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Formulation and development of Mucoadhesive tablets of Lamivudine by direct compression technique

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ABSTRACT

The goal of the present work is to outline mucoadhesive tablets of lamivudine for oral controlled discharge by direct pressure utilizing diverse folios. Lamivudine is against viral medication utilized as a part of the treatment of hepatitis B and HIV contaminations. It has a shorter half-existence of 2-6 hrs, oral accessibility is 86% and it is dispensed with quickly from the plasma compartment inside of couple of hours. Along these lines, successive organization is important to keep up its helpful focus. So as to keep up the helpful centralizations of lamivudine changed discharge details are vital. In the present work the mucoadhesive tablets of lamivudine was arranged to delay the home time at the site of use (or) retention and to encourage the close contact with the basic ingestion surface to enhance and improve the bioavailability. The mucoadhesive tablets of lamivudine were arranged by utilizing Carbopol, Hydroxy propyl methylcellulose, xanthan gum.

INTRODUCTION

Lamivudine (2(1H)-Pyrimidinone, 4-amino-1-[2-(hydroxymethyl)-1,3-oxathiolan-5-yl]-(2R-cis)-. (-)-1-[(2R, 5S) -2-(Hydroxymethyl)-1,3-oxathiolan-5-yl]cytosine.) is a white to off-white crystalline solid with a solubility of approximately 70 mg/mL in water at 20°C. Lamivudine is antiviral drug used in the treatment of hepatitis B and HIV infections [1-2].

It has a shorter half-life of 2-6 hrs, oral availability is 86% and it is eliminated rapidly from the plasma compartment within few hours. Prescribed dose is 300 mg daily, administered as either 150 mg twice daily or 300 mg once daily. Lactic acidosis and severe hepatomegaly with steatosis [3], Hepatic decompensation in patients co-infected with HIV-1 and Hepatitis C, Pancreatitis are side effect of Lamivudine [4].

MUCOADHESIVE DRUG DELIVERY SYSTEMS

Mucoadhesive medication conveyance frameworks delay the residency time of the measurement structure at the site of use or assimilation and encourage a close contact of the dose structure with the fundamental ingestion surface and along these lines add to enhanced and/or better remedial execution of medications. The potential site for connection of any bioadhesive framework or mucoadhesive frameworks incorporates buccal, oral, vaginal, rectal, nasal and visual destinations as these contain the mucosal covering layer [5, 6]. The term bioadhesion alludes to any security framed between two organic surfaces or a security between a natural and an orderly surface. On account of bio glue drug conveyance frameworks, the term bioadhesion is commonly used to portray the grip between polymers, either manufactured or characteristic, and delicate tissue (i.e., gastrointestinal mucosa). In spite of the fact that the objective of numerous bio glue conveyance frameworks may be a delicate tissue cell layer (i.e., epithelial cells), the real cement bond may frame with either the cell layer, or a mucous layer, or a mix of the two [7-10].

In occasions in which bonds shape in the middle of bodily fluid and polymer, the term mucoadhesion is utilized synonymously with bioadhesion. As a rule, bioadhesion is a comprehensive term used to portray cement associations with any organic or naturally inferred substance, and mucoadhesion is utilized just when depicting a bond including bodily fluid or a mucosal surface [8, 9, 2 - 4].

MECHANISMS OF BIOADHESION

The mechanisms responsible for the formation of bioadhesive bonds are not completely clear. In order to develop ideal bioadhesive drug delivery systems, it is important to describe and understand the forces that are responsible for adhesive bond formation [10 - 15]. Most research has focused on analyzing bioadhesive interactions between polymer hydro gels and soft tissue [16]. The process involved in the formation of such bioadhesive bonds has been described in three steps:

1. Wetting and swelling of polymer to permit intimate contact with biological tissue,
2. Interpenetration of bioadhesive polymer chains and entanglement of polymer and mucin chains,
3. Formation of weak chemical bonds between entangled chains.

