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Research

Formulation and evaluation of muco adhesive buccal tablets of chlorhexidine

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Abstract

Chlorhexidine is an antiseptic and disinfectant. It helps reduce the number of germs (bacteria) in your mouth or on your skin. It can help with: mouth infections, mouth ulcers and gum disease. Aim of the present work is to formulate and evaluate of mucoadhesive tablets of Chlorhexidine by using different polymers like HPMC K15M, Tragacanth and Carbopol. The tablets were formulated by direct compression method and were evaluated for various pre-compression and post compression parameters such as hardness, friability, thickness, weight uniformity, drug content, drug release, swelling index and In vitro drug release. FTIR showed no interaction between drug and polymers. The optimized formula consisted of Chlorhexidine and HPMC K15M with 20mg and showed maximum drug release for 8hours is 99.58 % for C3 formulation. The C3 formulation is consider as optimized formulation of mucoadhesive buccal tablets and Kinetics are done.

Keywords: Chlorhexidine, HPMC K15M,Tragacanth and Carbopol.

INTRODUCTION

Buccal delivery of drugs provides an attractive alternative to the oral route of drug administration, particularly in overcoming deficiencies associated with the latter mode of dosing .Problems such as first pass metabolism and drug degradation in the GIT environment can be circumvented by administering the drug via buccal route. Moreover, the oral cavity is easily accessible for self medication and be promptly terminated in case of toxicity by removing the dosage form from buccal cavity. It is also possible to administer drugs to patients who cannot be dosed orally via this route Successful buccal drug delivery using buccal adhesive system requires at least three of the following (a) A bioadhesive to retain the system in the oral cavity and maximize the intimacy of contact with mucosa (b) A vehicle the release the drug at an appropriate rate under the conditions prevailing in the mouth and (c) Strategies for overcoming the low permeability of the oral mucosa. Buccal adhesive drug delivery stem promote the residence time and act as controlled release dosage forms.

The use of many hydrophilic macromolecular drugs as potential therapeutic agents is their in adequate and erratic oral absorption. However, therapeutic potential of these compounds lies in our ability to design and achieve effective and stable delivery systems. Based on our current understanding, it can be said that many drugs can not be delivered effectively through the conventional oral route.

The main reasons for the poor bio-availability of many drugs through conventional oral route are:

- ✓ Pre-systemic clearance of drugs.
- ✓ The sensitivity of drugs to the gastric acidic environment which leads to gastric irritation. Limitations associated with gastro intestinal tract like variable absorption characteristics.

Buccal mucosa composed of several layers of different cells. The Epithelium is similar to stratified squamous epithelia found in rest of the at least one of which is biological nature are held together by means of interfacial forces.[1]

Buccal drug delivery is a type of bioadhesive drug delivery especially it is a mucoadhesive drug delivery system is adhered to buccal mucosa.

- ➢ The term bioadhesion is commonly defined as an adhesion between two materials where at least one of the materials is of biological origin. In the case of bioadhesive drug delivery systems, bioadhesion often refers to the adhesion between the excipients of the formulation (i.e. the inactive media) and the biological tissue.
- ➢ The term mucoadhesion can be considered to refer to a sub group of bioadhesion and, more specifically, to the case when the formulation interacts with the mucous layer that covers a mucosal tissue.

The mucosal layer lines a number of regions of the body including gastrointestinal tract, urogenital tract, airway, ear, nose and eye. Hence mucoadhesive drug delivery system includes the following: 1. Buccal delivery system; 2. Oral delivery system; 3. Ocular delivery system; 4. Vaginal delivery system;5. Rectal delivery system; 6. Nasal delivery system[2]

