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Development & evaluation of matrix type sustained release tablet of lamivudine by using natural polymers

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Abstract
The purpose of present study was to develop fenugreek as a release rate retardant excipient source. The matrix type sustained release tablets of Lamivudine were formulated using fenugreek polymer, gum tragacanth and gaur gum by wet granulation method. The three factor two level Box-Behnken design was selected for formulation development. The tablet was evaluated for hardness, friability test, wet variation test and drug content test. Also, effect of hardness of tablet, binder concentration (fenugreek polymer, gum tragacanth and gaur gum) and polymer concentration (HPMC k 100M) on the time required to release 35% of drug (t35) and percent release of drug was studied. Optimized batch of fenugreek polymer was predicted by software (Design Expert). The optimized batch (SSBF-OB) has given t35 up to 8.9 hrs and 97.09% drug release in a sustained way up to 24hrs. The comparative release potential of all the polymers was studied. In-vitro release data demonstrated that tablet with fenugreek polymer were successfully sustained the release of drug (97.09) up to 24 hrs as compare to the tablet with gum tragacanth (77.63%) and gaur gum (72.96%). LMV formulation by DOE showed that fenugreek-based polymer has a potential to act as release rate retardant excipients.

Keywords: fenugreek polymer, lamivudine, wet granulation, HPMC, gum tragacanth

Introduction
In recent years, in association with progress and innovation in the field of pharmaceutical technology, there has been increasing effort to develop prolonged release dosage forms for many drugs. Correspondingly, a growing number of new prolonged release dosage forms have been submitted for regulatory approval. Prolonged release dosage forms have many advantages in safety and efficacy over immediate release drug products in that the frequency of dosing can be reduced, drug efficacy can be prolonged and the incidence and/or intensity of adverse effects can be decreased. Sustained release dosage forms are designed to release a drug at a predetermined rate in order to maintain a constant drug concentration for a specific period of time with minimum side effects. The extended release formulations are the type of formulations which will improves the therapeutic index of drug concentration. These formulations make the drug available over extended time period after oral administration. The sustained release product will optimize therapeutic effect and safety of a drug at the same time improving the patient convenience and compliance. Hydrophilic polymers are widely used in the formulation of sustained release oral dosage forms [1, 2]. Various natural polymers are hydrophilic polymers has a hydrophilic matrices, in this matrices swelling as well as erosion of the polymer occurs simultaneously, and both of them contribute to the overall drug release rate. The matrix tablet play major role in the sustained release behavior of the drug and made a major impact in the novel drug delivery system. Hydroxy propyl methylcellulose was one of the commonly used hydrophilic polymer to prolong the release behavior of the of the drug molecule because of its robust mechanism, gelling property, rapid hydration, good compressibility property, cost effectiveness and most important its reproducible release profile [3].

Lamivudine (LMV) is commonly called as 3 TC, is an anti-retroviral drug mainly used in the treatment of AIDS and chronic hepatitis B. Due to moderate half-life about 5-7 hrs and multiple daily dosing (150 mg twice a daily), LMV is appropriate drug for a formulation in a once-a-day extended-release dosage form. Use of LMV in AIDS disease leads to the adverse side effects like accumulation of drug in multiple therapy, poor patient compliance and high cost[4]. In the pharmaceutical product development natural polymer have been studied in the different types of pharmaceutical dosage form like matrix type system for controlled release, buccal films system, film coating agent, suspension, and microspheres. This natural polymer was also plays role as stabilizer, emulsifier, solubilizer, viscosity enhancer, disintegrant, gelling agent in above mentioned pharmaceutical dosage form. In the present research work, it was attempted to develop sustained release matrix type tablet of LMV to be taken once daily with the combination of natural polymers like fenugreek gum tragacanth gum and guar gum with HPMC K 100M [5, 6].
The aim of present research work is to develop oral matrix type sustained release tablet for LMV by using different natural polymers and study the effect of natural polymers on the release profile of LMV. Developed LMV sustained release tablet formulation overcomes drawbacks related to the accumulation of drug, patient compliance and high costing etc.

