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EFFECT OF DIFFERENT DILUENTS ON RELEASE PROFILE OF LAMIVUDINE FROM SUSTAINED RELEASE MATRIX TABLET USING KOLLIDON SR AS RELEASE RETARDANT

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ABSTRACT

In the present work the effect of different diluents were studied on the release profile of Lamivudine from sustained release matrix tablet by using Kollidon SR as a release retarding agent. Sustained release matrix tablet of Lamivudine were prepared by direct compression method using Kollidon SR as a release retardant. Lactose and Microcrystalline cellulose were used as diluents in different concentration. Compatibility study was carried out by FT-IR. The powder were evaluated for their flow properties and tablet were evaluated for hardness, friability, thickness, % weight variation, % drug content and *in-vitro* dissolution test.

KEYWORDS

Matrix tablet, Diluents, Lamivudine, *In-vitro* drug release and Kollidon SR.

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INTRODUCTION[1-5]

Sustained released dosage form, a modern approach in the pharmaceutical sciences has proved its importance and compliance. The oral conventional types of drug delivery system are known to provide a prompt release of drug. Therefore, to achieve as well as to maintain the drug concentration with in the therapeutically effective range needed for treatment, it is often necessary to take this type of drug delivery system several times a day. This

results in a significant fluctuation in drug levels often with sub-therapeutic and/or toxic levels and wastage of drug. To overcome the problems associated with conventional dosage form sustained release matrix type dosage form were developed.

Lamivudine is an antiretroviral drug, belongs to class III of the BCS Classification with high solubility and low permeability. It is rapidly absorbed with a bioavailability of over 80% following oral ingestion. The drug half-life in plasma is approximately 5-7 hrs. It is bound to plasma proteins less than 36 %. It can inhibit both types (1 and 2) of HIV reverse transcriptase and also the reverse transcriptase of hepatitis B. Kollidon SR is a free-flowing non hygroscopic powder consisting of 80% water insoluble polyvinyl acetate(PVAc), 19% water soluble polyvi nylpyrrolidone, approximately 0.8sodium lauryl sul phate and about 0.2 % silica as stabilizers combined as a physical mixture. Kollidon SR is polyvinyl acetate and povidone based matrix- retarding agent. Polyvinyl acetate is insoluble in water. The povidone content is gradually leached out after introduction into water. Kollidon SR contains no ionic groups and is therefore inert to the drug substances. It is particularly suitable for the manufacture of pH independent sustained release matrix tablet by direct compression. Kollidon SR can be used for the production of the sustained release matrix preparation of tablets, pellets and granules.

Hence, the present work is aimed to prepare and evaluate sustained release matrix tablet of Lamivudine and to study the effect of different diluents on release profile by using Kollidon SR as release retardant.

MATERIAL AND METHODS

Materials

Lamivudine (Strides Arco labs ltd, Bangalore), Kollidon SR (Sigma-Aldrich, Bangalore), Lactose and Microcrystalline cellulose (S D fine chemical Ltd, Mumbai), Talc (S D fine chemical Ltd, Mumbai), Magnesium stearate (S D fine chemical Ltd, Mumbai), Potassium dihydrogen Orthophosphate (S D fine chemical Ltd, Mumbai) and Sodium hydroxide (S D fine chemical Ltd, Mumbai).

Drug-excipient compatibility studies[6-7]

FT-IR spectroscopy study was carried out to check the compatibility between the drug Lamivudine, polymer Kollidon SR and the diluent Lactose and Microcrystalline cellulose used for the preparation of Lamivudine matrix tablet. The FT-IR was performed for drug, polymer and physical mixture of drug, polymer and diluents. The spectra obtained from FT-IR spectroscopy at wavelength from 4000 to 400 cm^{-1}.

Preparation of matrix tablet

Matrix tablet were prepared by direct compression method. To prepare the tablets, the ingredients were weighed accurately and were screened through mesh (No.60). Lamivudine and diluent were mixed in a polybag for 15 mins, and the mixture was passed through mesh (No.60). Finally, Talc and Magnesium stearate was added to the previous blend and blended for (15-10 mins) for uniform distribution before the compression. Different formulae, having different combination and ratios of diluents were developed to study the effect of diluent on drug release.

