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Development and Evaluation of Mouth Dissolving Films Containing Selegiline

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ABSTRACT

The current investigation was aimed with the objective of formulating Selegiline fast dissolving oral thin films allowing fast reproducible drug dissolution in oral cavity thus bypassing the first pass metabolism to enhance the patient convenience and compliance in the effective treatment of Parkinson's disease. Oral thin films of Selegiline were prepared by solvent casting method with using different film forming agents like HPMC5LV, HPMC 15LV, HPMC50LV and HPMC K4M. Propylene glycol, Sucrose, Vanillin is used as a plasticizer, sweetening agent, flavouring agent respectively and citric acid as saliva stimulating agent. FDOFs were evaluated for physical characteristics, Surface pH, weight variation, thickness, folding endurance, percent drug content, percentage elongation, disintegration time, *in vitro* dissolution studies. Based on all the evaluation studies F18 is selected as optimized formulation and *in vitro* disintegration time and amount of drug release from the film was 9 seconds and 99.68% within 7 min respectively.

Keywords: Selegiline, HPMC, Solvent casting method, Parkinson's disease.

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INTRODUCTION

Flash release of Mouth dissolving film consists of solid dosage forms that are postage stamp-sized thin polymeric films, which when placed onto the tongue disintegrate or dissolve rapidly i.e., within seconds in the oral cavity without administration of water. Mouth dissolving films are a suitable alternative to conventional delivery as found in formulations by various formulators. [1]

The delivery system consists of a very thin oral strip, which is simply placed on the patient's tongue or any oral mucosal tissue, instantly wet by saliva the film rapidly hydrates and adheres onto the site of application. It then rapidly disintegrates and dissolves to release the medication for oro-mucosal absorption or with formula modifications, will maintain the quick dissolving aspects allow for gastrointestinal absorption to be achieved when swallowed. [2] The film is prepared

using the hydrophilic polymers (e.g., Hydroxypropyl methylcellulose) which dissolves on the tongue or buccal cavity in a no while. And upon contacting with liquid, the drug is delivered to the systemic circulation through dissolution. [3] Hydroxypropyl methylcellulose (HPMC) polymer is non-toxic, non-irritant and void of leachable impurities. It should have good wetting and spread ability characteristic. HPMC shows enough peel, shear and tensile strengths. Moreover, it is readily accessible and cheap. Accordingly, film strips should be tough adequately so that there would not be any damage while handling or transportation. [4] Selegiline's used in the treatment of Parkinson's disease are not fully understood, the selective, irreversible inhibition of monoamine oxidase type B (MAO-B) is thought to be of primary importance. MAO-B is involved in the oxidative deamination of dopamine in the brain. Selegiline binds to MAO-B within the nigrostriatal pathways in the central nervous system, thus blocking microsomal metabolism of dopamine and enhancing the dopaminergic activity in the substantial nigra. Selegiline may also increase dopaminergic activity through mechanisms other than inhibition of MAO-B. At higher doses, selegiline can also inhibit monoamine oxidase type A (MAO-A), allowing it to be used for the treatment of depression. The present work was aimed at developing a fast dissolving oral film of Selegiline to enhance therapeutic efficacy in the effective management of Parkinson's disease. [5]

MATERIALS AND METHODS

Materials

Selegiline API was procured from Hetero drugs Ltd, Hyderabad. HPMC 5LV, 15LV, 50LV and HPMC K4M procured from Granules India Ltd, Hyderabad. Crospovidone, Propylene glycol, Sucrose, Citric acid, Menthol, Vanillin procured from S. D. Fine Ltd, Mumbai.

Methods

Determination of dose of Selegiline

Amount of drug required per film = 5 mg of Selegiline.

The total amount of drug to be incorporated in the petridish is calculated as follows:

Internal Diameter of the petriplate = 9 cm

Radius of Petri plate = 4.5 cm

Area of Petri plate = πr^2 = 3.14 × 4.5 × 4.5 = 63.85 cm^2

Area of Film = 4 cm^2; Dose of API in 1 film = 5 mg

For 4 cm^2 area of film = 5 mg of drug

Then, 63.58 cm^2 area of petri plate = 4 ------ 5

63.58 -------?

= 79.47 mg

Therefore, an approximate amount of 79.47 mg drug was considered per Petridish.

