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FORMULATION DEVELOPMENT AND EVALUATION OF CANDESARTAN BUCCAL TABLETS

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ABSTRACT: Buccal tablets are prepared by direct compression method using different polymers like carbopol, hydroxypropyl methylcellulose and sodium alginate. Nine formulations were prepared while (F1) to (F3) were prepared by taking individual concentrations whereas all the remaining formulations were prepared by taking combinations of polymers. Aim of study is to develop and optimize mucoadhesive buccal tablets of candesartan by direct compression method. All the batches were evaluated for thickness, weight variation, hardness and content uniformity. *In-vitro* release study is carried and release mechanisms were explored. Individual carbopol concentration (F1) has high swelling index with low water absorption ratio. Individual concentration of sodium alginate (F3) obtained high drug release, while low concentration of carbopol and high concentration of hydroxypropyl methylcellulose in combinations (F4) gave 86% drug release and with equal ratios of carbopol and hydroxypropyl methylcellulose (F7) gave 88% drug release. But low concentration of hydroxypropyl methylcellulose and high concentration of sodium alginate (F5) in combination form gave 95% drug release. While equal ratios of both hydroxypropyl methylcellulose and sodium alginate in combination (F8) gave 98% drug release. Among all formulations (F3) sodium alginate showed 93% drug release, while (F7) with equal ratio of hydroxypropyl methylcellulose and sodium alginate showed 98% drug release within 8 h. Compared to all polymers sodium alginate showed good drug release either in individual or combinations. All formulations followed zero order release kinetics.

INTRODUCTION: Historically oral route of drug administration has been the one used most for both conventional as well as novel drug delivery [1].

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The concept of muco adhesion was introduced into controlled drug delivery in 1980's which become a major part of novel drug delivery system in the recent era.

Some of the potential sites for attachment of any mucoadhesive system are included in buccal cavity, nasal cavity, eyes, vagina, rectal, sublingual route and gastrointestinal area [2]. Mucoadhesive polymers are able to interact with mucus which is secreted by the underlying tissue.

The concept of mucoadhesive polymer has been accepted as a promising strategy to prolong the residence time and to improve localization of drug delivery systems on various membranes [3]. Buccal delivery of drugs is an alternative to oral route of drug administration this buccal route has numerous advantages like good accessibility, robustness of epithelium, facile removal of dosage form in case of need, relatively low enzymatic activity prevent drug degradation in gastro intestinal tract by avoiding hepatic first pass metabolism [4]. Candesartan belongs to class of angiotensin receptor antagonist which acts by binding selectively and non-competitively to angiotensin II receptor type 1 thus preventing actions of angiotensin II. Aim of the work is to develop buccal tablets for treatment of hypertension and congestive heart failure [5].

MATERIALS AND METHODS:

Materials: Candesartan was a gift sample from Aurobindo Pharma Ltd., Hyderabad. Carbopol, hydroxy propyl methylcellulose and sodium alginate were received from Loba Chemicals, Mumbai. Sodium saccharine, talc, magnesium stearate and mannitol were procured from S.D. Fine Chemicals, Mumbai.

Preparation of Buccal Tablets: Candesartan mucoadhesive buccal tablets are prepared by direct compression method. All the ingredients were passed through a 60 mesh sieve. Required quantity of drug, polymers in individual, combinations are taken and mixed properly. Powder blend was lubricated with magnesium stearate for 3-5 min by adding talc as glidant. Finally the powder blend was evaluated for pre-compression studies and directly compressed using 10 mm punches on 12 station compression machine (Sai Pharmatech Ltd, India) with tablet weight of 100 mg [6]. Composition of prepared formulations was shown in **Table 1**.

Precompression parameters: Powder blends were evaluated before compression to assess the flow properties [7, 8. 9].

TABLE 1: FORMULA OF CANDESARTAN BUCCAL TABLETS

Ingredients (mg)	CBF1	CBF2	CBF3	CBF4	CBF5	CBF6	CBF7	CBF8	CBF9
Candesartan	30	30	30	30	30	30	30	30	30
Carbopol	30	-	-	10	-	10	15	-	15
HPMC	-	30	-	20	10	-	15	15	-
Sodium alginate	-	-	30	-	20	20	-	15	15
Sodium saccharine	5	5	5	5	5	5	5	5	5
Magnesium stearate	3	3	3	3	3	3	3	3	3
Talc	2	2	2	2	2	2	2	2	2
Mannitol	30	30	30	30	30	30	30	30	30
Total weight(mg)	100	100	100	100	100	100	100	100	100

HPMC: Hydroxypropyl methyl cellulose

Angle of Repose: It is direct measure of flow property of powders. It is the maximum angle that can be obtained between free standing surface of a powder heap and the horizontal plane. It is calculated by the following formula.

$$\text{Angle of repose } (\theta) = \tan^{-1} (h/r)$$

Where h = height of pile, r = radius of pile.