Overview of the Oral Mucosa Structure The oral mucosa is composed of an outermost layer of stratified squamous epithelium. Below this lies a basement membrane, a lamina propria followed by the submucosa as the innermost layer18, 19 can be seen in figure 1. The epithelium of the buccal mucosa is about 40- 50 cell layers thick, while that of the sublingual epithelium contains somewhat fewer. The epithelial cells increase in size and become flatter as they travel from the basal layers to the superficial layers. The turnover time for the buccal epithelium has been estimated at 5-6 days[3], and this is probably representative of the oral mucosa as a whole. The oral mucosal thickness varies depending on the site: the buccal mucosa measures at 500-800 μm, while the mucosal thickness of the hard and soft palates, the floor of the mouth, the ventral tongue, and the gingivae measure at about 100-200 μm. The composition of the epithelium also varies depending on the site in the oral cavity. The mucosae of areas subject to mechanical stress (the gingivae and hard palate) are keratinized similar to the epidermis. The mucosae of the soft palate, the sublingual, and the buccal regions, however, are not keratinized[4]. The keratinized epithelia contain neutral lipids like ceramides and acylceramides which have been associated with the barrier function. These epithelia are relatively impermeable to water. In contrast, nonkeratinized epithelia, such as the floor of the mouth and the buccal epithelia, do not contain acylceramides and only have small amounts of ceramide [5-7]. They also contain small amounts of neutral but polar lipids, mainly cholesterol sulfate and glucosyl ceramides. These epithelia have been found to be considerably more permeable to water than keratinized epithelia.

The oral mucosa in general is somewhat leaky epithelia intermediate between that of the epidermis and intestinal mucosa. It is estimated that the permeability of the buccal mucosa is 4-4000 times greater than that of the skin[8]. As indicative by the wide range in this reported value, there are considerable differences in permeability between different regions of the oral cavity because of the diverse structures and functions of the different oral mucosae. In general, the permeabilities of the oral mucosae decrease in the order of sublingual greater than buccal, and buccal greater than palatal. This rank order is based on the relative thickness and degree of keratinization of these tissues, with the sublingual mucosa being relatively thin and non-keratinized, the buccal thicker and non-keratinized, and the palatal intermediate in thickness but keratinized.

MATERIALS

Chlorhexidine-Procured From Themis Laboratories PVT LTD, Mumbai (India). Provided by SURA LABS, Dilsukhnagar, Hyderabad,Hpmc k15m-Panchi Chemicals Pvt Ltd, Mumbai,Tragacanth-Alkem Labs Pvt, Ltd, Mumbai, Carbopol-Sd fine Chem.Ltd. Mumbai, Talc-SD Fine chemicals, Mumbai, Mg stearate-Qualigens fine chemicals, Mumbai,Lactose-SD Fine chemicals, Mumbai.

METHODOLOGY

Preformulation studies
Analytical method used in the determination of Chlorhexidine
Preparation of pH 6.8 phosphate buffer
Preparation of 0.2 M sodium hydroxide solution

Accurately weighed 8 g of sodium hydroxide pellets were dissolved in 1000 mL of distilled water and mixed. Dissolved 6.805 g of potassium dihydrogen orthophosphate in to 800mL of Purified water and mixed. Added 112mL of 0.2M NaOH solution in to this solution, diluted to volume with purified water. Then adjusted the pH of this solution to 6.8 with 0.2M NaOH solution.

Preparation of pH 7.4 phosphate buffer

Accurately measured 250 mL of 0.2M potassium dihydrogen ortho phosphate and 195.5 mL of 0.2M NaOH was taken into the 1000 mL volumetric flask. Volume was made up to 1000 mL with distilled water.

Preparation of standard graph in phosphate buffer pH 6.8

100 mg of Pure drug was dissolved in small amount of Methanol (5-10 ml), allowed to shake for few minutes and then the volume was made up to 100ml with phosphate buffer pH 6.8, from this primary stock (1mg/ml), 10 ml solution was transferred to another volumetric flask made up to 100 ml with phosphate buffer pH 6.8. From this secondary stock 1, 2, 3, 4, 5 ml was taken separately and made up to 10 ml with phosphate buffer pH 6.8 to produce 2,4, 6,8,10µg/ml respectively. The absorbance was measured at 280 nm using a UV spectrophotometer. Standard calibration curve values were shown in Table (9.1). The standard calibration curve of Chlorhexidine in phosphate buffer pH 6.8 was shown in fig 9.1.

