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Original Article

Formulation and Evaluation of Oral Fast Dissolving Sublingual Film of Propranolol HCl

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ABSTRACT

Objective: The objective of the present investigation was to formulation & evaluation of oral fast dissolving sublingual film of Propranolol HCl.
Methods: In the present investigation an attempt was made to develop fast dissolving sublingual film of propranolol HCl by using two polymers. Fast dissolving films of propranolol hcl were formulate using HPMC E15 & HPMC as a film forming agent and propylene glycol as plasticizer and Cross povidone as a disintegrating agent. Fast dissolving film was prepared by solvent casting method. The stability studies of the patch were performed for optimized batch as per ICH guideline. From the results of design batches, best batch was selected and evaluated for *in vivo* pharmacokinetic study in male/female Wistar rat model using optimized formulation F4 and observed that the excellent drug release in blood of the rat. The drug & excipients were characterized as per IP Drug and excipients studies using FT-IR. **Results:** Films were subjected to physicochemical characterization such as weight variation, thickness, tack test, drug content uniformity, surface pH, folding endurance, disintegration time, In vitro drug release, In vivo drug release, stability study. Among all the formulations (F1 to F13) prepared, batches F4, F5, F11 & F13 was the best formulation & released 109.86%, 104.73%, 97.74% & 100% in 10min. The statistically optimized formulation was characterized with FT-IR (Fourier transform-infrared spectroscopy) studies and found no chemical interactions between drug and polymer. **Conclusion:** Thus the prepared fast dissolving film of propranolol HCl could be a better alternative for tablet and capsules an achieving rapid oral bioavailability in treatment of migraine prophylaxis.

Keywords: Fast dissolving sublingual film, Propranolol HCl, solvent casting method, Drug release, Fast onset of action.

1. INTRODUCTION

The oral route is the most preferred route of administration for systemic effect. About 60% of all the formulations are solid dosage form. Tablet is the most preferred dosage form due to ease of transportation, manufacturing and more patient compliance. [1] Generally geriatric, pediatric and bedridden patient experience difficulties in swallowing the conventional oral dosage form. To overcome this problem a

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novel formulation was developed i.e. oral fast dissolving films. Fast dissolving films (FDF), a type of oral drug delivery system for the oral delivery of the drug, was developed based on the technology of the transdermal patch. This delivery system consists of a thin film, which is simply placed on the patient's tongue or mucosal tissue, instantly wet by saliva; the film rapidly dissolves. Then it rapidly disintegrates and dissolves to release the medication for oral mucosal absorption. [2, 3] This fast dissolving action is primarily due to the large surface area of the film, which wets quickly when exposed to the moistural environment. FDF is prepared using hydrophilic polymer that rapidly dissolves on the tongue or sublingual cavity, delivering the drug to the systemic circulation via sublingual mucosa.[4] The fast dissolving drug delivery system are specially designed for the drugs which have extensive first pass metabolism and have low dose, for the enhancement of bioavailability.[5]

Definition of FDF: Fast dissolving films are most advance form of solid dosage form due to its flexibility. It improve efficacy of Active pharmaceutical ingredient (API) dissolving in the short duration oral cavity after the contact with less amount of saliva as compared to dissolving tablet.

The Fast Dissolving Drug Delivery Systems was an advancement that came into existence in the early 1970's and combats over the use of the tablets, syrups, capsules which are the other oral drug delivery systems. Fast Dissolving Drug Delivery Systems serves as a major benefit over the conventional dosage forms since the drug gets rapidly disintegrated & dissolves in the saliva without the use of water.[6]The most popular oral solid dosage forms are tablets and capsules. Many patients find it difficult to swallow tablets and hard gelatin capsules particularly pediatric and geriatric patients and do not take their medicines as prescribed. Difficulty in swallowing or dysphagia is seen to afflict nearly 35% of the general population. In some cases such as motion sickness, sudden episode of allergic attack or coughing, fear of choking and an unavailability of water, the swallowing of tablet or capsules may become difficult. To overcome these difficulties, several fast dissolving drug delivery systems have been developed.[7] To eliminate the drawbacks of fast dissolving tablet a fast dissolving film can be placed. Fast dissolving films are very similar to ultra-thin strip of postage stamp in their shape, size and thickness. Fast dissolving film 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 oromucosal absorption. This fast dissolving drug delivery system (FDDS) is suited for the drugs which undergo high first pass metabolism and is used for improving bioavailability with reducing dosing frequency to mouth plasma peak levels, which in turn minimize adverse/side effects and also make it cost effective.[8] Drug delivery by per-oral administration arise some problems such as hepatic first pass metabolism and enzymatic degradation within the GI tract.[9] For certain class of drugs, these problems can be overcome by their administration through sublingual mucosa.