Preparation of Selegiline oral films

It was aimed to prepare fast dissolving oral films of Selegiline with the dose of 5 mg per 4 cm^2 film. Film forming polymers Hypromellose different grades were weighed accurately, added to a small amount of water in a small beaker, covered with an aluminium foil and soaked for 24 hours to ensure complete hydration. Then, PG was added and stirring was continued for 30 minutes at 50 rpm. Selegiline, sucrose, citric acid and vanillin were dissolved in sufficient quantity of water and added to the polymer mixture. This film forming solution was then stirred well to obtain a homogenous solution. Dry and clean Petridish was selected and the solution was poured into it. Drying was carried out at 45°C in a hot air oven for 6 hours. The Petridish was then removed and left aside to cool down to room temperature. The film was then peeled carefully using surgical scalpel by making a small incision in the film on one side of the Petridish. Small films of 4 cm^2 were cut from one big film and packed primarily in aluminium foil and secondarily in a self- sealing polythene bag to ensure least moisture penetration and the resulting films were evaluated. The composition of Selegiline fast dissolving oral films with different HPMC grades are shown in Table 1, 2, 3.

Table 1: Formulation Trails Using HPMC 5LV and HPMC 15 LV

Ingredients	F1	F2	F3	F4	F5	F6
Selegiline (mg)	79.47	79.47	79.47	79.47	79.47	79.47
HPMC 5LV	80	80	80	100	100	100
HPMC 15LV	100	110	120	130	140	150
Crospovidone	1	2	3	4	5	6
Propylene glycol	100	100	100	110	110	110
Sucrose	10	10	10	10	10	10
Citric acid	50	50	50	50	50	50
Menthol	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
Vanillin	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
Water	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S

Table 2: Formulation Trails Using HPMC 15LV and HPMC 50 LV

Ingredients	F7	F8	F9	F10	F11	F12
Selegiline (mg)	79.47	79.47	79.47	79.47	79.47	79.47
HPMC 15 LV	80	80	80	100	100	100
HPMC 50 LV	120	140	160	180	200	220
Crospovidone	7	8	9	10	11	12
PG	120	120	120	130	130	130
Citric acid	50	50	50	50	50	50
Sucrose	10	10	10	10	10	10
Menthol	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
Vanillin	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
Water	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S

Table 3: Formulation Trails Using HPMC 15LV and HPMC K4M

Ingredients	F13	F14	F15	F16	F17	F18
Selegiline (mg)	79.47	79.47	79.47	79.47	79.47	79.47
HPMC 15 LV	80	80	80	100	100	100
HPMCK4M	240	260	280	300	320	340
Crospovidone	13	14	15	16	17	18
PG	140	140	140	150	150	150
Citric acid	50	50	50	50	50	50
Sucrose	10	10	10	10	10	10
Menthol	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
Vanillin	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
Water	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S

Evaluation of Selegiline Fast Dissolving Oral Films

Physical characterization of FDOFs

Physical characterization of FDOFs can be carried out by visual inspection for characteristics such as colour, thickness, brittleness, peeling ability, transparency, surface smoothness, tack property and film forming capacity.

The prepared films were subjected for in vitro evaluation tests like Surface pH [6], weight variation [7] and Thickness [8], Folding Endurance [9], Morphological properties, Moisture content, %Drug content and content uniformity [10], Percent elongation [11], Tensile strength [12], *In vitro* Disintegration time and *In vitro* Dissolution studies.

In vitro disintegration studies

Disintegration time was performed using disintegration test apparatus. Film (4 cm^2 of each) was placed in the basket, raised and lowered it in such a manner that the up and down movement was done at a rate equivalent to thirty times a minute. Time required by the film, when no traces of film remain above the gauze was noted. [13]

In vitro dissolution studies

The *in-vitro* dissolution studies were conducted using phosphate buffer pH 6.8 (300 mL). The dissolution studies were carried out using USP dissolution apparatus XXIV (Electrolab, Mumbai, India) at 37 ± 0.5°C and at 50 rpm using specified dissolution media. Each film with dimension (4 cm^2 of each) was placed on a stainless-steel wire mesh with sieve opening 700µm. The film sample placed on the sieve was submerged into dissolution media. Samples were withdrawn at regular time intervals and filtered through 0.45µm Whatman filter paper and were analyzed spectrophotometrically at 220 nm. To maintain the volume, an equal volume of fresh dissolution medium maintained at same temperature was added after withdrawing samples. The absorbance values were converted to concentration using standard calibration curve previously obtained by experiment. The dissolution testing studies were performed in triplicate for all the batches. [14]