MUCOADHESIVE POLYMERS

Mucoadhesive polymers are water insoluble and water dissolvable polymers which are swellable systems joined by cross-connecting specialists [17 - 19]. The polymer ought to have ideal extremity to verify that it is adequately wetted by the bodily fluid and ideal smoothness that allows the shared adsorption and interpenetration of polymer and bodily fluid to occur. A perfect polymer for a mucoadhesive medication conveyance framework ought to have non dangerous [20], non-aggravation and nonabsorbable from the gastrointestinal tract. What's more, it ought to stick rapidly to wet tissue and ought to have some site specificity. The polymer ought to permit simple consolidation of the medication [21] and must not decay on capacity or amid rack life of the dose structure [22 - 29]. What's more, it ought to ideally shape a solid non covalent bond with the mucin epithelial cell surfaces.

METHODS

Construction of Standard Curve of Lamivudine

Lamivudine can be estimated spectrometrically at 270 nm as it obeys beer-lambert's law. Stock solution is 100mg of lamivudine was dissolved in 100ml of 0.1 N HCl, so as to get a solution 1000 µg/ml concentration [30, 31].

Standard solution

10ml of stock solution was made to 100ml with 0.1 N HCl thus giving a concentration of 100 µg/ml. Aliquot of standard drug solution ranging from 4ml to 24 ml were transferred in to 10ml volumetric flask and were diluted up to the mark with 0.1 N HCl. Thus the final concentration ranges from 4-24 µg/ml. Absorbance of each solution was measured at 270 nm against 0.1 N HCl as a blank. A plot of concentrations of drug versus absorbance was plotted.

Table 1: Standard curve of Lamivudine in 0.1 N HCL

S No	Concentration (mcg/ml)	Absorbance at 270 nm
1	0	0.000
2	4	0.060
3	8	0.103
4	12	0.160

5	16	0.216
6	20	0.267
7	24	0.307

Slope : 0.0129, Regression : 0.9989

Calibration curve

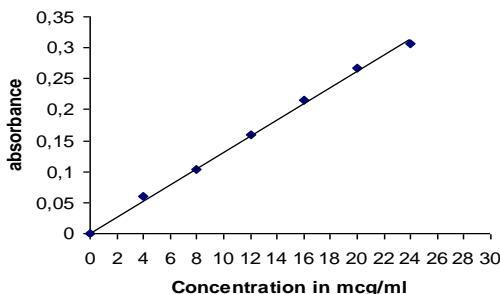


Figure 1: Calibration Curve

COMPATIBILITY STUDY

The medication was distinguished and affirmed by FTIR range. Fig 02 demonstrated the IR range of lamivudine. Fig 03 and Fig 04 demonstrates the IR range of the polymer Ethylcellulose and Hydroxy propyl methylcellulose separately. Fig 03 demonstrates the IR range of the physical blend of Carbopol, hydroxy propyl methylcellulose, xanthan gum and the medication lamivudine [28-31]. From the Fig 13 it was inferred that the medication alongside the polymer demonstrated no adjustment in any trademark crest of the medication, which affirms that there is no collaboration between the medication and the polymer [31 - 37].

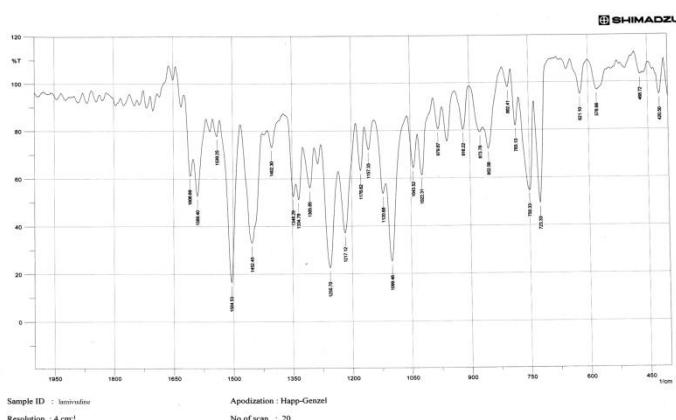


Figure 2: FTIR (KBr) spectrum of Lamivudine (Pure drug).

