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International Journal of Current Research and Innovation in Pharma Sciences

Journal homepage: https://www.ijcrips.com/

Research Article

FORMULATION AND EVALUATION OF A MUCOADHESIVE BUCCAL TABLET OF TELMISARTAN

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ARTICLE INFO

Article history:
Received: 30-06--2022
Accepted: 26-07-2022
Available online: 31-07-2022

Keywords:
Telmisartan.
Buccal tablet.
Mucoadhesive.
Drug Release.
HPMC K4M Etc.

ABSTRACT

Buccal route of administration has many advantages such as improving patient compliance, bypassing the GIT and hepatic first pass effect. The objectives are to formulate mucoadhesive buccal tablet using Telmisartan and compatible excipients, and to evaluate the product using quality control tests and in vitro tests. The ingredients were subjected to Fourier Transform Infrared Spectroscopy studies for compatibility test and the results showed no interaction. Two batches of Telmisartan tablet were prepared. The tablet thickness and diameter are 5.80 mm and 14 mm respectively. All tablets are within the specification of +/- 5%. The in-house tablet hardness is 5-15 kg and percent friabilation is not more than 0.8%. The disintegration test showed that all tablets disintegrated within 2 hours. The content uniformity showed that tablets are within the range of 85%-115%. The tablet weight is within the 5% range. The percent swelling is 53.83% to 58.86% and moisture absorption is 11.79% to 14.56%. The surface pH of the tablet is close to the salivary pH, which means that it would not irritate the buccal mucosa. The buccal tablet has a mucoadhesiveness of 0.196 to 0.200. There was no change in pH and size after subjecting it to stability studies in human saliva. Drug release studies showed 87.7% to 97.4% after 3 hours. Even after 3 months of subjecting the tablets to 40 ºC and 75% RH, results are within acceptable range. The results show the potential of the formulation as a mucoadhesive buccal tablet.

INTRODUCTION:

The oral course of drug management is the maximum not unusual and favored route for drug transport, as it enables smooth ingestion, self-medicine, accurate dosage, bendy and controlled dosing agenda, and affected person compliance with a low threat of management problem [1, 2]. It additionally has some foremost dangers which includes the primary-pass impact, gastrointestinal enzymatic degradation, and slow onset of movement [3]. To triumph over these disadvantages, mucoadhesive drug delivery and sublingual drug transport will be higher options [4].

Mucoadhesive dosage forms are mainly designed to adhere to the mucosal floor, as a consequence intensifying retention of the drug on the web site of utility, [5].

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while presenting a controlled charge of drug release for better therapeutic final results. To mention, some mucoadhesive drug shipping systems are adhesive patches, adhesive gels, adhesive tablets, adhesive movies, adhesive discs, and many others. [6]. several regions which includes the gastrointestinal (GI) tract, the urogenital tract, the ear, the nasal route, and the airways in the body are coated through the mucosal layer. those are both single-layered epithelium determined within the GI tract, bronchi, and intestines or multi-layered stratified epithelium determined inside the esophagus, vagina, and cornea and are the capacity web sites where mucoadhesive drug delivery systems can be beneficial [6, 7].

Buccal mucosa is one in every of such mucosal website online which has a excessive quantity of vascularization and allows direct drain of blood circulate the jugular vein, which allows to keep away from the feasible metabolism of drugs by way of the gastrointestinal direction and liver [8]. The buccal delivery consequently implies the absorption of medicine via the mucosal lining of the buccal cavity. Easier drug management, the

opportunity of prompt termination inside the situation of unexpected side consequences and emergencies, the opportunity of incorporating enzyme inhibitor/permeation enhancer, etc. are different predominant blessings of this drug transport system [9, 10].

Numerous mucoadhesive polymers (natural, semi-artificial, and artificial) used on this delivery system become adhesive on hydration [11], therefore may be used for targeting a drug to a specific region of the body. To start with, whilst the mucoadhesive product is in touch with the mucosal membrane, it swells and spreads, initializing deep contact with the mucosal layer and then mucoadhesive substances (polymers) are activated by the presence of moisture and drug releases slowly [12].

