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FORMULATION AND EVALUATION OF MUCOADHESIVE BUCCAL TABLETS OF NICARIDIPINE BY USING NATURAL POLYMERS

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Abstract:

The present study aims to formulate and evaluate mucoadhesive buccal tablets of Nicardipine, a calcium channel blocker with low oral bioavailability due to extensive first-pass metabolism. To overcome this limitation, buccal drug delivery was explored using natural polymers — Cashew nut tree gum, Xanthan gum, and Karaya gum — known for their mucoadhesive and biocompatible properties.

Tablets were prepared by direct compression and evaluated for pre-compression parameters (angle of repose, bulk density, tapped density, Carr's index, Hausner's ratio) and post-compression parameters (hardness, friability, weight variation, surface pH, drug content, swelling index, mucoadhesive strength, and in vitro drug release). All parameters were found to be within acceptable pharmacopeial limits, indicating the suitability of the formulations. Among all the formulations, F4 showed the most promising results, with a controlled drug release of 99.95% over 8 hours, along with excellent mucoadhesive strength and tablet stability. The study concludes that mucoadhesive buccal tablets of Nicardipine using natural polymers provide an effective alternative for enhancing bioavailability and ensuring sustained drug release, thereby improving therapeutic efficacy and patient compliance.

Keywords: *Nicardipine, Cashew nut tree gum, Xanthan gum, and Karaya gum*

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1. 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

MATERIAL AND METHODS

Nicardipine Procured From Lark laboratories, Bhiwadi, India. Provided by SURA LABS, Dilsukhnagar, Hyderabad.
Cashew nut tree gum Zydus Cadila, Ahmedabad
Xanthan gum Acurate Pharma
Karayagum Sd fine Chem.Ltd. Mumbai
MCC Chemdie Corporation.
Magnesium stearate Chemdie Corporation.
Talc Sd fine Chem.Ltd. Mumbai
Saccharin sodium Sd fine Chem.Ltd. Mumbai

List of equipment used

10 Station Rotary Tablet punching Machine Lab Press
Electronic Weighing Balance Sartorious
Digital vernier calipers Mitutoyo
Screw guage Micrometer,Ahmadabad
Bulk density Apparatus Cintex industrial corporation, Mumbai.
Tapped Density Apparatus Electrolab, India
Hardness Tester (Monsanto) Monsanto
Rotary shaker Remi equipments Ltd
UV/Visible-spectrophotometer Lab India
Dissolution Apparatus (U.S.P) Lab India
Franz diffusion cell Borosil Glass Works Ltd

METHODOLOGY

Preformulation studies

Analytical method used in the determination of Nicardipine

Preparation of 0.2M Potassium Dihydrogen Orthophosphate Solution: Accurately weighed 27.218 gm of monobasic potassium dihydrogen orthophosphate was dissolved in 1000 mL of distilled water and mixed.

Preparation of 0.2M sodium hydroxide solution: Accurately weighed 8 gm of sodium hydroxide pellets were dissolved in 1000 mL of distilled water and mixed

Preparation of pH 6.8 phosphate buffer: Accurately measured 250 mL of 0.2M potassium dihydrogen ortho phosphate and 112.5 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 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 0.2, 0.4, 0.6, 0.8, 1, ml was taken separately and made up to 10 ml with phosphate buffer pH 6.8 to produce 2, 4, 6, 8, 10 µg/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 Nicardipine in phosphate buffer pH 6.8 was shown in fig 8.1.

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 0.2, 0.4, 0.6, 0.8, 1 ml were taken separately and made up to 10 ml with phosphate buffer pH 7.4, to produce 2, 4, 6, 8, 10 µg/ml respectively. The absorbance was measured at 280 nm using a UV spectrophotometer. Standard calibration curve values were shown in Table (8.2). The standard calibration curve of Nicardipine in phosphate buffer pH 7.4 was shown in fig 8.2.