Moisture Content

The patches were weighed and kept in a desiccators containing calcium chloride at 40°C for 24 hours. The final weight was noted when there was no further change in the weight of patch. The percentage of moisture content was calculated as a difference between initial and final weight with respect to initial weight. [15]

Drug Excipients Compatibility Studies

The drug excipients compatibility studies were carried out by Fourier Transmission Infrared Spectroscopy (FTIR) method. [16]

Fourier Transform Infrared Spectroscopy (FTIR)

FTIR spectra for pure drug, physical mixture and optimized formulations were recorded using a Fourier transform Infrared spectrophotometer. The analysis was carried out in Shimadzu-IR Affinity 1 Spectrophotometer. The IR spectrum of the samples was prepared using KBr (spectroscopic grade) disks by means of hydraulic pellet press at pressure of seven to ten tons.

SEM studies

The surface characteristics of film were determined by scanning electron microscopy (SEM) (HITACHI, S-3700N). Photographs were taken and recorded at suitable magnification.

Stability studies

The stability study of the optimized fast-dissolving films was carried out under different conditions according to ICH guidelines. The film was packed in the aluminium foil and stored in a stability chamber for stability studies. Accelerated Stability studies were carried out at 40°C/75% RH for the best formulations for 6 months. The patches were characterized for the drug content and other parameters during the stability study period.

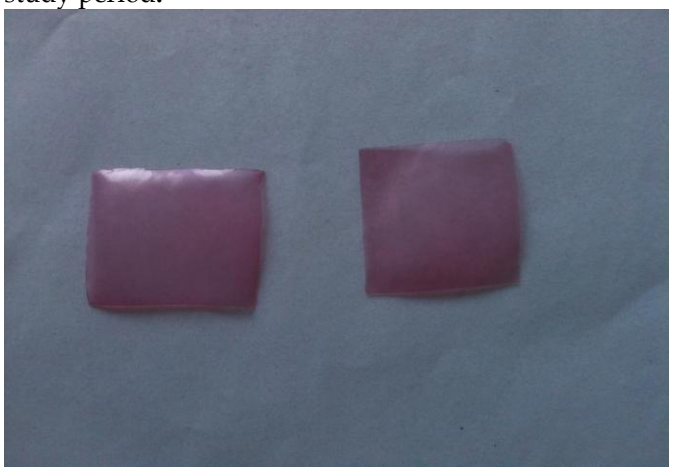

Fig. 1: Preparation of Selegiline mouth dissolving films

RESULTS AND DISCUSSION

Preparation of Selegiline oral films

It was aimed to prepare fast dissolving oral films of Selegiline with the dose of 5 mg per 4 cm^2 film. Total 18 formulations were prepared using different polymers, HPMC 5LV, HPMC 15LV, HPMC 50LV, HPMC K4M the resulting films were shown in Figure 1.

Physical Characterization of films

Physical characterization of FDOFs was carried out by visual inspection and the following results were observed. The films were evenly colored and no migration of color was observed. The increased thickness of film is attributed to the increase in the amount of HPMC 5LV, HPMC 15LV, HPMC 50LV, HPMC K4M and blend of polymers. All formulations were found to be excellent in film forming property, non-tacky, thin, flexible and easy to peel. The films obtained from all the formulations had smooth surface on either side.

Evaluation of fast dissolving oral films of Selegiline

Thickness & Weight variation

Thickness of all mouth dissolving films was measured with Digital Vernier calliper (Mitutoyo) (Table 4). The optimized film has thickness of 0.246 ± 0.05 mm. A result of thickness measurement showed that as the concentration of polymer increases, thickness of mouth dissolving film also increases. A result showed that as the concentration of polymer increases weight of film also increases. The weight variation of the optimised formulation was in the range of 22 ± 0.58 mm, which was acceptable.