2. MATERIALS AND METHODS

Propranolol hydrochloride was obtained as gift sample from IPCA Laboratories Limited Waluj, Aurangabad. Hydroxypropyl Methylcellulose, HPMC E-15, Propylene glycol & Cross povidone obtained from Labo Chemie, Citric acid obtained from Vikas Pharma, Aspartame obtained from Ozone International Mumbai.

Materials used in the experimental study:

The drug, excipients and chemicals / reagents used for various experiments are enlisted as follows.

Table 1: Material used with their source

SR. NO.	MATERIAL	PROPERTY	SOURCE
1.	Propranolol Hydrochloride	Pure drug	IPCA laborataries limited waluj, aurangabad.
2.	HPMC , HPMC E 15	Film former	Meher chemie, Labo chemie
3.	Propylene glycol	Plasticizer	Meher chemie, Labo chemie
4.	Cross povidone	Disintegrating agent	Meher chemie Mumbai
5.	Citric acid	Saliva stimulating agent	Vikas pharma
6.	Aspartame	Sweetening agent	Ozone international

Equipment

Following equipment were used in the present study

Table 2: Equipments used with their source

SR.NO	EQUIPMENT	MODELNO.	MAKE
1.	Oven Rotek	OR-203	Labindia
2.	Disintegration apparatus	DA-40	Electrolab
3.	Uv –spectrophotometer	Uv-1800	Shimadzu japan
4.	Digital balance	BL-22OH	Shimadzu
5.	Ph meter	Pico$^+$	Labindia
6.	Magnetic stirrer	LMS-28OE	Labtop
7.	Screw gauge	SG-001	Electrolab
8.	Sonicator	3-5 L100H	PCI analytics
9.	Dissolution apparatus	EDT -08LX	Electrolab
10.	IR-spectroscopy	Spectrum-2	PerkinElmer spectrum version

Preparation of Oral Fast dissolving sublingual film by using solvent casting method:

From the preliminary physical observation of the films prepared the best compositions were used for the incorporation of Propranolol hydrochloride. Calculated amount of propranolol hydrochloride was dissolved in the polymeric solution, after complete dissolution of the drug; propylene glycol (plasticizer) was added and stirred to form a homogeneous solution. The solution was casted on petridish then kept at room temperature for 24 hours. The film thus formed was cut into size of 2X2 cm diameter. Each

containing 10mg Propranolol hydrochloride. The detailed compositions of the propranolol hydrochloride sublingual film are given in table No: 3-

Table 3: Formulation Details of Propranolol hydrochloride Sublingual film

Ingredient(mg)/ Formulation	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12	F13
Propranolol hcl	160	160	160	160	160	160	160	160	160	160	160	160	480
HPMC E15	300	400	500	150	175	200							450
HPMC							300	400	500	150	175	200	
Propylene glycol	200	200	200	50	50	50	200	200	200	50	50	50	150
Citric acid	50	50	50	16	16	16	50	50	50	16	16	16	48
Aspartame	10	10	10	10	10	10	10	10	10	10	10	10	30
Cross povidone	16	16	16	16	16	16	16	16	16	16	16	16	48
Water	q.s	q.s	q.s	q.	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s.

EVALUATION OF SUBLINGUAL FILM: [10-15]

Drug-Polymer Interaction Study of film:

There is always a possibility of drug-excipient interaction in any formulation due to their intimate contact. The technique employed in this study to know drug-excipient interactions is IR spectroscopy; IR spectroscopy is one of the most powerful analytical techniques which offer the possibility of chemical identification. Infra-red spectra of pure drug Propranolol hydrochloride and formulations were scanned by using Perkin-Elmer FTIR SV-10, by a thin film method.

Weight Uniformity of film:

Weight variation is studied by individually weighing 3 randomly selected films and by calculating the average weight.

Thickness of films:

The thickness of film is determined by micrometer screw gauge at 5 different points of the film i.e central and the four corners and means thickness is calculated. For measurement of Uniformity of thickness, 5 film are randomly selected and thickness is measured on location of each formulation Maximum variation in the thickness of the films should be less than 5% and mean ±S. D. is calculated.