Preparation of standard graph in phosphate buffer pH 7.4

100 mg of drug was dissolved in small amount of phosphate buffer and make the volume up to 100ml with phosphate buffer pH 7.4, from this primary stock(1mg/ml), 10 ml solution was transferred to another volumetric flask made up to 100 ml with phosphate buffer pH 7.4. From this secondary stock 1, 2, 3, 4, 5 ml were taken separately and made up to 10 ml with phosphate buffer pH 7.4, to produce 2, 4, 6, 8,10µg/ml respectively. The absorbance was measured at 280 nm using a UV spectrophotometer. Standard calibration curve values were shown in Table (9.2). The standard calibration curve of Chlorhexidine in phosphate buffer pH 7.4 was shown in fig 9.2.

Solubility Studies

The solubility of Chlorhexidine in phosphate buffer solution pH 6.8 was determined by phase equilibrium method. An excess amount of drug was taken into 20 ml vials containing 10 ml of phosphate buffers (pH 6.8). Vials were closed with rubber caps and constantly agitated at room temperature for 24 hr using rotary shaker. After 24 hr, the solution was filtered through 0.2µm Whattman's filter paper. The amount of drug solubilized was then estimated by measuring the absorbance at 280 nm using a UV spectrophotometer.

The standard curves for Chlorhexidine were established in phosphate buffers (pH 6.8) and from the slope of the straight line the solubility of Chlorhexidine was calculated. The studies were repeated in triplicate (n = 3), and mean was calculated.

Evaluation of pre-compression blend

The quality of tablet, once formulated, by rule is generally dictated by the quality of physicochemical properties of blends. There are many formulations and process variables involved in mixing and all these can affect the characterization of blends produced. Prior to compression, granules were evaluated for their characteristic parameter such as Tapped density, Bulk density, Carr's index, Angle of repose, Hausner's ratio. Compressibility index was calculated from the bulk and tapped density using a digital tap density apparatus. The various characteristics of blends tested are as given below:

Angle of repose

The angle of repose of granules was determined by the funnel method. The accurately weighed granules were taken in a funnel. The height of the funnel was adjusted in such a way that the tip of the funnel just touches the apex of the heap of the granules. The granules were allowed to flow through funnel freely onto the surface. The diameter of the powder cone was measured and angle of repose was calculated using the following equation:

$$\tan\theta = h/r$$

Where, θ = angle of repose
h = height of the cone
r = radius of the cone base

Bulk density

Density is defined as weight per unit volume. Bulk density ρb, is defined as the mass of the powder divided by the bulk volume and is expressed as gm/cm^3. The bulk density of a powder primarily depends on particle size distribution, particle shape and the tendency of particles to adhere together. Bulk density is very important in the size of containers needed for handling, shipping and storage of raw material and blend. It is also important in size blending equipment. 30 gm of powder blend introduced into a dry 100 mL cylinder, without compacting. The powder was carefully leveled without compacting and the unsettled apparent volume V_0, was read. The bulk density was calculated using the formula:

$$\rho b = M/V_0$$

Where, ρb= Apparent bulk density.
M=Weight of the sample.
V=Apparent volume of powder.

Tapped density

After carrying out the procedure as given in the measurement of bulk density the cylinder containing the sample was tapped using a suitable mechanical tapped density tester that provides a fixed drop of 14±2 mm at a nominal rate of 300 drops per minute. The cylinder was tapped 500 times initially followed by an additional tap of 750 times until difference between succeeding measurement is less than 2% and then tapped volume, V_f was measured, to the nearest graduated unit. The tapped density was calculated, in gm per mL, using the formula:

$$\rho_{tap} = M/V_f$$

Where, ρ_{tap}= Tapped density.
M = Weight of the sample.
V_f= tapped volume of the powder.

