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A Study on Formulation and Evaluation of Oral Dispersible Tablets - Propranolol HCL

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Abstract: ***The main objective of the present work is to develop oral disintegrating of tablets of Propranolol hydrochloride. This study was aimed, which can disintegrate or dissolve rapidly once placed in the oral cavity. Propranolol hydrochloride is a Antihypertensive drug, which undergoes extensive hepatic degradation (76%), which have poor oral bioavailability for overcoming this problem oral disintegrating of tablets of Propranolol hydrochloride can be formulated which avoids extensive first pass metabolism and improvement in dissolution efficacy, disintegration time which results in improvement in bioavailability. The ODTs are prepared by direct compression technique. All the prepared formulations were subjected to various evaluation parameters like hardness, thickness, friability, weight variation, wetting time, water absorption ratio, in-vitro dispersion time, in-vitro disintegration, and in-vitro dissolution. The optimised formulation of F5 oral disintegrating tablets containing crosspovidone showed hardness of 4.2kg/cm^2,thickness of 2.61mm, friability of 0.28%,wetting time 45sec, water absorption ratio of 69%, disintegration time of 22 sec, content uniformity of 20.28mg and in-vitro drug release of 97.4% better than other formulations containing sodium starch glycolate and cross carmellose sodium. The advantage of this formulation is such that in case of hypertension attack patient can take the drug without the usage of water.***

Keywords: Propranolol HCl, Super disintegrants, Oral disintegrating tablets, Disintegration time, Direct compression

1. Introduction: [3,4,5,]

The performance of fast dissolving tablets depends on the technology used in their manufacture. The orally disintegrating property of the tablet is attributable to a quick ingress of water into the tablet matrix, which creates porous structure and results in rapid disintegration. Hence, the basic approaches to develop fast dissolving tablets include maximizing the porous structure of the tablet matrix, incorporating the appropriate disintegrating agent and using highly water-soluble excipients in the formulation. Following techniques have been used by various researchers to prepare fast dissolving tablets: • Freeze-Drying or Lyophilization • Tablet Molding • Spray Drying • Sublimation • Direct Compression • Cotton Candy Process • Mass-Extrusion

2. Need of Study

The oral route of administration is considered as the most widely accepted route. But the most evident drawback of the commonly used oral dosage forms like tablets and capsules is difficulty in swallowing, leading to patient's incompliance particularly in pediatric and geriatric patients. Oral dispersible tablets which gives advantages like absorption of drug directly into the systemic circulation; it is ideal dosage form for patients suffering from dysphagia, also useful in clinical conditions where water intake is limited and mainly useful for drugs undergoing high first pass metabolism. Oral dispersible tablet can disperse/disintegrate and dissolve rapidly in saliva without the need of drinking water. When such tablets are placed in oral cavity, saliva quickly penetrates into the pores to cause rapid tablet disintegration. Propranolol hydrochloride is a Antihypertensive drug, which undergoes extensive hepatic degradation (76%), which have poor bioavailability (24%) for overcoming this problem oral dispersible tablets of Propranolol hydrochloride can be formulated which avoids extensive first pass metabolism and improvement in dissolution efficacy, disintegration time which results in improvement in bioavailability. This formulation can be effectively used in case of hypertensive patients as it can be administered without the intake of water.

Therefore the main objective of the present work is to develop orodispersible tablets for Propranolol hydrochloride to improve bioavailability, disintegration time, dissolution efficacy and patient compliance.

3. Methods

3.1 Preformulation studies

It is one of the important prerequisites in development of any drug delivery system. Preformulation studies of the drug were performed, which included melting point determination, solubility and compatibility studies. The following preformulation studies were performed for Propranolol HCl.

3.1.1 Determination of melting point: Melting point of Propranolol hydrochloride was determined by capillary method. Fine powder of Propranolol hydrochloride was filled in glass capillary tube (previously sealed on one end). The capillary tube is tied to thermometer and placed in oil bath (light paraffin oil bath), The temperature at which it starts to melt was noted.