Preparation of Tablets:

Then the powder blend was compressed into tablets by the direct compression method using 8mm flat faced punches. The tablets were compressed using a ten station LAB PRESS rotary tablet-punching machine. The weight of the tablets was determined using a digital balance and thickness with digital screw gauge. Composition of the prepared bio adhesive buccal tablet formulations of Nicardipine were given in Table 7.4.

Table 7.4: Formulation Chart

INGREDIENTS (MG)	FORMULATION CODES								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
Nicardipine	10	10	10	10	10	10	10	10	10
Cashew nut tree gum	10	20	30	-	-	-	-	-	-
Xanthan gum	-	-	-	10	20	30	-	-	-
Karaya gum	-	-	-	-	-	-	10	20	30
MCC	61	51	41						
Magnesium stearate	4	4	4	4	4	4	4	4	4
Talc	5	5	5	5	5	5	5	5	5
Saccharin sodium	10	10	10	10	10	10	10	10	10
Total weight	100	100	100	100	100	100	100	100	100

RESULTS AND DISCUSSION:

Solubility Studies:

Table 8.1: Solubility studies

S.No	Medium	Amount present (µg/mL)
1	Phosphate pH 6.8 buffer	98.12
2	Phosphate pH 7.4 buffer	96.53

Saturation solubility of Nicardipine in various buffers were studied and shown in the Table 8.1. The results revealed that the solubility of the Nicardipine was increased from pH 6.8 to 7.4. The solubility of the Nicardipine in phosphate buffer pH 6.8 is 98.12µg/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} 281 nm)

Standard graph of Nicardipine was plotted as per the procedure in experimental method and its linearity is shown in Table 8.2 and Fig 8.1. The standard graph of Nicardipine showed good linearity with R^2 of 0.999, which indicates that it obeys "Beer- Lamberts" law.

Table 8.2: Standard graph values of Nicardipine in pH 6.8 phosphate buffer

Concentration (µg/mL)	Absorbance
0	0
2	0.129
4	0.261
6	0.388
8	0.512
10	0.638

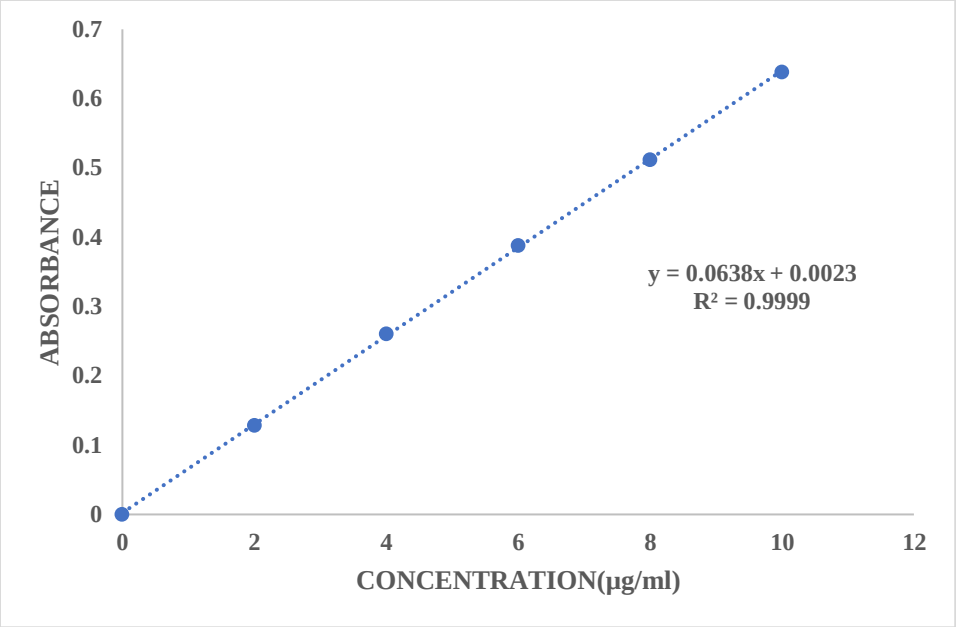

Fig 8.1: Standard graph of Nicardipine in pH 6.8 phosphate buffer

Standard graph in phosphate buffer pH 7.4 (λ_{max} 282 nm)

Standard graph of Nicardipine was plotted as per the procedure in experimental method and its linearity is shown in Table 4.3 and Fig 8.2. The standard graph of Nicardipine showed good linearity with R^2 of 0.999, which indicates that it obeys "Beer- Lamberts" law.