Table 4: Evaluation parameters of Selegiline mouth dissolving films

Formulation Code	Weight (mg)	Transparency	Thickness (mm)	Disintegration time (sec)
F1	24 ± 0.59	Clear	0.259 ± 0.09	16 ± 0.35
F2	24 ± 0.60	Clear	0.268 ± 0.07	12 ± 0.23
F3	25 ± 0.80	Clear	0.262 ± 0.02	14 ± 0.24
F4	24 ± 0.79	Clear	0.261 ± 0.02	18 ± 0.36
F5	25 ± 0.72	Clear	0.258 ± 0.07	19 ± 0.40
F6	26 ± 0.68	Clear	0.254 ± 0.05	15 ± 0.36
F7	24 ± 0.60	Clear	0.253 ± 0.05	13 ± 0.24
F8	25 ± 0.62	Clear	0.251 ± 0.02	11 ± 0.21
F9	23 ± 0.59	Clear	0.248 ± 0.07	14 ± 0.24
F10	26 ± 0.80	Clear	0.249 ± 0.09	13 ± 0.24
F11	27 ± 0.72	Clear	0.255 ± 0.05	18 ± 0.36
F12	28 ± 0.79	Clear	0.269 ± 0.09	12 ± 0.23
F13	26 ± 0.68	Clear	0.262 ± 0.02	17 ± 0.36
F14	23 ± 0.59	Clear	0.260 ± 0.02	15 ± 0.36
F15	25 ± 0.79	Clear	0.254 ± 0.05	14 ± 0.24
F16	26 ± 0.68	Clear	0.258 ± 0.09	12 ± 0.22
F17	24 ± 0.60	Clear	0.250 ± 0.02	10 ± 0.20
F18	25 ± 0.58	Clear	0.246 ± 0.05	9 ± 0.19

Values are expressed in mean± SD (n=3)

Table 5: Evaluation parameters of Selegiline mouth dissolving films

Formulation Code	Drug Content (%)	Moisture content (%)	Folding Endurance (count)	Surface pH
F1	90.21 ± 0.45	3.41 ± 0.30	115 ± 2	6.85 ± 0.5
F2	89.76 ± 0.42	3.66 ± 0.45	114 ± 1	6.81 ± 0.1
F3	88.64 ± 0.40	3.80 ± 0.50	119 ± 1	6.70 ± 0.1
F4	94.58 ± 0.56	3.37 ± 0.29	108 ± 3	6.54 ± 0.3
F5	96.74 ± 0.60	3.25 ± 0.18	105 ± 2	6.66 ± 0.5
F6	91.79 ± 0.49	3.15 ± 0.09	104 ± 1	6.79 ± 0.7
F7	90.12 ± 0.45	3.03 ± 0.04	101 ± 2	6.90 ± 0.1
F8	92.34 ± 0.50	4.29 ± 0.20	97 ± 1	6.85 ± 0.5
F9	97.46 ± 0.62	4.34 ± 0.23	98 ± 2	6.82 ± 0.2
F10	91.61 ± 0.49	4.69 ± 0.35	101 ± 1	6.71 ± 0.1
F11	89.62 ± 0.42	3.59 ± 0.34	119 ± 2	6.66 ± 0.5
F12	90.92 ± 0.45	3.64 ± 0.45	111 ± 2	6.42 ± 0.2
F13	92.61 ± 0.50	3.85 ± 0.54	108 ± 2	6.54 ± 0.3
F14	93.79 ± 0.52	3.90 ± 0.58	102 ± 3	6.67 ± 0.6
F15	94.44 ± 0.56	3.95 ± 0.60	104 ± 1	6.72 ± 0.2
F16	91.67 ± 0.49	3.98 ± 0.62	98 ± 2	6.74 ± 0.3
F17	93.12 ± 0.52	4.32 ± 0.23	110 ± 4	6.89 ± 0.8
F18	99.64 ± 0.69	4.12 ± 0.18	121 ± 4	6.98 ± 0.7

Values are expressed in mean± SD (n=3)

Folding endurance

Folding endurance gives an indication of brittleness of the film. It was shown that as the concentration of polymer and plasticizer increases, folding Endurance of mouth dissolving film increases (Table 5). The optimized film (F18) has folding endurance value of 121 ± 4, which was desirable.

Surface pH

Surface pH of all mouth dissolving films prepared by using different polymers was found to be in the range of 6.42 to 6.98 pH (Table 5), which was close to the neutral pH, which indicated that films may have less potential to irritate the sublingual mucosa, and hence, more acceptable by the patients.

% Drug content

All the fast dissolving oral films were found to contain an almost uniform quantity of the drug, as per content uniformity studies indicating reproducibility of the technique. Drug content in the films was evaluated and the values were found to be between 88.64 to 99.64% (Table 5) for three different cuts from each film, formulation F18 shown best drug content. As per the USP requirements, the films found to meet the criteria for content uniformity. No significant difference in the drug content among the films indicated good content uniformity.

In vitro disintegration studies

The disintegrating time of all the formulations was ranges from 8 to 19 sec. The disintegration time of optimized formulation (F18) was found to be 8 sec, which was very less and desirable for quick onset of action (Table 4).

