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FORMULATION AND EVALUATION OF A LACOSAMIDE MUCOADHESIVE BUCCAL TABLETS

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ABSTRACT

This study focuses on the formulation and evaluation of mucoadhesive buccal tablets containing lacosamide, an antiepileptic drug, to enhance its bioavailability and provide sustained therapeutic effects. Buccal delivery offers advantages such as bypassing first-pass metabolism, rapid onset, and improved patient compliance. Due to lacosamide's low oral bioavailability and short half-life, buccal tablets were prepared using natural and synthetic polymers to optimize mucoadhesion, drug release, and mechanical properties. Polymers including Carbopol 934 and Hydroxypropyl methylcellulose (HPMC) were evaluated for mucoadhesive strength and controlled release. Tablets were formulated by direct compression and assessed for hardness, friability, weight variation, thickness, Swelling index drug content uniformity and surface pH. In vitro mucoadhesion and drug release studies were conducted under simulated buccal conditions. The optimized Carbopol 934 and HPMC-combination based formulation (F1) showed strong mucoadhesive properties compatible with buccal mucosa and released 95% of lacosamide within one hour. Comparative studies with the marketed product (Lacosam 50®) confirmed the formulation's potential as an effective buccal delivery system. Further in vivo pharmacokinetic and pharmacodynamic studies are recommended to validate its clinical efficacy.

KEYWORDS: Lacosamide, Buccal tablets, Mucoadhesive, Swelling index, HPMC, Carbopol 934.

INTRODUCTION

With its ease of use, self-administration, precise dosage, flexible and controlled schedules, high patient compliance, and low risk of administration problems, the oral route is the most popular and frequently advised drug delivery technique.[1]

Mucoadhesive drug delivery system

Mucoadhesion has attracted a lot of interest in pharmaceutical technology since the 1980s. It describes the connection made between a substance and a biological surface that is maintained by interfacial forces like interlocking mechanisms or valence interactions. Mucoadhesive drug delivery methods improve medication absorption and therapeutic efficacy by extending the duration of dosage forms' residency at the application site. While mucoadhesion refers specifically to adherence with mucosal surfaces, bioadhesion, a more general term, refers to adhesion between synthetic or natural polymers and biological surfaces. By using channels such as buccal, oral, vaginal, rectal, nasal, and ocular delivery, these systems provide localized medication delivery and enhanced systemic control. In order to improve drug performance, mucoadhesive techniques use polymers to provide extended contact with mucosal tissues.[2]

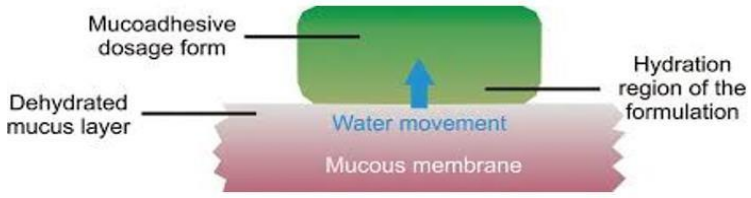


Fig. 1: Interaction of mucous membrane with mucoadhesive dosage form.

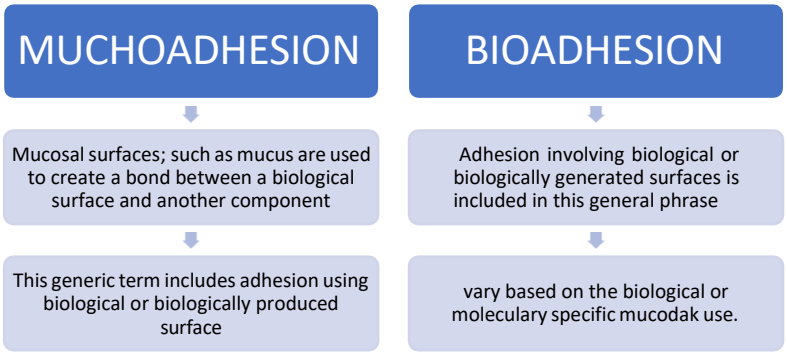


Fig. 2: Flow chart of adhesion.