Carr's index

The compressibility index (Carr's index) is a measure of the propensity of a powder to be compressed. It is determined from the bulk and tapped densities. In theory, the less compressible a material the more flowable it is. As such, it is measure of the relative importance of interparticulate interactions. In a free-flowing powder, such interactions are generally less significant, and the bulk and tapped densities will be closer in value. For poorer flowing materials, there are frequently greater interparticle interactions, and a greater difference between the bulk and tapped densities will be observed. These differences are reflected in the compressibility index which is calculated using the following formula:

$$\text{Carr's index} = [(\rho_{tap}-\rho b)]/\rho_{tap}]\times 100$$

Where, ρb= bulk density
ρ_{tab}= tapped density

Hausner's ratio

It is the ratio of tapped density to the bulk density. Hausner's found that this ratio was related to interparticle friction and, as such, could be used to predict powder flow properties. Generally a value less than 1.25 indicates good flow properties, which is equivalent to 20% of Carr's index.

$$\text{Hausner's Ratio} = \rho_{tap}/\rho b$$

Where, ρ_{tap} = Tapped density.
ρb = Bulk density.

Table 1: Formulation Chart

Ingredients	C1	C2	C3	C4	C5	C6	C7	C8	C9
Chlorhexidine	20	20	20	20	20	20	20	20	20
Hpmc k15m	10	20	30	-	-	-	-	-	-
Tragacanth	-	-	-	10	20	30	-	-	-
Carbopol	-	-	-	-	-	-	10	20	30
Talc	5	5	5	5	5	5	5	5	5
Mg stearate	5	5	5	5	5	5	5	5	5
Lactose	60	50	40	60	50	40	60	50	40
Total weight	100	100	100	100	100	100	100	100	100

RESULTS AND DISCUSSION

Solubility Studies

Table 2: Solubility studies

S.No	Medium	Amount present µg/mL)
1	Phosphate pH 6.8 buffer	98.18
2	Phosphate pH 7.4 buffer	96.71

Saturation solubility of Chlorhexidine in various buffers were studied and shown in the Table 9.1. The results revealed that the solubility of the Chlorhexidine was increased from pH 6.8 to 7.4. The solubility of the Chlorhexidinein phosphate buffer pH 6.8 is 98.18µg/mL and it was selected as the suitable media for the release studies because the pH of the phosphate buffer pH 6.8 is nearer to that of buccal mucosa pH.

Standard graph in phosphate buffer pH 6.8 (λ_{max} 280 nm)

Standard graph of Chlorhexidinewas plotted as per the procedure in experimental method and its linearity is shown in Table 9.2 and Fig 9.1**.** The standard graph of Chlorhexidineshowed good linearity with R^2 of 0.998, which indicates that it obeys "Beer- Lamberts" law.

