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FORMULATION, DEVELOPMENT AND *IN-VITRO* EVALUATION OF HYDROGEL BASED CONTROLLED RELEASE MATRIX TABLET OF PROPRANOLOL HYDROCHLORIDE

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ABSTRACT: Hypertension is the most life-threatening disease amongst all lifestyle diseases. So, there is always a need for such a dosage that can release the drug for a long period from a single dose which will reduce the dose burden for the patient. The propranolol HCL is a non-selective beta-adrenergic blocking agent extensively used in various cardiovascular diseases. In the present study hydrogel matrix tablets of anti-hypertensive drug, Propranolol HCL were prepared and evaluated. The HPMC was used as a rate retarding polymer, whereas Talc was used as filler, and magnesium stearate was used as a lubricant. The present study results point out that the rate of propranolol HCL release from HPMC matrices is mainly controlled by the drug: HPMC ratio. When the concentration of HPMC was enhanced, the release of the drug from the matrix tablet was retarded. The prepared hydrogel matrix tablets were evaluated for various parameters like Angle of Repose, Bulk Density, Tapped Density, Carr's Index, hardness, friability, uniformity of weight, uniformity of drug content, and disintegration studies. The drug-polymer interaction studies were carried out by FTIR studies where it showed that there was no significant interaction. The *in-vitro* drug release was carried out for all the formulations, and formulation F1 showed about 96% drug release at 12 h. It was concluded that the hydrogel matrix tablet of Propranolol HCL by using HPMC can be prepared to get the desired release of the drug up to 12 h.

INTRODUCTION: The controlled release formulations have many advantages over the conventional dosage form [1]. Among all the controlled release dosage form matrix technologies have got wide acceptance due to many reasons. It includes advantages like oral controlled release formulation, have less stability problem for raw material and finished item, have good reproducebility, good *in-vitro in-vivo* correlation and ease of scale-up technology [2, 3].

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The matrix drug delivery devices are prepared from hydrophobic or hydrophilic polymer where the drugs are homogeneously dispersed [4]. Hydroxypropyl methylcellulose (HPMC) is a class of semisynthetic cellulose derivatives. It is extensively used in the formulation of controlled-release (CR) dosage forms which act as hydrophilic swellable

polymer [5]. It has many acceptable properties like nontoxic, easy to handle and compress, can incorporate a large amount of active substance, and can be used to prepare as simple tablet manufacturing technology, which makes it an excellent drug carrier polymer. There are many factors reported which have an impact on the release pattern of a drug from the HPMC matrix devices. Some of them are viscosity, particle size, and drug: polymer ratio, the solubility of the drug, and other tablet properties [6-9]. The propranolol HCL is a non-selective beta-adrenergic blocking agent. The drug is widely used in the treatment of various disease conditions like hypertension, angina pectoris, and many other cardiovascular disorders [10].

The drug is highly lipophilic and absorbed completely after oral administration. But the drug reaches only 25% of the systemic circulation because of the first-pass metabolism. The drug has an elimination half-life of about 2 to 6 h. The solubility of the drug is also pH-dependent. About 225 mg/mL is soluble at pH 1.2, while at pH 6.8 it is 130 mg/mL soluble [11]. The drug is also stable at acidic pH 3 and decomposes rapidly when exposed to an alkaline condition. A conventional tablet of propranolol HCL, which contains a dose of 20 to 40 mg is used 3 to 4 times a day in various conditions of cardiovascular disorders such as hypertension, angina pectoris, and arrhythmias. The frequency of dose creates problems as patient compliance and therapeutic efficacy creates problem [12-14]. The purpose of the present investigation was to prepare a hydrogel-based matrix tablet of propranolol HCL to enhance the stability of the drug and to release the drug in a controlled manner up to 12 h. The study was conducted to know the influence of drug: polymer ratio, with a fixed grade of HPMC-E15 on the release of the drug. During the investigation, the various other parameters regarding optimizing the formula were also evaluated.