Materials and Methods
Materials
Lamivudine was purchased from TCI chemical (India) pvt, Ltd., Fenugreek seeds were purchased from local market, Aurangabad, Maharashtra and polymer was extracted from seeds of *Trigonella foenum-graecum L.*, Guar gum and Tragacanth gum was purchased from Chemphasol

chemicals, Mumbai, Hydroxypropyl Methylcellulose K 100 M Microcrystalline Cellulose PH 101, Polyvinyl alcohol (PVA-EG-40PW), Aerosil and Magnesium Stearate purchased from S.D. fine chemical, Mumbai. Tablets were compressed using rotary tablet compression machine, 12 stations (New LABO Tab Xpress) (PLTCMC- 12), analysis were performed using UV visible spectrophotometer (BIO-AGE UV-2600).

Methods

Preliminary trial batches [7, 8]

The matrix tablets of LMV were prepared by wet granulation method. All three natural polymers (Fenugreek gum, gaur gum, gum tragacanth) were taken in different concentrations with the appropriate quantity of HPMC K 100 M, Polyvinyl pyrrolidone (PVP K 30), microcrystalline cellulose PH101, aerosil, magnesium stearate etc. after weighing all the starting material (Intra-granular ingredients) were shifted from through sieve #40. After shifting granulation process were carried out with the granulating fluid (10 % w/v PVP K30 solution in IPA and water) (IPA: Water, 50:50). Finally, granules were obtained and passed through sieve no #25. Lastly the granules were dried in tray dryer.

Experimental Design

The experimental design was developed with Design Expert software (Design Expert VR (Version 8.7.0.1 Stat- Ease, Minneapolis, MN) two level factorial design (2^3) was used. The formulation process variables and design matrix that consists of 8 experimental runs was constructed shown in table 1.

Table 1: Box-behnken design of Lamivudine tablet batches

Formulation and process variables				
Sr. No.	**Independent variables**		**Levels**	
			Low	**High**
1	Hardness (mm)	4	6	1
2	Binder concentration (%)	5	10	2
3	Polymer concentration (%)	10	40	3
Box-behnken design batches				
Batch code	Factor 1	Factor 2	Factor 3	
	Hardness (Kg/cm2)	Binder concentration (%)	Polymer concentration (%)	
SSBF-1	6	5	25	
SSBF-2	5	10	10	
SSBF-3	6	7.5	10	
SSBF-4	4	5	25	
SSBF-5	4	10	25	
SSBF-6	6	10	25	
SSBF-7	5	5	40	
SSBF-8	6	7.5	40	
SSBF-9	4	7.5	10	
SSBF-10	4	7.5	40	
SSBF-11	5	5	10	
SSBF-12	5	10	40	

Formulation of matrix sustained release tablets [9, 10]

The sustained release tablets of metoprolol tartrate were prepared by wet granulation method. HPMC K100M were mixed with other excipients for 15 min in porcelain mortar except aerosil, magnesium Stearate and the mass was prepared using Polyvinyl Pyrollidone (PVP K-30) as binder and isopropyl alcohol as granulating fluid. The composition of batches as per experimental design was showed in table 2. Then passed the mass through 40 # sieve and granules were allowed to dry in oven at 50 °C for 30 min. dried granules passed through 24 # sieve. Then 15% fine was added in the granules and mixed with magnesium stearate and aerosil for 5 min and processed for compression by using round flat faced punches of rotary tablet machine using round 12 mm punch and compression force were adjusted in the range of 4-6 kg/cm^2. Weight of tablet adjusted to 330 mg.