Table 3: Standard graph values of Chlorhexidinein pH 6.8 phosphate buffer

Concentration (µg/mL)	Absorbance
0	0
2	0.135
4	0.256
6	0.379
8	0.502
10	0.629

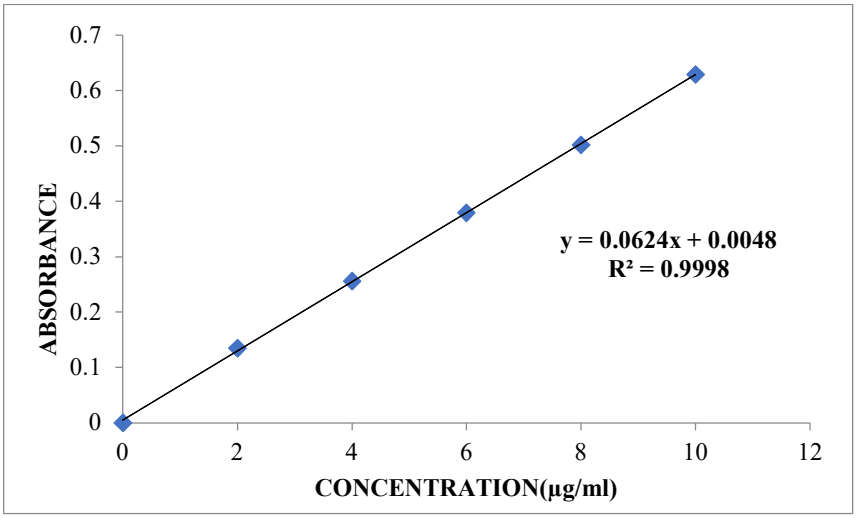

Fig 1: Standard graph of Chlorhexidine in pH 6.8 phosphate buffer

Standard graph in phosphate buffer pH 7.4 (λ_{max} 280 nm)

Standard graph of Chlorhexidinewas plotted as per the procedure in experimental method and its linearity is shown in Table 9.3 and Fig 9.2. The standard graph of Chlorhexidineshowed good linearity with R^2 of 0.999, which indicates that it obeys "Beer- Lamberts" law.

Table 4: Standard graph values of Chlorhexidinein pH 7.4 phosphate buffer

Concentration (µg/mL)	Absorbance
0	0
2	0.166

4	0.307
6	0.449
8	0.593
10	0.726

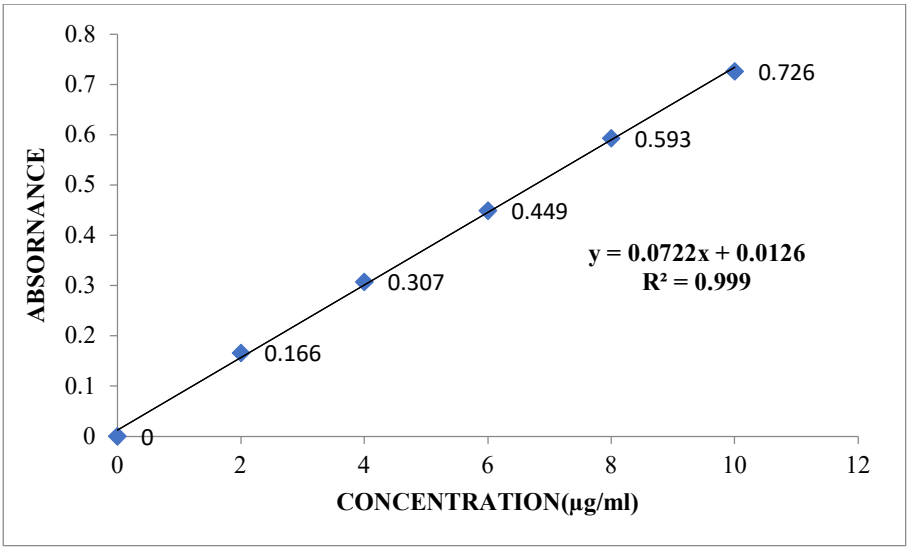

Fig 2: Standard graph of Chlorhexidinein pH 7.4 phosphate buffer

Evaluation

Characterization of pre-compression blend

The pre-compression blend of Chlorhexidine buccal tablets were characterized with respect to angle of repose, bulk density, tapped density, Carr's index and Hausner's ratio**.** Angle of repose was less than 23.45º, Carr's index values were less than 14.7 for the pre-compression blend of all the batches indicating good to fair flowability and compressibility. Hausner's ratio was less than 1.24 for all the batches indicating good flow properties.