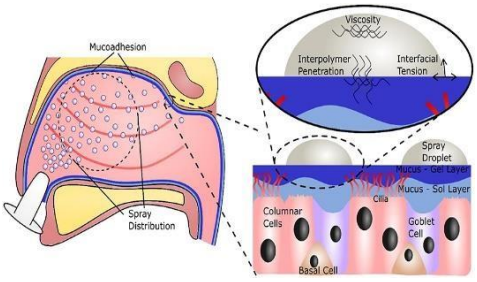


Fig. 3: Mucoadhesion representation Buccal drug delivery system.

One of the most researched dosage forms for buccal drug administration is buccal tablets. These tablets usually have an oval form, are flat, and have a diameter of 5-8 mm. Buccal mucoadhesive tablets, in contrast to regular tablets, do not substantially impair speech or drinking. When they come into touch with saliva, they become softer, stick to the

mucosal surface, and stay there until the medication is completely dissolved or released. The palate, the inner cheek lining, or the space between the lip and gums are some of the oral cavity surfaces where these tablets can be placed. For successive administration, they can also be positioned alternatively on either side of the mouth.[2,3]

Figure 4: Administration of buccal tablet Mucoadhesive dosage forms.

Tablets

Small and oval (5–8 mm), mucoadhesive tablets stick to mucosal tissues and provide improved bioavailability, regulated medication release, and effective absorption. They offer longer drug release, fewer doses, systemic or localized effects, and better patient compliance. Their rigidity, however, may restrict comfort during extended use.[3]

Films

Mucoadhesive films solve the short residence duration of oral gels and provide more comfort and flexibility than tablets. They lessen discomfort, shield the surfaces of wounds, and improve oral disease therapy. For pleasant, efficient use, ideal films should be robust, flexible, elastic, and have good adherence without causing undue swelling.[4]

Patches

Like transdermal systems, mucoadhesive patches are made up of a mucoadhesive layer, a drug reservoir, and an impermeable backing. They are made by either direct milling (mixing and compressing components) or solvent casting (casting drug-polymer solution and evaporating solvent). During use, the backing layer keeps the device intact, regulates drug release, and guards against loss.[5]

Gels and Ointments

Gels and ointments are examples of semisolid formulations that distribute readily on the oral mucosa but lack precise dosing. Carbopol, hyaluronic acid, and sodium CMC are examples of polymers that improve viscosity, retention, and sustained release. Hydrogels provide prolonged action and patient comfort by encasing medications in hydrated polymers for slow diffusion or erosion. Antimicrobials are delivered into gum pockets by these formulations, which effectively treat periodontitis. Up to eight hours of adherence are guaranteed by components like hydroxypropyl cellulose and HPMC.[2,3,6]

MATERIALS AND METHODS

Lacosamide obtained as a gift sample, Sodium bicarbonate, Hydroxypropyl methylcellulose, Carbopol 934, Magnesium stearate, Talc of analytical grade and distilled water as required

Method of Preparation

Preparation of a calibration curve for lacosamide[12-13]

The pH 6.8 phosphate buffer solution was used to create the lacosamide calibration curve.

Preparation of stock solution

In a volumetric flask, 50 milligrams of lacosamide were carefully weighed, dissolved in methanol, and the volume was then adjusted to 100 millilitres using the same solvent.[9]

Preparation of phosphate buffer solution pH 6.8

Melt 35.084 g of disodium hydrogen phosphate and 13.872 g of potassium dihydrogen phosphate in enough water to make 1000 millilitres Keep cold.[10]

Preparation of working standard solutions

From the stock solution 0.5,1,1.5,2,3,3.5ml were pipette out and the volume was made up to 100ml with phosphate buffer solution of pH 6.8 to produce concentrations of 5,10,15,20,25,30,35 respectively. A scan was performed in order to determine the max and the absorbance of diluted solution was measured at the max obtained using spectrophotometer against blank buffer solution of PH 6.8 as the blank. The max was found to occur 210 nm. The findings are reported, and the absorbance was plotted against the to create a calibration curve. quantity of lacosamide present. A regression equation was derived from the plot, which was used for the estimation of lacosamide in phosphate buffer solution of pH 6.8. The method obeyed beer's law in concentration range of 5-50 ml and is suitable for the estimation of lacosamide from different sample solutions.[4,5,11]