3.1.2 Solubility studies: [1,2]
The solubility studies conducted by shake flask method. Solubility studies in 6.8pH phosphate buffer: The 10ml of 6.8pH phosphate buffer taken in volumetric flask and add small amount of drug and shake the flask to dissolve the drug then add again small amount of drug and shake. These processes continued up to above saturation level of buffer and shake for 24hrs.After 24hrs the above solution was

diluted and measure the absorbance at 290nm. Calculate the propranolol solubility in 6.8pH phosphate buffer.

3.1.3 Solubility studies in distilled water:
The 10ml of distilled water taken in volumetric flask and add small amount of drug and shake the flask to dissolve the drug then add again small amount of drug and shake. This process continued up to above saturation level of water and shake for 24hrs. After 24hrs the above solution was diluted and measure the absorbance at 290nm. Calculate the propranolol solubility in distilled water

3.1.4 Determination of λ max of Propranolol HCl:
Identification of Propranolol hydrochloride was carried out by UV spectroscopy

3.1.5 Drug Excipient compatibility
Infrared spectrophotometry is an analytical technique utilized to check the chemical interaction between the drug and other excipients used in the formulation. One milligram of the sample was powdered and intimately mixed with 100mg of dry powdered potassium bromide. The powdered mixture was taken in a diffuse reflectance sampler and the spectrum was recorded by scanning in the wavelength region of4000-400cm^{-1} in an FTIR spectrophotometer (Bruker). The IR spectrum of the drug was compared with that of the physical mixture to check for any possible drug-excipients interaction.

3.1.6 Formulation design
Preparation of tablets:Nine batches of tablets (F1 to 9) were prepared with the help of three superdisintegrants (sodium starch glycolate (SSG), crospovidone and crosscarmellose) by direct compression method. Each superdisintegrant was used in 2%,4%,6%

Table 1: Composition of Propranolol hydrochloride oral disintegrating tablets:

Formulation code	Ingredients(mg)									
	Propranolol HCl	Lactose	SSG	CP	CCS	MCC	Aspartame	Magnesium Sterate	Talc	Total Weight
F1	20	106	2%			50	10	2	10	200
F2	20	104	4%			50	10	2	10	200
F3	20	102	6%			50	10	2	10	200
F4	20	106		2%		50	10	2	10	200
F5	20	104		4%		50	10	2	10	200
F6	20	102		6%		50	10	2	10	200
F7	20	106			2%	50	10	2	10	200
F8	20	104			4%	50	10	2	10	200
F9	20	102			6%	50	10	2	10	200

3.1.7 Direct compression method:
Except lactose and magnesium stearate mix all ingredients pass through sieve no 40 and collect the mixture. The mixture was blend with lactose and magnesium stearate (pre- sifted through sieve no 80). Then subject the blend for compression by using 7mm flat punches (Shakti compression machine).

3.2 Evaluation of oral disintegrating tablets of propranolol HCl:

The powder was evaluated for bulk density, tapped density, Carr's index, Hausner's ratio and angle of repose. The prepared tablets were evaluated for thickness, hardness, friability, weight variation test, drug content, swelling index and *in-vitro* release studies.

3.2.1 Pre-compression parameters:
The following tests were performed for blend:

Angle of Repose: [6,7]
Angle of repose was determined using funnel method. The blend was poured through funnel that can be raised vertically until a maximum cone height (h) was obtained. Angle of repose was calculated using the formula
$\theta = \tan^{-1}(h/r)$
Where, θ is the angle of repose, h is height of pile; r is radius of the base of pile.

Bulk Density: [6,7]
Apparent bulk density (ρb) was determined by pouring the blend into a graduated cylinder. The bulk volume (*Vb*) and weight of powder (*m*) was determined. The bulk density was calculated using the formula

$$\rho b = \frac{m}{Vb}$$

m= mass of powder taken Vb= apparent unstirred volume

Tapped Density: [7,9]
The measuring cylinder containing known mass of blend was tapped for a fixed time. The minimum volume (*Vt*) occupied in the cylinder and weight (M) of the blend was measured. The tapped density (*ρb*) was calculated using the following formula
Tapped density.