Table 5: Physical properties of pre-compression blend

Formulation Code	Angle of repose (Ɵ)	Bulk density (gm/cm^3)	Tapped density (gm/cm^3)	Carr's Index (%)	Hausner's ratio
C1	18.8	0.38	0.43	11.6	1.13
C2	19.6	0.39	0.44	11.3	1.12
C3	19.4	0.42	0.47	10.6	1.11
C4	21.9	0.40	0.45	11.1	1.12
C5	17.5	0.41	0.46	10.8	1.12
C6	19.2	0.37	0.43	13.9	1.16
C7	19.5	0.38	0.46	17.3	1.21
C8	21.3	0.39	0.45	13.3	1.15
C9	18.3	0.44	0.48	12.1	1.18

Evaluation of buccal tablets

Physical evaluation of Chlorhexidine buccal tablets

The results of the weight variation, hardness, thickness, friability and drug content of the tablets are given in Table 9.5. All the tablets of different batches complied with the official requirement of weight variation as their weight variation passes the limits. The hardness of the tablets ranged from 4.0 to 5.6 kg/cm^2 and the friability values were less than 0.77 % indicating that the buccal tablets were compact and hard. The thickness of the tablets ranged from 4.01 – 4.92 mm. All the formulations satisfied the content of the drug as they contained 95.38-99.82 % of Chlorhexidine. Thus all the physical attributes of the prepared tablets were found to be practically within control limits.

Table 6: Physical evaluation of Chlorhexidine buccal tablets

Formulation code	Weight variation (mg)	Thickness (mm)	Hardness (Kg/cm^2)	Friability (%)	Content uniformity (%)
C1	98.73	1.58	2.38	0.26	99.38
C2	99.08	1.63	2.43	0.21	100.39
C3	100.12	1.48	2.58	0.12	97.53
C4	99.67	1.43	2.62	0.35	98.68
C5	102.38	1.19	2.33	0.44	99.67
C6	99.12	1.39	2.51	0.37	99.28
C7	98.22	1.58	2.49	0.29	98.22
C8	97.68	1.33	2.67	0.31	97.47
C9	98.23	1.12	2.54	0.48	98.86

Swelling Index

Table 7: Swelling Index and Mucoadhesive strength (G)

S.NO.	Formulations	Swelling Index (%)	Mucoadhesive strength(G)
1	C1	0.82	11.82±0.82
2	C2	1.19	13.28±0.85
3	C3	2.26	12.44±0.92
4	C4	2.96	15.72±0.79
5	C5	1.25	14.20±1.44
6	C6	2.31	18.23±1.11
7	C7	3.10	19.23±1.09
8	C8	4.21	15.24±1.75
9	C9	2.38	14.38±1.28

Swelling index is an important parameter in judging the mucoadhesion property, at least in the initial stages, since water uptake is important for the polymers to uncoil and interact with the mucin. The swelling indices of the Chlorhexidine buccal tablets reveals that while the buccal tablet formulations are all made of different materials, the extent of swelling differs based on the individual tablet composition. The Swelling indices of the first three formulations are quite low because of the fact that they started to disintegrate and lose mass soon after placing them upon the Petri-dish. The formulations containing higher levels of the polymers Carbopol displayed the highest swelling index.

***In vitro* release studies**

In vitro drug release studies were conducted in phosphate buffer pH 6.8 and the studies revealed that the release of Chlorhexidine from different formulations varies with characteristics and composition of matrix forming polymers.

Table 8: *In vitro* dissolution data for formulations F1 – F9

CUMULATIVE PERCENTE OF DRUG RELEASE									
TIME(HRS)	**C1**	**C2**	**C3**	**C4**	**C5**	**C6**	**C7**	**C8**	**C9**
0	0	0	0	0	0	0	0	0	0
0.5	21.68	28.44	32.62	25.11	30.72	28.72	38.85	33.34	27.56
1	28.21	33.53	49.54	31.82	38.34	35.91	47.79	56.29	36.83
2	33.82	41.84	54.63	43.51	46.21	43.59	58.66	62.14	49.65
3	49.37	45.64	60.86	50.22	51.26	59.28	62.29	70.28	54.88
4	53.49	57.91	64.64	57.32	61.33	65.82	70.78	76.95	63.38
5	67.61	63.81	79.73	63.81	65.82	69.61	76.16	82.24	75.31
6	71.24	65.62	85.89	70.12	72.34	76.15	83.43	86.32	82.08
7	84.59	78.41	93.92	76.23	86.21	85.25	90.45	92.11	93.12
8	89.26	92.89	99.58	86.15	90.14	92.69	95.28	97.58	98.23