MATERIALS AND METHOD:

Materials: Propranolol Hydrochloride (CAS No. 3506-09-0) was procured from the Department of Pharmaceutical Sciences, West Bengal. HPMC-E15 was procured from Marck, New Delhi. All other chemicals and reagents used were of pharmaceutical or analytical grade and were used as received.

Methods:

Preparation of Matrix Hydrogel Tablets: Controlled Release Hydrogel Matrix Tablet with hydrophilic polymer HPMC E15 grade was prepared by the wet granulation but the non-aqueous method using different ratios of drug and polymer [4-6]. All the powder materials were passed through sieve number 60# mesh and mixed uniformly.

The mixed powders were granulated using isopropyl alcohol (IPA). The prepared wet granules were dried using a tray drier at 60 °C. Finally, the dried granules were blended with talc (1%w/w) and magnesium stearate (1%w/w). The blended powders were then compressed using a single station tablet compression machine (Cadmach). Matrix tablets were prepared, and further evaluations were carried out for the optimization of tablets [7-9]. The compositions of the various ingredients with drugs are listed in **Table 1.**

Evaluation of Micromeritics Properties of Granules:

Angle of Repose: This test was carried out by Fixed Funnel methods for the prepared granules. The weighed granules were poured through the funnel to form a cone or heap [15, 16]. The tip of the funnel was held close to the rising cone and slowly rises as the pile grows to reduce the impact of falling granules. The height (h) of the heap and the diameter (r) of the powder cone was measured, and the angle of repose was calculated using the following equation [17-18].

$$\text{Tan } \theta = h / r$$

Where, h = height of the cone

r = radius of powder cone

Bulk Density: The bulk density can be defined as the ratio of the untapped powder mass and the volume of the powder mass, including the interparticle void space or gape or volume. Thus, the bulk density of a powder mass depends on the density of the powders and how the particles are arranged in the powder bed [15-16]. The bulk density is expressed in various terms as grams per mL (g/mL), kilograms per cubic meter (1 g/mL = 1000 kg/m3) and grams per cubic centimeter (g/cm3). To determine the bulk density, the volume of the known weight of the sample powder is measured

by pouring into a graduated cylinder (known as Method-I), or by the use of a voltmeter (known as Method II) or a measuring vessel (Method III).

In the present study, we have used method-I, where approximately 100 g of the sample (M) is gently poured into a dry graduated of 250 mL measuring, and it was carefully level the powder without compacting [16]. The apparent unsettled volume (V_0) was noted, and the bulk density was calculated using the following formula:

Bulk density (g/mL) = M / Vo

Where, M = mass of powder

Vo = apparent unstirred volume

Tapped Density: Tapped density is the density of the sample powder attained after tapping the measuring cylinder mechanically by rising to a fixed height and dropped under its own weight. The tapping is continued until a little further, volume or weight change is observed [17-19]. In the recent study, we have used Electrolab's Tap Density Tester ETD-1020, and it is calculated by the following formula:

Tapped density (g/mL) =M/Vf

Where M = weight of sample powder

Vf = tapped volume

Measures of Powder Compressibility: As the interparticle arrangement has an influence on the bulk properties of a powder, it also interferes with the powder flow properties. The comparative study of bulk and tapped densities can provide data for the relative importance of these interactions in the given powder sample. These comparisons can be often used as an index of the ability of the powder to flow, which are determined as the Compressibility Index or the Hausner Ratio [15]. The compressibility index was determined by comparing the bulk density and tapped density which was given as Carr's Index.

Compressibility Index = (Tapped density - Bulk density) / (Tapped density) × 100

The Hausner's ration is an indication of the degree of densification that could result from the vibration of the feed hopper. A significant value is suggesting as the lower the Hausner ratio, the better is flowability [16].

