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Formulation and Evaluation of gastro retentive Tablet of verapamil

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ABSTRACT
This study developed and evaluated mouth disintegrating tablets (MDTs) of Empagliflozin to enhance patient compliance and rapid drug onset. Using UV spectrophotometry (λmax 225nm in 0.1NHCl), MDTs were prepared via direct compression with superdisintegrants SSG, Crospovidone, and Croscarmellose sodium. All formulations met pharmacopeial standards. Batch F-6 with Crospovidone showed the best performance, releasing 99% of the drug within 30 minutes. The findings confirm the effectiveness of a minimal-excipient, direct compression method for efficient Empagliflozin delivery.
Keywords: Empagliflozin, Mouth Disintegrating Tablets, Superdisintegrants, In Vitro Drug Release, Patient Compliance, UV Spectrophotometry

A R T I C L E I N F O

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C O N T E N T S

1. Introduction

Oral controlled release drug delivery have recently been of increasing interest in pharmaceutical field to achieve improved therapeutic advantages, such as ease of dosing administration, patient compliance and flexibility in formulation. Drugs that are easily absorbed from gastrointestinal tract (GIT) and have short half-lives are eliminated quickly from the systemic circulation.

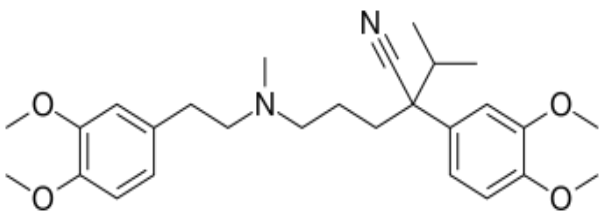

Fig.1: Verapamil

IUPAC Name: RS)-2-(3,4-Dimethoxyphenyl)-5-{[2-(3,4-dimethoxyphenyl)ethyl]-(methyl)amino}-2-prop-2-ylpentanenitrile
Molecular Formula : C27H38N2O4
Molecular Weight : 454.602 g/mol
Official Pharmacopoeia : USP

Physicochemical properties:
Description (Physical State): Liquid
Solubility: water solubility 4.47 mg/L
Stability: Infusion soln stability studies indicate that verapamil HCl does not adsorb to glass, PVC, or polyolefin containers. It is physically compatible in soln over a pH range of 3-6 but may precipitate in solns having pH>6or 7.
Storage Conditions: should be stored at room temperature & protected from light.
Dosage: Tablet

Melting point: < 25 °C
pKa(strongest acidic): 9.68
Log P: 3.79
Pharmacokinetic properties:
Bioavailability : 35.1%
Half-life : 2.8-7.4 hours
Absorption : 90%
Protein binding : 90%
Metabolism : liver
Excretion : kidney: 11%
Adverse effects: Blue lips and fingernails, blurred vision burning, crawling, itching, numbness, prickling, "pins and needles", or tingling feelings
Pharmacodynamics: Verapamil is an L-type calcium channel blocker that also has antiarrythmic activity. The R-enantiomer is more effective at reducing blood pressure compared to the S-enantiomer. However, the S-enantiomer is 20 times more potent than the R-enantiomer at prolonging the PR interval in treating arrhythmias.

2. Materials and Methods

Analytical method development:

Determination of absorption maxima:

A solution containing the concentration 10 µg/ mL drug was prepared in 0.1N HCL UV spectrum was taken using Double beam UV/VIS spectrophotometer. The solution was scanned in the range of 200 – 400 nm.

Preparation calibration curve:

10mg Verapamil pure drug was dissolved in 10ml of methanol (stock solution1) from stock solution 1ml of solution was taken and made up with10ml of 0.1N HCL (100µg/ml). From this 1ml was taken and made up with 10 ml of 0.1N HCL (10µg/ml). The above solution was subsequently diluted with 0.1N HCL to obtain series of dilutions Containing 2, 4, 6, 8, 10µg /ml of per ml of solution. The absorbance of the above dilutions was measured at 278nm by using UV-Spectrophotometer taking 0.1N HCL as blank. Then a graph was plotted by taking Concentration on X-Axis and Absorbance on Y-Axis which gives a straight line Linearity of standard curve was assessed from the square of correlation coefficient (R^2) which determined by least-square linear regression analysis.