Table 2: Composition of sustained release formulation of Lamivudine

Ingredients	SSBF-1	SSBF-2	SSBF-3	SSBF-4	SSBF-5	SSBF-6	SSBF-7	SSBF-8	SSBF-9	SSBF-10	SSBF-11	SSBF-12
LMV (gm)	0.30	0.30	0.30	0.30	0.30	0.30	0.30	0.30	0.30	0.30	0.30	0.30
HPMC K 100 M (gm)	2.475	0.99	0.99	2.475	2.475	2.475	3.96	3.96	0.99	3.96	0.99	3.96
Fenugreek polymer (gm)	0.495	0.99	0.742	0.495	0.99	0.99	0.495	0.742	0.742	0.742	0.495	0.99
PVP (gm)	1.83	1.83	1.83	1.83	1.83	1.83	1.83	1.83	1.83	1.83	1.83	1.83
MCC (gm)	3.9	4.89	3.9	3.9	3.405	3.405	2.415	2.167	5.137	2.167	5.385	1.92
Aerosil (gm)	0.27	0.27	0.27	0.27	0.27	0.27	0.27	0.27	0.27	0.27	0.27	0.27
M. Stearate (gm)	0.18	0.18	0.18	0.18	0.18	0.18	0.18	0.18	0.18	0.18	0.18	0.18
Total (gm)	9.45	9.45	9.45	9.45	9.45	9.45	9.45	9.45	9.45	9.45	9.45	9.45

Evaluation of powder blend [11, 12, 13, 14, 15]

Pre compression parameters

The prepared powder blend was evaluated for various parameters like bulk density, tapped density, angle of repose, compressibility index and Hausner's ratio and was showed in table 3.

Post compression parameters

After tablet compression, all the tablets were evaluated for

different parameters as hardness, friability, uniformity of weight, drug content. In vitro dissolution studies were carried out in USP dissolution test apparatus (Type 2), using distilled water (900ml, 37± 0.5oC) at 100 rpm for 24 hrs. All post compression parameter was showed in table 3.

Weight variation
Twenty tablets were selected randomly and the average weight was determined. Then the individual tablets were weighed and the individual weight was compared with the average weight which is shown in table 5.

Hardness and Friability
Hardness of the tablets (n=3) was determined using Monsanto hardness tester. Friability of the tablets was checked using Roche friabilator. Pre-weighed sample of tablets (n=10) was placed in the friabilator, it was operated for 100 revolutions. Tablets were then dusted and reweighed shown in table 5.

Drug content
Five tablets of each formulation were weighed and powdered. The quantity of powder equivalent to 10 mg of drug was transferred into 100 ml volumetric flask and dissolve with distilled water by keeping in a sonicator for 10-15 min, then it was filtered, suitable dilutions were made and absorbance was recorded by using UV spectrophotometer at 270 nm the results were shown in table 5.

Swelling index
Tablets of each formulation were weighed and dispersed in 900 ml of phosphate buffer (pH 6.8) at 37±0.5 °C, at 100 rpm. Tablets were withdrawn at 30 min, 1hr, 2hr, 4hr, 6 hr, and 8hr intervals and socked with filter paper to absorb excess buffer solution and weighed again. Percentage of swelling of tablets can be calculated by following equation.
Swelling index = Wt-W0/W0 ×100
Where,
Wt = Weight of swollen tablet at time t
W0 = Initial weight of the tablet

FTIR analysis of LMV
FTIR spectroscopy was conducted using an IR Spectrophotometer (FT-IR ALPHA) and the spectrum was recorded in the wavelength region of 4000–400 cm−1. The powder was placed in the light path and the spectrum was recorded. All spectra were collected as an average of three scans at a resolution of 2 cm−1.

Differential scanning Colorimetry (DSC)
The surface morphology of the fenugreek polymer and LMV was investigated by using scanning electron microscope (SEM) (JSM-6510, JEOL). Sufficient quantity was weighed and mounted on the stub. This specimen was then coated with platinum particles and observed with scanning electron microscope. Images were recorded using the back scattered electron (BSE) compositional signal with an accelerating voltage of 5KV.

In-*Vitro* dissolution release
In vitro release studies of batch SSBF-1 to SSBF-12 designed from the design expert software were conducted by using USP eight station dissolution test apparatus (Electrolab). The dissolution medium consisted of phosphate buffer (pH6.8) for the 24 hours. 900 ml of dissolution medium was maintained at 37±0.5 °C, at 100 rpm (paddle method). Aliquots (fractional) of 5 ml were withdrawn at predetermined time intervals and an equivalent amount of fresh solvent at the same temperature was replaced. The samples were analyzed by measuring the absorbance at 270 nm.