METHODOLOGY

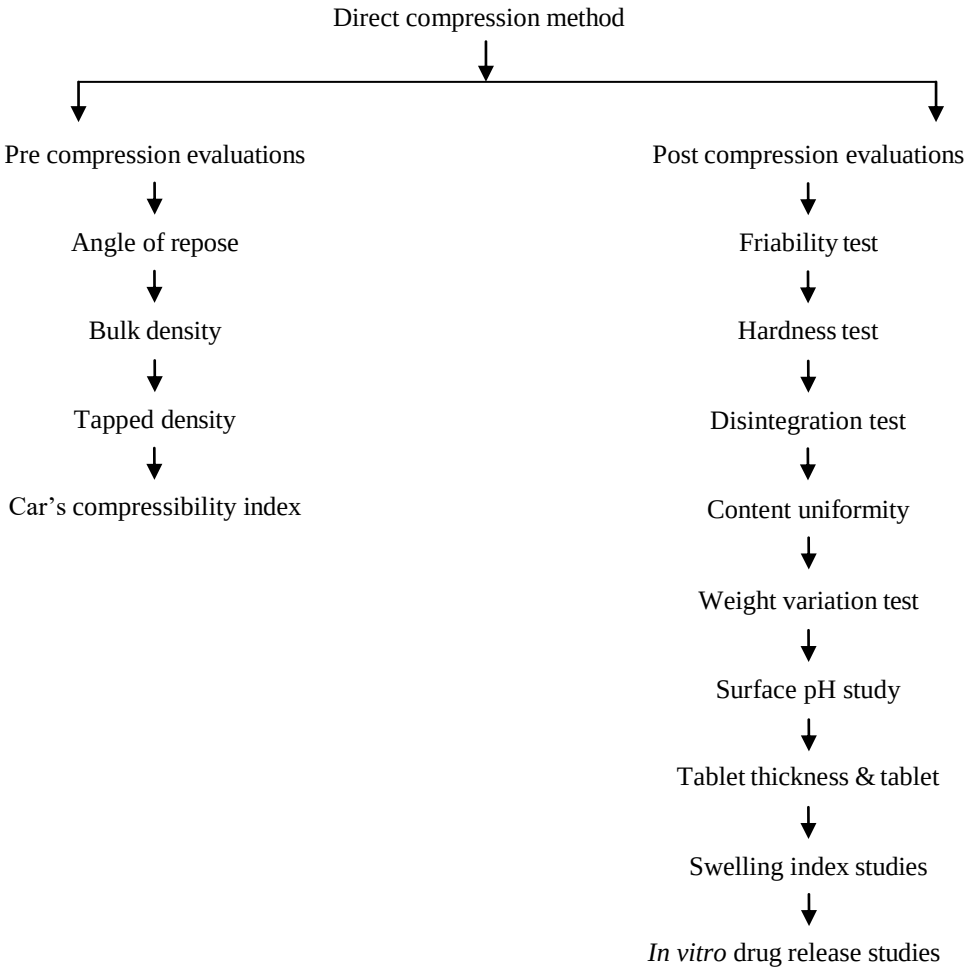
Preparation of lacosamide mucoadhesive tablets

- The mucoadhesive buccal tablets was formulated using direct compression method.
- By using varying proportions of different grades of polymer. All the powders in pure form were accurately weighed All ingredients passed through a sieve with mesh number 60.
- The mixture was compacted into tablets that weighed 250 mg on average. The tablets were made by compressing the blended powder with a compression machine.[5]

Table 1: Formulation of mucoadhesive buccal lacosamide tablets.