EVALUATION OF LAMIVUDINE TABLETS

Precompression parameter[8-11]

Angle of repose

Angle of repose (θ) is the maximum angle passible between the surfaces of a pile of powder and horizontal plane. It is determined by using fixed funnel method. The angle of repose (θ) was calculated using the formula:

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

Where, h - is height of the pile, r is radius of the pile and θ is angle of repose

Bulk density

Apparent bulk density (Pb) was determined by pouring the granules into a graduated cylinder.

The bulk volume (Vb) and mass of the powder (M) was noted and bulk density was calculated using the formula:

$$Pb = M/Vb$$

Where, M is mass of the granules, Vb is bulk volume and Pb is bulk density.

Tapped density

The measuring cylinder containing a known mass of granules was tapped for a fixed time. The minimum volume (Vt) occupied in the cylinder and the weight of the granules was measured (M). The tapped density (Pt) was calculated by using formula:

$$Pt=M/Vt$$

Where, M is mass of the granules, Vt is tapped volume and Pt is tapped density.

Compressibility index

The simplest way for measuring of free flow of powder was compressibility, an indication of the ease with which a material can be induced to flow was given by compressibility index (I).

$$I= (Vb-Vt/Vb) \times 100$$

Where, Vb is the bulk volume and Vt is tapped volume.

Carr's consolidation index

Specific amount of granules was transferred to measuring cylinder and the initial volume occupied was noted as (Vb) and the content was tapped for 100 times and the volume was noted (Vt). Then calculated the Carr's consolidation index by using the following formula

$$\text{Carr's consolidation index} = (Pt-Pb/Pt)\ 100$$

Hausner's ratio

Hausner's ratio is an indirect index of ease of powder flow. It was calculated by using the formula

$$\text{Hausner ratio}=Pt/Pd$$

Where, Pt is tapped density and Pd is bulk density lower hausner's ratio (<1.25) indicates better flow properties than higher ones (> 1.25)

Post compression parameters[12-15]

Weight variation

In this method twenty tablets are selected and individually weighed of twenty tablets was noted. The average weight of these tablets is determined. The weight variation of individual tablet is determined with respect to average weight and percentage weight variation.

% Weight variation = (Individual weight-Average weight/Individual weight) × 100

Thickness test

The thickness of tablets was measured by using Digital caliper. Six tablets were used and average values were calculated.

Hardness test

Hardness of six tablets was measured individually by using Monsanto Hardness tester.

Friability

Twenty tablets are weighed accurately in digital balance (W_1). The weighed tablets are placed in the drum of Roche friabilator. The friabilator is allowed to rotate for 4mins. That is 100 revolutions. The tablets are dusted and removed from the drum. These tablets are dusted and weighed again (W_2). The difference between the initial weight of the tablets (W_1) and weight of the tablets after subjecting to friabilator (W_2) gives the friability of the tablet.

$$F= (W_1-W_2/W_1)\ 100$$

Where, W_1 is weight of the tablets before and W_2 is weight of the tablets after test.

Drug content uniformity

Ten tablets were powdered in a mortar. An accurately weighed quantity of powdered tablets (100 mg) was extracted with pH 7.4 buffer and the solution was filtered through 0.45 µ membranes. The absorbance was measured at 270 nm after suitable dilution. The drug content in each tablet was calculated using the standard calibration curve of lamivudine in phosphate buffer pH 7.4 solution.

***In-vitro* drug release study**

The release rate of Lamivudine from tablets was determined using United States Pharmacopeia (USP) Dissolution Testing Apparatus 2 (paddle method; Veego Scientific, Mumbai, India). The dissolution test was performed using 900 ml of pH 7.4 phosphate buffer, at 37 ± 0.5 ºC and 75 rpm. A sample (5 ml) of the solution was withdrawn from the dissolution apparatus and the samples were replaced with fresh dissolution medium. The samples were filtered through a 0.45 µ membrane filter and diluted to a suitable concentration with pH 7.4 phosphate buffer. Absorbance of these solutions was measured at 270 nm spectrophotometrically.

Cumulative percentage drug release was calculated using an equation obtained from a standard curve.