Data fitting
Outcome of each batch in terms of response was plotted using the software "Design Expert". Data was processed by using above mentioned software. Mathematical equations showing correlation of critical factors, their levels and the net outcomes were obtained and reported. The surface response curves were plotted and the optimized batch was predicted using "Design Expert" software.
The composition of the optimized batch predicted by the software was used further to develop the said batch in laboratory. Optimized batch was generated and the responses were recorded. The results of the responses were reported. On the basis of responses of the optimized batch, the potential of the natural polymers as a release retardant was identified.

Comparative In-*Vitro* dissolution release study
The comparative release study of the optimized batch having the good composition of the binder, polymer and hardness with the same concentration of gum tragacanth and gaur gum was studied. The batch with gum tragacanth and gaur gum were evaluated as same as the batch with fenugreek polymer [13, 15].

Results and Discussion
Preliminary trials
In the preliminary trials polymers like HPMC K 100M, MCC and fenugreek polymer are used in the different concentration for the release behavior of the LMV. In the trail batches it was observed that the HPMC K 100 M forms the gel in high concentration but do not hydrate quickly. On the other hand, fenugreek polymer hydrates quickly as compare to HPMC and MCC. When the HPMC and MCC concentration was low, the drug was rapidly diffuse from the matrix and burst release was observed. Also the tablet prepared with only HPMC and MCC was results in the lower crushing strength as compared to the fenugreek polymer. On the basis of properties, fenugreek polymer was selected as release rate modifying polymer.

Evaluation of powder blend
Pre-compression parameter
Flow properties are one of the best parameter to evaluate the compression parameter of sustained release tablet of LMV. Three types of flow measurements can be used to evaluate the nature of powder flow which is bulk density, tapped density, angle of repose; Carr's index and Hausner's ratio shown in table no 3. It is stated that, smaller the value of angle of repose (<30°), lesser the internal friction or cohesion between the particles and greater the flow characteristics & vice-versa and Carr's index and Hausner's ratio are also less than 21 & 1.25 respectively indicating the good flow properties. The angle of repose of pre compression powder blend was obtained in the range of 21.09-27.20 indicating the excellent flow. Carr's index and

Hausner's ratio in the range of 17.65 -24.88 and 1.21-1.37 respectively indicates good flow properties.

Post-compression parameter

Post- compression parameter like weight variation, hardness, friability and drug content also evaluated shown in table no 3. Weight variation test was passing and the variability in the weight was observed in the range of 320 ± 10.0 to 329 ± 1.0. Hardness and the drug content of the tablet were obtained in the range of 4 ± 0.0 to 5.5 ± 0.5, 86.148 ± 0.6 to 98.99 ± 0.5 respectively. Swelling index of all batches was obtained in the range of 49.48% to 86.39 % indicating the swelling of the fenugreek polymer.

Table 3: Pre & Post-compression parameters of powder blend

Pre-compression parameters of powder blend					Post-Compression parameters of Lamivudine tablet					
Batch	Angle of Repo-se (θ)	Bulk den-sity	Tap-ped den-sity	% Compr-essibility	Hau-sner Ratio	Weight Variati-on (mg)	Har-dness (Kg/cm2)	Fria-bility (%)	Drug cont-ent (%)	Swe-lling Index %
SSBF 1	27.2	0.42	0.56	24.88	1.33	322	5.5	0.43	88.78	81.65
SSBF2	23.19	0.43	0.57	24.57	1.32	320	4.5	0.50	86.34	83.71
SSBF3	25.9	0.42	0.57	26.26	1.35	327	5.5	0.36	86.14	86.39
SSBF4	24.56	0.42	0.55	22.23	1.28	324	4	0.44	92.98	63.48
SSBF5	21.8	0.41	0.54	24.24	1.32	321	4	0.51	98.99	68.24
SSBF6	20.37	0.40	0.56	27.03	1.37	328	5.5	0.35	91.11	49.48
SSBF7	28.49	0.42	0.56	24.81	1.33	325	4.5	0.41	92.55	64.57
SSBF8	21.09	0.44	0.58	23.85	1.31	323	5.5	0.39	86.78	53.46
SSBF9	21.5	0.43	0.56	21.98	1.28	321	4	0.37	88.93	69.51
SSBF10	22.95	0.42	0.55	23.51	1.3	325	4	0.31	85.68	70.15
SSBF11	26.93	0.43	0.54	20.8	1.26	328	4.5	0.42	91.07	82.18
SSBF12	21.65	0.42	0.51	17.65	1.21	329	4.5	0.36	87.94	66.97

