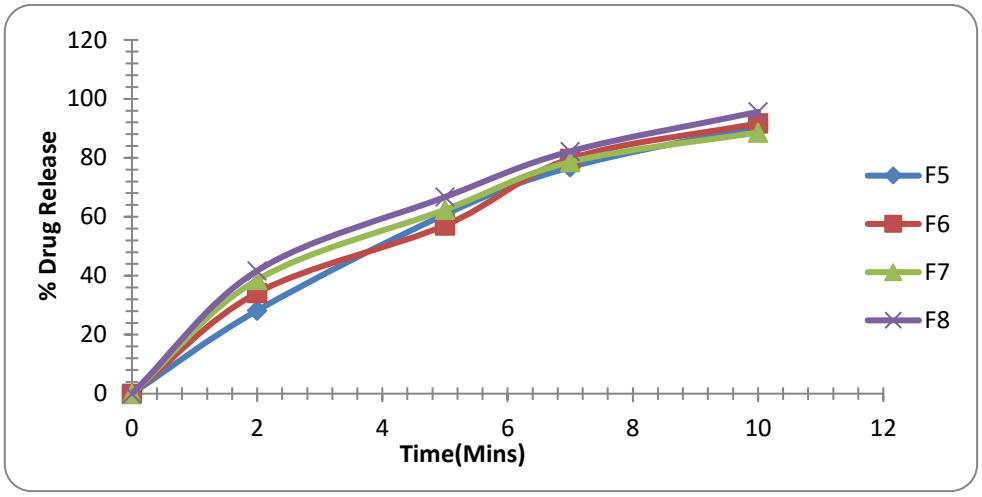


**Fig 13: Comparision of *In-vitro* Dissolution profle of F5-F8**

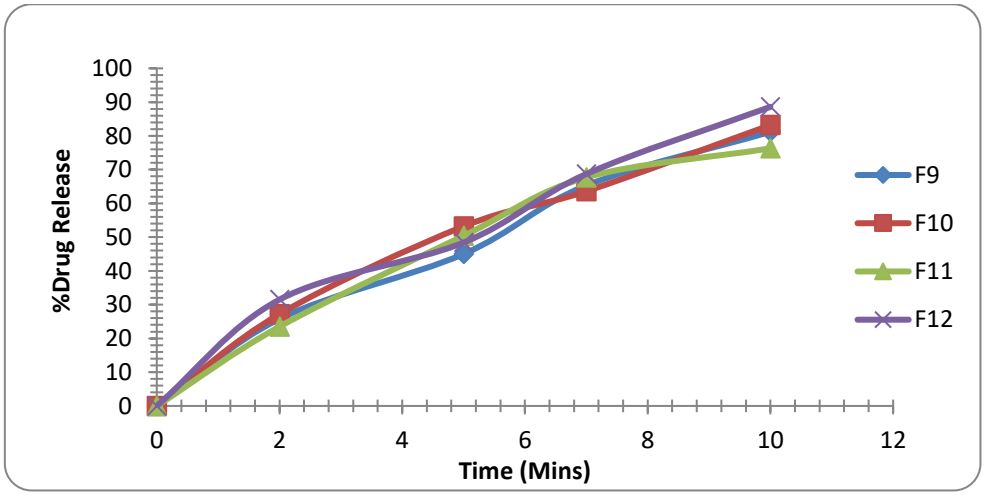


**Fig 14: Comparision of *In-vitro* Dissolution profle of F9-F12**

**CONCLUSION:**

Mouth dissolving tablets of Carvedilol can be efficiently and successfully formulated by employing Direct Compression method. The FTIR analysis revealed that the natural superdisintegrants and excipients used were compatible with Carvedilol. Evaluation parameters like hardness (2.8±0.10 kg/cm$^2$), friability (0.76%), weight variation 152±0.8mg and drug (102%) content indicate that values were within permissible limit for all formulations. The wetting time (57 ± 1.25sec), water absorption ratio (16 ± 0.85 %), *in-vitro* disintegration time (40 sec) and *in-vitro* dispersion time (52 ± 1.14 sec), revealed that a successful formulation of Carvedilol as mouth dissolving tablets. The *in-vitro* release studies showed 98.8% of drug release at the end 10 minutes for the formulation F4 by using Guar gum as natural super disintegrating agent. Further detailed investigation is required to know the bioavailability of these novel mouth dissolving tablets.

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