Preformulation parameters: The quality of tablet, once formulated by rule, is generally dictated by the quality of physicochemical properties of blends. There are many formulations and process variables involved in mixing and all these can affect the characteristics of blends produced. The various characteristics of blends tested as per Pharmacopoeia.

Angle of repose:

The frictional force in a loose powder can be measured by the angle of repose. It is defined as, the maximum angle possible between the surface of the pile of the powder and the horizontal plane. If more powder is added to the pile, it slides down the sides of the pile until the mutual friction of the particles producing a surface angle, is in equilibrium with the gravitational force. The fixed funnel method was employed to measure the angle of repose. A funnel was secured with its tip at a given height (h), above a graph paper that is placed on a flat horizontal surface. The blend was carefully pored through the funnel until the apex of the conical pile just touches the tip of the funnel. The radius (r) of the base of the conical pile was measured. The angle of repose was calculated using the following formula:

$\tan \theta = h / r$ $\tan \theta$ = Angle of repose
h = Height of the cone, r = Radius of the cone base

Bulk density:

Density is defined as weight per unit volume. Bulk density, is defined as the mass of the powder divided by the bulk volume and is expressed as gm/cm^3. The bulk density of a powder primarily depends on particle size distribution, particle shape and the tendency of particles to adhere together. Bulk density is very important in the size of containers needed for handling, shipping, and storage of raw material and blend. It is also important in size blending equipment. 10 gm powder blend was sieved and introduced into a dry 20 ml cylinder, without compacting. The powder was carefully leveled without compacting and the unsettled apparent volume, Vo, was read.

The bulk density was calculated using the formula:

$\text{Bulk Density} = M / V_o$

Where, M = weight of sample
V_o = apparent volume of powder

Tapped density:

After carrying out the procedure as given in the measurement of bulk density the cylinder containing the sample was tapped using a suitable mechanical tapped density tester that provides 100 drops per minute and this was repeated until difference between succeeding measurement is less than 2 % and then tapped volume, V measured, to the nearest graduated unit. The tapped density was calculated, in gm per L, using the formula:

$\text{Tap} = M / V$

Where, Tap= Tapped Density
M = Weight of sample
V= Tapped volume of powder

Measures of powder compressibility:

The Compressibility Index (Carr's Index) is a measure of the propensity of a powder to be compressed. It is determined from the bulk and tapped densities. In theory, the less compressible a material the more flowable it is. As such, it is measures of the relative importance of interparticulate interactions. In a free- flowing powder, such interactions are generally less significant, and the bulk and tapped densities will be closer in value. For poorer flowing materials, there are frequently greater interparticle interactions, and a greater difference between the bulk and tapped densities will be observed. These differences are reflected in the Compressibility Index which is calculated using the following formulas:

$\text{Carr's Index} = [(\text{tap} - b) / \text{tap}] \times 100$

Where, b = Bulk Density
Tap = Tapped Density

Evaluation of post compression parameters for prepared Tablets: The designed compression tablets were studied for their physicochemical properties like weight variation, hardness, thickness, friability and drug content.

Weight variation test:

To study the weight variation, twenty tablets were taken and their weight was determined individually and collectively on a digital weighing balance. The average weight of one tablet was determined from the collective weight. The weight variation test would be a satisfactory method of deter mining the drug content uniformity. Not more than two of the individual weights deviate from the average weight by more than the percentage shown in the following table and none deviate by more than twice the percentage. The mean and deviation were determined. The percent deviation was calculated using the following formula.

% Deviation = (Individual weight – Average weight / Average weight) × 100

Hardness:

Hardness of tablet is defined as the force applied across the diameter of the tablet in order to break the tablet. The resistance of the tablet to chipping, abrasion or breakage under condition of storage transformation and handling before usage depends on its hardness. For each formulation, the hardness of three tablets was determined using Monsanto hardness tester and the average is calculated and presented with deviation.

Thickness:

Tablet thickness is an important characteristic in reproducing appearance. Tablet thickness is an important characteristic in reproducing appearance. Average thickness for core and coated tablets is calculated and presented with deviation.