Folding Endurance of film:

Folding endurance is measured by manually repeated folding of film at same place till it broke. The number of time the film is folded without breaking is known as the folding endurance value. The flexibility or elasticity of film can be measured. Folding endurance was measured by manually or practically for the prepared films. Take a 2X2cm films and folded repeatedly at the same place till it broke. The no times the film could be folded at the same place without breaking gave the exact valve of folding endurance.

Surface pH of film:

The film to be tested was placed in a petridish and was moistened with 1ml of distilled water and kept for 30s. The pH was noted after bringing the electrode of the pH meter in contact with the surface of the formulation and allowing equilibration for 1min. The average of three determinations for each formulation was done.

Drug content uniformity of films:

Standard solution:

Accurately about 10mg of propranolol hydrochloride was weighted and transferred in to a 10 ml of volumetric flask. Then add PBS (pH 6.8) solution with mechanical shaking up to 10 ml (1000 µg/ml). Then this solution was filtered through the whatman filter paper. Then 0.1 ml of filtrate was pipette out and diluted up to 10 ml with the PBS solution in 10 ml of volumetric flask so as to get 10 µg/ml final concentrations.

Test solution:

One film of Propranolol hydrochloride was dropped into a 10 ml of volumetric flask. Then add PBS (pH 6.8) solution with mechanical shaking up to 10 ml. then this solution was filtered through the whatman filter paper. Then 0.1 ml of filtrate was pipette out and diluted up to 10 ml with the PBS solution in 10 ml of volumetric flask so as to get 10 µg/ml final concentration. Content uniformity was calculated using following formula:

%Label claim =Abt/Abs x Ds/Dt x 100/Lc x100.

Where,

Abs = Abs. of standard solution,

Lc = Label claim,

Ds = Dilution of standard,

Dt = Dilution of test,

Abt = Abs. of test solution.

In vitro Drug Release:

The release rate of the Propranolol hydrochloride fast dissolving film was determined by the help of USP Dissolution Test Apparatus-II. The dissolution test was performed using 300 ml Phosphate Buffer Solution pH 6.8, at 37 0.50C with 50 rpm of the paddle speed. Aliquot 5 ml of the solution was collected from the dissolution apparatus at time interval of 1 min and at the same time add 5 ml or same amount of fresh dissolution medium. The Aliquot filtered through the whatman filter paper. The absorbance of the filtered solution was measured at 290 nm. The aliquot should be withdrawn at the zone between the surface of the dissolution medium and the top of rotating paddle not less than 1 cm apart from the vessel wall. Cumulative percent drug release can be calculated by using the equation obtained from the standard curve or % drug release formula. (A = Con. Of Std. / Abs. of Std. X Abs. of sample X volume of dissolution apparatus X Dilution factor / 1000, B = A-Value/Label claim X 100).

Stability study: The stability study of fast dissolving film should be carried out with the help stability chamber. The stability study conducted by ICH guideline. Short term stability studies were performed in a stability chamber over a period of 3 week (21days) on the promising fast dissolving film formulations F4 & F11. Sufficient number of films formulation were packed in stability container and kept in a stability chamber at temperature 45 0C & RH 75%.

Disintegration time: The disintegration time limit is of 30 s or less for orally disintegrating tablets, as described in CDER guideline and can be applied to fast dissolving oral

film. No official guideline is available for oral fast dissolving films. Pharmacopoeial disintegrating test apparatus may be used for this study. Typical disintegration time for film is 5-30 sec.

In vivo drug release study: (Protocol no.:- CPCSEA/CBPL/AH10)

In vivo studies of Propranolol hcl Oral Dispersible Films: In vivo studies were carried out for Male/Female Wistar rats weighing 180- 200gms. 18 rats were divided into 3 groups of each group containg 6 rats.

Group 1: In this group containg 6 rats are Normal without any treatment (Control group).

Group 2: Pure drug is administered by calculating the dosage based on animal weight. The animal dose for the drug is 0.10mg/kg by oral route by preparing a suspension of drug in sodium cmc.