Telmisartan is an angiotensin II receptor antagonist (ARB) used inside the management of hypertension. Normally, angiotensin II receptor blockers (ARBs) including telmisartan bind to the angiotensin II type 1 (AT1) receptors with excessive affinity, inflicting inhibition of the action of angiotensin II on vascular smooth muscle, in the long run leading to a reduction in arterial blood strain. Current studies advocate that telmisartan can also have PPAR-gamma agonistic houses that would doubtlessly confer useful metabolic outcomes. Telmisartan is an orally lively nonpeptide angiotensin II antagonist that acts at the AT1 receptor subtype. It has the very best affinity for the AT1 receptor amongst commercially available ARBS and has minimal affinity for the AT2 receptor. New studies advise that telmisartan might also have PPARγ agonistic properties that would doubtlessly confer beneficial metabolic effects, as PPARγ is a nuclear receptor that regulates particular gene transcription, and whose target genes are involved inside the law of glucose and lipid metabolism, in addition to responses. This remark is presently being explored in scientific trials. Angiotensin II is formed from angiotensin I in a response catalyzed by angiotensin-converting enzyme (ACE, kininase II). Angiotensin II is the most important pressor agent of the renin angiotensin device, with outcomes that consist of vasoconstriction, stimulation of synthesis and release of aldosterone, cardiac stimulation, and renal reabsorption of sodium. Telmisartan works through blocking the vasoconstrictor and aldosterone secretory outcomes of angiotensin II. Literature evaluation of Telmisartan shown that there were several techniques for formulation like immediately launch drugs, conventional release tablets, speedy disintegrating drugs, sublingual tablets, and mini capsules.[5] The intention of the prevailing study turned into to formulate and compare sustained launched tablet of telmisartan the usage of eudragit polymer [13-17].

MATERIALS AND METHOD:

Materials:

Telmisartan pure drug was gift sample from Kilitch drugs (india) Ltd. Carbopol 940 P, Hydroxy Propyl methyl cellulose K15, Microcrystalline cellulose, Talc & Magnesium Stearate was obtained from Merk chemicals, Mumbai. All other chemicals used were of analytical grade.

Method:

POSTCOMPRESSION EVALUATION [18-23]

Thickness of tablet

Three tablets were taken and thickness was measured using Vernier calipers. The tablet thickness should control within ±5 % variation of standard value.

Hardness of tablet

The pfizer hardness tester was used to determine the tablet hardness.

Friability of tablet

Friability was evaluated by means of friability test apparatus known as Roache friabilator. Twenty preweighed tablet were placed in the friabilator and then operated at 25 rpm for 4 minutes. The tablets were then removed and weighed again. The difference in the two weights was used to calculate friability.

$F= 100 X [1-W/W0]$

Where, WO is initial weight W is final weight

Weight variation test

Ten tablets were weighed individually, then calculate the average weight and comparing individual tablet weight to average weight of tablet. The tablets pass the test if not more than two tablets are outsides the percentage limit.

Drug content uniformity

Take five tablets randomly from each formulation, crush in mortal and pestle. Then take powder equivalent to 200 mg Telmisartan and dissolved into 200 ml phosphate buffer of pH 6.8. Then this solution was further diluted to get the solution of 10 ppm. Finally Analyzed spectrophotometrically at 253nm.using UV visible spectrophotometer (Shimadzu, Japan) against phosphate buffer of pH 6.8 as blank.

Surface pH study

The surface pH of mucoadhesive buccal tablets was determined in order to investigate the possibility of any side effects in vivo. As an acidic or alkaline pH may cause irritation to mucoadhesive mucosa. The tablet was allowed to swell by keeping it in contact with 1 ml distilled water for 2 h at room temp. The pH was measured by bringing the electrode in contact with the surface of

tablet and allowing it to equilibrate for 1 min.

Bioadhesion strength and bioadhesion time

Bioadhesive strength of the mucoadhesive buccal tablets was measured on the "Modified Physical Balance method". The method used goat mucus membrane as the model mucosal membrane. The fresh goat GIT mucosa was cut into pieces and washed with phosphate buffer pH 6.8. A piece of mucosa was tied to the glass slide which was moistened with phosphate buffer pH 6.8. The tablet was stuck to the lower side of another glass slide with glue. The both pans were balanced by adding an appropriate weight on the left- hand pan. The glass slide with mucosa was placed with appropriate support, so that the tablet touches the mucosa. On the side of balance powder (equivalent to weight) was added slowly to it until the tablet detach from the mucosal surface. The weight required to detach the tablet from the mucosal surface gave the bioadhesive strength. The experiment was performed in triplicate and average value was calculated. Bioadhesive strength was assessed in terms of weight [gm] required to detach from membrane. Bioadhesion strength which was measured as force of adhesion in Newton by using formula.