$$\rho b = \frac{m}{Vt}$$

m = weight of sample powder taken Vt = tapped volume

Carr's compressibility index: [7,9]
The simplest way of measurement of free flow of powder is compressibility, an indication of the ease with which a material can be induced to flow is given by compressibility. The compressibility index of the granules was determined by Carr's compressibility index, which is calculated by using the following formula

$$\text{carr's index} = \frac{\text{tapped density} - \text{poured density}}{\text{tapped density}} * 100$$

Hausner's ratio: [7,8]

$$\text{Hausner's ratio} = \frac{\text{tapped density}}{\text{poured density}}$$

Where Lower Haunser's ratio (< 1.25) indicates better flow properties than higher ones (>1.25).

3.2.2 Post compression evaluation parameters for formulated tablets:

Thickness: [8]

Thickness of tablets was measured by using digital Vernier caliperse. Three tablets from each batch were used, and an average value was calculated.

Hardness: [6,8]

Hardness or tablet crushing strength is force required to break a tablet in a diametric compression was measured using Monsanto hardness tester. It is expressed in kg/cm^2. Five tablets were randomly selected from each batch and hardness of tablets was determined by using hardness tester. The mean values and standard deviation for each batch were calculated.

Friability: [6,7,8]

Friability of the tablets was determined using Roche Friabilator. This device subjects the tablets to the combined effect of abrasion and shock in a plastic chamber revolving at 25 rpm and dropping the tablets at a height of 6 inches in each revolution. Pre weighed sample of tablets was placed in the friabilator and were subjected to 100 revolutions. Tablets were dedusted using a soft muslin cloth and reweighed. The friability (f) is calculated by given the formula.

$$\text{friability} = \frac{\text{initial weigt} - \text{final weight}}{\text{initial weight}} * 100$$

Weight variation : [6,8]

Twenty tablets from each formulation were selected at random and average weight was determined. Then the individual tablets were weighed and were compared with average weight.

$$\%\text{Deviation} = \frac{\text{individual weight} - \text{average weight}}{\text{Average weight}} * 100$$

***In-vitro* Disintegration time:** [8,10,11]

The disintegration time for all formulations was carried out using tablet disintegration test apparatus. Six tablets were placed individually in each tube of disintegration test apparatus and discs were placed. The water was maintained at a temperature of 37±0.5°C and time taken for the entire tablet to disintegrate completely was noted.

Wetting time and water absorption ratio: [10,11]

A piece of paper folded twice was kept in a Petridish containing 6 ml of purified water. A tablet having a small amount of Rosaline dye powder on the upper surface was placed on the tissue paper. The time required to develop a red color on the upper surface of the tablet was recorded as the wetting time. Water absorption ratio was done with the same procedure as that of wetting time. In this test initial weight of tablet was taken before placing on petridish. After complete wetting the wetted tablet was then weighed.

Water absorption ratio, R was determined using the equation:

$R = [Wb - Wa/Wb] \times 100$

Where, Wa and Wb were the weights of the tablet before and after water absorption.

***In-vitro* dispersion time:** [11]

Tablet was added to 10 ml of phosphate buffer solution, pH 6.8 at 37±0.5ºc, Time required for complete dispersion of a Tablet was measured.

Content uniformity: [10,11]

For determination of drug content 20 tablets from each batch were weighed individually and powdered. The quantity of powder was equivalent to 20 mg. The equivalent weight propranolol HCL was transferred into 100 ml volumetric flask diluted to 100ml with sufficient amount of buffer (6.8pH phosphate buffer).Then aliquot of the filtrate was diluted suitably and analyzed spectrophotometrically at λ max of 290 nm against blank.The content uniformity should not be less than 90% and not more than 110% of the labeled value.

***In-vitro* dissolution studies:** [9,10,11]

Dissolution studies were carried out for all the formulations employing USP - II paddle method and 900ml of 6.8pHphosphate buffer as the dissolution medium. The medium was allowed to equilibrate to temperature of 37°c ±0.5°c. Tablet was placed in the vessel and the vessel was covered the apparatus was operated for 30min in 6.8pH at 50 rpm. At definite time intervals of 5 ml of the aliquot of sample was withdrawn by using pipette and filtered.Thevolume replaced with equivalent amount of the fresh dissolution medium. The samples were analyze spectrophotometrically at 290 nm using UV-spectrophotometer.