Group 3: Film formulation is given onto mouth mucosa. For the administration of sample (tablet or film) preparation, 50 µl of distilled water was dropped into the rat oral cavity under light ether anesthesia by inhalation and then two halves (1 cm×0.5 cm) of the film preparation were applied to the sublingual cavity bilaterally. Blood specimens were taken (every 0.5 ml) in a centrifuge plastic capillary tube by the retro orbital route at 15 min, 30 min, 45 , 60, 120, 240, and 480min after drug administration. Blood was subjected to centrifugation at 10,000rpm for 15 min, then plasma was taken in a polyethylene tube to the plasma of 100 microlitres, 100 microlitres of acetonitrile is added and mixed by vortexing for 15min, then centrifuged at 15,000 rpm for 30min and the sample were check into Uv Spectroscopy.

3. RESULT AND OBSERVATION

Preparation of standard Calibration curve of Propranolol Hydrochloride:

Propranolol hydrochloride showed maximum absorption at wavelength 290 nm in PBS PH 6.8. Standard curve was plotted by taking absorption of diluted stock solutions (5, 10, 15, 20, 25, 30 µg /ml) at wavelength 290 nm.

Table 4: Calibration curve readings (Conc. vs. Abs)

Conc.(µg/ml)	Abs.
0	0.000
5	0.145
10	0.283
15	0.42
20	0.562
25	0.696

Standard Calibration curve of Propranolol hydrochloride:-

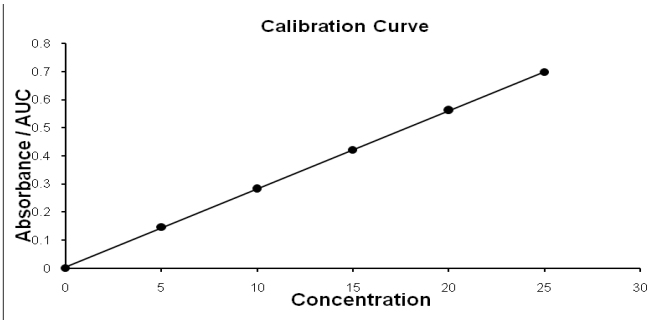

Fig 1: Calibration curve of Propranolol HCl

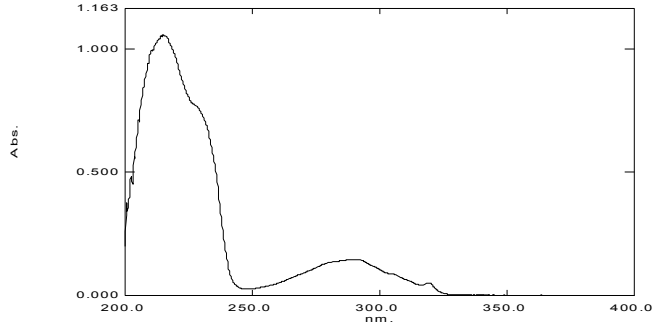

Fig 2: UV Spectra of Propranolol HCl in PBS (pH 6.8)

FTIR study

FTIR studies were carried out for detection of drug polymer interaction. In the present study the IR study of pure drug Propranolol hydrochloride, polymer HPMC E-15, drug with HPMC E-15, drug with HPMC, drug with propylene glycol &citric acid, aspartame ,cross povidone.

The infrared spectrum of propranolol hydrochloride recorded on Perkin Elmer Infrared Spectrophotometer. From the Infrared frequencies & the respective functional group are given below.

A. FTIR Spectra of Propranolol hydrochloride.

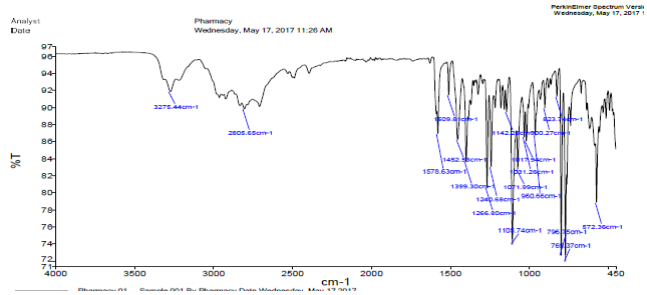

Fig 3: FTIR Spectra of Propranolol hydrochloride.

B. FTIR Spectra of Propranolol Hcl + HPMC E15.

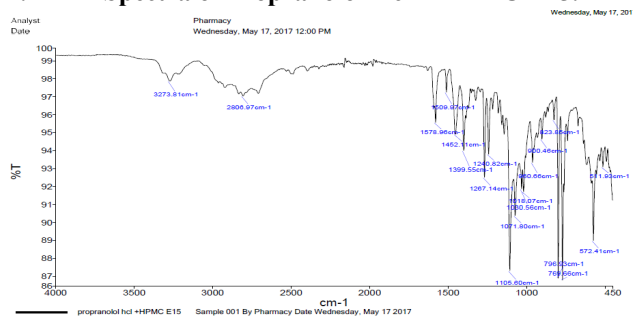

Fig 4: FTIR Spectra of Propranolol hydrochloride +HPMC E15.