Bioadhesion time determination

The ex-vivo mucoadhesion time was examined after application of the mucoadhesive buccal tablet on freshly cut goat mucus mucosa. The fresh goat mucus mucosa was tied on the glass slide, and a mucoadhesive core side of each tablet was wetted with 1 drop of phosphate buffer pH 6.8 and pasted to the sheep mucus mucosa by applying a light force with a fingertip for 30 seconds. The glass slide was then put in the beaker, which was filled with 200 ml of the phosphate buffer pH 6.8 and kept at 37 ± 1°C. After 2 minutes, stirring was applied slowly to simulate the GIT environment and tablet adhesion was monitored for 8 h. The time for the tablet to detach from the goat mucus mucosa was recorded as the mucoadhesion time.

Swelling index

The swelling studies were carried out by determining the swelling index using USP type I apparatus. Tablets were initially weighed (W1) and then placed in basket and revolved at 50 rpm for 8 hr. At interval of 1 h, tablet was removed from basket and weighed (W2). Then swelling index was calculated by using formula

%Swelling index = W2-W1/W1×100

Where, W1 is initial weight

W2 is final weight

In-vitro dissolution study

Dissolution studies were performed using USP type II apparatus and phosphate buffer pH 6.8 at 50 rpm and 37 + 0.5 0C. Aliquots of 1ml of each sample were withdraw periodically at suitable time interval and volume was replaced with equivalent amount of same dissolution medium. The samples were filtered through whatmann filter paper and analyzed after appropriate dilution by UV spectrophotometer (Shimadzu, Japan) at 253 nm.

Diffusion study

The in-vitro drug permeation studies were carried out by using Franz diffusion cell. The goat GIT mucoasa was cut and hair was removed and clamped between the receptor and donor compartments. The receptor compartment was filled with 6 ml of diffusion medium (Phosphate buffer pH 6.8). The contents were stirred at 50 rpm. The temperature of the system was maintained at 37.0±2 0C. Put tablet on goat GIT mucoasa. At 1 h intervals, aliquots 1 ml were collected and diluting upto 10 ml with phosphate buffer and absorbance was measuring at 253 nm using a double beam UV spectrophotometer. Duration of the experiment was 8 hours. The amount of drug permeated through mucoasa was calculated from absorbance of aliquots.

Kinetic data analysis

In order to investigate the mode of drug release from the tablets the release data were analyzed with the following mathematical models. Kinetic data analysis was done with the help of Microsoft excel based software PCP Disso v2.08.

Stability studies

The aim of stability testing is to show how the consistency of the formulation of drugs changes over time under the influence of different environmental conditions such as temperature, humidity, light. Form this study recommended storage conditions humidity, light, re-test periods and self-life of the drug can be established. The selected formulations were subjected for 3 months for stability study as per ICH guidelines. The selected formulation was a placed in a wide mouth glass bottles, mouth of the bottle was tightly closed and packed in aluminum foil. In the present study, stability studies were carried out at 40 0C ±2 0C/75% RH ±5 RH for a specific period of 3 month for the selected formulation.

RESULTS AND DISCUSSION:

EVALUATION PARAMETER

Precompression parameter

The powder blend of each formulation were evaluated for bulk density, tapped density, Carr's index, Hausner's ratio, angle of repose and result obtained are shown in Table.

Table 1: Precompression parameter of formulations

Formulation	Bulk density (gm/cm^3)	Tapped density(gm/cm^3)	Carr's index	Hausner ratio	Angle of repose (θ)
F1	0.44±0.017	0.51±0.017	13.72	1.15	$30^0.55'$±0.36
F2	0.41±0.011	0.47±0.023	12.76	1.14	$28^0.80'$±0.33
F3	0.47±0.023	0.58±0.028	12.96	1.14	$27^0.90'$±2.01
F4	0.44±0.017	0.51±0.017	13.72	1.15	$30^0.77'$±0.68
F5	0.41±0.011	0.47±0.023	12.76	1.14	$29^0.34'$±1.16
F6	0.44±0.017	0.51±0.015	13.72	1.15	$29^0.29'$±0.66
F7	0.41±0.011	0.47±0.023	12.76	1.14	$29^0.80'$±0.33
F8	0.44±0.017	0.51±0.017	13.72	1.15	$31^0.77'$±0.68

*Values are expressed in mean ±SD (n=3)

POST COMPRESSION EVALUATION:

Table 2: Post compression parameter of formulation

Formulation	Hardness (kg/cm^2)	Thickness (mm)	Friability (%)	Weight variation (mg)	Drug content (%)	Surface pH
F1	5.46±0.20	3.21 ±0.02	0.37±0.04	307.86±1.89	97.03±1.62	5.89± 0.04
F2	5.43±0.35	3.19 ± 0.05	0.44±0.02	305.61±3.42	95.89±1.63	5.72± 0.04
F3	5.53± 0.30	3.20 ± 0.03	0.58±0.03	305.66±4.07	96.33±1.68	6.66± 0.42
F4	5.3±0.20	3.16 ± 0.04	0.57± 0.02	305.31±5.72	95.56±1.87	6.78± 0.05
F5	5.66±0.51	3.20 ± 0.07	0.70± 0.03	304.62±4.52	96.98± 0.58	6.5± 0.03
F6	5.46±0.37	3.17 ± 0.04	0.77±0.02	308.12±3.93	96.62±2.14	6.42±0.06
F7	5.49±0.20	3.21 ±0.02	0.37±0.04	307.86±1.89	97.53±1.62	5.88± 0.04
F8	5.45±0.35	3.19 ± 0.05	0.44±0.02	305.61±3.42	95.59±1.63	5.76± 0.04

Bioadhesive strength and bioadhesive time of formulation

The aim of study is to formulate tablet that can adhere to membrane for about 8 hours and release the drug for 8 hours. It was found that near about all formulation achieve adhesion property and there was no much difference in adhesion time of formulations.

Table 3: Bioadhesive strength and bioadhesion time of different formulations.

Formulation	Bioadhesive strength (gm)	Bioadhesion force (N)	Bioadhesion time (h)
F1	5.13	0.49	6.10
F2	7.21	0.68	7.30
F3	10.98	1.07	8.10
F4	9.80	0.96	7.35
F5	10.11	0.99	7.40
F6	8.10	0.79	6.15
F7	9.11	0.99	7.40
F8	9.80	0.95	7.36

The bioadhesives property of tablets of Telmisartan containing varying Proportions of polymers was determined with an insight to develop the tablets with adequate bioadhesiveness. For the maximum adhesion of tablet with mucus membrane the tablet should possess the some bioadhesive strength. All the

formulations show optimum level of bioadhesive strength. The bioadhesive strength was found to be in the range of 5.13-10.98 gm. The highest adhesion force and highest strength of the mucoadhesive bond was observed with the formulation F3 and F5. Tablets of formulation F1 and F8 containing showed least adhesion force than tablet of all other formulation. Bioadhesion time was also found to be optimum which is requiring for the formulation to be remaining within the mucus membrane.

Swelling study of formulations

All the formulations were studied for the percentage swelling index. This is the important parameter to be studied for drug release from polymeric matrix system.

Table 4: Cumulative percent swelling of formulations

Times (h)	Cumulative percent swelling index							
	F1	F2	F3	F4	F5	F6	F7	F8
1	8.17	12.57	16.53	20.42	24.53	28.94	23.53	28.94
2	22.31	26.71	30.41	34.21	38.48	48.31	34.48	48.31
3	36.97	40.85	44.75	49.78	53.42	62.48	51.42	62.48
4	50.53	54.73	58.72	63.43	67.31	76.53	62.31	76.53
5	64.75	68.54	72.63	77.84	81.70	90.37	78.70	90.37
6	73.47	77.32	81.43	86.53	90.31	99.84	85.31	97.84
7	-	-	90.21	94.31	98.39	102.42	92.39	101.42
8	-	-	98.57	103.23	107.41	110.53	98.41	109.53

It should be necessary that polymer to be swell, so by the diffusion it can release the drug. As time increases there was more swelling observed and it also depend upon the ratio of polymer in the formulation, it was clearly observed from result obtained.

From the result obtained after swelling study it was concluded that Swelling index increased by increasing concentration of HPMC K15M. In formulation F1 and F2 swelling index is upto 6 h due to initial bursting. In formulation F3, F4, F5, F6, F7 and F8 there is increase in swelling index due to increase concentration of HPMC K15M. So, optimum swelling showed in formulation F3.

Dissolution study

All the formulation evaluated for the percentage drug release. Table showed average cumulative percentage of drug released of formulations.