Table 8.3: Standard graph values of Nicardipine in pH 7.4 phosphate buffer

Concentration (µg/mL)	Absorbance
0	0
2	0.124
4	0.244
6	0.359
8	0.488
10	0.599

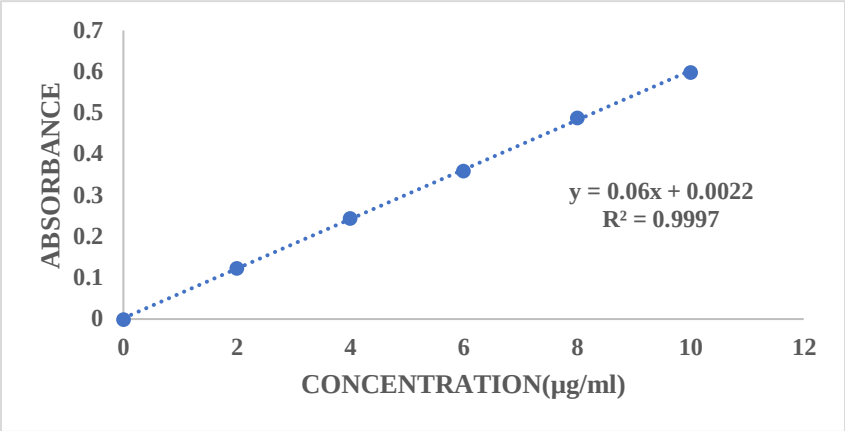

Fig 8.2: Standard graph of Nicardipine in pH 7.4 phosphate buffer

Evaluation:

Characterization of pre-compression blend: The pre-compression blend of Nicardipine 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 29.58º, Carr's index values were less than 16.07 for the pre-compression blend of all the batches indicating good to fair flowability and compressibility. Hausner's ratio was less than 1.19 for all the batches indicating good flow properties.

Table 8.4: 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
F1	28.75	0.481	0.572	15.90	1.18
F2	27.33	0.475	0.566	16.07	1.19
F3	25.38	0.524	0.599	12.52	1.14
F4	26.43	0.412	0.483	14.69	1.17
F5	24.77	0.488	0.537	9.12	1.10
F6	26.42	0.439	0.521	15.73	1.18
F7	28.19	0.559	0.649	13.94	1.16
F8	29.58	0.331	0.393	15.77	1.18
F9	28.73	0.362	0.428	15.42	1.18

Evaluation of buccal tablets:

Physical evaluation of Nicardipine 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 Nicardipine. Thus, all the physical attributes of the prepared tablets were found to be practically within control limits.

Table8.5: Physical evaluation of Nicardipine buccal tablets

Formulation code	Weight variation (mg)	Thickness (mm)	Hardness (Kg/cm^2)	Friability (%)	Content uniformity (%)
F1	98.47	2.01	3.9	0.56	96.10
F2	16.92	2.92	3.0	0.36	98.65
F3	19.30	2.35	4.3	0.24	99.10
F4	17.12	2.87	3.1	0.68	97.34
F5	18.82	2.28	4.2	0.59	98.58
F6	19.27	2.13	4.6	0.32	96.14
F7	100.04	2.79	3.1	0.77	99.82
F8	98.75	2.35	4.0	0.62	95.38
F9	97.80	2.60	3.8	0.43	98.76

***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 Nicardipine from different formulations varies with characteristics and composition of matrix forming polymers.