In-vitro dissolution studies:

In present work, an attempt has been made to increase the % drug release of Propranolol hydrochloride with changes in concentration of polymers & plasticizers by solvent casting method. F4, F5 & F11, F13 are best formulation (Optimized batches). All the sublingual films of Propranolol hydrochloride prepared were subjected to *in vitro* drug release studies for a period of 10 min.The formulation F13 (P1, P2 & P3) which are prepared using with HPMC E15 in conc. 450mg ,Propylene glycol 150mg & Cross povidone 48mg released 103.64%, 106.84% & 101.08% at the end of 10 min respectively. The detail in vitro released data were shown in table no-6 and the same data were plotted for cumulative percentage drug released Vs time as shown in figure no-8.

Table 5: In-vitro dissolution study of Propranolol hydrochloride [F1-F12].

Time (min)	% Drug release											
	F_1	F_2	F_3	F_4	F_5	F_6	F_7	F_8	F_9	F_{10}	F_{11}	F_{12}
1	28.03	6.86	3.38	18.37	15.44	12.07	15.00	19.02	28.58	20.65	22.93	13.16
2	38.60	21.20	10.06	24.97	23.95	23.02	37.84	28.79	32.75	46.30	45.47	42.48
3	48.25	25.24	11.42	65.57	64.64	55.12	43.36	33.71	35.35	49.35	54.04	49.70
4	56.10	36.62	23.67	84.57	66.25	59.07	48.63	45.99	39.40	53.84	63.07	55.51
5	61.02	38.42	35.13	88.45	68.52	60.35	52.23	50.97	41.87	56.66	67.67	63.58
6	64.71	43.92	40.27	97.58	72.44	63.82	60.99	52.22	42.64	63.21	72.98	66.76
7	69.52	47.55	50.69	100.5	81.51	67.65	62.17	65.86	44.72	68.11	77.06	68.14
8	74.08	59.37	55.63	102.2	89.95	69.90	64.77	70.37	46.60	69.39	81.19	73.98
9	76.63	64.10	56.62	105.3	93.95	85.63	66.20	72.99	51.43	80.55	91.67	77.40
10	82.13	67.16	60.21	109.8	104.7	93.03	68.53	75.84	52.97	86.56	97.74	81.40

Table 6: In-vitro dissolution study of propranolol hydrochloride (F13)

Time	% Drug release (F13)		
	P1	P2	P3
1	14.46	18.48	9.90
2	21.43	25.30	11.37
3	38.40	65.36	53.58
4	59.89	84.47	68.37
5	72.05	88.56	71.23
6	78.76	96.72	92.80
7	92.07	98.36	94.61
8	94.94	100.88	96.97
9	101.96	104.38	98.70
10	103.64	106.84	101.08

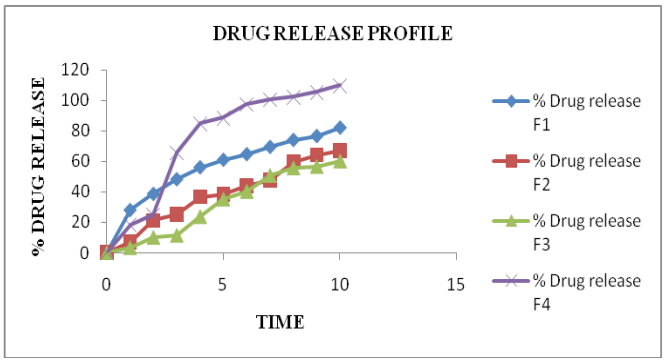

Fig 5: In-vitro dissolution study/profile Propranolol Hcl of batches F1-F4.