Table 5: Average cumulative percentage of drug released of formulations

Time (h)	Average cumulative percentage of drug released from							
	F1	F2	F3	F4	F5	F6	F7	F8
1	24.79	20.54	13.41	11.21	9.87	8.78	13.41	9.87
2	38.41	33.62	21.98	18.49	16.08	15.27	21.98	16.08
3	54.38	49.43	35.13	30.14	27.89	25.77	35.13	27.89
4	69.15	64.25	51.10	44.12	40.11	37.49	51.10	40.11
5	85.24	77.54	66.98	51.10	53.92	40.58	66.98	53.92
6	95.21	86.37	82.41	71.59	65.28	51.24	82.41	65.28
7	-	94.78	90.18	78.35	72.39	58.23	85.18	70.39
8	-	-	94.26	82.03	75.23	61.91	90.25	74.28

Drug release studies were made to determine whether the release of the drug is slow enough, i.e., which polymer ratio is enough to sustain the release of the drug for 8 h. As we increase the ratio of HPMC K15M in the formulation, there is more swelling were observed which also responsible for the drug release and it also sustained the drug release at the 8 h. The drug release in F1 and F2 formulation is 95.21% and 94.78% respectively but there is initial abrupt bursting effect. Drug release in formulation F3, F4, F5, F6, F7 and F8 decreases with increases concentration of HPMC K15M. Drug release in formulation F3 is 94.26% which sustained at 8 h.

Therefore, optimized formulation was F3 having the polymer ratio 1:1.5 [Carbopol 940P: HPMC K15]. From, the comparison study of all formulation it was concluded that the order of drug release among formulations was found to be F3> F2> F1> F4> F5> F6> F7> F8.

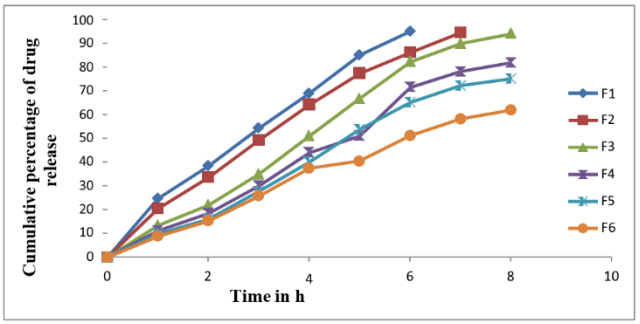
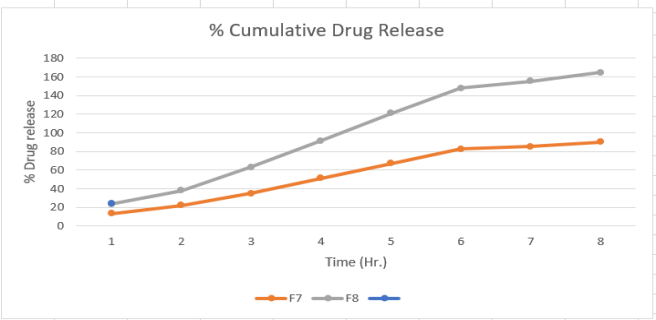


Fig. 1: Cumulative percent drug release profiles of formulations F1-F6.



Drug diffusion study

Diffusion study was carried out by using Franz diffusion cell. Table 7.8 showed average cumulative percentage of drug diffusion from formulations.

Table 6: Average cumulative percentage of drug diffusion from F1-F8.

Time (h)	Average cumulative percentage of drug diffusion from							
	F 1	F 2	F 3	F 4	F 5	F 6	F7	F8
1	26.87	22.53	14.37	13.48	11.28	9.43	13.41	9.87
2	40.52	35.68	23.49	20.14	17.47	15.89	21.98	16.08
3	56.34	51.89	36.71	33.54	28.31	25.40	35.13	27.89
4	71.82	64.54	51.40	48.21	39.84	36.18	51.10	40.11
5	87.51	76.48	66.83	61.39	51.32	47.28	66.98	53.92
6	96.49	88.74	81.04	72.45	60.15	56.11	82.41	65.28
7	-	96.23	91.75	80.41	67.49	62.38	85.18	70.39
8	-	-	95.87	85.37	72.14	67.44	90.25	74.28

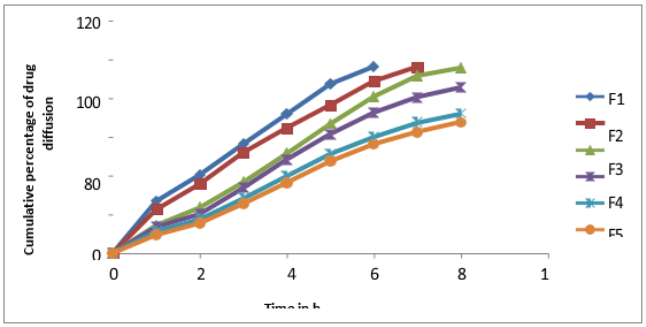


Fig. 3: Cumulative percent of drug diffusion profiles of F1-F6.