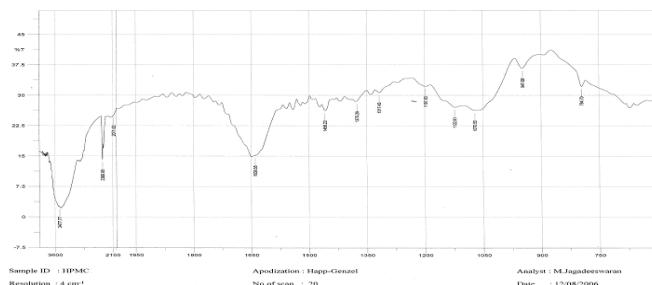


Figure 3: FTIR (KBr) spectrum of Hydroxy propyl methylcellulose

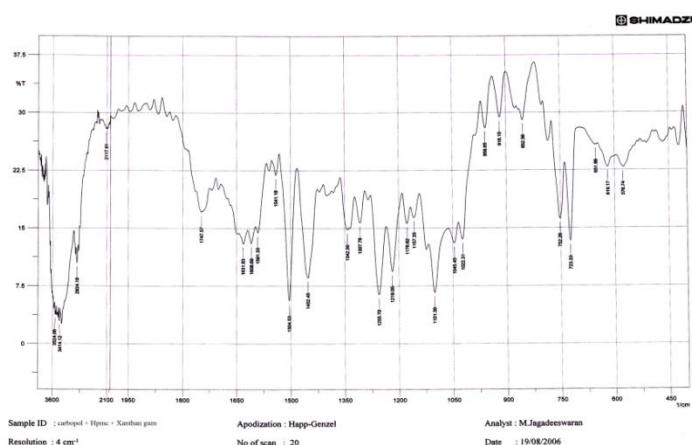


Figure 4: spectrum of physical mixture for xanthan gum, hpmc and lamivudine

PREPARATION OF TABLETS

Mucoadhesive I tablets containing lamivudine were arranged by direct pressure system. The elements of the center layer (Table No: 02) were measured precisely and blended by trituration in a glass mortar & pestle [37 - 42]. The blend was then packed utilizing 8mm bite the dust by a tablet press. To acquire consistent tablet weight the splash dried lactose was included as filler excipient in the center layer. After pressure of tablet the upper punch was uprooted deliberately without aggravating the set up and blended elements of the support layer were included over the tablet and packed once more [42 - 50].

Table 2: Evaluation of blend Characteristics of Lamivudine

Formula code	Drug(mg)	CP	HPMC	Xanthan gum	Mg. Stereate
F1	150	-	30	-	5
F2	150	10	20	-	5
F3	150	15	15	-	5
F4	150	-	-	30	5
F5	150	10	-	20	5
F6	150	15	-	15	5

Flow Property

The stream property was dictated by measuring the edge of rest. With a specific end goal to focus the stream property, the point of repose(s) was dead set. It is the most extreme point that can be acquired between [51 - 55] the unsupported surface of a powder stack and the flat plane. Estimations are seldom under 20, and estimations of up to 40o show sensible stream potential. Over 50°C, then again, the powder streams just with trouble if by any means [56 - 65].

$$\theta = \tan^{-1} (h/r)$$

Where h = tallness the heap, r = range of the heap, θ = point of rest

The specimen was taken in a pipe, which settled in a holder (5cm) over the surface at a suitable stature and a chart of sheet was set beneath the channel. The specimen was gone through the pipe gradually [66]. The tallness of the powder load shaped was measured. The perimeter shaped was drawn with a pencil on the chart paper [67 - 70]. The span was measured and the point of rest was dead set. This was rehashed three times for a sample [71 - 76].

Determination of bulk density and tapped density

The powder (W) was precisely filled the graduated measuring barrel and the volume (VO) was measured [77 - 82]. At that point the graduated barrel was shut with cover and tapped 100 times and after that, the volume (Vf) was measured and proceeded with operation till the two successive readings were approach [83 - 90]. The mass thickness, and tapped thickness were computed utilizing the accompanying recipes

$$\text{Mass thickness} = W / VO, \text{Tapped thickness} = W / Vf$$

Where, W = weight of the powder, VO = introductory volume, Vf = last volume.

Compressibility index (Carr's index)

Compressibility file is an essential measure that can be gotten from the mass and tapped densities. In principle, the less compressible a material the more stream capable it is. A material having estimations of under 20 to 30% is characterized as the free streaming material [91 - 96, 60].

$$CI = 100 (VO - Vf)$$

EVALUATION OF TABLETS

Friability test

Friability of the tablets was tried utilizing a Roche friabilator. The heaviness of 10 tablets was noted at first (W1) and set in the friabilator for 4min/100rpm. The tablets were reweighed and noted as (W2). The distinction in the weight is noted and communicated as rate [97 - 104, 62].

$$\text{Rate friability} = (W1 - W2) 100/W1$$

Weight variety test

Twenty tablets were chosen indiscriminately and the normal weight was resolved [63 - 65]. Not more than two of the individual weights digress from the normal weight by more than the rate deviation indicated in table and none strays by more than double the rate. IP authority cutoff points of rate deviation of tablet are introduced in the I.P [105 - 111, 68].