Ingredients(mg)	F1	F2	F3	F4
Lacosamide	150	150	150	150
HPMC	60	20	80	0
Carbopol 934	20	60	0	80
Sodium Bicarbonate	40	40	40	40
Magnesium stearate	q. s	q. s	q. s	q. s
Talc	q. s	q. s	q. s	q. s

Compression evaluation flow chart



Compression Evaluations Angle of repose

$$\theta = tan^{-1}\left(\frac{h}{(r)}\right)$$

Where, "h" stands for height of pile, "r" stands for base of the pile[6]

Bulk density

$$Pb = M/Vb$$

Where, "pb" stands for apparent bulk density, "M" stands for weight of the powder to be measured, and bulk volume by "Vb".[7]

Tapped density

$$Pt = M/VI$$

Where "pt" stands for tapped density, "M" is made for measurements of weight of the co- processed blend and the minimum volume "VI".[9]

Car's compressibility index

$$CI = \frac{(Vo - V)}{(Vo \times 100)}$$

Where "CI" is car's compressibility index "vo" is the starting volume and "V" is the tapped density.[7]

Post compression evaluations

Hardness test

Twenty (n=20) tablets were taken for hardness test every tablet is placed in between two probes, one of which was stationary and the other was moving. Subsequently, the movable probe was used to apply force, and the force needed to break the table was measured.[8-10]

Friability test

$$\% \text{ Friability} = \frac{Initial\ Weight - Final\ Weight}{Initial\ Weight}\ X\ 100$$

The above formula was used to determine the percent friability: new formulations should have a percent friability of no more than 0.8%.[9]

Swelling index studies: Three tablets from each batch were weighed independently (W1) and put in separate petri plates with five milliliters of pH 6.8 phosphate buffer. They were withdrawn from the petri dish at intervals of 1, 2, 4, and 8 hours, and filter paper was used to remove any extra water. Each tablet's percentage of hydration was determined by reweighing the swollen tablets (W2).[15]

$$Swelling\ index = \frac{W2 - W1}{W1}\ X\ 100$$

In Vitro drug release study

Mefenamic acid in vitro drug release investigations were carried out at 50 rpm and 37 ± 0.5°C utilizing a paddle-type USP dissolving equipment and phosphate buffer (pH 6.8) as the medium. Five milliliters of samples were taken out and replaced with new buffer every 15, 30, 45, 60, 90-, 120-, 150-, and 180-minute intervals. A UV spectrophotometer set at 279 nm was used to measure the drug's concentration.[12,13-14]

RESULTS AND DISCUSSION

Calibration curve of lacosamide

The λ max was found to occur at 210 nm. The results are tabulated in Table 2. A calibration curve was constructed by plotting the absorbance against the concentration of lacosamide.

Table 2: UV absorbance values of lacosamide.

Concentration (µg/ml)	Absorbance (nm)
0	0
2	0.341±0.2
4	0.574±0.1
6	0.784±0.2
8	0.998±0.4
10	1.246±0.6

*Each value of absorbance indicated with S.D (n=3)

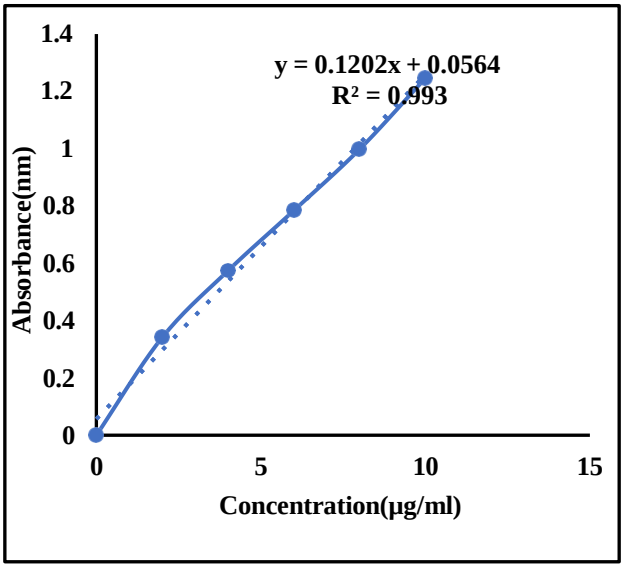


Fig 8: Calibration curve of lacosamide in phosphate buffer PH 6.8.

The correlation value (R) was found to be 0.993 indicating a positive correlation between the concentration of lacosamide and the corresponding absorbance values. The regression line describes the relation between the concentration and absorbance was as follows. Y= 0.1202x + 0.0564 where, Y is the absorbance at 210 nm and X is the concentration of lacosamide in µg/ml.