Table 8.6: *In vitro* dissolution data for formulations F1 – F9

TIME (H)	CUMULATIVE PERCENTE OF DRUG RELEASE								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
0.5	22.98	18.27	21.09	21.21	15.28	14.29	16.56	14.35	12.85
1	27.23	36.05	29.53	34.38	25.37	21.07	24.91	19.29	21.61
2	39.85	46.39	33.71	42.15	36.09	28.15	31.72	29.06	27.17
3	53.19	62.64	39.62	51.55	48.71	36.99	37.95	38.81	36.01
4	68.45	68.95	47.38	57.99	59.43	47.24	50.11	47.28	55.32
5	79.37	79.89	61.14	68.13	65.01	56.08	68.93	53.99	67.24
6	91.51	83.24	66.69	75.56	71.02	64.71	76.35	68.67	75.99
7	97.12	87.81	78.36	83.08	76.73	71.69	86.98	78.41	86.73
8		93.31	89.75	99.95	88.16	76.21	94.37	88.43	91.38

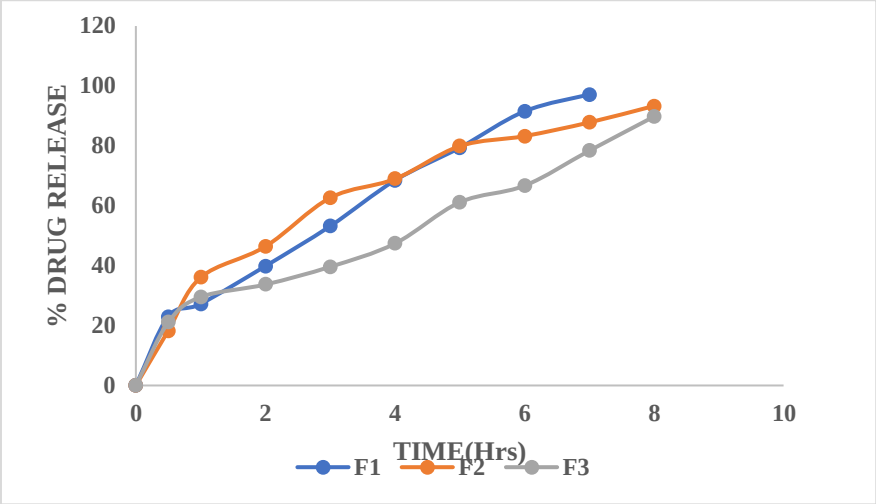

Fig 9.3: *In vitro* dissolution data for formulations F1 – F3 by using Cashew nut tree gum polymer

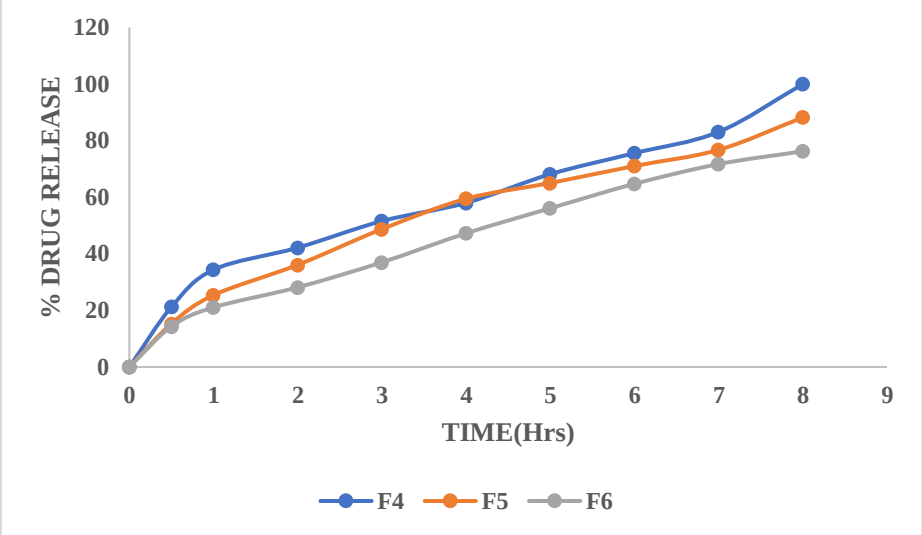

Fig 9.4: *In vitro* dissolution data for formulations F4 –F6 by using Xanthan gum polymer