Medication content consistency

Focus the substance of dynamic ingredient(s) in each of 10 tablets taken aimlessly utilizing the system given as a part of the monograph or by some other suitable scientific strategy [111 - 119]. The tablets conform to the test if not more than one of the individual values accordingly acquire is outside the limits 85 to 115% of the normal quality and none is outside the limits 75 to 125% of the normal worth [120 - 123].

Take the readied Lamivudine tablet and separate the two layers (center and support). Take tablets and pulverized in mortar to fine powder [124-129]. At that point disintegrate the aggregate powder in 100ml phosphate cradle (pH 6.8). The arrangement was suitably weakened with pH 6.8-phosphate cushion. Examine at 270nm in uv-vis spectrophotometry [130 - 136].

Water ingestion examines

The water engrossing limit of tables was controlled by gravimetry. The swelling rate of the bioadhesive tablets was assessed by utilizing 1% agar gel plate. The normal weight of the tablet was computed (w_1) [137 - 139]. The tablets were set on gel surface in a petridish put in a hatchery at $37 \pm 1^\circ\text{C}$. Tablets was evacuated at distinctive time interims (0.5, 1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0, 8.0 h) [140, 141], wiped with channel paper and reweighed (w_2) [142 - 150]. The swelling record was figured by the equation Swelling list = $(w_2-w_1)/ w$

Estimation of surface pH

The tablets were permitted to swell by keeping them in contact with 1ml of refined water (pH 6.8 ± 0.05) for 2hrs and pH was noted by acquiring the anode contact with the surface of the definitions and permitting it to equilibrate for 1min [151 - 159].

In vitro Dissolution studies

Dissolution done by utilizing USP XXIII paddle method, Tablet was keep initial 2 hrs in 0.1 n HCl and after that phosphate buffer [159 - 164].

RESULTS AND DISCUSSION

Evaluation of blend characteristics of lamivudine

Table 3: Flow Property

Formulation code	Angle of repose \pm S.D (n=3)
F ₁	32°59' \pm 1.464
F ₂	33°12' \pm 1.175
F ₃	33°27' \pm 1.018
F ₄	34°27' \pm 1.019
F ₅	33°35' \pm 0.606
F ₆	33°20' \pm 1.103

Table 4: Physical characteristics of lamivudine blend

Formulation Code	Bulk density (gm/cc)	Tapped density (gm/cc)	Compressibility Index
F ₁	0.433	0.52	16.66
F ₂	0.371	0.43	14.28
F ₃	0.406	0.49	17.18

F ₄	0.433	0.50	13.33
F ₅	0.382	0.47	14.70
F ₆	0.317	0.43	14.28

Table 5: Physical Characteristics

Formulation Code	Thickness (mm) ± S.D.(n=3)	Hardness (kg/sq.cm) ± S.D.(n=3)	Friability (%)
F ₁	3.34 ± 0.128	5.2 ± 0.447	0.467
F ₂	3.36 ± 0.203	5.4 ± 0.548	0.412
F ₃	3.40 ± 0.057	5.8 ± 0.447	0.353
F ₄	3.39 ± 0.061	5.6 ± 0.548	0.414
F ₅	3.50 ± 0.147	5.4 ± 0.548	0.409
F ₆	3.34 ± 0.106	5.6 ± 0.548	0.353

Table 6: Weight variation test

Formulation Code	Average weight of Tablet	% Weight variation from Average	
		+	-
F ₁	169.0	3.540	3.00
F ₂	167.9	4.228	4.705
F ₃	168.8	1.303	2.251
F ₄	167.7	3.756	3.398
F ₅	167.9	3.037	2.918
F ₆	170.8	1.873	3.395