Mean ± SD (n=3)

FTIR analysis of LMV

The absorption band 1487.45cm^{-1} showed the presence of amine group with N-H bends. The IR wave number 1382.75 cm^{-1}and 1277.27 cm^{-1} indicates the presence of alkenes and alcohol functional group respectively. 1154.57 cm^{-1} indicates the presence of ester group. The FTIR spectra of LMV were shown in figure 1.

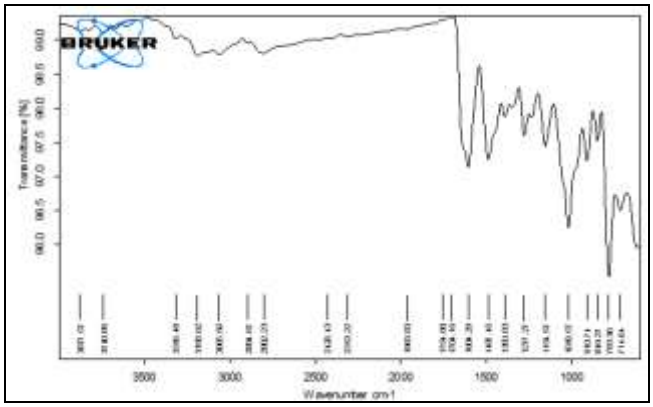

Fig 1: FTIR spectra of Lamivudine

Differential Scanning Colorimetry analysis

In the DSC thermogram of Fenugreek polymer and LMV was observed at 110.23°C and 178.44°C showed the melting of the LMV. The DSC thermogram was shown in figure no 2.

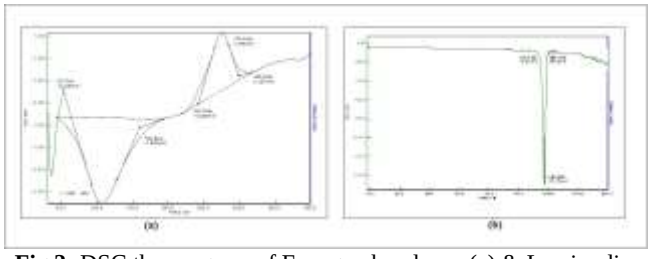

Fig 2: DSC thermogram of Fenugreek polymer(a) & Lamivudine (b)

In-*Vitro* dissolution release

In vitro drug release studies of the matrix type sustained release tablet of LMV were conducted for a period of 24 hours. According to the experimental design batches i.e. batch SSBF-1 to SSBF-12 the sustained release behavior of each batch was studied shown in table no 4 and the percent release graph of batch SSBF-1-SSBF 12 were shown in figure no.3. Batch SSBF-4, SSBF-6, SSBF-8 and SSBF-12 showed low release profile due to the high binder and polymer concentration present in the composition. Batch SSBF-1, SSBF-2 SSBF-3 and SSBF-11 contain the medium concentration of binder and polymer gives good release profile. Also the effect of the hardness of the tablet matters a lot in the release kinetics. High hardness slowdown the release of the tablet due to the high compressibility i.e. the binder and polymer very strongly binds to drug which take time to dissolve the polymer & binder in the dissolution media. The percent release was obtained in the range of 63.89% to 98.46% which is highly variable due to the different composition of the tablet.