Hausner ratio = (Tapped density) / (Bulk density)

Physical Characterization of Tablets: [19-21]

Drug Content: The matrix tablets were triturated and powdered. An amount of powder equivalent to 40 mg propranolol hydrochloride was taken for the drug content analysis. It was dissolved with 100 ml phosphate buffer (pH 7.4) in a stoppered conical flask and shaken for 30 min. After shaking 5 ml, aliquots were withdrawn and filtered using Whatman filter paper no 40. The filtrate was analyzed in UV spectrophotometrically at 290 nm [19, 20].

Weight Variation: Weight variation was carried out to ensure that each of the tablets contains the proper amount of drugs. For carrying out the test, from the prepared batch of matrix tablets, 20 tablets were taken randomly, and the average weight was determined. The weight of the individual tablet was taken and was compared with the average weight of the 20 tablets [20]. The percentage of weight variation was calculated by using the following formula:

Percentage of weight variation = (Initial wt.-Average wt.) / (Average wt.) × 100

Hardness: Hardness is the strength of the tablet which is required to crush or break the tablet, and it is measured as a force in kg/cm^2 or Newton. The hardness test was carried out by using the Monsanto tablet hardness tester. The hardness testing was done for 20 tablets by placing the tablets in the hardness tester, and the crushing strength required to break the tablet was recorded [20, 21].

Friability: The friability testing is carried out to test the durability or the tendency of a tablet to break into smaller pieces during packing and transportation. The friability test was carried out for 20 tablets by using Roche friabilator.

The 20 tablets were weighed and introduced into the friabilator at a speed of 25 rpm for 4 min. After 20 min tablets were removed, and it was dedusted. The final weights of the tablets were recorded and the friability in percentage (F) was calculated using the following equation [20, 21].

Friability (F) = (Tablet weight before friability - Tablet weight after friability) / (Tablet weight after friability) × 100

Disintegration: This test is carried out to determine the time required for the tablet to break down or disintegrate into small pieces within the prescribed periods when the tablet is placed in a liquid medium under the experimental conditions [19]. The disintegration test was carried out by the use of USP-type apparatus model number ED-2AL. In the disintegration apparatus, 6 tablets in each station were placed, and the test was carried out for the time taken to completely disintegrate; the tablets were recorded [20, 21].

Fourier Transforms Infra-red Spectroscopy: The detection of compatibility between drug and polymer was carried out by the FTIR spectro-photometer (Bruker ALPHA II) [12, 13]. Separately the FTIR for pure propranolol HCL and the physical mixer of the matrix tablet content was carried out. The FTIR spectrum was recorded between 4000 to 400 cm^{-1} [22-25].

***In-vitro* Drug Release Studies:** [22-24]

Preparation of Standard Curve: The propranolol HCL was taken equivalent to 100 mg and dissolved in a 100 ml volumetric flask containing methanol as a solvent to form a primary stock solution with a concentration of 1000 µg/ml [22, 23]. From the primary stock, a 10 ml solution was taken and diluted up to 100 ml to give the secondary stock solution with a concentration of 100 µg/ml [22, 23]. From the secondary stock, it was further diluted to obtain the required concentration between the range 2-20 µg/ml. The absorbances at 290 nm λmax for the specific concentration were measured, and the regression value was calculated [22-24].

Dissolution Studies: Dissolution studies were carried out using an 8 station basket type (Apparatus-1) dissolution apparatus (Electro-lab EDT-08Lx) for propranolol HCl matrix tablet. The study was conducted at 37 °C with 900mL of phosphate buffer pH-7.4 as dissolu¬tion media at 50 rpm [22]. The study was carried out for 12 hours release study, and each time, a 5 ml sample was collected at an interval of 1 hour and then filtered using a Whatman filter paper.

To maintain the sink condition in the dissolution study, 5 ml fresh medium was added after each 5 ml sample collection. The samples were then filtered and analyzed by UV spectrophotometer at 290 nm [22-24].