Accelerated stability study[16-17]

Whenever a new formulation is developed, it is very essential to establish that the therapeutic activity of the drug has not undergone any change. To conform this, the selected formulations were subjected to stability studies. Accelerated stability testing studies was performed for 6 months. The optimized formulations were kept at 40 ± 2 ºC and 75 ± 5% RH. Physical appearance, drug content and % drug release were fixed as evaluation parameter for stability study.

RESULTS AND DISCUSSION

Compatibility studies evaluation of drug-polymer interaction

FTIR spectral studies are shown in Figure No 1-3. Pure Lamivudine spectra showed. Principal peaks at different wave numbers corresponding to its functional groups. The IR spectra of Lamivudine exhibited peak at 3207.73 cm^{-1}(OH stretching), 3325.39 cm^{-1}(-NH2 stretching), 1647.26 cm^{-1}(C=O stretching carbony gp), 1284.63 cm^{-1}(C-O-C stretching of oxathiolane ring), 1058.63 cm^{-1}(C-O stretching of primary alcohol), 787.30 cm^{-1}(N-H bending of primary amine). The characteristic peak of Lamivudine was also appeared in the physical mixture also. This study indicates that there is no interaction of the drug with polymers and other excipients used.

Pre-compression parameters

The powder blends for the preparation of tablets were evaluated for various pre-compression parameters. The values reported in Table No.2. Angle of repose of all the formulations was found to be ranging from 25.3 ± 0.76 - 27.3 ± 0.50, bulk density was found to be 0.45 ± 0.01 - 0.47 ± 0.010 g/cc, tapped density was in between 0.54 ± 0.014 - 0.57 ± 0.010 g/cc, Carr's index was found to be within 14.4 ± 0.77 - 17.7 ± 0.44 and Hausner's ratio was found to be within 1.18 ± 0.03 - 1.23 ± 0.03. The results of Precompression parameter confirmed that the blends for all the formulation had good flow property and compressibility, suitable for direct compression.

Post-compression parameters

The thickness of the tablet indicates that die fill was uniform. The thickness depends upon the size of the punch and the weight of the tablet. The thickness of the batch from F1-F6 was found to be 4.11 ± 0.11 – 4.26 ± 0.12 mm and hardness was found to be 5.75 ± 0.27 – 6.08 ± 0.37 kg/cm^2. The results are shown in Table No.3. This result confirmed that the tablets prepared from the entire formulation batch showed uniform size of the tablet and with sufficient hardness of having good mechanical strength.

Friability is needed for tablets to withstand force of compression applied during the manufacture of tablets. The friability of all the formulated tablets of Lamivudine was found to be between 0.45 - 0.62 % are shown in Table No.3 and all the formulated tablets of Lamivudine were shown the % friability within the official limits (*i.e.* not more than 1%).

Prepared tablets were evaluated for weight variation and percentage deviation from the average weight is shown in Table No.3. From the results it was found to be within (±5) the prescribed official limits.

The drug content of all the nine formulations of Lamivudine tablets were found to be within the range of 98.9 ± 0.6 to 100 ± 0.8 % which were within the limits of compendial specifications. The drug content of all the formulations of Lamivudine tablets are shown in Table No.3.

***In-vitro* dissolution study**

In-vitro drug release of Lamivudine matrix tablet in phosphate buffer pH 7.4 was performed. The *in-vitro* drug release profile of Lamivudine matrix tablet from different batches of formulated matrix tablets is illustrated in Table No.4-5 and graphical representation are shown in Figure No.4-5. The release of Lamivudine from matrix tablet was varied according to concentration of Kollidon SR and diluent used. It has been concluded that, if we increase the concentration of Kollidon SR, decrease in drug release rate was observed. This may be due to the reason that the polymer in higher concentrations in the tablets might have produced dense matrix around the drug particles, providing

more barriers for them to escape and dissolve. The percentage of the drug released from the formulations F1, F2 and F3 was found to be 96.2 ± 0.32 %, 94.42 ± 0.44 % and 92.51 ± 0.56 % respectively. The percentage of the drug released from the formulations F4, F5 and F6 was found to be 93.92 ± 0.684 %, 91.93 ± 0.285 % and 89.22 ± 0.466 % respectively. From the dissolution studies, it was observed that the matrix tablets extended the release of Lamivudine up to 12 hrs. The rate of drug release was faster from the tablets containing soluble diluent lactose, when compared with other diluent such as MCC. This may be due higher hydrophilicity of lactose which enhances the water penetration in to tablet. Hence, formulation F1-F3 showed faster drug release. But the tablets formulated with insoluble diluents such as MCC, the release was extended due to poor swellability. Hence, the formulation having MCC as insoluble diluent the slower the rate of drug release was observed. Among the formulation F6 with higher content of Kollidon SR showed better controlled release over a period of 12 hrs.