Compatibility studies

FTIR

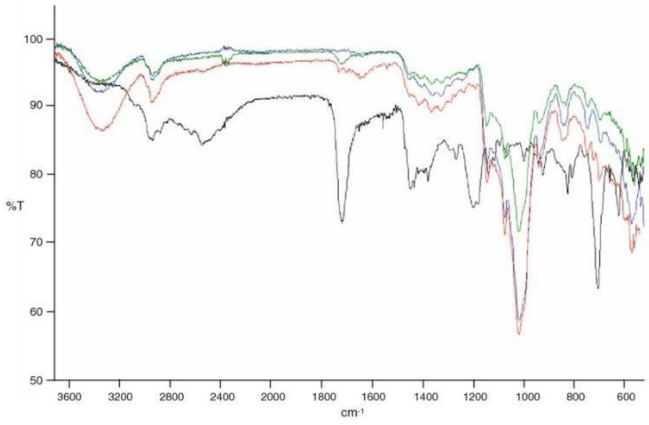


Fig 9: FTIR of Lacosamide.

Functional group	Wavelength range	Type of vibration
O-H	3600	Stretching
C-H	3000	Stretching
C-C	1600	Stretching
C-H	1500	Bending

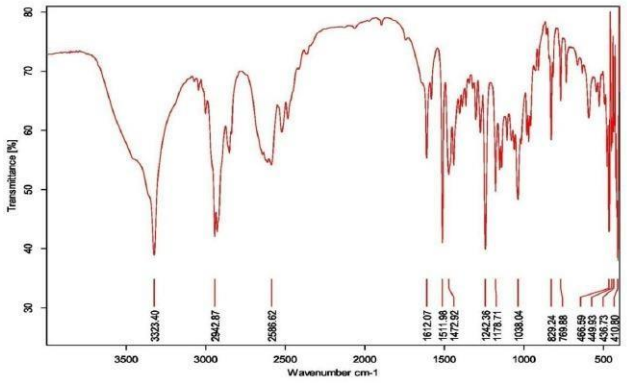


Fig. 10: FTIR of optimized formulation.

Functional group	Wavelength range	Type of vibration
O-H	3233	Stretching
C-H	2942	Stretching
C-C	1519	Stretching
C-H	1451	Bending

We performed FTIR spectroscopy on both the medication and its enhanced formulation. The drug's spectrum and that of the manufactured buccal mucosomal tablets did not significantly differ in terms of shifts or loss of functional peaks, according to the data.

Precompression evaluations results

From the results of precompression evaluation study in table 3 it was concluded that all the prepared batches were in the specified limits. Then the prepared powder blends were subjected to compression for formulating buccal lacosamide tablets.

Table 3: Pre compression parameters of the prepared lacosamide orally disintegrating tablets.

Formulation Code	Bulk density (g/cc)	Tapped density(g/cc)	Car's index	Hauser's ratio	Angle of repose (θ)
F1	0.37± 0.04	0.42 ±0.02	13.3± 0.18	1.15 ±0.01	24.53± 0.21
F2	0.36±0.03	0.40±0.02	10.0±0.15	1.11±0.02	24.45±0.19
F3	0.34± 0.01	0.41 ±0.01	12.5± 0.02	1.12 ±0.05	24.33 ±0.21
F4	0.35±0.02	0.43±0.01	18.6±0.20	1.23±0.03	25.00±0.25

Post compression parameters results

Table 4: Evaluation data of the prepared lacosamide orally disintegration tablets.

Formulation code	Thickness (mm)	Hardness (kg/cm^2)	Weight variation (%)	Friability (%)	Drug content	Surface pH	Disintegration time (sec)
F1	3.7± 0.01	5.3± 0.20	0.25	1.19± 0.05	95±0.8	6.9 ±0.08	39 ±1.4
F2	3.5±0.02	5.0±0.22	0.24	0.95±0.04	88±0.7	6.7±0.07	35±1.2
F3	3.2± 0.01	4.5 ±0.18	0.23	0.66 ±0.03	78±0.6	6.3± 0.08	31± 1.0
F4	3.6±0.02	4.8±0.19	0.26	1.05±0.04	92±0.9	6.8±0.09	37±1.3

Swelling index: The swelling index of four batches up to 8hrs as listed in tablet 5.