Bulk Density: 25gm of powder blend was weighed accurately which was previously passed through 30# sieve and transferred in 100 ml graduated cylinder. Carefully measure powder level without compacting and read the unsettled apparent volume (Vo). Calculate the apparent bulk density in gm/ml by following formula.

$$\text{Bulk density} = \text{Weight of powder} / \text{Bulk volume}$$

Tapped density: 25 gm of drug was weighed accurately, which was previously passed through 30# sieve and transferred in 100 ml graduated cylinder. Then mechanically tap cylinder containing the sample by raising the cylinder and allowing it to drop under its own weight using mechanically tapped density apparatus (Electro Lab, India).

The cylinder was tapped for 500 times initially tapped volume (V_1) was measured to the nearest graduated units. Tappings were repeated on additional 100 times and the tapped volume (V_2) was measured. The tapped bulk density was measured in gm/ml by the following formula.

$$\text{Tapped density} = \frac{\text{Volume of powder } (V_1)}{\text{Tapped volume } (V_2)}$$

Carr's Index: It is simplest way for measuring free flow property of powder. Compressibility is an indication of ease with which a material can be induced to flow is given by % compressibility that is calculated by the following formula.

$$\text{Carr's index} = \frac{\text{Tapped density - Bulk density}}{\text{Tapped density}} \times 100$$

Hausner's Ratio: It is an indirect index of ease of powder flow. It is calculated by the following formula. Lower value of hausner ratio (< 1.25) indicates better flow properties than higher ones (>1.25). The results are given in **Table 2**.

$$\text{Hausner's ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

Post Compression Parameters:

Weight Variation: Twenty tablets are selected from each formulation and average weight was checked on digital balance (Shimadzu, Japan). The tablets are weighed individually and compared with average weight. U.S. Pharmacopoeia allows a little variation in weight of tablet [10].

Thickness: Tablets are randomly selected and their thickness was measured by using Vernier callipers (Pharma Labs, Ahmedabad, India) reading was recorded in millimetres [11].

Hardness: Hardness of tablet is directly proportional to friability loss and convenient in handling the tablets. Breaking under the condition of transportation and handling before the use depends on its hardness. Monsanto hardness tester (E 30, Dwaraka Mai, India) is used to measure hardness of tablets for every batch [12].

Drug Content: Content uniformity of candesartan buccal tablet was determined; from each batch ten tablets were weighed and finely powdered. An amount of powder equivalent to 4mg was accurately weighed and dissolved in pH 6.8 phosphate buffer. The resulting solution was suitably diluted with pH 6.8 phosphate buffer, analysed by using UV Spectrophotometer (Shimadzu, India) at 233 nm. The results are given in **Table 3** and **4**.

Friability: Ten tablets were weighed (W_0) and placed in Roche friabilator (Electro Lab, India) which are rotated at 25 rpm for 4 min. After revolutions, tablets were dedusted and weighed again (W). The percentage friability was measured by the following formula [13].

$$\% \text{ Friability} = \frac{\text{Initial weight - Final weight}}{\text{Initial weight}} \times 100$$

Where, W_0 = Initial weight of tablet, W = Weight of tablet after revolution.

Swelling Studies: Buccal tablets were weighed individually (W_1) and placed separately in petridish containing 15 ml of pH 6.8 phosphate buffer. At regular time intervals (1, 2, 3, 4, 5, 6, 7, 8 h) the buccal tablets were removed from the petridish and excess surface water was removed carefully with the filter paper. The swollen tablets are then reweighed (W_2**)** and swelling index (water uptake) was calculated according to the following equation [14].

$$\text{Swelling index} = [(W_2 - W_1)/W_1] \times 100$$

Where, W_1= Initial weight of tablet, W_2= Weight of tablet after swelling.