From the dissolution studies observed Total Nine Formulation are prepared. The formulations prepared with HPMC K15M in different concentrations. The formulation C3was maximum drug released 99.58% in 8 h. Concentration of polymer increased the drug release was decreased. The formulation was prepared with

Tragacanth the drug release was observed, the formulation C6 was showed 92.69% maximum drug release in 8 hours. The formulation was prepared with Carbopol the drug release was observed, the formulation C9was showed 98.23% maximum drug release in 8 hours. Among all formulations C3was showed maximum drug release in 8 hrs. So Formulation C3 was selected as optimised formulation.

Table 9: Moisture absorption, surface pH of selected formulations

Formulation Code	Moisture absorption	Surface pH
C3	92	6.19
C6	98	6.01
C9	95	6.22

The moisture absorption studies give important information of the relative moisture absorption capacities of polymers and it also give information regarding whether the formulations maintain the integrity or not. Among the selected formulations C3formulation shown good moisture absorption.

The surface pH of the buccal tablets was determined in order to investigate the possibility of any side effects. As an acidic or alkaline pH may cause irritation to the buccal mucosa, it was determined to keep the surface pH as close to neutral as possible. The surface pH of the selected formulations was found to be 6.01 to 6.19 and the pH was near to the neutral. These results suggested that the polymeric blend identified was suitable for oral application and formulations were not irritant to the buccal mucosa.

Release kinetics

Data of *in vitro* release studies of formulations which were showing better drug release were fit into different equations to explain the release kinetics of Chlorhexidine release from buccal tablets. The data was fitted into various kinetic models such as zero, first order kinetics; higuchi and korsmeyer peppas mechanisms and the results were shown in below table.

Table 10: Release kinetics and correlation coefficients (R^2)

CUMULATIVE (%) RELEASE Q	TIME (T)	ROOT (T)	LOG(%) RELEASE	LOG (T)	LOG (%) REMAIN	RELEASE RATE (CUMULATIVE % RELEASE / t)	1/CUM% RELEASE	PEPPAS log Q/100	% Drug Remaining	Q01/3	Qt1/3	Q01/3-Qt1/3
0	0	0			2.000				100	4.642	4.642	0.000
32.62	0.5	0.707	1.513	-0.301	1.829	65.240	0.0307	-0.487	67.38	4.642	4.069	0.572
49.54	1	1.000	1.695	0.000	1.703	49.540	0.0202	-0.305	50.46	4.642	3.695	0.946
54.63	2	1.414	1.737	0.301	1.657	27.315	0.0183	-0.263	45.37	4.642	3.567	1.075
60.86	3	1.732	1.784	0.477	1.593	20.287	0.0164	-0.216	39.14	4.642	3.395	1.246
64.64	4	2.000	1.811	0.602	1.549	16.160	0.0155	-0.189	35.36	4.642	3.282	1.359
79.73	5	2.236	1.902	0.699	1.307	15.946	0.0125	-0.098	20.27	4.642	2.727	1.915
85.89	6	2.449	1.934	0.778	1.150	14.315	0.0116	-0.066	14.11	4.642	2.416	2.225
93.92	7	2.646	1.973	0.845	0.784	13.417	0.0106	-0.027	6.08	4.642	1.825	2.816
99.58	8	2.828	1.998	0.903	-0.377	12.448	0.0100	-0.002	0.42	4.642	0.749	3.893

Drug – excipient compatibility studies by physical observation

Chlorhexidine was mixed with various proportions of excipients showed no color change at the end of two months, proving no drug-excipient interactions.