3.5.3 Stability Studies: [6,11,13,14]

The stability study of the tablets was carried out according to ICH guidelines by storing tablets in stability chamber at 25±2°C/60±5% RH and 40±2°C/75±5% RH for 3 months. The effects of temperature and time on the physical characteristics of the tablet are evaluated for assessing the stability of the prepared formulations. The different parameters that are to be studied are disintegration time, hardness, friability, drug content and dissolution rate.

4. Results and Discussion

4.1 Preformulation studies

Melting point determination

The melting point of Propranolol hydrochloride was found to be 161-164ºC. Which complied with IP standards thus indicating purity of obtained drug sample.

Solubility study:

The solubility of Propranolol hydrochloride in various solvent reveals that it was freely soluble in water and methanol.

Determination of ʎmax:

Solution of propranolol containing concentration 10µg/ml was prepared by dissolving in 6.8 pH phosphate buffer. The solution was scanned in the range of 200 – 400 nm. The ʎmax of propranolol was found to be 290nm.

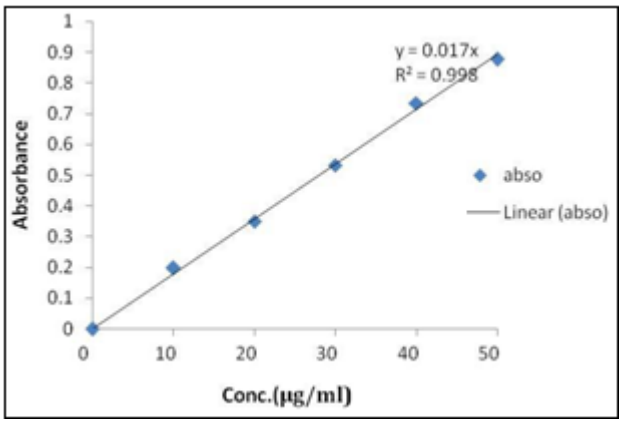

Figure 1: Calibration curve

Compatibility studies:

FTIR Spectroscopy

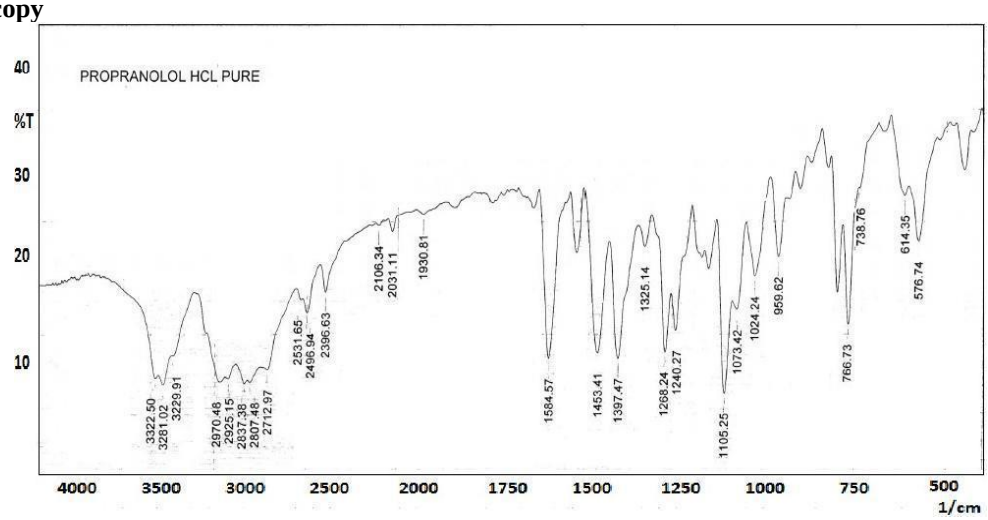

Figure 2: Spectra of pure Propranolol hydrochloride

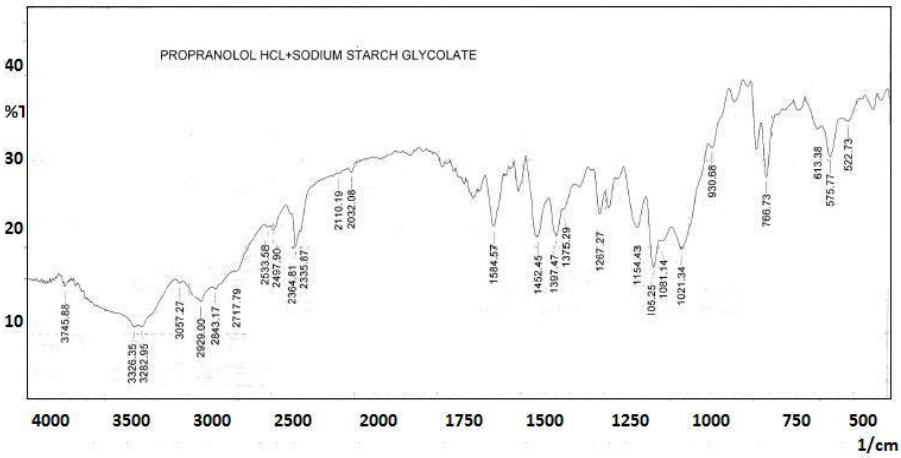

Figure 3: IR spectra of physical mixture of Propranolol hydrochloride and sodium starch glycolate

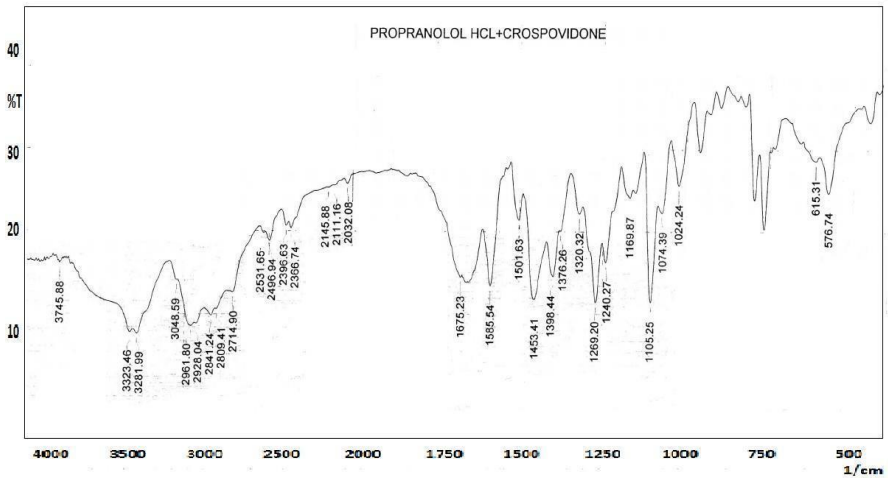

Figure 4: IR spectra of physical mixture of Propranolol hydrochloride and Crospovidone