Tensile strength and Percent Elongation

The tensile testing gives an indication of the strength and elasticity of the film, reflected by the parameters, tensile strength and elongation at break. Results revealed that optimized formulation (F18) showed better tensile strength (11.6 g/cm²) and moderate % elongation (9.7) (Table 6).

Table 6: Tensile Strength and Percent Elongation

Formulation code	Tensile strength (g/cm²)	Percent elongation (%)
F18	11.6	9.7

Table 7: *In vitro* drug release Studies of Formulation F1 to F6

Time (min)	F1	F2	F3	F4	F5	F6
0	0 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 0
1	33.12 ± 2.16	40.15 ± 2.75	48.74 ± 2.89	35.17 ± 2.25	50.24 ± 2.90	39.11 ± 2.31
3	48.34 ± 2.89	59.63 ± 3.20	52.26 ± 2.98	48.22 ± 2.89	62.28 ± 3.42	45.29 ± 2.86
5	55.56 ± 3.05	72.84 ± 4.10	64.67 ± 3.42	69.34 ± 3.52	72.41 ± 4.10	58.75 ± 3.19
7	69.78 ± 3.52	82.22 ± 4.49	71.11 ± 4.09	75.64 ± 4.12	88.39 ± 4.95	64.18 ± 3.42
9	81.25 ± 4.48	93.34 ± 5.02	88.38 ± 4.98	80.36 ± 4.50	94.45 ± 5.05	72.27 ± 4.10
10	95.06 ± 5.10		96.40 ± 5.12	93.70 ± 5.02		89.09 ± 4.98

Values are expressed in mean ± SD (n=3)

Table 8: *In vitro* drug release Studies of Formulation F7 to F12

Time (min)	F7	F8	F9	F10	F11	F12
0	0 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 0
1	48.45 ± 2.89	37.11 ± 2.29	40.87 ± 2.75	54.19 ± 3.05	56.16 ± 3.06	33.20 ± 2.18
3	54.34 ± 3.02	56.36 ± 3.06	58.64 ± 3.20	68.26 ± 3.51	60.32 ± 3.38	48.23 ± 2.89
5	68.28 ± 3.51	65.17 ± 3.48	69.21 ± 3.52	72.33 ± 4.10	71.28 ± 4.10	54.87 ± 3.06
7	81.13 ± 4.48	74.24 ± 4.15	83.29 ± 4.50	85.49 ± 4.48	82.56 ± 4.48	61.64 ± 3.38
9	95.20 ± 5.10	83.44 ± 4.50	96.14 ± 5.12	90.36 ± 5.01	91.54 ± 5.02	79.72 ± 4.58
10		97.09 ± 5.14				94.05 ± 5.05

Values are expressed in mean ± SD (n=3)

Table 9: *In vitro* drug release Studies of Formulation F13 to F18

Time (min)	F13	F14	F15	F16	F17	F18	Marketed product
0	0 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 0
1	30.12 ± 2.10	34.28 ± 2.20	49.25 ± 2.90	54.35 ± 3.04	58.29 ± 3.21	64.66 ± 3.50	28.14 ± 1.30
3	46.35 ± 2.85	54.39 ± 3.04	67.37 ± 3.51	62.24 ± 3.40	65.36 ± 3.42	82.19 ± 4.50	36.29 ± 2.29
5	58.41 ± 3.20	78.18 ± 4.20	76.56 ± 4.12	73.67 ± 4.09	79.14 ± 4.15	90.04 ± 5.01	48.74 ± 2.86
7	70.29 ± 4.08	84.34 ± 4.48	83.34 ± 4.50	86.48 ± 4.50	82.34 ± 4.50	99.68 ± 5.38	68.29 ± 3.51
9	84.98 ± 4.45	92.03 ± 5.02	90.12 ± 5.01	93.06 ± 5.02	89.28 ± 4.98		72.39 ± 4.10
10	90.45 ± 5.01		92.26 ± 5.02		95.40 ± 5.10		85.45 ± 5.02

Values are expressed in mean± SD (n=3)

In-vitro drug dissolution study of formulation batches F1 to F18

The cumulative % drug release for the formulations F1 to F18 are tabulated in Table 7-9 and Figure 3-4. The graphs are depicted in Figure. The optimized formulation (F18) shows highest Percent of drug release 99.68 ± 5.38 within short time of 7 min when compared with other formulations.