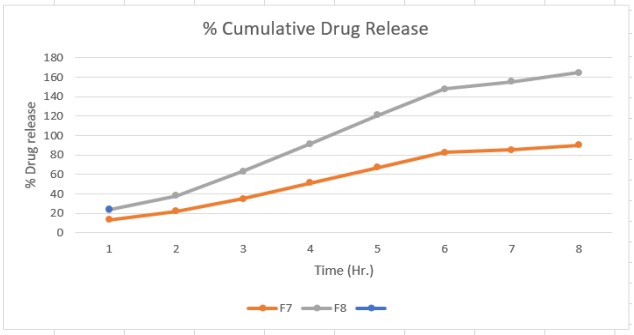


Fig. 4: Cumulative percent of drug diffusion profiles of F7-F8.

Drug diffusion studies were made to determine whether the diffusion of the drug is slow enough, i.e., which polymer ratio is enough to sustain the release of the drug for 8 h. As shown in fig, that all formulation show the percentage drug diffusion. As we increases the ratio of HPMC K15M in the formulation, there is more swelling were observed which also responsible for the drug diffusion and it also sustained the drug diffusion. The drug diffusion in F1 and F2 formulation was 96.49% and 96.23 % respectively but there is initial abrupt bursting effect. Drug diffusion in formulation F3, F4, F5, F6, F7 and F8 decreases with increases concentration of HPMC K15M. Drug diffusion in formulation F3 is 95.87 % which sustained for 8 h. So, optimized formulation was found to be F3 having the polymer ratio 1:1.5 [Carbopol 940P:HPMC K15M]. Also other formulations show optimum drug diffusion. From, the comparison study of all formulation it was concluded that the order of drug diffusion among formulations was found to be F3> F2> F1> F4> F5> F6> F7> F8.

Drug release kinetics of formulations

The drug release data of the selected formulation (F3) was fitted to various models like zero order, first order, Higuchi's model, Hixon Crowell and Korsmeyer's model. The Kinetic model fitting of drug release data was done with the help of Microsoft excel based software PCP-Disso v2.08. The calculated slope, the intercept and R^2 are shown in Table 7.9. Formulation (F3) was best fitted for Hixon Crowell model with regression value 'R^2' of 0.9544. Slope value suggested that the release of Telmisartan from floating tablets followed Case-II transport mechanism. Formulation (F3) follows zero order release kinetics with regression value 'R2' of 0.9934.

Table 7: Drug release kinetic of selected formulation (F3)

Model	R2	Slope	Intercept
Zero order	0.9934	12.66	0.0651
First order	0.8563	0.1968	0.7010
Hixon Crowell	0.9544	1.1229	1.9409
Korsmeyer-Peppas model	0.3451	1.0121	1.2093
Higuchi model	0.9530	0.0245	0.5708

Stability Study:

Formulation F1 to F7 were prepared by wet granulation method using different polymers. F3 was found to be best among all other formulations, because it has exhibited satisfactory sustain release when compared to all other formulations. Therefore F3 was subjected to stability study at 37 ±1 ° C and RH 75% ± 5% up to 3 months.

Table No.8: Stability study data of optimized batch

Physical Parameter	Observations		
	30thday	60th day	90th day
% Drug content	98.10	98.23	98.75

CONCLUSION:

From the present study it was concluded that the muccoadhesive drug delivery system of Telmisartan was deliver the drug in sustained release manner, for 8 h. Also it successfully avoids the extensive first pass metabolism and improves the bioavailability of Telmisartan. It was also found that Carbopol 940P and HPMC K15M can be promising polymers for muccoadhesive drug delivery systems and also as we increases the ratio of HPMC K15M in the formulation there is decrease in the drug release rate of Telmisartan. The optimized formulation sustained the release up to 8 h, followed Zero order kinetics while the drug release mechanism was found to be case II transport, controlled by diffusion through the swollen matrix. Sustained drug release with adhesion time of about 8 h and good bioadhesive strength was observed in case of optimized formulation. The swollen tablet also maintained its physical integrity during the drug release study.

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Cite this article: Shital Misal, Jaydeep Pawar, Dhananjay landge, Formulation and Evaluation of a Mucoadhesive Buccal Tablet of Telmisartan, International Journal of Current Research and Innovation in Pharma Sciences, 2022; 1(II):53-52.