In-vitro **Drug Release Study:** The prepared tablets were supposed to release drug from one side only therefore an impermeable backing membrane was placed on other side of tablet. The tablet was further fixed to a 2x2 cm glass slide with a solution of cyanoacrylate adhesive. *In-vitro* drug release studies was carried out in 900 ml of pH 6.8 phosphate buffer for 8 h using Paddle apparatus Type II (Electro Lab, Mumbai, India) for 50 rpm at 37 ± 0.5 °C. At predetermined time intervals 5 ml samples were withdrawn and replaced with fresh medium. Samples are analysed by UV spectrophotometer (Shimadzu, India) at 233 nm. Mechanism of drug release is determined by best fit of release data to Zero, First order, Korsmeyer-Peppas plots [15].

Water Absorption Ratio and Wetting Time: A piece of tissue paper folded twice was placed in a petridish containing 5 ml of water. A pre weighed tablet (W_B) was placed on paper and the time for complete wetting was measured. Wetted tablet are reweighed (W_A) and water absorption ratio is determined by formula [16].

$$\text{Water absorption ratio (R)} = (W_A - W_B / W_B) \times 100$$

Where, W_A = weight of tablet after absorption of water, W_B = weight of tablet before absorption of water.

Determination of Surface pH: Surface pH of prepared candesartan buccal tablets was determined to evaluate the possible irritation effects on buccal mucosa. Buccal tablets were placed in glass tube and allowed to come in contact with distilled water (12 ml) and pH was measured with pH paper allowing it to equilibrate for 1 min [17].

RESULTS: In present work Candesartan buccal tablets are prepared by direct compression method as it is feasible and simple.

The best parameters obtained for Candesartan buccal tablets are evaluated based on drug release.

TABLE 2: EVALUATION DATA OF POWDER BLEND OF CANDESARTAN BUCCAL FORMULATIONS

Powder Blends	Angle of repose* (θ)	Bulk density* (gm/ml)	Tapped density* (gm/ml)	Carr's index* (%)	Hausner's ratio*
CBF1	19.03 ± 0.11	0.562 ± 0.02	0.636 ± 0.02	11.62 ± 0.02	1.131 ± 0.07
CBF2	19.03 ± 0.11	0.566 ± 0.06	0.647 ± 0.03	15.91 ± 0.04	1.189 ± 0.03
CBF3	17.17 ± 0.11	0.540 ± 0.06	0.642 ± 0.06	15.85 ± 0.02	1.189 ± 0.08
CBF4	20.55 ± 0.51	0.549 ± 0.05	0.623 ± 0.05	11.85 ± 0.06	1.134 ± 0.05
CBF5	19.03 ± 0.11	0.500 ± 0.06	0.647 ± 0.03	15.91 ± 0.01	1.189 ± 0.06
CBF6	17.17 ± 0.11	0.540 ± 0.06	0.642 ± 0.06	15.85 ± 0.04	1.189 ± 0.04
CBF7	20.55 ± 0.51	0.549 ± 0.05	0.623 ± 0.05	11.85 ± 0.06	1.134 ± 0.02
CBF8	19.01 ± 0.11	0.546 ± 0.05	0.640 ± 0.03	11.15 ± 0.08	1.189 ± 0.03
CBF9	17.17 ± 0.11	0.640 ± 0.06	0.642 ± 0.06	15.85 ± 0.01	1.189 ± 0.06

Each value is an average of three determinations *

TABLE 3: EVALUATION DATA OF CANDESARTAN BUCCAL FORMULATIONS (CBF1 - CBF4)

Evaluation parameters	CBF1	CBF2	CBF3	CBF4
Weight variation (mg)[a]	99 ± 0.86	97.1 ±1.16	106 ± 3.57	102 ± 0.88
Thickness (mm) [b]	4.40 ± 0.01	4.59 ± 0.05	5.32 ± 0.01	4.38 ± 0.07
Friability (%)[b]	0.192 ± 0.57	0.198 ± 0.12	0.218 ± 0.17	0.236 ±0.27
Hardness (Kg/cm ^{2})[c]	4.10 ± 0.23	4.85 ± 0.25	5.41 ± 0.05	4.22 ± 0.15
Content uniformity (%)[c]	98.4 ± 0.73	101 ± 1.61	99.2 ± 0.12	99.1 ±0.40
Swelling index (%)[c]	72.28 ± 0.04	63.58 ± 0.69	68.15 ± 1.58	69.03 ± 0.91
Surface pH [c]	6.6 ± 0.34	6.5 ± 0.07	6.7 ± 0.07	6.9 ± 0.01
Water absorption ratio (%)[c]	15.4 ± 0.34	17.5 ± 0.24	33.77 ± 0.14	38.77 ± 0.34