Kinetic model data analysis

In-vitro drug release data of all formulations were fitted to Zero order, First order, Higuchi and Korsmeyer-Peppas equations to ascertain the pattern of drug release. And also *In-vitro* drug release data for all the formulations were subjected to release kinetic study according to Zero order, First order, Higuchi and Korsemeyer-Peppas equation to ascertain the mechanism of drug release. Upon the application of different drug release model kinetics is given in Table No.6. From the results it was found that all formulation follows First order model. The 'n' values for all the formulation were found to be more than 0.5. This indicates that the release approximates Non-Fickian diffusion mechanism.

Accelerated stability studies

Accelerated stability studies were carried out at 40 ± 2 ºC and 75 ± 5 % RH for the optimized formulation F6 and monitored for physical appearance, drug content, and dissolution profile study. The results are shown in Table No.7, which indicated that all the tablets were stable during storage period.

Table No.1: Formulation design of matrix tablet of Lamivudine

S.No	Ingredients	F1	F2	F3	F4	F5	F6
1	Lamivudine	150	150	150	150	150	150
2	Kollidon SR	150	225	300	150	225	300
3	Lactose	200	125	50	-	-	-
4	MCC	-	-	-	200	125	50
5	Magnesium stearate	2.0	2.0	2.0	2.0	2.0	2.0
6	Talc	2.0	2.0	2.0	2.0	2.0	2.0

Table No.2: Pre-compression evaluation of tablet blend of Lamivudine

S.No	Formulation	Angle of repose (ɵ)	Bulk density (g/cc)	Tapped density (g/cc)	Carr's index	Hausner's ratio
1	F1	25.3±0.76	0.45±0.012	0.57±0.010	14.4±0.77	1.23±0.03
2	F2	27.3±0.50	0.45±0.011	0.54±0.014	16.7±0.60	1.20±0.05
3	F3	26.1±0.52	0.47±0.010	0.55±0.007	17.7±0.44	1.18±0.02
4	F4	26.6±0.36	0.46±0.015	0.55±0.001	16.9±0.69	1.18±0.03
5	F5	25.5±0.32	0.46±0.011	0.55±0.014	17.6±0.62	1.20±0.04
6	F6	27.0±0.51	0.45±0.01	0.54±0.017	16.8±0.67	1.21±0.04

Mean ±SD n=3

Table No.3: Post-compression evaluation of Lamivudine matrix tablet

S.No	Formulation	Hardness *(kg/cm^2)	Thickness* (mm)	Friability # (%)	**Weight variation	**Drug content
1	F1	5.75±0.27	4.26±0.12	0.45	0.017±0.38	99.4±0.7
2	F2	6.00±0.31	4.25±0.10	0.51	0.037±0.20	99.9±0.8
3	F3	5.91±0.20	4.18±0.07	0.49	0.075±0.22	100±1.4
4	F4	6.00±0.31	4.23±0.08	0.62	0.018±0.21	99.8±1.3
5	F5	6.08±0.37	4.11±0.11	0.53	0.028±0.21	100±1.1
6	F6	6.00±0.31	4.26±0.12	0.55	0.075±0.23	98.9±0.6

Mean ±SD *n=6, **n=10 and #n=20

Table No.4: *In-vitro* release study of formulation F1-F3

S.No	Time (hr)	%CDR		
		F1	F2	F3
1	0	0	0	0
2	1	35.26±0.33	33.96±0.503	31.86±0.251
3	2	56.27±0.61	52.61±0.29	50.04±0.250
4	4	75.6±0.54	73.00±0.769	70.02±0.250
5	6	84.17±0.50	82.3±0.503	80.82±0.888
6	8	90.61±0.51	87.57±0.296	85.76±0.66
7	12	96.2±0.32	94.42±0.444	92.51±0.56