Friability: It is measured of mechanical strength of tablets. Roche friabilator was used to determine the friability by following procedure. Pre weighed tablets were placed in the friabilator. The tablets were rotated at 25 rpm for 4 minutes (100 rotations). At the end of test, the tablets were re-weighed, and loss in the weight of tablet is the measure of friability and is expressed in percentage as

$$\% \text{ Friability} = [(W1-W2) / W1] \times 100$$

Where, W1 = Initial weight of tablets

W2 = Weight of the tablets after testing

Determination of drug content:

Both compression-coated tablets of were tested for their drug content. Ten tablets were finely powdered quantities of the powder equivalent to one tablet weight of Verapamil were accurately weighed, transferred to a 100 ml volumetric flask containing 50 ml water and were allowed to stand to ensure complete solubility of the drug. The mixture was made up to volume with water. The solution was suitably diluted and the absorption was determined by UV –Visible spectrophotometer. The drug concentration was calculated from the calibration curve.

***In vitro* Buoyancy studies:**

The *in vitro* buoyancy was determined by floating lag time, and total floating time. The tablets were placed in a 100ml beaker containing 0.1N HCL. The time required for the tablet to rise to the surface and float was determined as floating lag time (FLT) and duration of time the tablet constantly floats on the dissolution medium was noted as Total Floating Time respectively (TFT).

***In vitro* drug release studies**

Dissolution parameters:

Apparatus -- USP-II, Paddle Method
Dissolution Medium -- 0.1 N HCL
RPM -- 50
Sampling intervals (hrs) -- 0.5,1,2,3,4,5,6,7,8,10,11,12
Temperature -- 37°c $\pm$ 0.5°c

As the preparation was for floating drug release given through oral route of administration, different receptors fluids are used for evaluation the dissolution profile.

Procedure:

900ml 0f 0.1 HCL was placed in vessel and the USP apparatus –II (Paddle Method) was assembled. The medium was allowed to equilibrate to temp of 37°c $\pm$ 0.5°c. Tablet was placed in the vessel and the vessel was covered the apparatus was operated for 12 hours and then the medium 0.1 N HCL was taken and process was continued from 0 to 12 hrs at 50 rpm. At definite time intervals of 5 ml of the receptors fluid was withdrawn, filtered and again 5ml receptor fluid was replaced. Suitable dilutions were done with media and analyzed by spectrophotometrically at 278nm using UV-spectrophotometer.

Application of Release Rate Kinetics to Dissolution Data:

Various models were tested for explaining the kinetics of drug release. To analyze the mechanism of the drug release rate kinetics of the dosage form, the obtained data were fitted into zero-order, first order, Higuchi, and Korsmeyer-Peppas release model.

Zero order release rate kinetics:

To study the zero–order release kinetics the release rate data ar e fitted to the following equation.

$$F = K_o t$$

Where, 'F' is the drug release at time't', and 'K_o' is the zero order release rate constant. The plot of % drug release versus time is linear.

First order release rate kinetics: The release rate data are fitted to the following equation

$$\text{Log } (100-F) = kt$$

A plot of log cumulative percent of drug remaining to be released vs. time is plotted then it gives first order release.

Higuchi release model: To study the Higuchi release kinetics, the release rate data were fitted to the following equation.

$$F = k\ t1/2$$

Where, 'k' is the Higuchi constant.

In higuchi model, a plot of % drug release versus square root of time is linear.

Korsmeyer and Peppas release model:

The mechanism of drug release was evaluated by plotting the log percentage of drug released versus log time according to Korsmeyer- Peppas equation. The exponent 'n' indicates the mechanism of drug release calculated through the slope of the straight Line.

$$M_t / M_\infty = K\ t^n$$

Where, M_t / M_∞ is fraction of drug released at time 't', k represents a constant, and 'n' is the diffusional exponent, which characterizes the type of release mechanism during the dissolution process. For non-Fickian release, the value of n falls between 0.5 and 1.0; while in case of Fickian diffusion, n = 0.5; for zero-order release (case I I transport), n=1; and for supercase II transport, n > 1. In this model, a plot of log (M_t / M_∞) versus log (time) is linear.

Drug – Excipient compatibility studies

Fourier Transform Infrared (FTIR) spectroscopy:

The compatibility between the pure drug and excipients was detected by FTIR spectra obtained on Bruker FTIR Germany(Alpha T).The solid powder sample directly place on yellow crystal which was made up of ZnSe. The spectra were recorded over the wave number of 4000 cm^{-1} to 550 cm^{-1}.