Table 7: Mucoadhesive strength

Formulation Code	Mucoadhesive strength (gms) ± S.D. (n=3)
F ₁	9.2 ± 0.16
F ₂	16.0 ± 0.12
F ₃	14.0 ± 0.16
F ₄	10.0 ± 0.16
F ₅	15.0 ± 0.08
F ₆	12.4 ± 0.54

Table 8: Drug content uniformity

Formulation code	% Drug content ± S.D. (n=3)
F ₁	96.1 ± 1.31
F ₂	99.4 ± 1.52

F ₃	98.5 ± 1.31
F ₄	97.1 ± 1.46
F ₅	97.8 ± 1.45
F ₆	98.3 ± 1.00

Table 9: Measurement of Surface pH Table

Formulation code	Surface pH ± S.D. (n=3)
F ₁	7.0 ± 0.10
F ₂	7.2 ± 0.23
F ₃	7.3 ± 0.10
F ₄	7.1 ± 0.11
F ₅	6.9 ± 0.10
F ₆	7.4 ± 0.05

Table 10: *In vitro* dissolution profile of Formulation F1

S. No	Time (hrs)	Absorbance (245nm)	Concentration in mcg/ml	Cumulative amount drug released (mg)	*Cumulative percentage of drug released
0	0	0	0.000	0.000	0.000
1	1	0.0201	1.552	1.397	22.347±0.90
2	2	0.0271	2.094	1.886	30.176±0.42
3	3	0.0328	2.537	2.287	34.594±0.55
4	4	0.0328	2.537	2.287	37.594±0.55
5	5	0.0352	2.707	2.443	39.089±1.20
6	6	0.042	3.249	2.933	46.929±1.30
7	7	0.057	4.409	3.981	63.688±0.60
8	8	0.060	4.641	4.194	69.100±0.45
9	9	0.066	5.105	4.616	73.857±0.84
10	10	0.070	5.414	4.900	78.394±0.76
11	11	0.078	6.030	5.459	87.346±0.65
12	12	0.0829	6.412	5.807	92.915 ±0.53