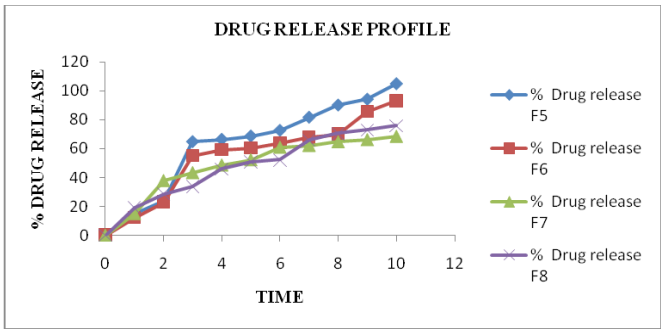

Fig 6: In-vitro dissolution study/ profile Propranolol Hcl of batches F5-F8.

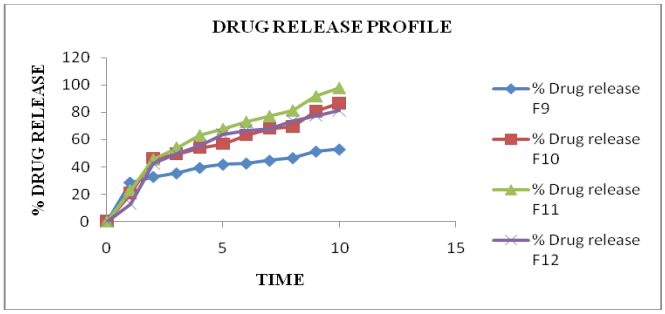

Fig 7: In-vitro dissolution study/ profile Propranolol Hcl of batches F9-F12.

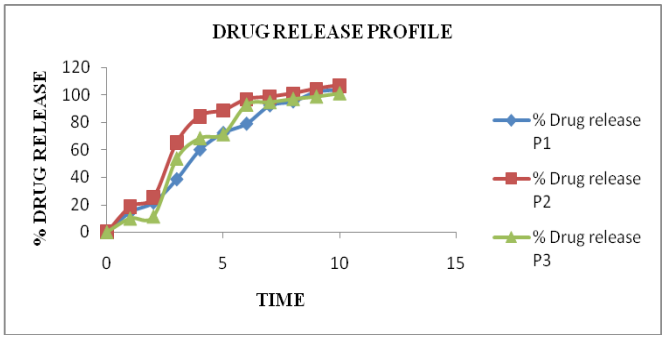

Fig 8: In-vitro dissolution study/ profile Propranolol Hcl of batches F13 (P1 - P3).

Table 7: Evaluation parameter of Fast dissolving film (F1-F12)

Formulations	Tack Test	Weight (mg±SD)	Thickness (mm±SD)	Folding Endurance (n±SD)	D.T (sec)	Surface P^H	Content uniformity(mg/cm^2±SD)
F1	Non tacky	37±2.62	0.15±0.014	90±3.74	41±1.24	6.4 ±0.20	10.2 ±0.006
F2	Non tacky	45±3.55	0.17±0.015	62±3.74	48±1.24	6.2 ±0.21	10 ±0.006
F3	Non tacky	49±4.18	0.21±0.016	126±10.2	61±1.70	6.4 ±0.24	9.8 ±0.0021
F4	Non tacky	21±1.41	0.6±0.08	120±4.92	15±0.81	6.6± 0.17	10.1± 0.0016
F5	Non tacky	24±1.70	0.8±0.09	100±2.44	19±0.82	6.5 ±0.16	10.3 ±0.0025
F6	Non tacky	30±2.16	0.9±0.04	138±5.79	28±1.24	6.5 ±0.17	9.5 ±0.16
F7	Non tacky	39±3.55	0.17±0.012	76±8.37	44±3.3	6.5 ±0.25	10.4 ±0.045
F8	Non tacky	48±4.02	0.25±0.012	104±4.49	53±2.49	6.1 ±0.17	10.3 ±0.007
F9	Non tacky	51±5.09	0.31±0.013	80±2.16	61±1.24	6.4 ±0.12	10.4 ±0.0032
F10	Non tacky	21±1.24	0.7±0.08	97±3.4	19±0.81	6.5± 0.08	10.2± 0.0033
F11	Non tacky	25±1.70	0.11±0.014	57±4.6	19±1.24	6.2 ±0.17	9.9 ±0.0017
F12	Non tacky	31±2.94	0.13±0.008	137±11.2	30±1.63	6.2 ±0.16	10 ±0.0034

Table 8: Evaluation parameter of fast dissolving film (F13).