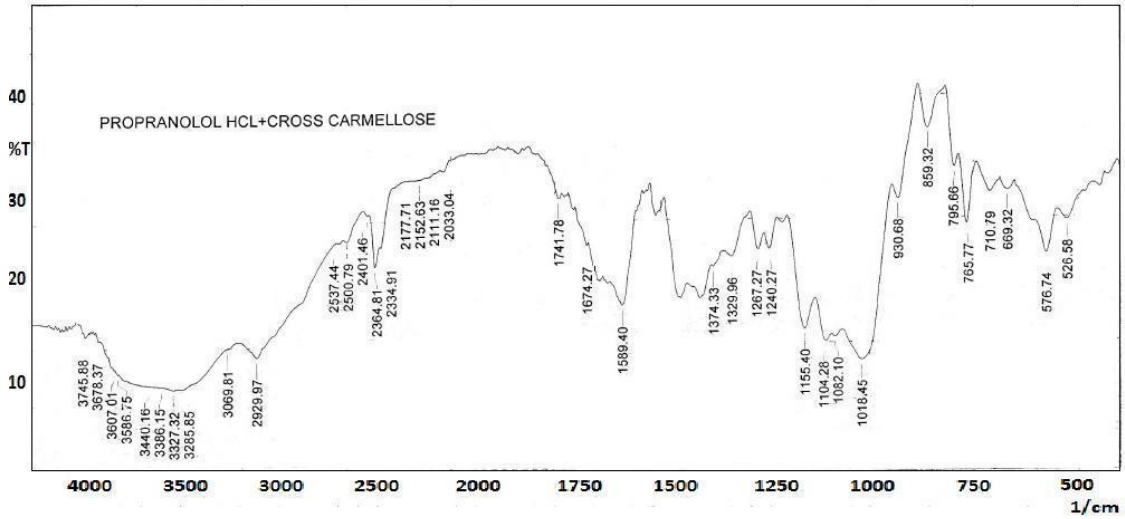

Figure 5: IR Spectra of propanolol Hcl and Cross povidone

4.2 Evaluation of oral disntegrating tablets of Propranolol hydrochloride

4.2.1Evaluation of Pre-compression parameters:

Table 2: Evaluation of micrometrics properties of blend

Formulationn code	Angle of repose (θ)(±SD)	Bulkdensity (gm/c c) (SD)	Tapped density (gm/cc) (SD)	Compressibility index (%)(±SD)	Hausner'sratio (±SD)
F1	20.41 ± 0.11	0.401 ± 0.0026	0.471 ±0.0032	14.81 ± 0.141	1.07±0.104
F2	21.52±0.5	0.402 ± 0.0015	0.489 ±0.0017	17.76 ± 0.010	1.01 ± 0.20
F3	20.61 ± 0.10	0.398 ± 0.0028	0.470 ±0.0021	15.00 ± 0.102	1.07± 0.0
F4	17.68 ± 0.18	0.422 ± 0.0012	0.492 ±0.0010	14.15 ± 0.058	1.06 ± 0.04
F5	20.37 ± 0.12	0.411 ± 0.0046	0.483 ±0.0041	14.03± 0.607	1.17±0.002
F6	19.44 ± 0.16	0.405 ± 0.0022	0.481 ±0.0022	15.70 ± 0.028	1.18 ± 0.006
F7	19.50 ± 0.19	0.419± 0.0009	0.491 ±0.0027	14.91 ± 0.038	1.17±0.005
F8	20.46 ± 0.14	0.402 ± 0.0015	0.489 ±0.0017	17.71 ± 0.010	1.01 ± 0.206
F9	17.67 ± 0.19	0.401± 0.0026	0.471 ±0.0032	14.81 ± 0.141	1.07 ± 0.104

The values represent mean ±SD, n = 3.

4.2.2 Evaluation of post compression parameters:

The properties of oral disintegrating tablets were evaluated for thickness, hardness, friability, weight variation test, wetting time, water absorption ratio, *in-vitro* disintegration test, *in-vitro* dispersion time, content uniformity and *in-vitro* drug release studies and the results were reported, as shown in Table 4.4 and table 4.5

Table 3: Post compression parameters weight variation, hardness, thickness and friability

Formula	Weight variation(mg)	Hardness (kg/cm2)	Thickness (mm)	Friability (%)
F1	201±0.21	3.6 ± 0.47	2.60±0.3	0.31±0.12
F2	199±0.79	3.2± 0.56	2.61±0.2	**0.29±0.13**
F3	200±0.51	4.1± 0.49	2.65±0.1	0.33±0.08
F4	202±0.51	3.5± 0.65	2.66±0.1	0.32±0.09
F5	200±0.24	4.2± 0.28	2.61±0.2	0.28±0.14
F6	202±0.38	3.9± 0.66	2.61±0.3	**0.34±0.09**

F7	199±0.87	3.9±0.71	2.64±0.2	0.32±0.09
F8	200±0.72	3.6±0.53	2.63±0.2	0.32±0.09
F9	200±0.28	3.9±0.89	2.62±0.3	0.31±0.12

Table 4: Post compression parameters wetting time, water absorption ratio, disintegration time, *in-vitro* dispersion time and content uniformity