Table 5: Swelling index of batches.

Formulation	Swelling index			
	1hr	2hr	4hr	8hr
F1	47.6	59.6	65.5	79.4
F2	26	34.2	46.2	58.8
F3	23.6	39.92	41.8	59.4
F4	26.4	37.6	43.6	54.5

In vitro dissolution study

Dissolution studies were conducted for the batches (F1, F2, F3, F4) from the results it was found that the tablets which prepared by using F1formulation has the best drug release rate (95.1%) compared to other batches. When compared to marketed tablets and directly compressed tablets, the dissolution rate of buccal tablets is more and less affected by the P^H deviation on drug release.

Table 6: Values of *in vitro* dissolution profile of lacosamide buccal tablet.

Time(min)	% Cumulative drug release			
	F1	F2	F3	F4
0	0	0	0	0
15	20.2	18.2	13.5	11.2
30	35.2	27.3	22.7	18.4
45	44.3	32.6	36.3	25.1
60	56.3	47.4	47.9	32.4
75	68.4	52.7	54.8	45.7
105	75.5	62.3	62.3	54.5
120	87.7	73.6	71.4	62.3
135	95.1	82.2	78.3	71.4

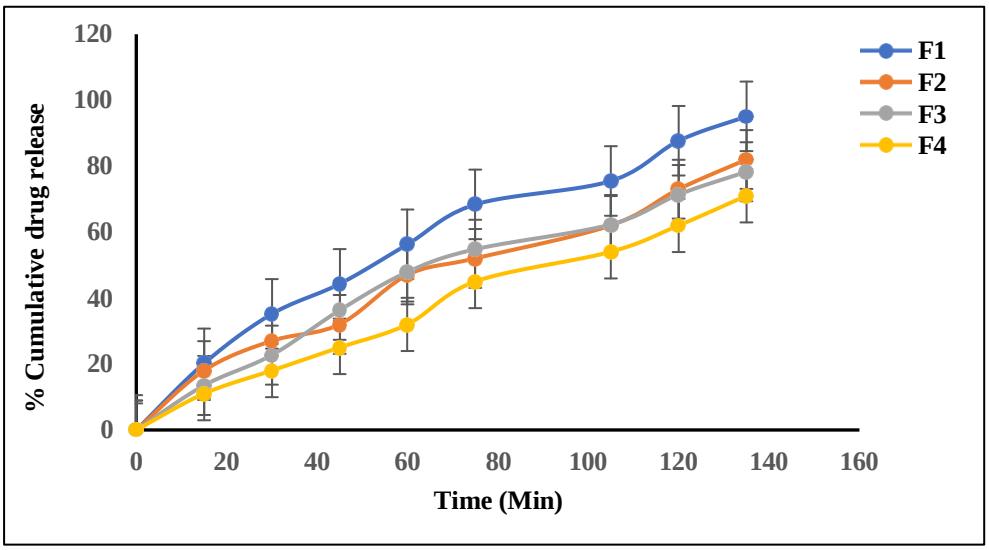


Fig. 11: *in vitro* dissolution profile of formulated lacosamide buccal tablet.

Comparison of optimized formulation of lacosamide and conventional marketed formulation

The *in vitro* drug release profile of the selected formulation F1 was first compared with the conventional marketed formulation of lacosamide. From the results it was found that buccal tablet formulation F1 exhibited better dissolution profile and maximum drug release close to marketed tablet. From the result of comparison study, the F1 batch had a better dissolution rate 95.1%. Hence it can be concluded that the increased dissolution rate of F1 formulation may be attributed due to the adopted mucoadhesive buccal tablet.

Table 7: *In vitro* dissolution profile of lacosamide buccal tablet formulation 1 and marketed formulation.