Tablet No.5: *In-vitro* release study of formulation F4-F6

S.No	Time(hr)	%CDR		
		F4	F5	F6
1	0	0	0	0
2	1	25.04±0.140	23.19±1.015	21.06±0.255
3	2	35.29±0.355	32.86±0.665	30.59±0.475
4	4	51.37±0.498	47.28±0.351	44.25±0.285
5	6	70.73±0.604	67.20±0.236	65.91±0.541
6	8	84.48±0.518	78.67±0.499	75.68±0.335
7	12	93.92±0.684	91.93±0.285	89.22±0.466

Table No.6: Best fit model for all formulations

S.No	Formulation	Zero order	First order	Higuchi order	Peppas order	‘ n’ value	Best Fit Model
1	F1	0.7453	0.9885	0.9464	0.7216	2.0369	First order
2	F2	0.7611	0.9824	0.9542	0.7249	2.0252	First order
3	F3	0.7746	0.9748	0.9594	0.7302	2.0165	First order
4	F4	0.9101	0.9892	0.9890	0.7703	1.9881	First order
5	F5	0.9288	0.9900	0.9885	0.7646	1.9664	First order
6	F6	0.9332	0.9929	0.9851	0.7786	1.9532	First order

Table No.7: Accelerated stability studies for Lamivudine matrix tablet F6

S.No	Temperature and RH	Parameters	After (months)		
			0	3	6
1	40 ± 2ºC and 75 ± 5%	Hardness*	6.0±0.316	5.9±0.204	5.8±0.273
		Drug content**	98.92±0.68	98.88±0.605	98.8±0.581
		Percentage# drug release	89.22±0.46	88.94±0.41	88.86±0.35