FTIR

FTIR spectra of the drug and the optimized formulation were recorded. The FTIR spectra of pure Chlorhexidine drug, drug with polymers (1:1) shown in the below figures respectively. The major peaks which are present in pure drug Chlorhexidine are also present in the physical mixture, which indicates that there is no interaction between drug and the polymers, which confirms the stability of the drug.

There was no disappearance of any characteristics peak in the FTIR spectrum of drug and the polymers used. This shows that there is no chemical interaction between the drug and the polymers used. The presence of peaks at the expected range confirms that the materials taken for the study are genuine and there were no possible interactions.

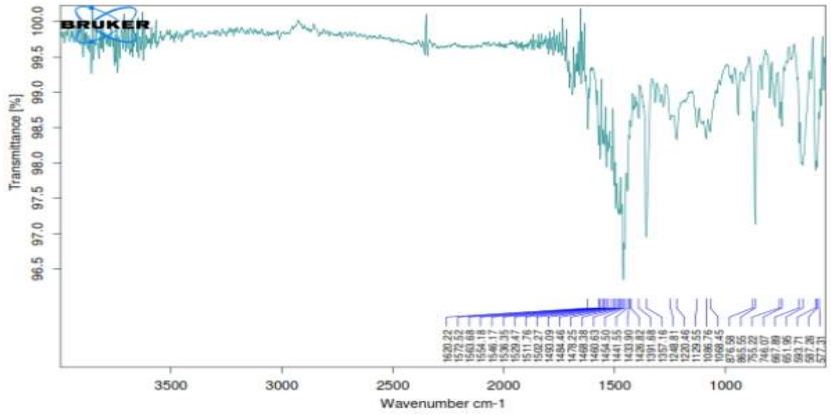

Fig 3: FTIR Peak of pure drug Chlorhexidine

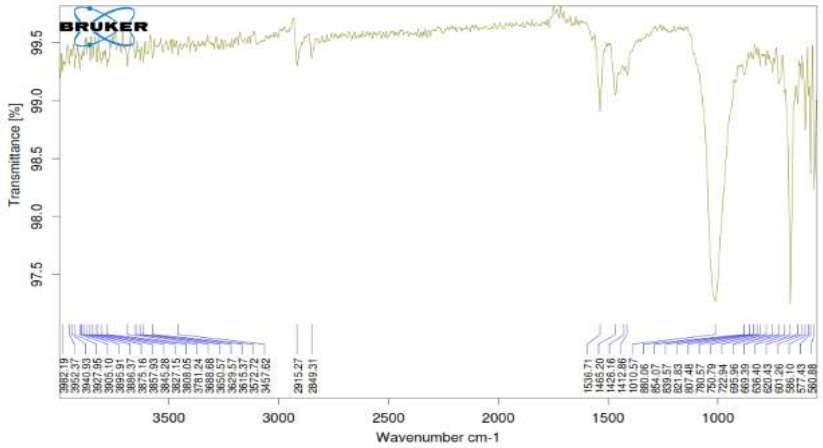

Fig 4: FTIR Peak of Optimised formulation

CONCLUSION

Mucoadhesive buccal tablets containing Chlorhexidine were prepared successfully by direct compression method by using different polymers like HPMC K15M. Tragacanth and Carbopol and were subjected to various evaluation parameters such as weight variation , Friability, Hardness, Drug content, swelling index, In-vitro drug release. It was revealed that tablets of all batches had acceptable physical parameters. FTIR studies revealed that there was no interaction between Chlorhexidine and other excipients used in tablets. Different polymers were selected on the basis of their effect on the retardation release of drug from tablet. The optimized formulation containing HPMC K15M with 99.58 %.

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