Table 4: Percent (%) Drug release of batch SSBF1-SSBF12

Time (hrs)	SSBF 1	SSBF 2	SSBF 3	SSBF 4	SSBF 5	SSBF 6	SSBF 7	SSBF 8	SSBF 9	SSBF 10	SSBF 11	SSBF 12
0	0	0	0	0	0	0	0	0	0	0	0	0
0.5	9.17	12.63	18.36	5.2	6.23	6.73	11.86	5.32	11.23	11.23	11.23	11.23
1	18.2	23.56	28.12	8.05	15.29	10.73	23.84	9.37	23.26	24.26	27.26	21.26
2	27.71	32.78	34.91	10.44	26.37	18.67	34.89	13.42	34.7	31.28	30.73	35.96

3	42.94	48.93	50.29	17.54	36.89	24.18	41.83	22.13	46.73	41.86	50.73	42.39
6	56.94	61.20	59.09	25.33	48.79	30.57	52.40	34.20	54.12	57.12	57.12	51.26
9	76.93	75.63	67.01	35.68	59.37	41.34	61.480	49.56	68.72	65.00	72.72	65.94
12	89.76	90.84	83.76	64.08	71.50	52.96	72.50	58.28	75.52	80.39	86.39	70.96
24	94.53	93.27	98.46	75.39	84.60	63.89	80.90	69.90	86.87	88.64	94.67	79.24

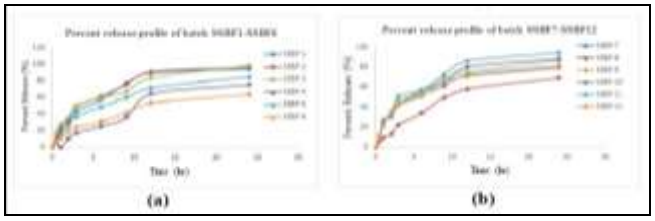

Fig 3: Percent release profile of batch SSBF1-SSBF6 (a) & SSBF6-SSBF12 (b)

Data fitting

In the experimental design the effect of the hardness, binder concentration and polymer concentration on the time required to release 35% of drug (t35) was studied and shown in figure no.4 A SRM (Surface response method) plot was obtained by taking the two responses. In the first response i.e. t35, 2FI (2- factors interactions) model was aliased. The Model F-value of 17.15 implies the model was significant. There was only a 0.34% chance that a "Model F-Value" this large could occur due to noise. Values of "Prob> F" (0.0034) less than 0.0500 indicate model terms are significant. Final Equation in Terms of Coded Factors given as follows:

Time required to release 35% drug (t35) =+10.92-0.23 *A+2.4 * B+2.42* C-0.92*A* B+1.19* A * C+2.19*B*C

The effect of hardness and binder concentration on the time required to release 35% of drug shows when the binder concentration and hardness of the tablet increases, the time required to release 35% of drug is also increased i.e. the release of the drug is decrease. Binder concentration and hardness affects the release profile of the tablet due to the high binding affinity of the binder and high compressibility due to the compression force. Similar way, the polymer is used in the sustained release due to its viscosity which plays a major role in the sustained release behavior of the tablet. Because of the high viscosity of HPMC k 100 M it is used in sustained release. In RSM plot when the polymer concentration is high the time required to release the drug will be high due the viscous nature of the polymer. The double effect of the binder and polymer on the release profile was observed. The time required to release the 35% of drug was very high due the double effect of the binder and polymer.

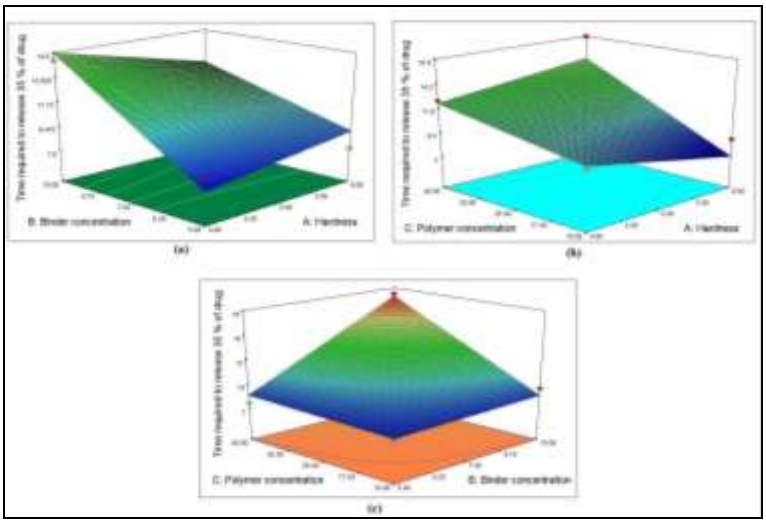

Fig 4: Effect of hardness & binder concentration (a), polymer concentration & hardness (b) and Polymer concentration & binder concentration(c) on time required to release 35% of drug (t35)