Mean ±SD *n=6, **n=10 and #n=3

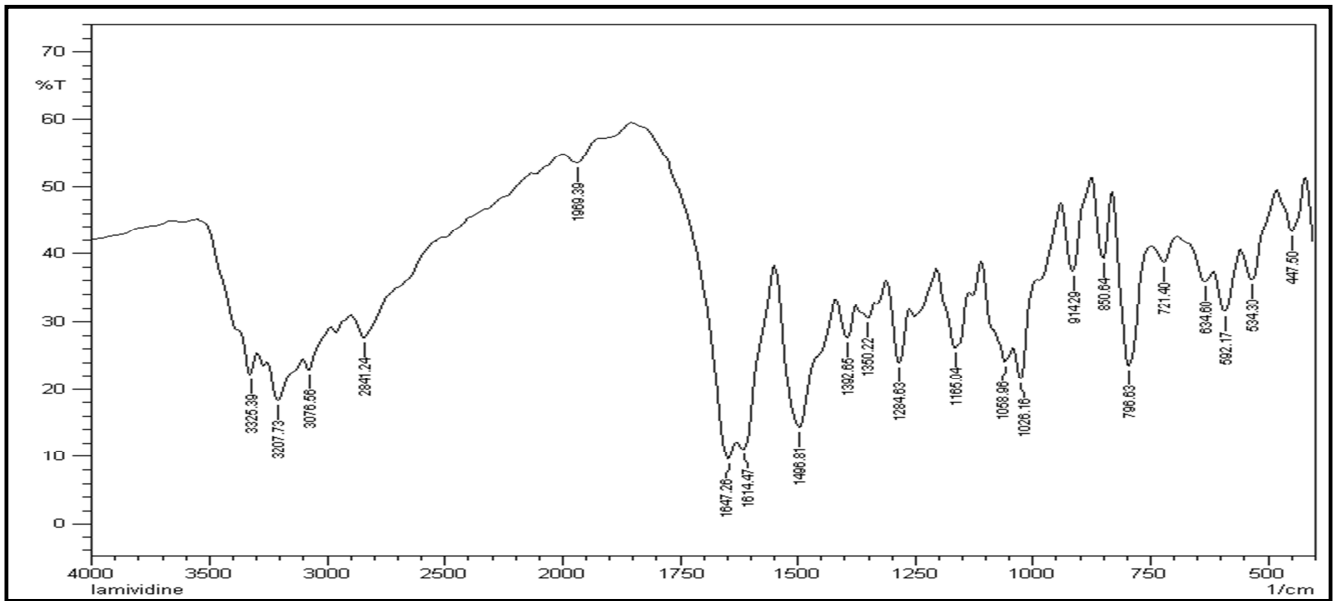

Figure No.1: FTIR spectrum of Lamivudine

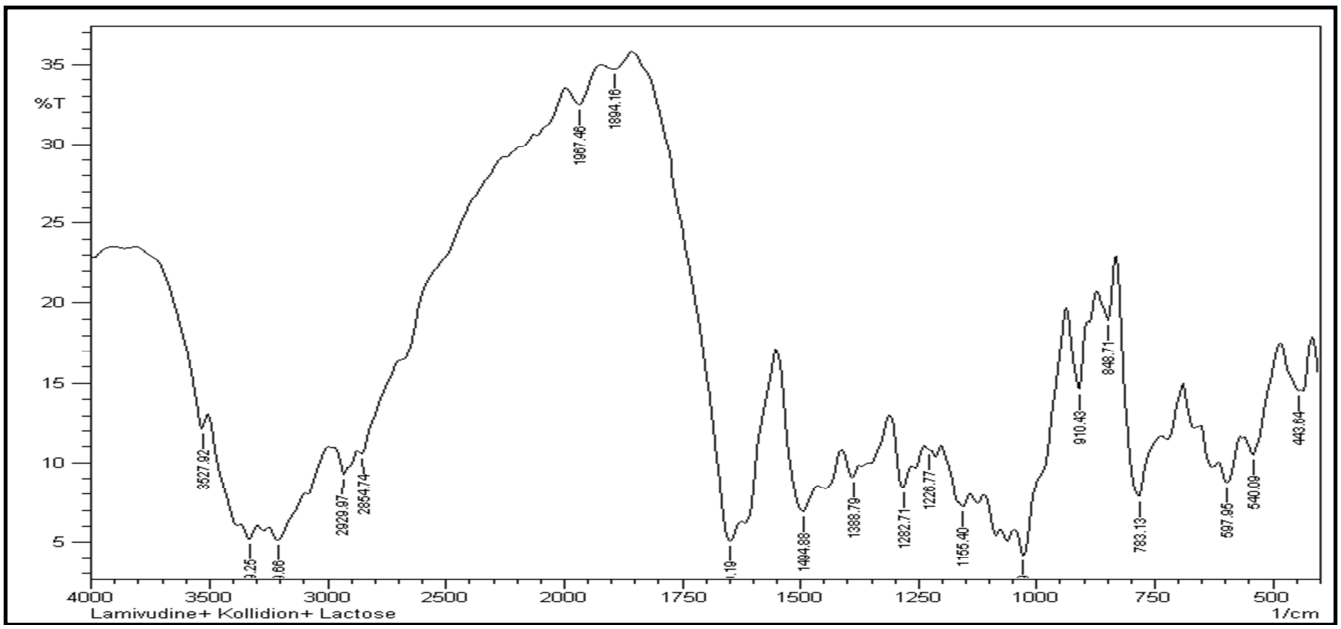

Figure No.2: FTIR spectrum of Lamivudine, Kollidon SR and Lactose

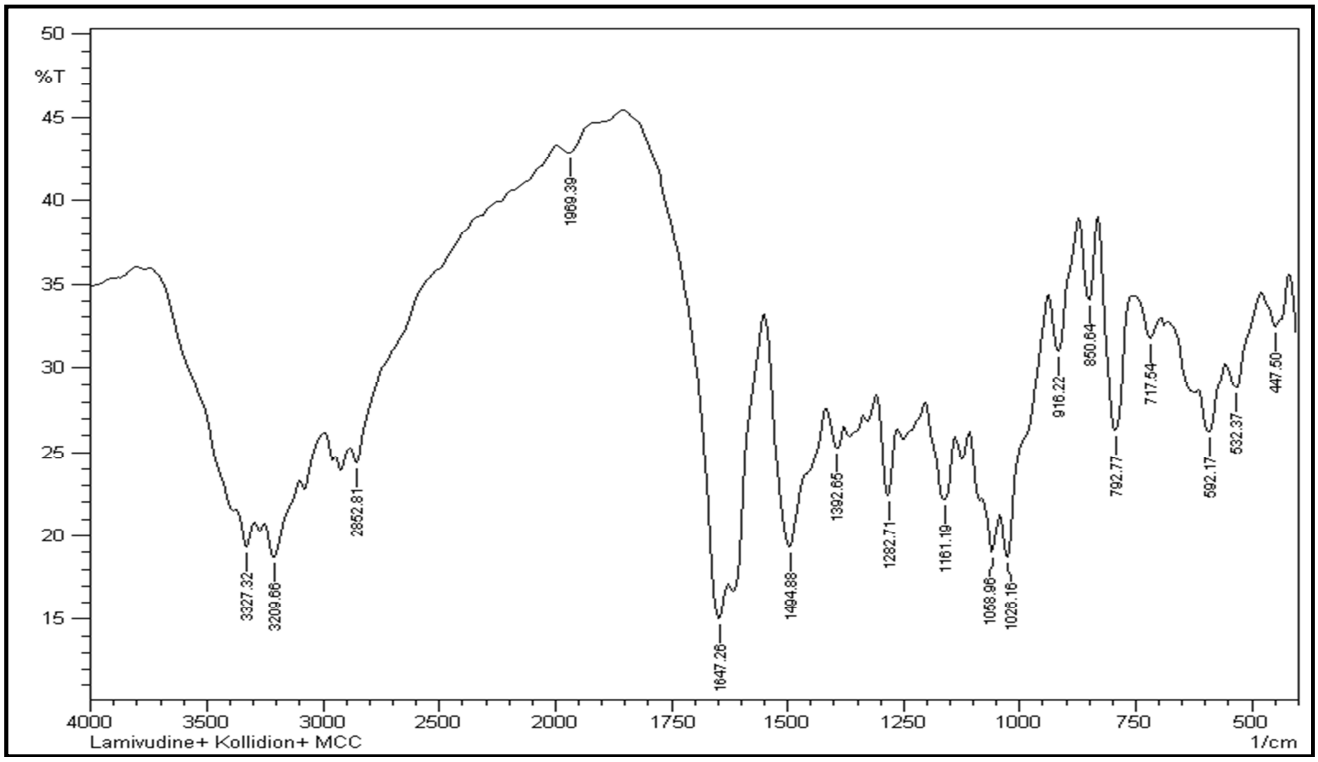

Figure No.3: FTIR spectrum of Lamivudine, Kollidon SR and MCC

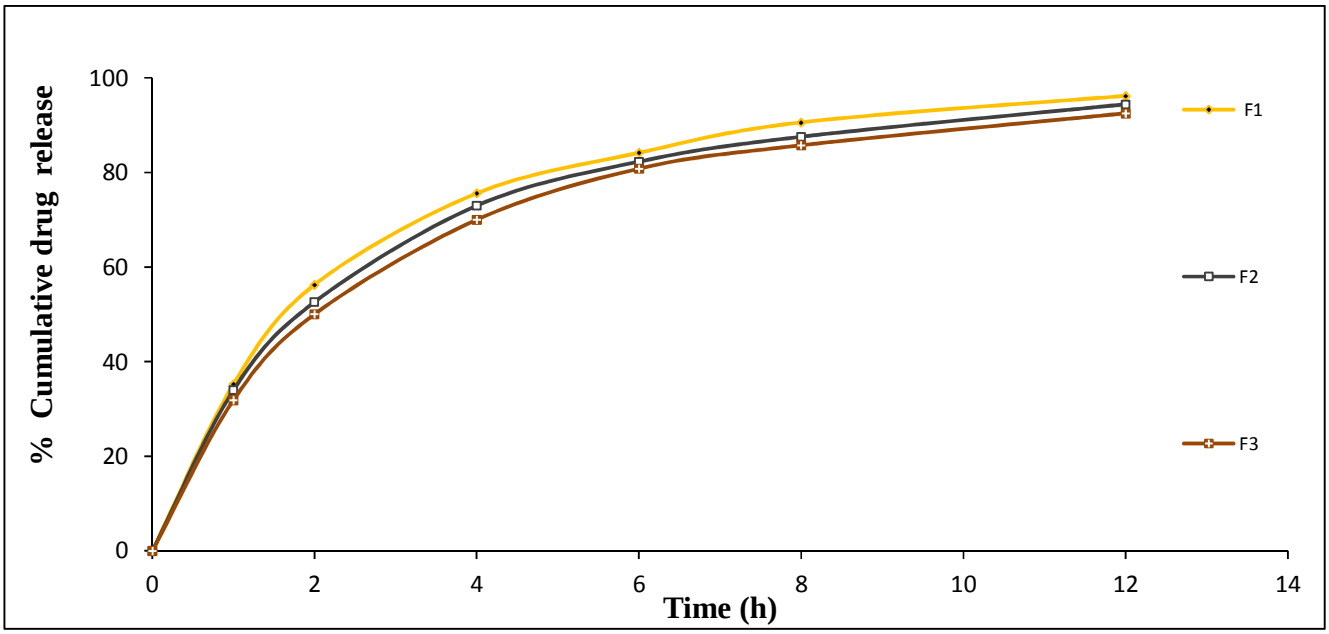

Figure No.4: *In-vitro* release profile of formulation F1-F3

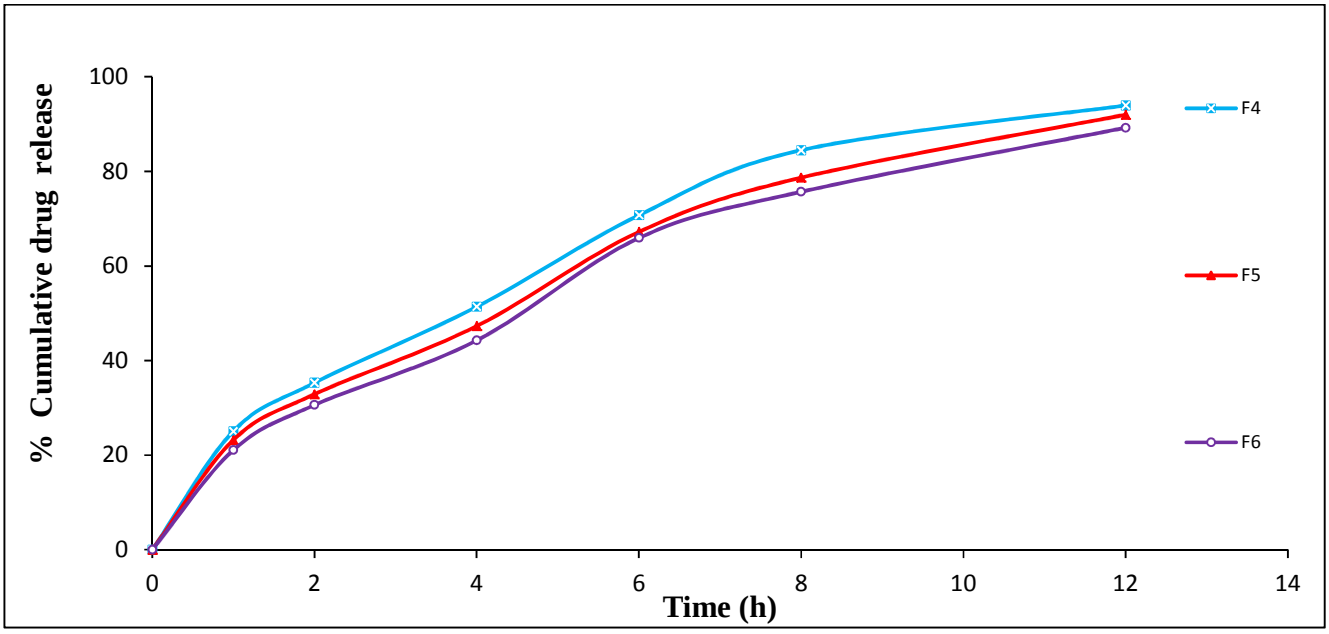

Figure No.5: *In-vitro* release profile of formulation F4-F6

CONCLUSION

Studies indicate that sustained release matrix tablets Lamivudine can be successfully prepared using Kollidon SR as release retardant. Kollidon SR itself acts as good retardant however the choice of diluents such as lactose and microcrystalline cellulose showed a significant effect on the release of Lamivudine from sustained release matrix tablet. It has been concluded that, if we increase the concentration of Kollidon SR, decrease in drug release rate was observed. Among various formulations, formulation (F6) containing 300mg of Kollidon SR was identified as ideal and better formulation among all formulations developed for Lamivudine matrix tablets. F6 formulation taken as a optimized formulation and taken for stability study. It was found that drug release follows first order kinetics.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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