Table 1: Angle of Repose values (as per USP)

Angle of Repose	Nature of Flow
<25	Excellent
25-30	Good
30-40	Passable
>40	Very poor

Table 2: Carr's index value (as per USP)

Carr's index	Properties
5 – 15	Excellent
12 – 16	Good
18 – 21	Fair to Passable
2 – 35	Poor
33 – 38	Very Poor
>40	Very Very Poor

Table 3: Formulation composition for Floating tablets

Ingredients	V1	V2	V3	V4	V5	V6	V7	V8	V9
Verapamil	40	40	40	40	40	40	40	40	40
HPMC K15M	20	40	60	-	-	-	-	-	-
Xanthan gum	-	-	-	20	40	60	-	-	-
Ethyl cellulose	-	-	-	-	-	-	20	40	60
$NaHCO_3$	15	15	15	15	15	15	15	15	15
PVPk30	10	10	10	10	10	10	10	10	10
Talc	5	5	5	5	5	5	5	5	5
Magnesium Stearate	5	5	5	5	5	5	5	5	5
MCC	105	85	65	105	85	65	105	85	65
Total Weight	200	200	200	200	200	200	200	200	200

All the quantities were in mg

Table 4: Pharmacopoeial specifications for tablet weight variation

Average weight of tablet (mg) (I.P)	Average weight of tablet (mg) (U.S.P)	Maximum percentage difference allowed
Less than 80	Less than 130	10
80-250	130-324	7.5
More than	More than 324	5

3. Results and Discussion

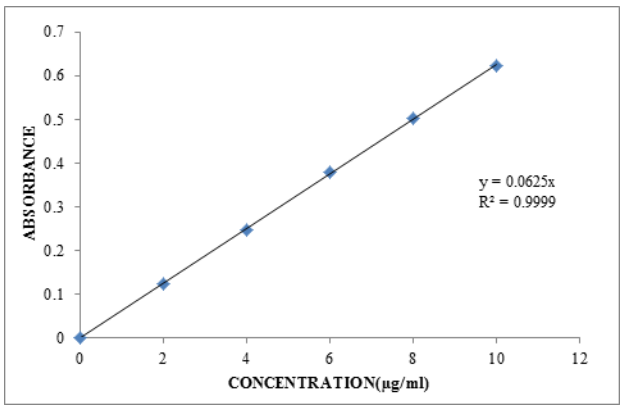

Fig.2: Standard graph of Verapamil in 0.1N HCL

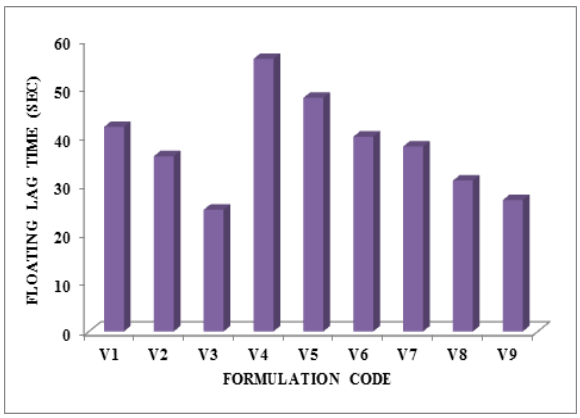

Fig.3: Floating lag time (sec)

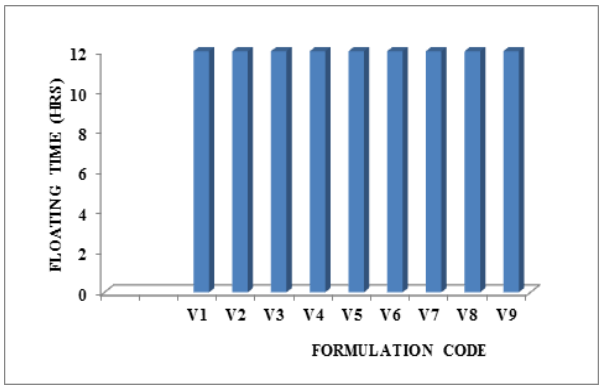

Fig.4: Total Floating Time (Hrs)