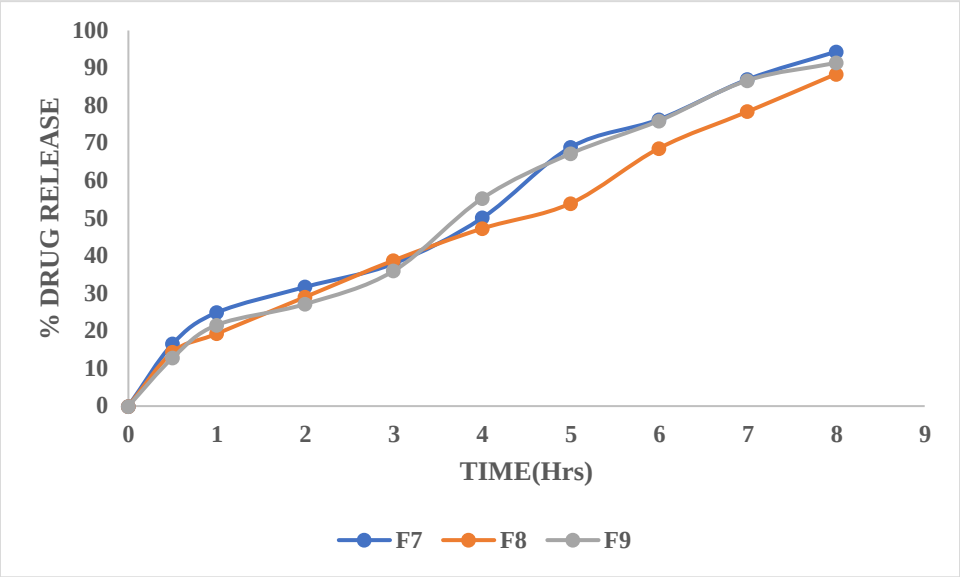

Fig 9.5: *In vitro* dissolution data for formulations F7- F9 by using Karaya gum polymer

From the above graphs it was evident that Cashew nut tree gum in the concentration of 20mg of polymer of the total tablet weight (F2) drug with other Two Formulations F1, F3. Where as in F2 formulation the quantity of polymer was less hence it showed more drug retardation with more drug release that is 93.31% in 8 hrs.

From the above graphs it was evident that Xanthan gum in the Polymer concentration of 20mg (F4) is showing better result 99.95% drug release when compared with other two formulations F5, F6, as the concentration of polymer increases the retarding of drug release decreased.

From the above graphs it was evident that Karayagum in the Polymer concentration 20mg formulation (F7) is showing better result 94.37% drug release when compared with other two formulations. Where as in F8, F9 formulations the concentration becomes high and the drug release was less.

Table 8.7: Moisture absorption, surface pH of selected formulations

Formulation Code	Moisture absorption	Surface pH
F2	88	5.12
F4	98	6.20
F7	96	6.09

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 F4 formulation 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 5.12 to 6.20 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 Nicardipine 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 8.8: Release kinetics and correlation coefficients (R^2)

CUMULATIVE (%) RELEASE Q	TIME (T)	ROOT (T)	%) REL	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
21.21	0.5	0.707	1.327	-0.301	1.896	42.420	0.0471	-0.673	78.79	4.642	4.287	0.355
34.38	1	1.000	1.536	0.000	1.817	34.380	0.0291	-0.464	65.62	4.642	4.033	0.608
42.15	2	1.414	1.625	0.301	1.762	21.075	0.0237	-0.375	57.85	4.642	3.868	0.774
51.55	3	1.732	1.712	0.477	1.685	17.183	0.0194	-0.288	48.45	4.642	3.646	0.996
57.99	4	2.000	1.763	0.602	1.623	14.498	0.0172	-0.237	42.01	4.642	3.476	1.165
68.13	5	2.236	1.833	0.699	1.503	13.626	0.0147	-0.167	31.87	4.642	3.170	1.471
75.56	6	2.449	1.878	0.778	1.388	12.593	0.0132	-0.122	24.44	4.642	2.902	1.740
83.08	7	2.646	1.919	0.845	1.228	11.869	0.0120	-0.081	16.92	4.642	2.567	2.074
99.95	8	2.828	2.000	0.903	0.452	12.494	0.0100	0.000	0.05	4.642	0.368	4.273