*Average of three value, ± Standard deviations

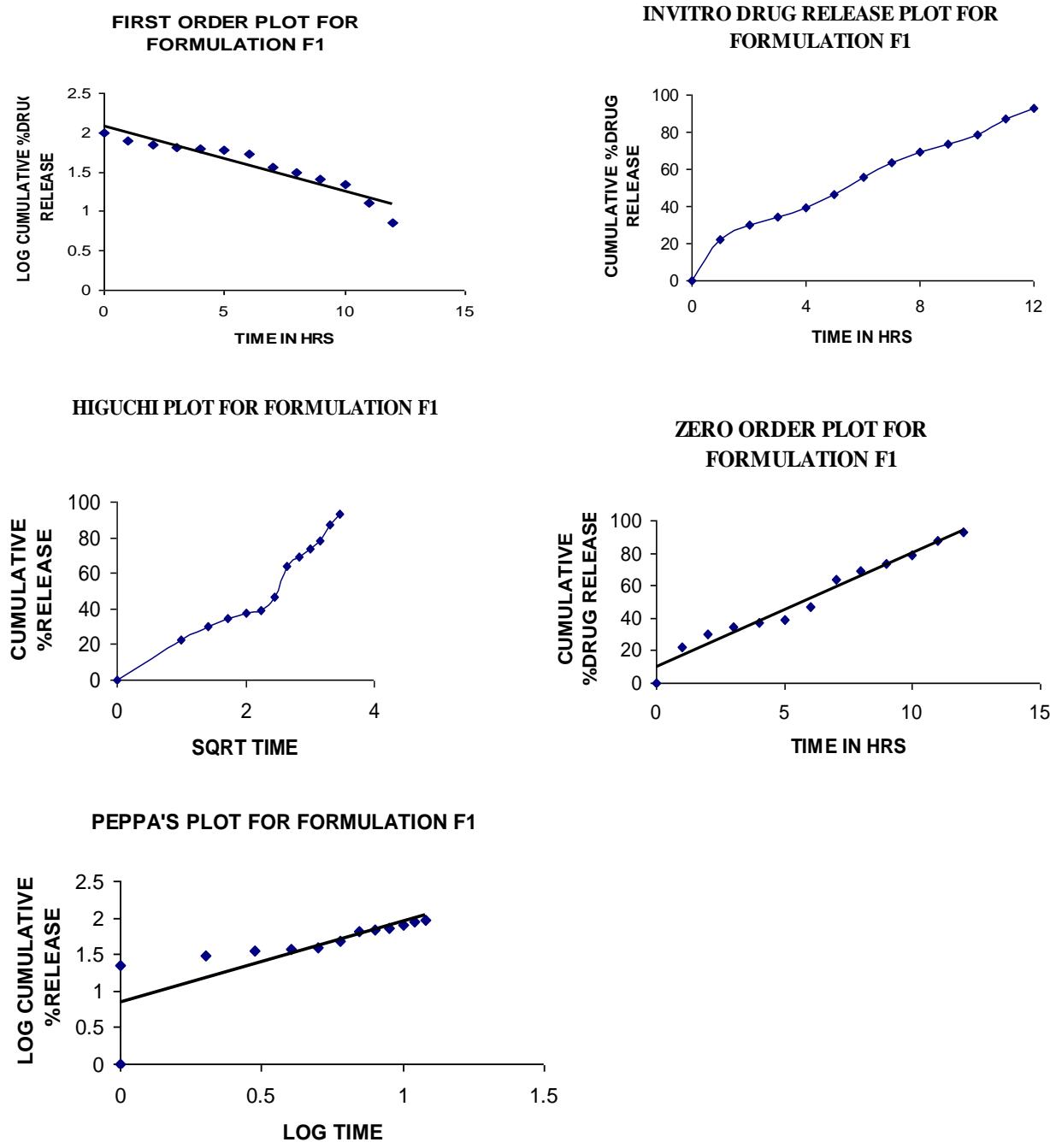


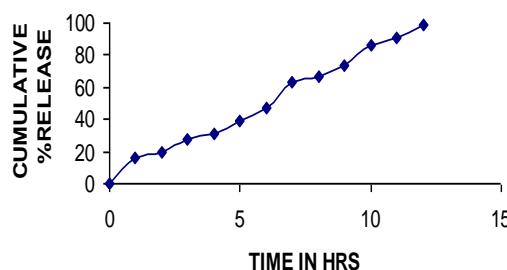
Table 11: Vitro dissolution profile of Formulation F2

S. No	Time(hrs)	Absorbance (245nm)	Concentration in mcg/ml	Cumulative amount drug released (mg)	*Cumulative percentage of drug released
0	0	0	0.000	0.000	0.000
1	1	0.014	1.108	0.998	15.962±1.00
2	2	0.018	1.388	1.250	20.000±0.65
3	3	0.025	1.934	1.743	27.885±0.58
4	4	0.028	2.166	1.954	31.258±0.48
5	5	0.035	2.707	2.443	39.089±1.20

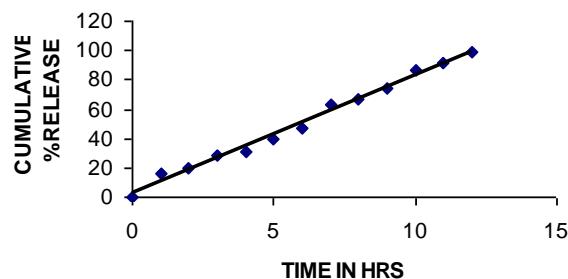
6	6	0.042	3.249	2.933	46.929±1.30
7	7	0.057	4.409	3.981	63.688±0.60
8	8	0.060	4.641	4.194	67.100±0.45
9	9	0.066	5.105	4.616	73.857±0.84
10	10	0.077	5.988	5.41	86.51±1.40
11	11	0.081	6.300	5.69	91.09±0.90
12	12	0.088	6.815	6.16	98.61±0.80