Table 10: Physicochemical characteristics of optimized formulation stored at 40 ± 2°C / 75 ± 5% RH

Retest Time For Optimized formulation (F18)	Disintegrating Time (sec)	Drug Content	*In vitro* drug release profile (%)
0 days	09	99.64	99.68
30 days	10	98.12	98.12
60 days	10	97.23	97.24
90 days	11	97.04	96.21
120 days	11	96.21	96.01
180 days	12	95.67	95.32

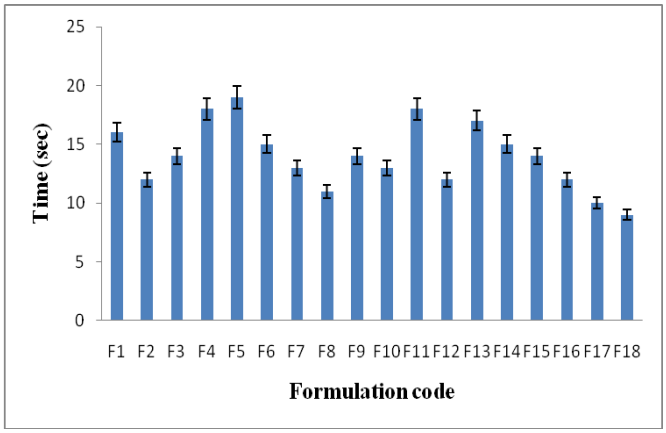

Fig. 2: *In vitro* disintegrating time of all Formulations F1-F18

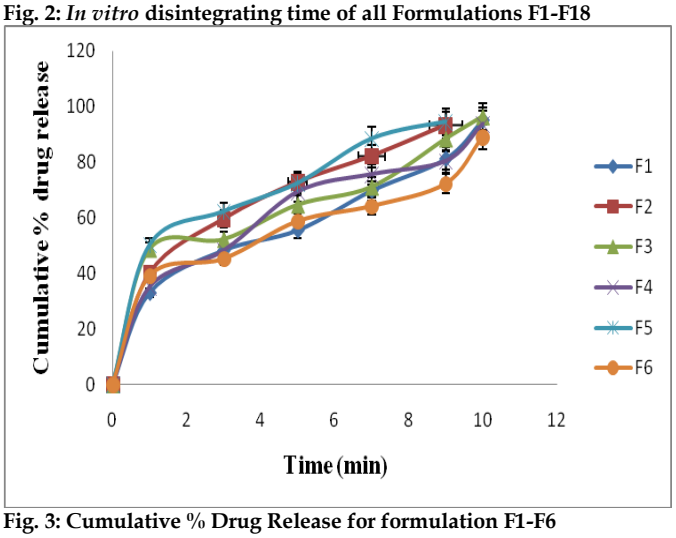

Fig. 3: Cumulative % Drug Release for formulation F1-F6

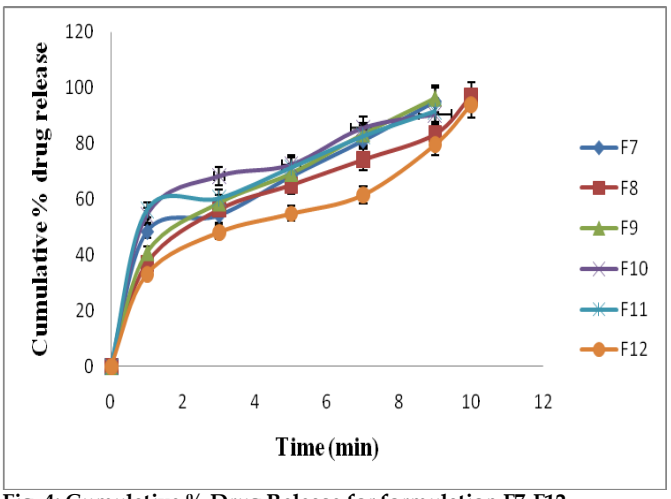

Fig. 4: Cumulative % Drug Release for formulation F7-F12

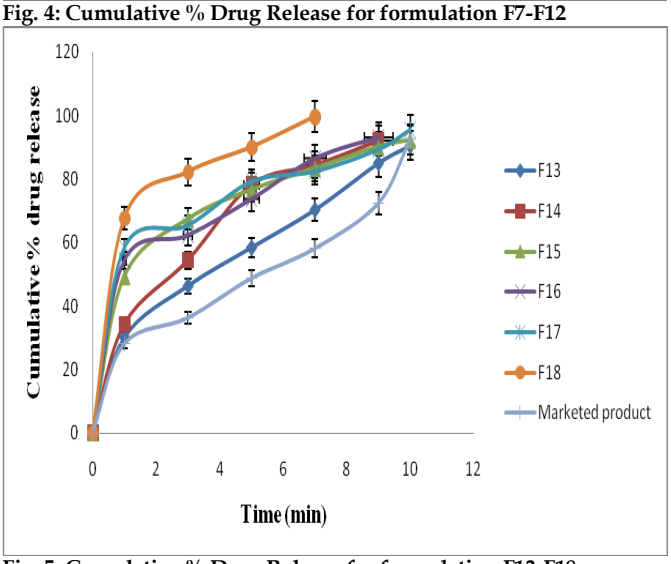

Fig. 5: Cumulative % Drug Release for formulation F13-F18

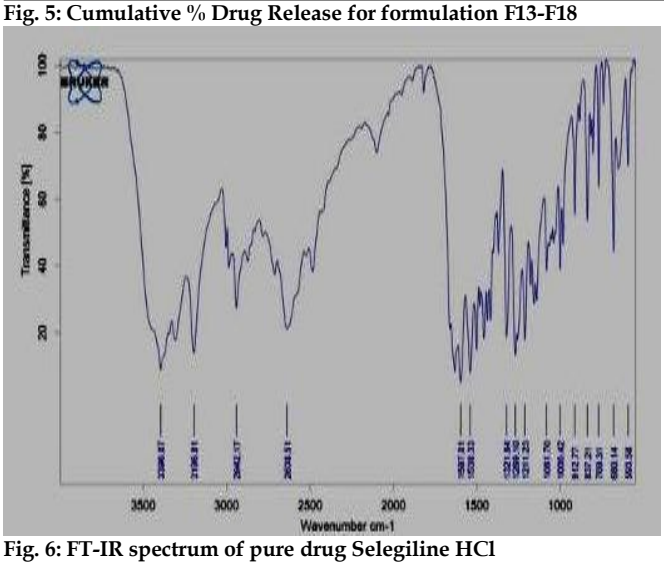

Fig. 6: FT-IR spectrum of pure drug Selegiline HCl

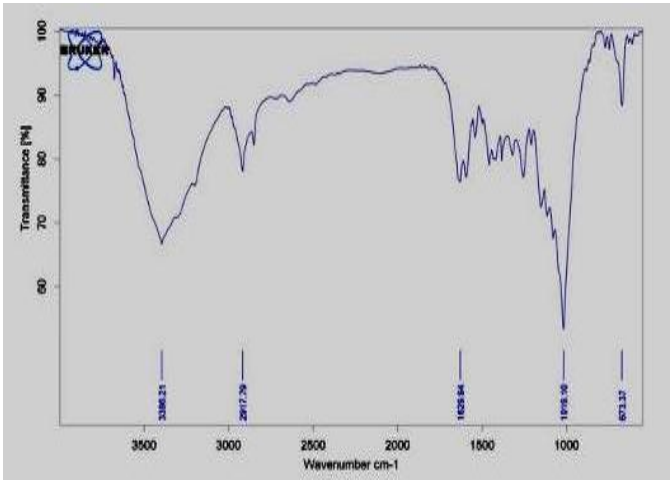

Fig. 7: FT-IR spectrum of Selegiline HCl optimized formulation F18

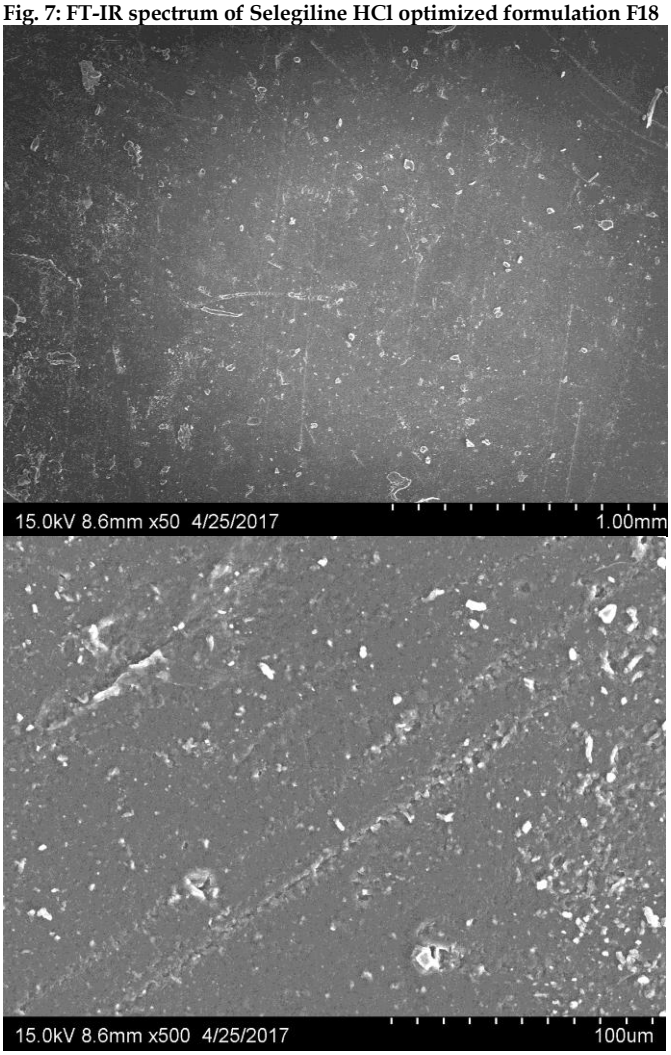

Fig. 8: Scanning electron micrograph of Selegiline optimized mouth dissolving films F18

Release order kinetics

The optimized formulation of Selegiline mouth dissolving film (F18) was best explained by first order, as the plots showed the highest linearity (r2 = 0.980), followed by, Higuchi (r2 = 0.955), Korsmeyer Peppas (r2=0.930) and then zero order (r2 = 0.930). The corresponding plot for the Korsmeyer-Peppas equation of the optimized formulation F 18 indicated good linearity. The release exponent 'n' was found to be for F18 is 0.438, which appears to indicate Fickian diffusion and may indicate that the drug release was controlled by first order release Table 10 and Figure 6-13.