Stability Study of the Optimized Hydrogel Matrix Formulation: [22, 26-28] Stability testing of the optimized formulation was done according to ICH guidelines to assess the stability of the formulation. As per ICH guidelines of accelerated testing, the formulation was sealed in aluminum packaging and kept in a humidity chamber maintained at 40 ºC temp and 75% RH for 3 months. After the specified time period, the parameters like physical appearance, drug content and in vitro dissolution rate were determined.

RESULTS AND DISCUSSION: The matrix tablet for propranolol HCL was prepared, and the results were evaluated. The prepared granules for the preparation of the matrix tablets were evaluated for the preformulation evaluation parameters, and the results were listed in **Table 2**. After the preparation of the hydrogel matrix tablets, it was studied for the post-compression parameters, and the results were listed in **Table 3**. The drug content of the hydrogel matrix tablets was found in the range of 86.39 ± 1.72 to 95.13 ± 0.71 %. The hardness was recorded in the range of 4.77 ± 0.15 kg/cm^2 to 5.20 ± 0.20 kg/cm2 for all the formulations. The uniformity of weight for the prepared formulation was in the range of 244.86 ± 0.21 mg to 247.21 ± 0.47 mg. The % friability was recorded in the ranges of 0.477 ± 0.057 to 0.557 ± 0.015. The drug and polymer interaction was checked by comparing the IR spectra of the pure propranolol HCl and the drug excipient physical mixture. The FTIR spectra for pure propranolol HCl are shown in **Fig. 1**, and the FTIR spectra of propranolol HCl and excipient mixture is shown in **Fig. 2**. The propranolol HCL gives the standard peaks in IR spectrum nearby at 2922.64 cm^{-1} due to the presence of a secondary amine group, 3276.76 cm^{-1} due to the hydroxyl group (secondary), the aryl alkyl ether display a stretching band at 1265.18 $cm^{-1,}$ and the peak at 795.59 cm^{-1} due to a-substituted naphthalene. The FTIR spectra of propranolol with excipient revealed the presence of peaks at 2915.91 cm^{-1}, 3274.05 cm^{-1}, 1266.80 $cm^{-1,}$ and 796.59 cm^{-1}.

This shows that the peaks of functional groups for propranolol HCL remained intact in the physical mixture containing different polymers; thus, there was no major interaction between the drug and excipients used in the study. The *in-vitro* release

study of the prepared formulation was carried out. To find out the percentage drug release, the standard curve for the propranolol HCL was determined, and the regression value (R2) was found as 0.9931. The R2 value was used to determine the drug release in percentage from the hydrogel matrix tablet, and the drug release data were listed in **Table 4.** A graph between percentage drug release *vs.* time was plotted and shown in **Fig. 3**. The drug release was found in the range between 57.24 ± 0.60 to 96.08 ± 0.36 %. From the release studies, it was confirmed that the F1 formula showed the optimum release parameter, and it was due to the concentration of HPMC E15 in the formulation. As the concentration of HPMC E15 increases, the drug release was retarded. Thus, the F1 formulation was considered as an optimized formulation and further utilized for the stability studies. The stability study was carried out at an accelerated condition as per the ICH guidelines, and the data were listed in **Table 5**. During the studies, it was found that was no major change in various physicochemical parameters evaluated like appearance, hardness, drug content, *in-vitro* dissolution pattern after 3 months of studies. There was no significant difference between the initial values and the results obtained after the stability studies.

TABLE 1: COMPOSITION OF THE HYDROGEL MATRIX TABLET

Ingredient (mg/Tablet)	F1	F2	F3	F4	F5
Propranolol HCL	40	40	40	40	40
HPMC E15	90	100	110	120	130
MCC	100	90	80	70	60
Talc	10	10	10	10	10
Magnesium Stearate	5	5	5	5	5
Total Weight	245	245	245	245	245