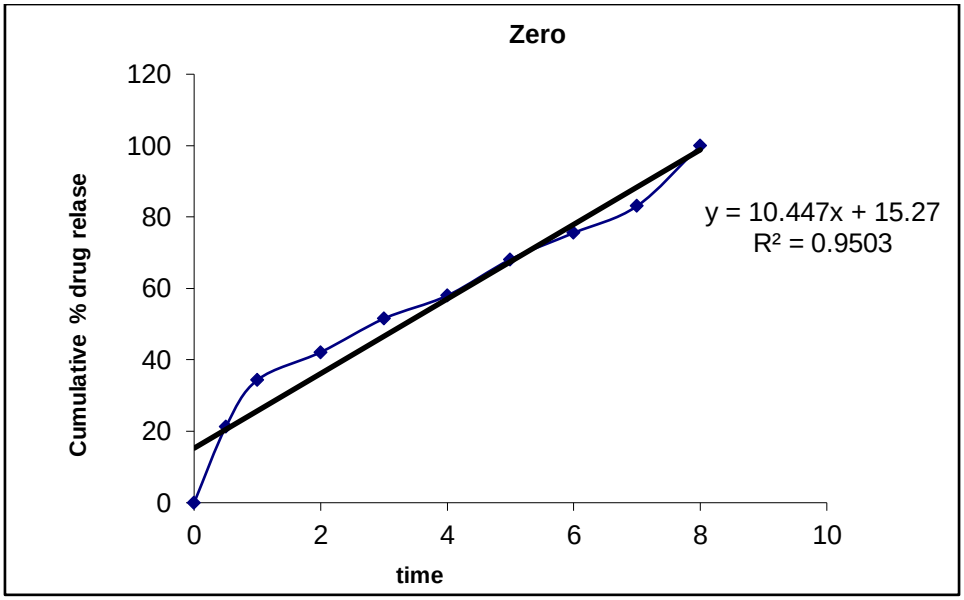

Fig 8.6: Zero order plot of optimized formulation

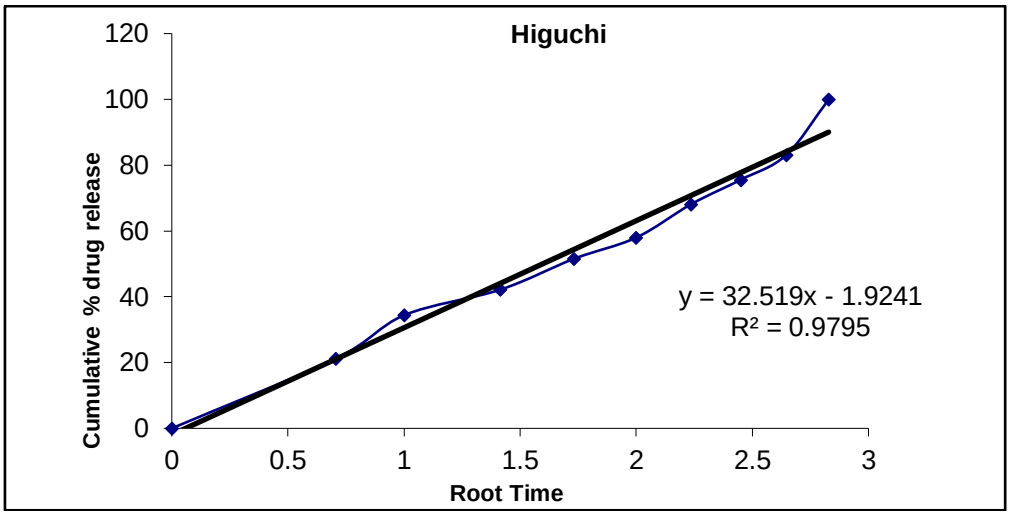

Fig 8.7: First order plot of optimized formulation

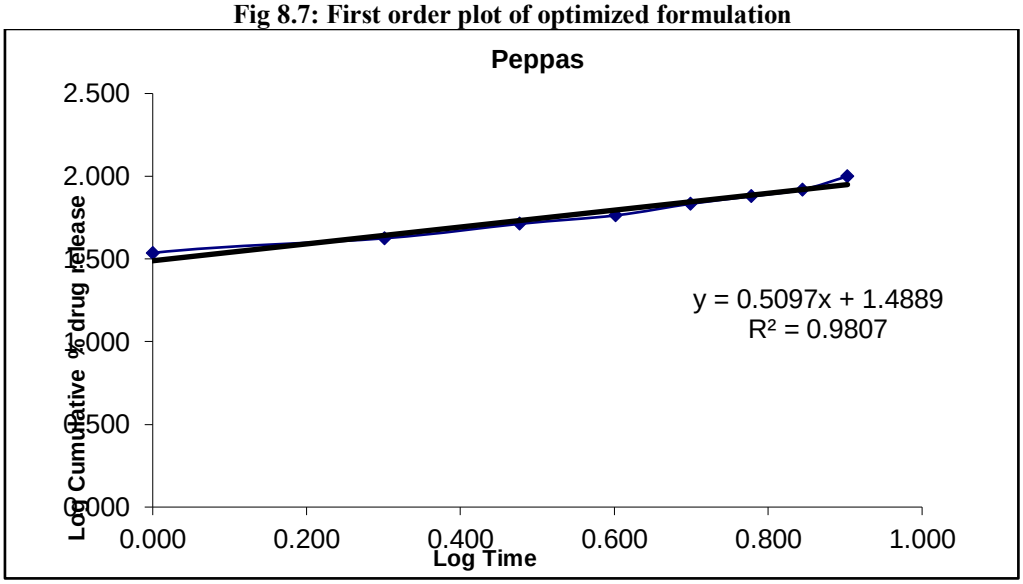

Fig 8.8: Higuchi plot of optimized formulation

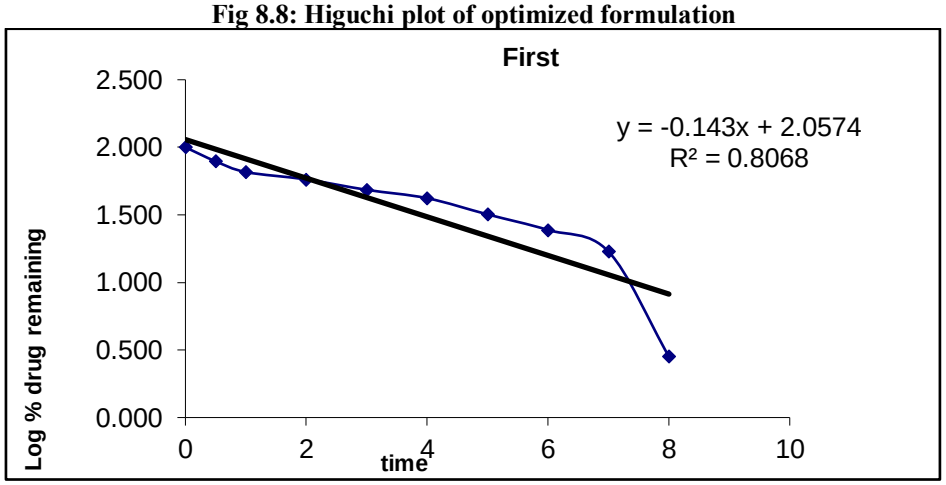

Fig 8.9: Kores Meyer-peppas plot of optimized formulation.

This formulation was following Higuchi release mechanism with regression value of 0.972.

Drug – excipient compatibility studies by physical observation:

Nicardipine 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 Nicardipine drug, drug with polymers (1:1) shown in the below figures respectively. The major peaks which are present in

pure drug Nicardipine 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.