Form-ulation code	Wetting time (S)	Water absorption ratio (%)	Disintegration time(s)	*In-vitro* dispersion time(s)	Content uniformity (mg)
F1	61±1.47	49±0.3	53±3.66	42±1.23	19.76
F2	62±1.20	58±0.3	48±5.32	39±1.15	19.81
F3	73±1.84	63±0.2	39±3.41	33±1.58	19.27
F4	55±3.51	52±0.4	50±3.56	38±1.69	20.12
F5	45±2.33	69±0.1	22±2.46	29±1.42	20.28
F6	49±2.22	74±0.3	32±3.43	17±1.18	20.32
F7	20.32	60±0.3	46±2.93	38±1.98	20.18
F8	51±2.73	55±0.4	38±3.64	30±1.81	19.87
F9	43±2.88	58±0.3	29±3.41	21±1.47	20.83

Table 5: *In-vitro* drug release data of Oral disintegrating tablets of Propranolol hydrochloride (F1-F9) containing sodium starch glycolate

s. no	Time (min)	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	0	0	0	0	0	0	0	0	0	0
2	5	25.8	32.5	36.74	35.08	39.05	38.04	32.13	36.18	40.68
3	10	38.06	44.7	49.56	44.5	52.5	43.8	43.21	51.64	59.67
4	15	51.39	65	69.5	61.89	78	69.2	55.19	63.07	70.01
5	20	68.19	71.6	75.8	73.13	87.05	81.1	62.89	69.37	79.27
6	25	73.5	79.3	81.6	84.96	95.8	92.4	73.56	75.93	90.17
7	30	79.18	83.45	90.3	87.68	97.4	94.3	86.93	86.78	93.89