HPMC: Hydroxypropyl methylcellulose MCC: micro-crystalline cellulose

TABLE 2: PRECOMPRESSION STUDIES OF HYDROGEL MATRIX

Parameters	Values ± SD
Average Angle of Repose, θ ±SD	28.37 ± 0.15
Average Bulk Density (gm/mL) ±SD	0.49 ± 0.01
Average Tapped Density (gm/mL) ±SD	0.58 ± 0.01
Average Carr's Index (%) ±SD	15.54 ± 1.94
Hausner ratio ±SD	1.18 ± 0.03

All values are mean of 3 readings, SD: standard deviation

TABLE 3: POST-COMPRESSION STUDIES OF HYDROGEL MATRIX TABLET

Parameters	F1	F2	F3	F4	F5
Drug content (%) ± SD	95.13 ± 0.71	87.66 ± 1.02	89.05 ± 1.58	86.39 ± 1.72	88.28 ± 0.98
Weight variation (mg) ± SD	247.21 ± 0.47	244.86 ± 0.21	245.05 ± 0.49	245.23 ± 0.63	245.64 ± 0.82
Hardness (kg/cm^2) ± SD	5.20 ± 0.20	4.77 ± 0.15	5.03 ± 0.12	5.10 ± 0.20	4.87 ± 0.21
Friability (%) ± SD	0.477 ± 0.057	0.557 ± 0.015	0.543 ± 0.006	0.527 ± 0.047	0.547 ± 0.025

All values are mean of 3 readings, SD: standard deviation

TABLE 4: *IN-VITRO* DRUG RELEASE STUDY, PERCENTAGE (%) DRUG RELEASED

Time (h)	F1 (%) ± SD	F2 (%) ± SD	F3 (%) ± SD	F4 (%) ± SD	F5 (%) ± SD
0	0.00	0.00	0.00	0.00	0.00
1	9.91 ± 0.60	5.79 ± 0.35	5.08 ± 0.34	6.06 ± 0.42	5.80 ± 0.62
2	26.02 ± 0.40	19.39 ± 0.58	15.69 ± 0.48	19.11 ± 0.73	16.21 ± 1.05
4	41.39 ± 0.78	23.34 ± 0.58	26.77 ± 0.59	25.46 ± 0.32	21.80 ± 0.51
6	56.01 ± 0.74	45.21 ± 2.22	38.19 ± 0.56	34.21 ± 0.59	30.70 ± 0.73
8	71.50 ± 0.88	57.01 ± 0.33	54.09 ± 0.56	39.66 ± 0.86	39.53 ± 1.27
12	96.08 ± 0.36	87.68 ± 0.61	75.07 ± 0.56	62.85 ± 0.84	57.24 ± 0.60

All values are mean of 3 readings, SD: standard deviation, h: hour

TABLE 5: PHYSICOCHEMICAL PARAMETERS OPTIMIZED FORMULATION (F1) DURING STABILITY STUDIES

Tests	Limits	Initial Result	3rd Month Result
Appearance	White, Compound Cup shaped hydrogel matrix tablets	Same as Limit	Same as Limit
Average weight	± 7.5%	246.21 ± 0.47	246.13 ± 0.47
Hardness (kg/cm^2)	4.00 to 6.5 kg/cm^2	5.23 ± 0.22 kg/cm^2	4.95 ± 0.32 kg/cm^2
Friability (%)	0.5 to 1%	0.432 ± 0.041	0.416 ± 0.062
Drug Content	90-110%	96.17 ± 0.55	93.33 ± 0.54
Drug release after 8 h	Not less than 90%	96.72 ± 0.37	95.76 ± 0.46