S. No	Formulation 1	Marketed product
1	20.2 ±0.15	25.4 ±0.25
2	35.2 ±0.19	37.64±0.32
3	44.3 ±0.14	45.7 ±0.63
4	56.3 ±0.48	58.9±0.59
5	68.4 ±0.38	69.6 ±0.51
6	75.5 ±0.23	76.4 ±0.45
7	82.6 ±0.22	83.6 ±0.28
8	87.7 ±1.01	90.7 ±0.17
9	95.1 ±0.17	97.8 ±0.91

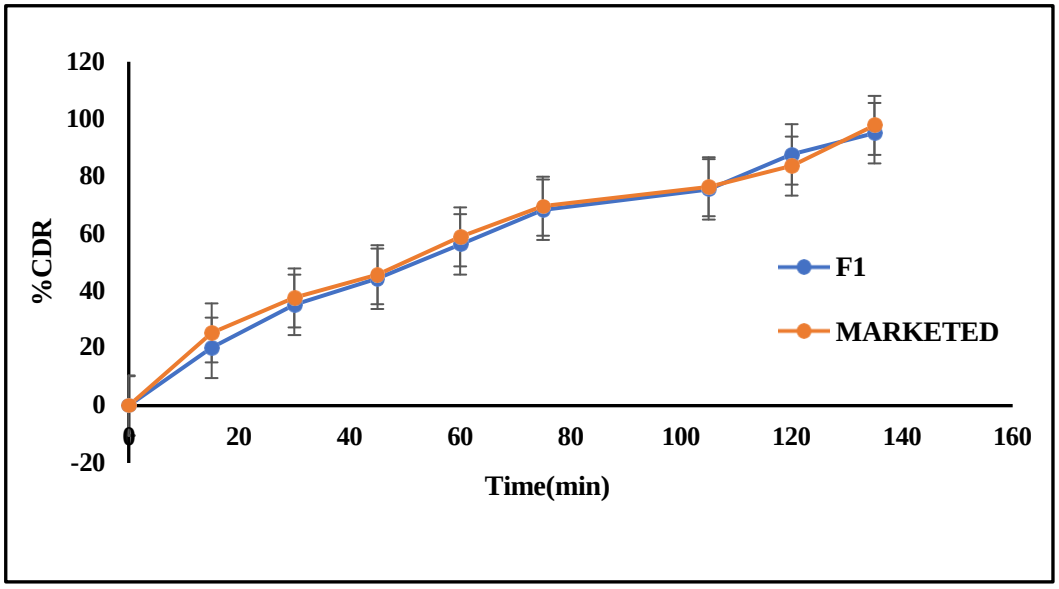


Fig 12: In vitro dissolution of lacosamide and conventional lacosamide tablet.

SUMMARY

The thickness of the tablet and hence its total weight must be appropriate in order to obtain good mucoadhesion. As the mucoadhesive property is also dependent on the geometry of the dosage form, the hardness of lacosamide buccal tablets is low, but the friability data suggests that the tablets are quite robust enough to withstand the normal handing. There is negligible or no change in the surface pH of the tablets. Hence, no irritation to the buccal cavity is assumed.

The formulation that was successful has an effective dissolving profile and, according to the regression value, a zero-order drug release profile. Slow, controlled and maximum release of lacosamide over a period of 3 h was obtained from buccal tablets F1 formulation containing HPMC. Further work is to be carried out in order to determine its efficacy and safety by long term pharmacokinetic and pharmacodynamic studies in human beings.

CONCLUSION

Drug was mixed with different quantity of Carbopol 943, HPMC and combinations were employed. Out of several polymer combinations, the best polymer composite was chosen for preparation of buccal tablets. Drug with HPMC and Carbopol 943 combination of F1 showed increased buccal tablets' mucoadhesive strength than the drug with Carbopol and HPMC. In terms of criteria including thickness, hardness, drug content, in vitro dissolution the optimized polymer composite showed promising results with F1 formulation. Comparative invitro drug release studies were done with marketed drug. The buccal method of administration improves the medicines' bioavailability and provides a quick onset

of effect. The thesis work highlights in the development and assessment of buccal drug delivery system of lacosamide to reduce gastrointestinal adverse effects and facilitate non-invasive oral administration. The future work entails adjusting formulation techniques, such as adding permeability enhancers, pH modifiers, and enzyme inhibitors can able to enhance bioavailability of mucosomal buccal drug delivery.

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