*Average of three value, \pm Standard deviations

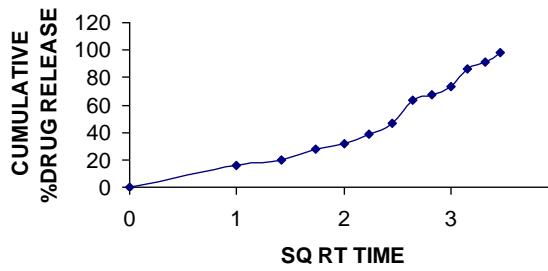
IN VITRO DRUG RELEASE PLOT FOR FORMULATION F2



ZERO ORDER PLOT FOR FORMULATION F2



HIGUCHI PLOT FOR FORMULATION F2



FIRST ORDER PLOT FOR FORMULATION F2

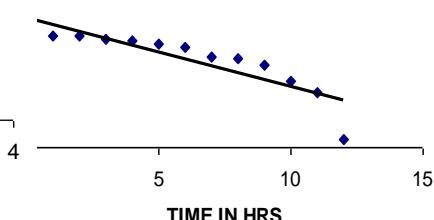


Table 12: In vitro dissolution profile of Formulation F3

S. No	Time(hrs)	Absorbance (245nm)	Concentration in mcg/ml	Cumulative amount drug released (mg)	*Cumulative percentage of drug released
0	0	0.000	0.000	0.00	0.00
1	1	0.016	1.215	1.09	17.50±0.80
2	2	0.020	1.554	1.40	22.40±0.75
3	3	0.028	2.166	1.95	31.23±0.65
4	4	0.044	3.403	3.07	49.09±0.90
5	5	0.047	3.897	3.52	52.25±0.54
6	6	0.050	3.897	3.52	56.25±0.54
7	7	0.053	3.897	3.52	60.25±0.54
8	8	0.057	4.409	3.981	65.688±0.60
9	9	0.066	5.105	4.616	70.857±0.84
10	10	0.070	5.414	4.900	78.394±0.76

11	11	0.078	6.030	5.459	87.346±0.65
12	12	0.081	6.281	6.102	95.023±1.10

*Average of three value ± Standard deviations

Table13: In vitro dissolution profile of Formulation F4

S. No	Time(hrs)	Absorbance (245nm)	Concentration in mcg/ml	Cumulative amount drug released (mg)	*Cumulative percentage of drug released
0	0	0.0000	0.000	0.000	0.000
1	1	0.0170	1.313	1.181	18.900±0.60
2	2	0.0207	1.603	1.444	23.100±1.10
3	3	0.0250	1.934	1.743	27.892±0.34
4	4	0.031	2.166	1.954	35.258±0.48
5	5	0.035	2.707	2.443	39.089±1.20
6	6	0.042	3.249	2.933	43.929±1.30
7	7	0.0472	3.651	3.293	51.693±0.65
8	8	0.060	4.641	4.194	65.100±0.45
9	9	0.066	5.105	4.616	71.857±0.84
10	10	0.070	5.414	4.900	75.394±0.76
11	11	0.078	6.030	5.459	89.346±0.65
12	12	0.088	6.815	6.16	96.61±0.80

*Average of three value, ± Standard deviations

Table14: In vitro dissolution profile of Formulation F5

S.No	Time (hrs)	Absorbance (245nm)	Concentration in mcg/ml	Cumulative amount drug released (mg)	*Cumulative percentage of drug released
0	0	0	0	0	0
1	1	0.0201	1.552	1.397	22.347±0.90
2	2	0.0271	2.094	1.886	30.176±0.42
3	3	0.0328	2.537	2.287	36.594±0.55
4	4	0.0358	2.537	2.287	39.594±0.55
5	5	0.0425	3.897	3.52	42.929±1.30
6	6	0.053	3.897	3.52	46.929±1.30
7	7	0.0605	4.680	4.227	57.693±0.65
8	8	0.0625	4.833	4.370	69.100±0.45
9	9	0.066	5.105	4.616	75.857±0.84
10	10	0.070	5.414	4.900	79.394±0.76
11	11	0.078	6.030	5.459	91.346±0.65
12	12	0.082	6.281	6.102	97.023±1.10

*Average of three value, ± Standard deviations

Table 15: In vitro dissolution profile of Formulation F6

SI No	Time(hrs)	Absorbance (245nm)	Concentration in mcg/ml	Cumulative amount drug released (mg)	*Cumulative percentage of drug released
0	0	0	0.000	0.000	0.000

1	1	0.014	1.108	0.998	15.962±1.00
2	2	0.018	1.388	1.250	20.000±0.65
3	3	0.025	1.934	1.743	27.885±0.58
4	4	0.028	2.166	1.954	31.258±0.48
5	5	0.035	2.707	2.443	39.089±1.20
6	6	0.042	3.249	2.933	46.929±1.30
7	7	0.057	4.409	3.981	63.688±0.60
8	8	0.060	4.641	4.194	67.100±0.45
9	9	0.066	5.105	4.616	73.857±0.84
10	10	0.070	5.414	4.900	78.394±0.76
11	11	0.078	6.030	5.459	87.346±0.65
12	12	0.081	6.281	6.092	94.023±1.10