All values are mean of 3 readings

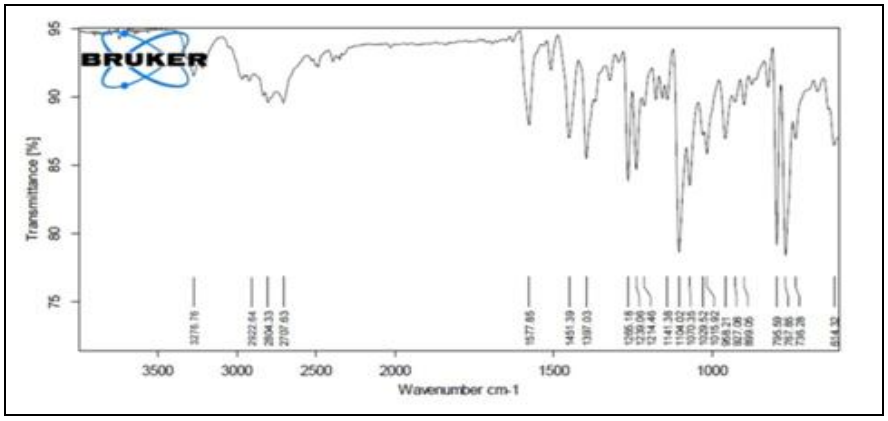

FIG. 1: FTIR SPECTRA OF PURE PROPRANOLOL HCL

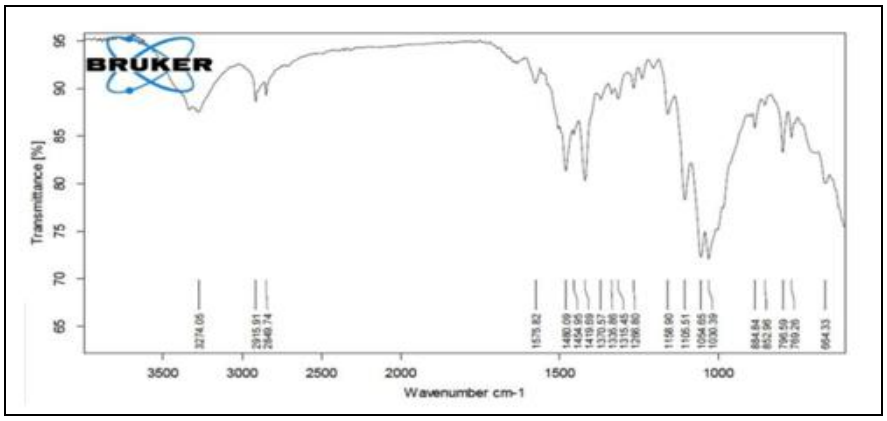

FIG. 2: FTIR SPECTRA OF PROPRANOLOL HCL AND THE EXCIPIENTS

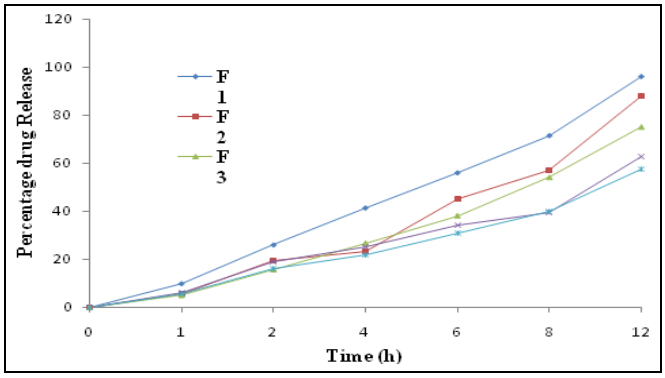

FIG. 3: CUMULATIVE PERCENTAGE DRUG RELEASE *VS* TIME GRAPH OF HYDROGEL MATRIX TABLETS

CONCLUSION: In the present study, the hydrogel matrix tablet was successfully prepared by using HPMC E15 as a polymer. We were able to optimize a formulation that gives us the ideal drug release profile for 12 h, which was the primary object of matrix tablets. The stability study also reveals that the formulation was stable for the desired duration of time. The release of the drug from the hydrogel-forming matrix device can be controlled by the concentration of the polymer. Thus the hydrogel matrix tablet for propranolol HCL prepared from HPMC E15 may represent a promising approach for delivering the drug to the desired period of 12 h.

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CONFLICTS OF INTEREST: Nil

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