Drug excipients compatibility studies by FTIR spectroscopy

The FTIR spectrum of pure drug selegiline HCl **(**Figure 6**)** exhibited property absorption peaks at 1456, 1093, 1464 and 858 cm^{-1} which show the attendance of wide, - N- bending fluctuation, C-N bending, and -N- wagging vibration, respectively. Additionally, C-H stretching vibrations at the end of the aliphatic chain, CΞC stretching vibrations and bending vibrations bonds were exhibited at 2942, 2120 and 698 cm^{-1} , respectively. Overall there was no alteration in peaks of Selegiline HCl pure drug and optimized formulation **(**Figure 7**)**, suggesting that there was no interaction between drug & excipients. There is additional peaks appeared or disappeared hence no significant changes in peaks of optimized formulation was observed when compared to pure drug indicating absence of any interaction.

Scanning electron microscopy

SEM of Selegiline mouth dissolving film shows the rough and uneven surface with circular pits with the absence of particles suggesting the presence of the drug in dissolved state in the polymer HPMC. They further ensure the loss of crystallinity when formulated as a film comprising amorphous HPMC (Figure 8).

Stability Studies for optimized formulation

Optimized formulation was selected for stability studies on the basis of high cumulative % drug release. Disintegrating time, drug content and In vitro drug release studies were performed for 6 months according to ICH guidelines. From these results it was concluded that, optimized formulation F18 is stable and retained their original properties with minor differences which depicted in the table (10).

Current research work is to formulate and evaluate mouth dissolving films of Selegiline. Fast dissolving films were formulated by varying proportions of polymers by solvent casting method and they were evaluated**.** The physical appearance of the film formulations was transparent in nature. The drug content of the formulations was in the values were showing content uniformity. The thickness uniformity of the film formulations generally assures its dose accuracy per strip. It was observed that as the polymer concentration increased thickness was also increased. Upon increasing addition of super disintegrating agent crospovidone it was noted that for F18 it shows better disintegration property 9 sec. In vitro drug release studies were carried out to select appropriate polymer composition for the formulation having suitable drug dissolution property for the dosage form. Maximum drug was released from the formulation F18 within 7 minutes. Based on the physico-mechanical properties and in-vitro drug release, the formulation F-18 was concluded as the Optimized formulation. In the present work, it can be concluded that the fast dissolving film formulation can be an innovative and promising

approach for the delivery of Selegiline for the treatment of Parkinson's disease.

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