The second response was evaluated by RSM plot which represent the effect of the hardness, binder concentration and polymer concentration on the total percent release of the drug from the tablet of Lamivudine (LMV) shown in figure no.5. 2FI (Response surface 2- factors interactions) model was aliased. The Model F-value of 5.24 implies the model is significant. There was only a 4.47% chance that a "Model F-Value" this large could occur due to noise. Values of "Prob> F" (0.0447) less than 0.0500 indicate model terms are significant. Final Equation in Terms of Coded Factors:

Percent release = +87.79+0.32*A-8.20*B+0.17*C-1.48*A*B-0.46*A*C+0.51*B*C

The response plot of Binder concentration and hardness on the percent release profile of the LMV showed the increase in the binder concentration and hardness results in lowering the release of the drug up to certain concentration. Plot showed when the concentration of the binder was about 7.5 % the release of the tablet was 81.5 % when the concentration increases the release profile of the drug decreases. On the other site, when hardness of the tablet was about 4.5 the percent release was about 98 % shown in the plot. But, when the hardness of the tablet increases the percent release profile of the drug decreases.

The effect of Polymer concentration and hardness on the percent release profile of the LMV showed the concentration of the polymer increase the percent release decreases also the effect of the hardness of the tablet affect the percent release of the drug. The effect of polymer concentration and hardness on the percent release profile of the LMV shows the increase in the percent release with

decreasing the concentration of the polymer. Also, the increase in the binder concentration affects the release profile of the LMV.

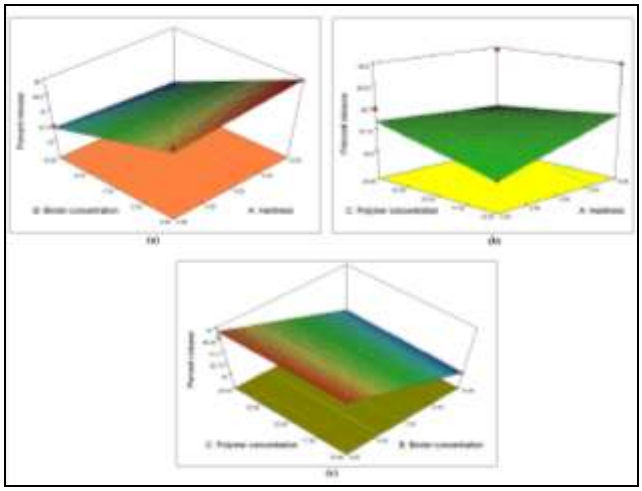

Fig 5: Effect of binder concentration & hardness (a), polymer concentration & hardness (b) and polymer concentration &binder concentration (c) on the percent (%) release of the tablet

After the RSM plot results the batches predicted by the software was obtained from that the optimized batch was selected shown in table no 5.

Table 5: Predicted batches by DOE software

Predicted batches by DOE software					
Batch	**Hardness (kg/cm2)**	**Binder conc (%)**	**Polymer Conc (%)**	**Predicted results by software (t35)**	**Predicted results by software (% drug release)**
SSBP-1	6	8.27	25.74	11.36 ± 0.3	85.11 ± 0.4
SSBP-2	4.64	5.85	13.73	8.080 ± 0.1	94.96 ± 0.1
SSBP-3	6	5.78	22.62	9.33 ± 0.5	94.86 ± 0.3
SSBP-4	5.62	5.3	37.19	10.74 ± 0.2	96.03 ± 0.5
SSBP-5	6	5.23	20.91	8.9 ± 0.4	97.09 ± 0.1
Optimized batch obtained by DOE software					
SSBF-OB	6	5.23	20.91	8.9	97.09

Comparative In-*Vitro* dissolution release study

The composition of optimized batch of fenugreek polymer with batches of gum tragacanth and gaur gum were shown in table no 6. The comparative release study of the optimized batch having the good composition of the binder, polymer and hardness with the same concentration of gum tragacanth and gaur gum was studied. The batch with gum tragacanth and gaur gum were evaluated as same as the batch with fenugreek polymer. The percent release profile of optimized batch with fenugreek polymer (SSB-OB), gum tragacanth (SSB-GT) and guar gum (SSB-GG) were shown in table no7. The comparative release profile was shown in figure no. 6.