Each value is an average of twenty determinations [a], Each value is an average of ten determinations [b], Each value is an average of three determinations [c]

TABLE 4: EVALUATION DATA OF CANDESARTAN BUCCAL FORMULATIONS (CBF5 - CBF9)

Evaluation Parameters	CBF5	CBF6	CBF7	CBF8	CBF9
Weight variation (mg)[a]	105 ± 0.88	106 ± 3.57	102 ± 0.88	97.1 ± 1.16	106 ± 3.57
Thickness (mm)[b]	4.18 ± 0.07	5.32 ± 0.01	4.38 ± 0.07	5.22 ± 0.01	4.18 ± 0.07
Friability (%)[b]	0.216 ± 0.07	0.116 ± 0.07	0.198 ± 0.12	0.218 ± 0.17	0.216 ± 0.07
Hardness (Kg/cm ^{2})[c]	4.15 ± 0.15	4.15 ± 0.15	4.85± 0.25	4.41 ± 0.05	4.15 ± 0.15
Content uniformity (%)[c]	99. 02 ± 0.12	99.2 ± 0.12	99.1 ± 0.40	98.4 ± 0.73	98.4 ± 0.73
Swelling index (%)[c]	67.90 ± 0.48	65.92 ± 0.74	53.14 ± 1.99	63.70 ± 1.81	66.04 ± 0.12
Surface pH [c]	6.9 ± 0.09	6.8 ± 0.10	6.6 ± 0.20	6.7 ± 0.46	6.9 ± 0.12
Water absorption ratio (%)[c]	15.41 ± 0.44	38.4 ± 0.34	36.2 ± 0.34	23.1 ± 0.24	35.46 ± 0.14

Each value is an average of twenty determinations [a], Each value is an average of ten determinations [b], Each value is an average of three determinations [c]

TABLE 5: KINETICS DATA OF CANDESARTAN BUCCAL TABLET

Batch no.	Zero order (R^2)	First order (R^2)	Higuchi (R^2)	Korsmeyer-Peppas (R^2)	n
CBF1	0.998 ± 0.35	0.945 ± 0.25	0.922 ± 0.45	0.999 ± 0.43	0.898 ± 0.15
CBF2	0.997 ± 0.78	0.957 ± 0.77	0.886 ± 0.29	0.997 ± 0.34	0.958 ± 0.16
CBF3	0.993 ± 0.76	0.970 ± 0.65	0.901 ± 0.77	0.977 ± 0.57	0.879 ± 0.29
CBF4	0.982 ± 0.67	0.908 ± 0.35	0.865 ± 0.66	0.992 ± 0.82	0.939 ± 0.94
CBF5	0.997 ± 0.78	0.933 ± 0.25	0.899 ± 0.43	0.993 ± 0.25	0.961 ± 0.89
CBF6	0.996 ± 0.25	0.955 ± 0.99	0.930 ± 0.14	0.993 ± 0.85	0.841 ± 0.15
CBF7	0.991 ± 0.13	0.975 ± 0.65	0.902 ± 0.34	0.997 ± 0.87	0.903 ± 0.04
CBF8	0.992 ± 0.98	0.962 ± 0.67	0.885 ± 0.78	0.994 ± 0.29	0.935 ± 0.12
CBF9	0.995 ± 0.05	0.975 ± 0.05	0.937 ± 0.45	0.995 ± 0.34	0.925 ± 0.18

*Each value is an average of three determinations ± S.D. SD: Standard deviation

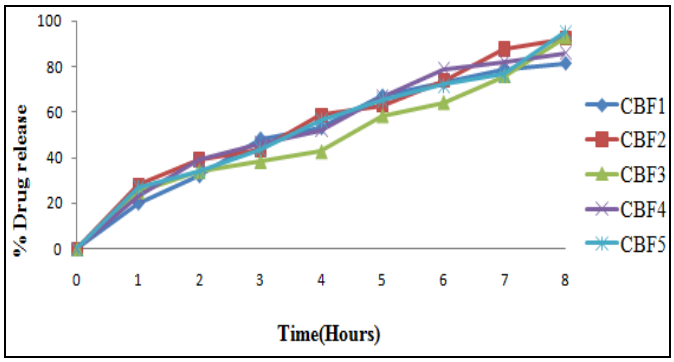

FIG. 1: CUMULATIVE % DRUG RELEASE PLOT OF CANDESARTAN BUCCAL TABLETS (CBF1-CBF5)