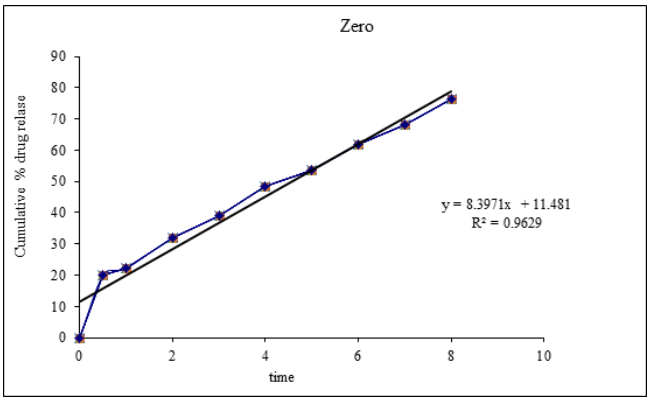

Fig.8: Zero order release kinetics

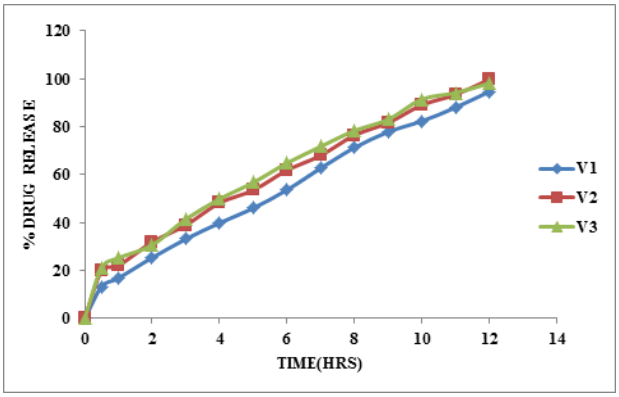

Fig.5: Dissolution data of Verapamil Floating tablets containing HPMC K15M

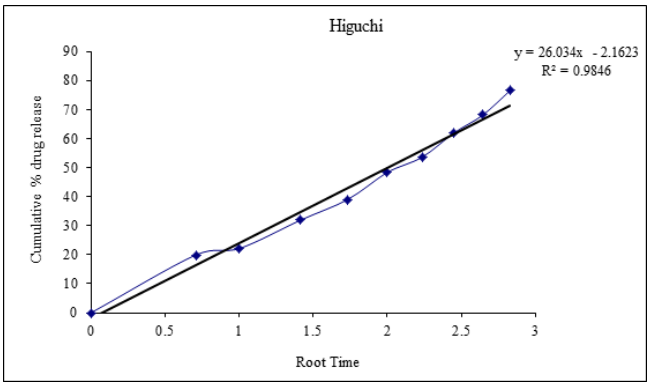

Fig.9: Higuchi release kinetics

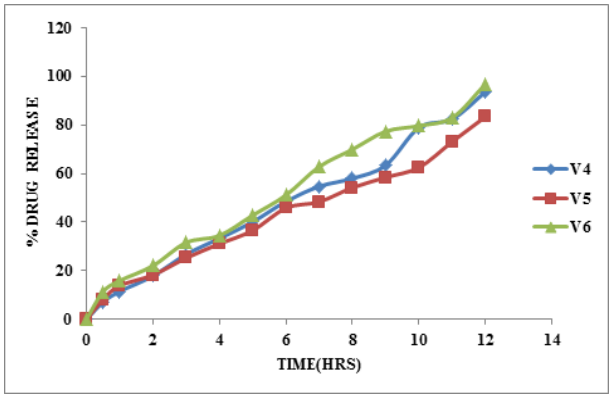

Fig.6: Dissolution data of Verapamil Floating tablets containing Xanthan gum

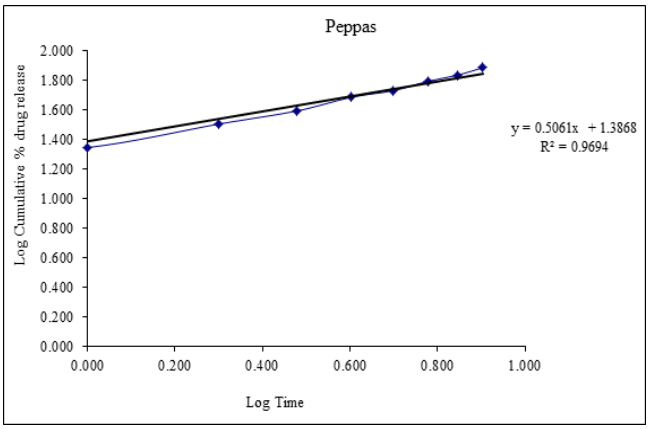

Fig.10: Kors mayer peppas release kinetics

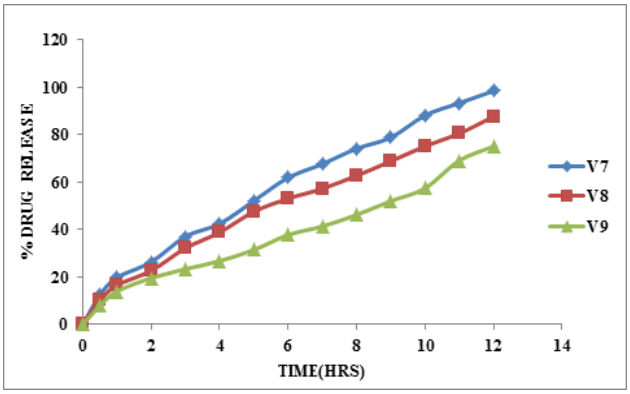

Fig.7: Dissolution data of Verapamil Floating tablets containing Ethyl cellulose

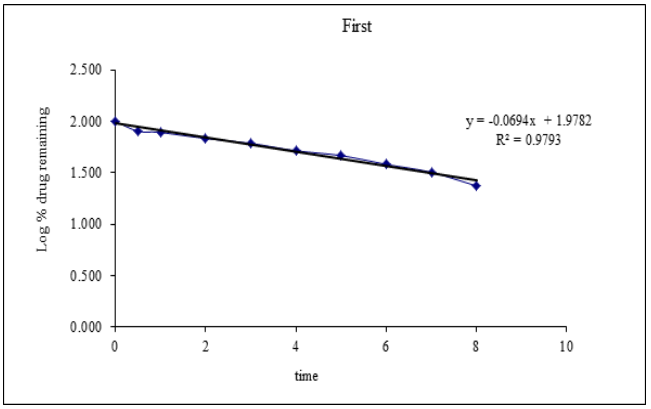

Fig.11: First order release kinetics

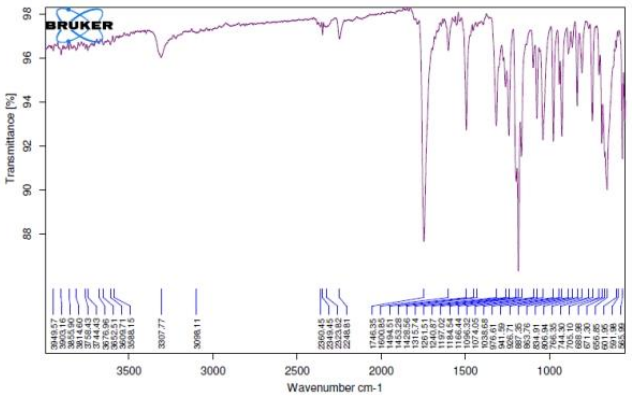

Fig.12: FTIR Spectrum of pure drug

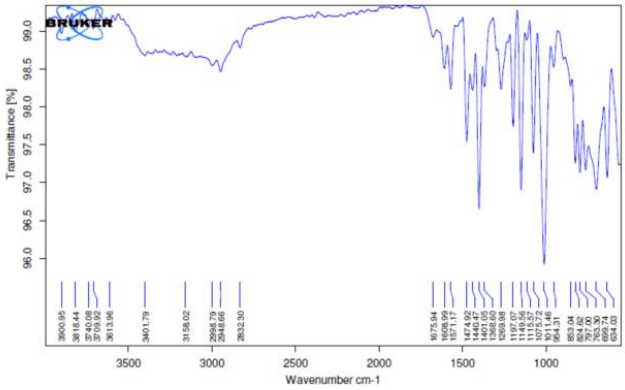

Fig.13: FTIR Spectrum of optimized formulation

Table 5: Pre-formulation parameters of blend

Formulation Code	Angle of Repose	Bulk density (gm/mL)	Tapped density (gm/mL)	Carr's index (%)	Hausner's Ratio
V1	25.56±0.3	0.57±0.01	0.61±0.01	10.11±0.8	1.13±0.02
V2	24.67±0.3	0.53±0.01	0.68±0.03	10.23±0.5	1.12±0.03
V3	25.56±0.2	0.52±0.06	0.64±0.03	10.34±1.0	1.14±0.06
V4	23.30±0.1	0.50±0.21	0.66±0.12	10.23±0.5	1.12±0.06