*Average of three value, ± Standard deviations

Table 16: Release kinetics

Formula Code	Drug release Kinetics						
	Zero order		First order		Higuchi	Peppa's	
	K ₀	r	K ₁	r	r	n	R
F ₁	11.3036	0.99079	0.44296	0.832653	0.9804	0.66007	0.99194
F ₂	9.17987	0.99571	0.369	0.766278	0.96207	0.76813	0.99052
F ₃	8.44584	0.99561	0.1635	0.947604	0.95609	0.8558	0.9958
F ₄	7.67705	0.99746	0.21105	0.895399	0.95477	0.85626	0.99093
F ₅	10.323	0.99688	0.38107	0.801977	0.96315	0.82223	0.9961
F ₆	8.6549	0.99617	0.31972	0.817707	0.95783	0.84842	0.99494

K₀- Zero order rate constant, K₁- First order rate constant, r - Coefficient of Correlation, n- diffusional exponent

DISCUSSION

In the present work endeavors have been made to create mucoadhesive tablets of lamivudine utilizing direct pressure system including mucoadhesive polymers like Carbopol, different cellulose ethers having diverse level of dissolvability and swellability, for example, Hydroxy propyl methyl cellulose and xanthan gum. Magnesium stearate was incorporated as against disciple [165- 169].

The FTIR ghastly investigation demonstrated that there was no appearance or vanishing of any trademark top, which affirms the nonattendance of concoction connection in the middle of medication and polymers.

The mix physical qualities were considered. The points of rest of all plan mixes F1 to F6 were in the reach 31°36' ± 0.825 to 34°35' ± 0.459. The mass thickness, tapped thickness, Corr's record and Hausner proportion were found in the scope of 0.317-0.433gm/cc, 0.43-0.52gm/cc, 13.33-17.18 and 1.15-1.2 separately. It uncovers that all the plan mixes were having great stream attributes and stream rates [170].

Thickness of all details F1-F6 were in the scope of 3.20 ± 0.142 to 3.50 ± 0.147 mm [171]. Hardness of all definitions F1-F8 were in the scope of 5.2 ± 0.447 to 5.8 ± 0.447 kg/sq.cm. Rate friability of all details F1 to F8 was in the scope of 0.353 to 0.467 %.

The Percentage weight variety for of all definitions F1 to F8 was in the scope of 1.3 to 4.7%. Rate of medication substance for all details F1 to F8 was in the scope of 96.1 ± 1.31 to 99.4

CONCLUSION

Mucoadhesion is a subject of current enthusiasm for the configuration of medication conveyance frameworks. Mucoadhesive medication conveyance frameworks are conveyance frameworks which get to be glue on hydration to the mucin layer of a mucosal tissue. These frameworks delay the home time of the measurements structure at the site of use or retention and encourage a cozy contact of the dose structure with the hidden ingestion surface and in this manner add to enhanced bioavailability and better helpful execution of medications.

In the present work mucoadhesive tablets of lamivudine were defined utilizing Carbopol, Hpmc and xanthan gum as polymer materials with other basic added substances in tablets and the tablets were assessed for medication discharge and in vitro Mucoadhesive properties. Oral controlled discharge plans of lamivudine were planned and were assessed. The accompanying conclusions are drawn from the outcomes got.

All the clusters of lamivudine tablets arranged utilizing CARBOPOL, HPMC and XANTHAN GUM were of good quality as to weight variation, hardness, friability, water assimilation studies, surface pH, medication content, invitro medication discharge. All the plans displayed odd (non-fickian transport) dispersion component and take after zero order active. The plan F6 (CP -15mg, HPMC -40mg, and Mag.Ste-20mg) was chosen as improved detailing taking into account t90% estimation of 10.67 hrs with $99.74 \pm 0.06\%$ of medication discharge at 12th hr and had great bioadhesion quality. The mucoadhesive tablets of lamivudine may be a decent approach to sidestep the far reaching hepatic first-pass digestion system and to enhance the bioavailability of lamivudine through mucosa

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