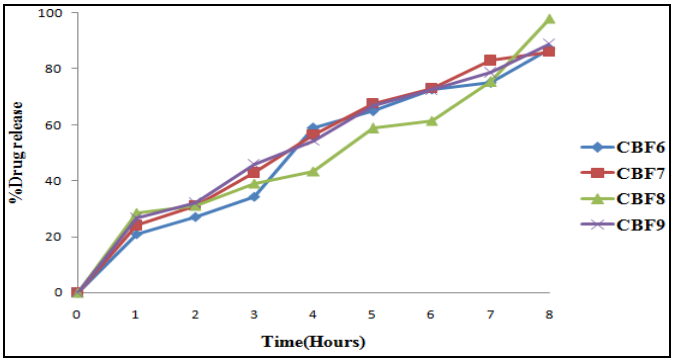

FIG. 2: CUMULATIVE % DRUG RELEASE PLOT OF CANDESARTAN BUCCAL TABLETS (CBF6-CBF9)

DISCUSSION: In the present study direct compression method was employed for preparation of candesartan buccal tablets. Powder blends are found to have good flow properties within prescribed limits. Bulk density was found in the range of 0.500-0.640 (gm/ml) and tapped density between 0.623-0.647 (gm/ml) for all the formulations. Compressibility index values 11.15-15.91 % which were found to be good flow with Hausner's ratio values in the range of 1.131-1.189 for all powder blends. This was further supported by the angle of repose values between 17.17-20.55°. As it was below 30° powder blend was found to have good flow properties.

All the tablets are having bevelled edged flat surface in round shape with white colour. Average weight of the tablets was in the range of 97-106 mg. Thickness of tablets was in the range of 4.18-5.32 mm. Hardness of tablets is determined by Monsanto hardness tester and found in range of 4.10-5.41kg/cm^2. As the aim of study is to release drug slowly hence hardness was kept in high range. Friability of all tablets is less than 1% with range of 0.116-0.236 % by acceptable limits which indicate formulations have good mechanical strength.

All the prepared formulations are subjected for content uniformity with range of 98.4-101 %. It was observed that all the formulations were as per I.P. specification limits (90.0 - 110.0%). Combination of carbopol and hydroxypropyl methylcellulose polymer shows highest swelling index. Swelling index indicates the uptake of water into tablet matrix producing an increasing in weight. Surface pH was determined in order to investigate the possibility of any side effects in the oral cavity. Surface pH of the buccal tablets depends on the nature and composition of mucoadhesive polymers. Surface pH of formulations is found in range of 6.5-7 hence, the prepared buccal tablet does not cause any irritation on mucosa. Swelling state of polymers in formulations was reported to be crucial for its boiadhesive behaviour, adhesion occurs shortly after swelling but the bond formed between the mucosal layer and polymer is not very strong.

Adhesion would increase with degree of hydration until point where over hydration leads to an abrupt drop in adhesive strength due to disentanglement at polymer/tissue interface. Individual carbopol concentration (F1) has high swelling index with low water absorption ratio. Combination of carbopol and hydroxypropyl methylcellulose (F4) obtained swelling index and water absorption ratio values at a higher extent. Individual concentration of sodium alginate (F3) obtained high drug release, but drug release of hydroxypropyl methylcellulose (F2) was nearer to sodium alginate in individual concentrations.

While low concentration of carbopol and high concentration of hydroxypropyl methylcellulose in combinations (F4) gave 86% drug release and with equal ratios of carbopol and hydroxypropyl methylcellulose (F7) gave 88% drug release. But low concentration of hydroxypropyl methyl cellulose and high concentration of sodium alginate (F5) in combination form gave 95% drug release. While equal ratios of both hydroxypropyl methyl cellulose and sodium alginate in combination (F8) gave 98% drug release.

CONCLUSION: In the present work an attempt was made to develop mucoadhesive buccal dosage form tablets of candesartan to improve better patient compliance.

Buccal tablets of candesartan were prepared using different polymers such as hydroxypropyl methylcellulose, sodium alginate and carbopol by changing the polymer quantities in individual ratios and combinations to study effect of these polymers on the physico-chemical characters, swelling index, surface pH, content uniformity, water absorption ratio and *in-vitro* drug release. Among all the nine formulations carbopol (F1) showed maximum swelling index value. Finally formulations (F8) with hydroxypropyl methylcellulose and sodium alginate in equal ratios gave 98% drug release which was most suitable for preparing buccal tablets. Compared to all polymers sodium alginate showed good drug release either in individual or combinations and all formulations were following zero order release kinetics.

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