V5	22.56±0.1	0.65±0.02	0.59±0.02	11.23±0.8	1.11±0.05
V6	23.89±0.2	0.50±0.04	0.68±0.04	11.34±0.6	1.14±0.03
V7	26.54±0.1	0.59±0.04	0.64±0.05	10.12±0.7	1.13±0.09
V8	23.67±0.3	0.58±0.12	0.58±0.04	10.23±1.0	1.11±0.07
V9	24.34±0.4	0.56±0.02	0.54±0.01	10.23±0.8	1.13±0.02

Table 6: *In vitro* quality control parameters

Formulation codes	Weight variation (mg)	Hardness (kg/cm^2)	Friability (%loss)	Thickness (mm)	Drug content (%)	Floating lag time (sec)	Total Floating Time (Hrs)
V1		4.6	0.34	3.15	99.27	42	12
V2		4.8	0.46	3.69	98.64	36	12
V3		5.1	0.29	3.81	100.05	25	12
V4		4.0	0.62	3.79	99.82	56	12
V5		5.2	0.72	3.56	97.19	48	12
V6		4.9	0.69	3.11	98.52	40	12
V7		5.6	0.28	3.29	99.13	38	12
V8		4.5	0.47	3.50	97.68	31	12
V9		4.8	0.52	3.74	98.49	27	12

Table 7: Dissolution data of Floating tablets

Time(Hrs)	V1	V2	V3	V4	V5	V6	V7	V8	V9
0	0	0	0	0	0	0	0	0	0
0.5	13.3	19.9	21.1	7.1	8.2	11.4	12.4	10.1	7.9
1	16.9	22.1	25.3	11.5	13.9	15.9	19.8	16.6	14.0
2	25.4	31.9	30.7	17.9	18.3	22.1	26.4	22.7	19.6
3	33.2	39.0	41.5	26.8	25.3	31.6	37.1	32.2	23.4
4	39.9	48.3	49.9	33.3	31.1	34.5	42.5	38.9	26.8
5	46.1	53.6	56.8	40.1	36.6	42.8	52.2	47.6	31.5
6	53.7	61.9	64.9	48.5	45.8	51.1	61.9	53.1	37.8
7	62.8	68.1	71.8	54.7	48.4	62.8	67.7	57.3	41.4
8	71.3	76.5	78.4	58.0	54.2	69.9	74.2	62.8	46.3
9	77.9	81.7	83.1	63.4	58.4	77.3	78.9	68.9	52.1
10	82.4	89.1	91.5	78.9	62.5	79.6	88.2	75.2	57.5
11	88.1	93.5	94.2	82.4	73.1	83.0	93.4	80.6	69.2
12	94.7	99.8	98.2	93.6	83.4	96.8	98.5	87.7	75.1

4. Conclusion

The present work described the pre-formulation and formulation development that led to the production of Verapamil Gastro retentive floating tablets by direct compression of powder blends/granules. To achieve the drug release up to 12hrs, studies have been carried out on direct compression method by using different polymers like HPMC K15M, Xanthan gum and Ethyl cellulose. The aim of the present work was completely fulfilled by the use of HPMC K15M, Xanthan gum and Ethyl cellulose as the drug release was extended up to 12hrs. Further drug release data were interpreted to determine the order, mechanism and drug release behavior from the dosage form. The results revealed that the drug release from the optimized formulation follows zero-order –kinetics and Higuchi kinetic model. The optimized formula V2 has fulfilled my objective. The drug release was found to be 99.8% in 12hrs

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