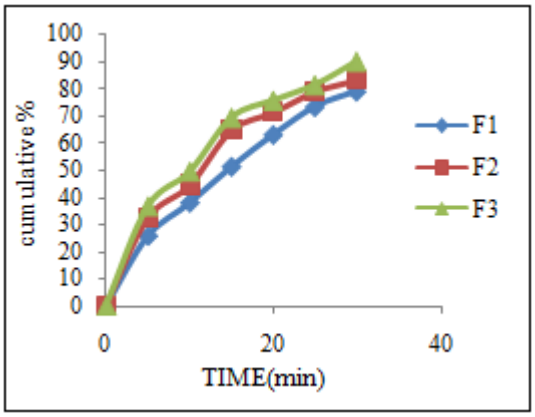

Figure 6: Cumulative % drug release of F1 to F3containing SSG

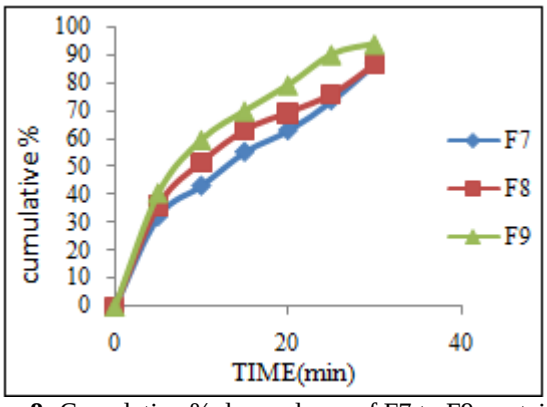

Figure 8: Cumulative % drug release of F7 to F9 containing SSG

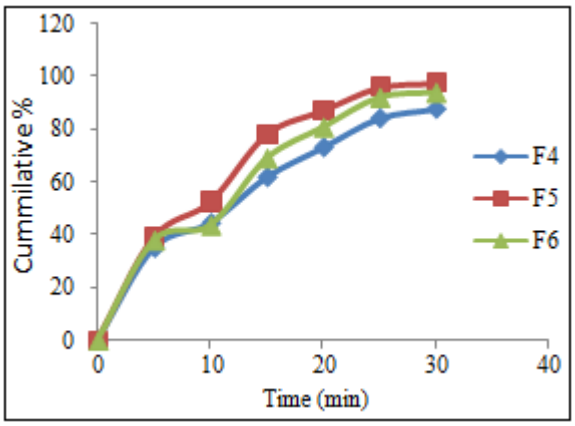

Figure 7: Cumulative % drug release of F4 to F6 containing SSG

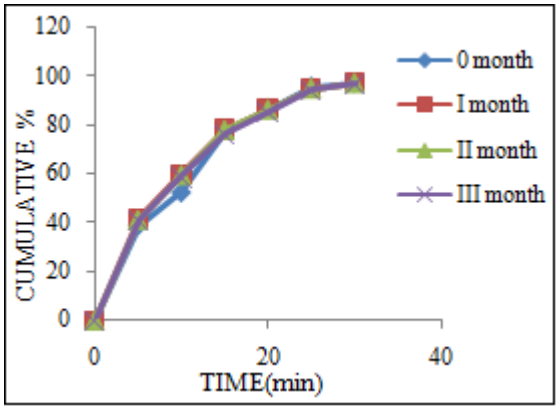

Figure 9: Stability dissolution of propranolol hydrochloride

4.3 Stability studies

Stability of a drug in a dosage form at different environmental conditions is important as it determines the expiry date of that particular formulation. The stability studies conducted as per ICH guidelines revealed that there is no change in physical appearance, hardness, disintegration time, drug content. The results were shown in table 7&8 and Fig 9.

Table 7: Stability studies of F5 formulation ODT of propranolol HCl at 40±2°C / 75±5%

Formulation	0 Month	I Month	II Month	III Month
Physical appearance	No Change	No Change	No Change	No Change
Disintegration Time	22 ± 3.43	24±4.13	24±6.67	26±4.53
Wetting Time (Secs)	45±2.22	46±3.43	46±1.24	47±1.74
Water Absorption Ratio (%)	74±0.2	75±0.1	76±0.2	77±0.1
Drug Content (Mg)	20.32	20.04	19.58	19.26

Table 8: Stability dissolution profile of ODT of propranolol HCl

Time (min)	0month	I month	II month	III month
5	39.05	41.88	41.12	40.92
10	52.5	59.84	59.5	58.73
15	78	78.16	77.84	76.68
20	87.05	86.88	86.21	85.59
25	95.8	95.04	94.84	94.46
30	97.4	97.36	97.06	96.92

5. Conclusions

The concept of formulating oral disintegarting tablets containing Propranolol hydrochloride offers a suitable, practical approach to achieve fast release of the drug. Absorption of these tablets takes place direct into the systemic circulation which avoids the hepatic first pass metabolism of Propranolol hydrochloride which ultimately results in the improvement in the bioavailability. In present work, oral disintegrating tablets of Propranolol hydrochloride were prepared successfully by direct compression method using the different superdisintegrants in different concentrations like Sodium starch glycolate, crospovidone and crosscarmellose sodium other excipients such as magnesium stearate as lubricant, talc as glidant. All the pre-compression parameters like angle of repose, bulk density, Carr's index were studied. The compressed tablets were subjected to weight variation, hardness, friability, wetting time, water absorption ratio, *in vitro* dispersion time, *in vitro* disintegration test, and *in vitro* dissolution studies.

Based on the above studies, following conclusions can be drawn.

1) The drug and excipients compatibility was studied by FTIR which reveal was no chemical or physical interaction.
2) The drug content was uniform in all the tablet formulations indicating uniform distribution of drug within the formulated tablet.
3) Nine formulations were prepared viz. F1-F9 in which F5 formulation shows highest drug release 97.4% which contains 4% crospovidon
4) From the results of disintegration time found to be 22sec, considered as better as it gives disintegration time 25seconds which fulfills official requirement (less than 30seconds). It was concluded that formulation F5 was found to be the most optimal formulation.
5) Formulation F5 containing 4% crospovidone can be effectively used in the clinical formulation of oral disintegrating tablets, especially in cases of sudden hypertension.
6) By studying above results crospovidone was most suitable superdisintegrant for formulation of oral disintegrating tablets of Propranolol hydrochloride.

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