Table 6: Optimized composition of LMV with fenugreek Polymer, gum tragacanth and guar gum

Ingredients	**LMV (gm)**	**HPMCK 100 M (gm)**	**Polymer (gm)**	**PVP (gm)**	**MCC (gm)**	**Aerosil (gm)**	**M. stearate (gm)**	**Total (gm)**
SSBF-OB (Fenugreek)	0.30	2.07	0.5187	1.83	4.281	0.27	0.18	9.45
SSB-GT (Gum tragacanth)	0.30	2.07	0.5187	1.83	4.281	0.27	0.18	9.45
SSB-GG (Guar gum)	0.30	2.07	0.5187	1.83	4.281	0.27	0.18	9.45

Table 7: % Drug release of batch SSB-OB (Fenugreek), SSB-GT (Gum Tragacanth) and SSB-GG (Guar gum)

SSBF-OB (Fenugreek) (%)	**SSB-GT (Gum Tragacanth) (%)**	**SSB-GG (Guar gum) (%)**
0 ± 0.0	0 ± 0.0	0 ± 0.0
9.27 ± 0.3	11.54 ± 0.4	8.26 ± 0.4
16.29 ± 0.4	21.63 ± 0.1	18.64 ± 0.3
24.96 ± 0.1	32.56 ± 0.3	24.72 ± 0.4
33.96 ± 0.3	43.96 ± 0.4	34.12 ± 0.2
63.42 ± 0.4	52.93 ± 0.2	48.51 ± 0.1
72.87 ± 0.1	60.46 ± 0.4	56.87 ± 0.4
83.29 ± 0.2	69.37 ± 0.5	67.20 ± 0.3
97.09 ± 0.4	77.63 ± 0.1	72.96 ± 0.2

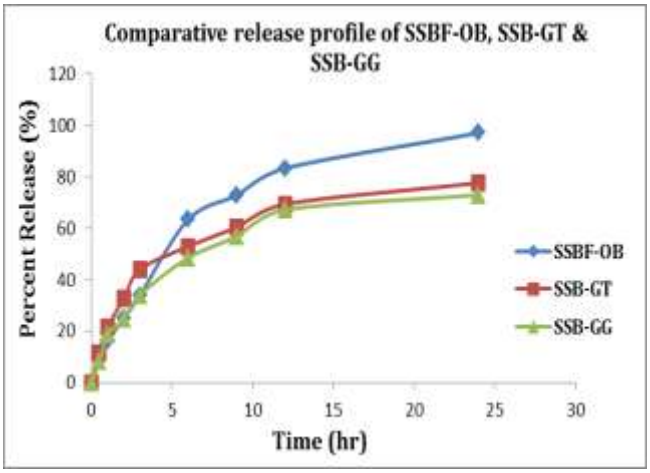

Fig 6: Comparative dissolution release profile of batch SSBF-OB; SSB-GT; SSB-GG

Conclusion

The potential of fenugreek polymer as a release rate retardant was established using Lamivudine as a model drug. The matrix type tablet formulation was developed using Quality by Design (QbD) approach. Also, other natural polymers like gum tragacanth, gaur gum were used in the tablet formulation of lamivudine. The comparative study of release retardant potential of polymer from fenugreek seeds with others were performed. The present work revealed that polymer obtained from the extraction of fenugreek seed was act as potential release retardant for the lamivudine.

Conflict of interest

The authors have no conflict of interest

Abbreviations used

LMV: Lamivudine, HPMC: Hydroxy Propylmethyl cellulose, MCC: Microcystlline Cellulose, DOE: Design of Experiments, Uv: Ultraviolet, FTIR: Fourier Transform Infrared Spectroscopy, IPA: Isopropyl Alcohol, RSM: Response Surface Methodology.

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