In vivo study:

Formulations (F13)	Tack Test	Weight (mg±SD)	Thickness (mm±SD)	Folding Endurance (n± SD)	D.T (sec)	Surface P^H	Content uniformity(mg /cm^2±SD)
P1	Non tacky	22±1.7	0.6±0.12	115±3.68	15±1.24	6.6±0.08	10±0.005
P2	Non tacky	21±1.24	0.7±0.16	112±2.44	17±2.05	6.5±0.12	10.2±0.006
P3	Non tacky	22±2.05	0.5±0.30	106±4.08	20±1.63	6.5±0.08	9.9±0.006

From the results F4 formulation of FDF showed Cmax of 0.769 mcg/ml of film & 0.520 mcg/ml of pure drug. The formulation showed in table no-28 AUC, Tmax &MRT of film 2.069mcg/ml, 45 min, 2.21h and pure drug 1.241mcg/ml, 45 min, 2.21h. It was shown in figure no-37. The In vivo study demonstrated in male/female Wistar rat using optimized formulation F4 and observed that the excellent drug release in blood of the rat.

Table 9: Comparison of pharmacokinetic parameter of Propranolol Hcl between the film & pure drug in Wister rat (Male/Female).

Parameters	Film	Pure drug
AUC (mcg/ml)	2.069	1.241
Cmax (mcg/ml)	0.769	0.520
Tmax (minute)	45	45
MRT (h)	2.21	2.21

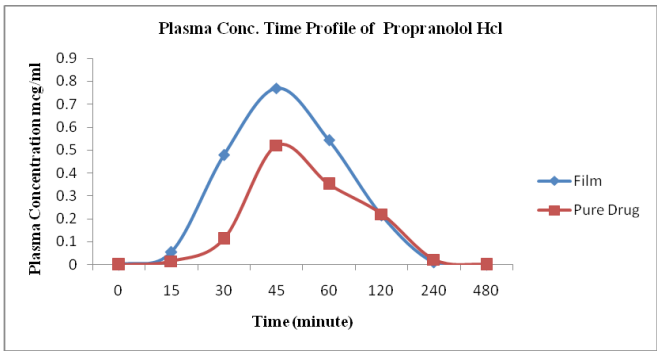

Fig 9: Plasma Conc. Time profile comparison study of Pure drug with Best Film Formulation.

Fig. No.10: Refrigerated centrifuge

Figure of F1, F2, F3.

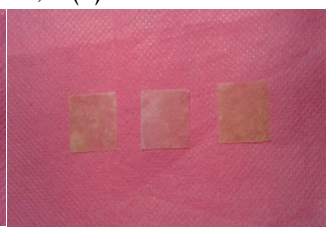

Figure of F4, F5 , F6.

Figure of F7, F8, F9.

Figure of F10, F11, F12.

Figure of F13 (P1, P2, P3.)

Fig 11: Figures of formulation F1-F13.

Stability study

The stability study conducted by ICH guideline. It showed no significant change in properties of the optimized formulation & the drug release. Short term stability studies were performed in a stability chamber over a period of 3 week (21 days) on the promising fast dissolving film formulations F4& F11. Sufficient number of films formulation were packed in stability container and kept in a stability chamber at Temperature 45^{0}C & RH 75%. Samples were taken on 21st day for drug content estimation; also the Appearance, thickness, weight, folding endurance, disintegration time, surface pH, content uniformity and in-vitro disintegration studies were performed to determine the drug release profile.

Table 10: accelerated stability study

Result of stability data for F4&F11 Batch									
Stability condition	Sampling time	Observation							
Accelerated condition (45±20^{0}C)	After 21 day	Tack test	Weight (mg)	Thickness (mm)	Folding endurance	D.T. (sec)	Surface pH	Content uniformity	%DR
F4		Non	19	0.6	115	13	6.5	10	106.3
F11		Non	23	0.11	54	15	6.0	9.8	96.05

4. CONCLUSION

Propranolol hydrochloride is first line agent for migraine prophylaxis. Propranolol hcl is a non-selective beta-adrenergic antagonist undergoes hepatic first pass metabolism, thus bioavailability is reduced to 25%. The first pass metabolism in the liver can be avoided by developing oral thin films of propranolol hydrochloride, and dose can be reduced in migraine prophylaxis. Oral thin films of propranolol hydrochloride were prepared successfully using HPMC E15 & HPMC as polymer by solvent casting method. The developed formulations showed satisfactory results for thickness, tackiness, weight variation, surface pH, folding endurance, film softening upon storage, disintegration time and drug content. The prepared best films were disintegrated within 15 to19 sec.

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