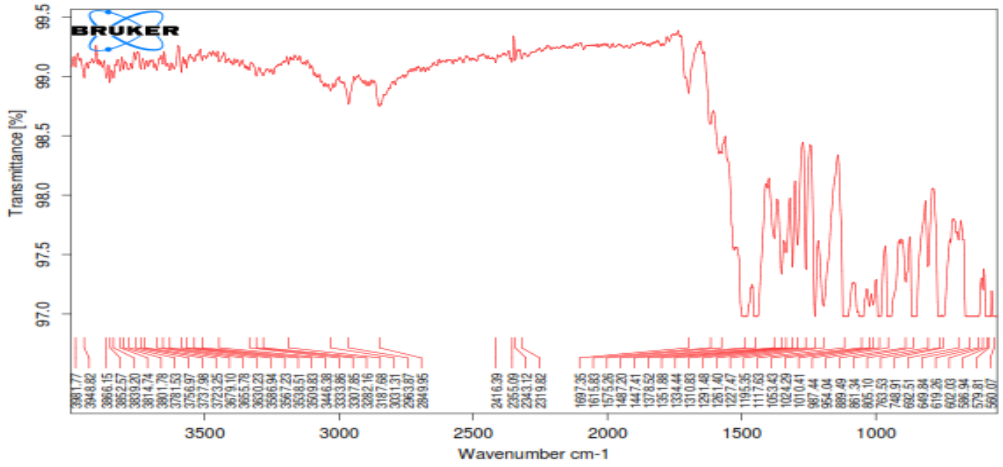

Fig 8.10: FTIR Peak of pure drug Nicardipine

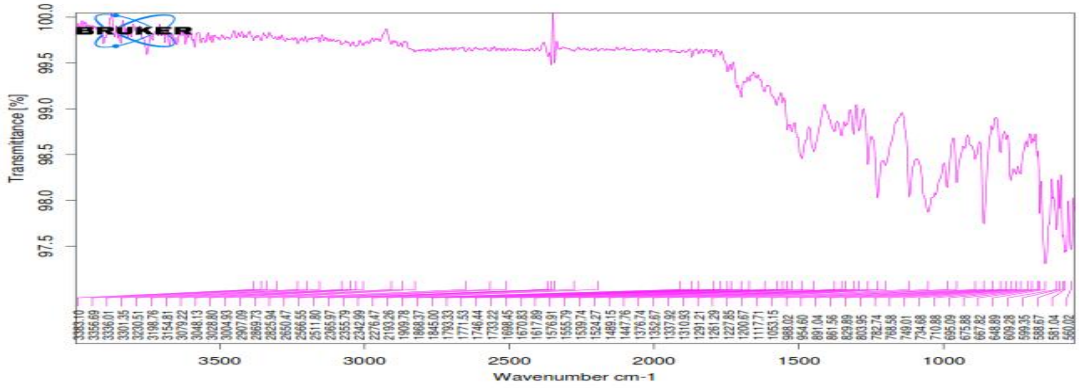

Fig 8.11: FTIR Peak of Optimized formulation

CONCLUSION:

The present study successfully demonstrated the formulation and evaluation of mucoadhesive buccal tablets of Nicardipine using natural polymers such as [insert specific natural polymers used, Cashew nut tree gum, Xanthan gum and Karaya gum.. The prepared formulations were evaluated for various physicochemical parameters including hardness, friability, weight variation, surface pH, swelling index, drug content, mucoadhesive strength, and in vitro drug release.

Among the various formulations, F4exhibited optimal results, showing satisfactory mucoadhesive strength, sustained drug release over 8 hours indicating its potential for effective buccal delivery of Nicardipine. The use of natural polymers not only enhanced the bio adhesion but also ensured biocompatibility and safety for mucosal administration.

Overall, this study highlights the feasibility of using natural mucoadhesive polymers for developing buccal tablets of Nicardipine, which may offer a promising alternative to conventional oral administration by improving patient compliance, avoiding first-pass metabolism, and achieving controlled drug release.

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