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Design and Evaluation of Extended-Release Carbamazepine Formulation for Seizure Control: Improving Patient Compliance

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ABSTRACT

The current study was aimed at evaluating and comparing the performance of three different polymers—Carbopol, HPMC K4M, and HPMC K15M in the formulation of extended-release tablets of Carbamazepine. The primary focus was to investigate how the physico-chemical properties of both the active drug and polymers influenced the drug release kinetics. Pre-compression parameters such as angle of repose, bulk density, tapped density, and compressibility index confirmed the suitability of the formulations for direct compression. Post-compression evaluation revealed satisfactory outcomes for all tested parameters, including tablet thickness, weight variation, hardness, content uniformity and in vitro drug release. The results demonstrated that Carbamazepine is a suitable candidate for extended-release formulations, as it exhibited a sustained drug release profile that helps maintain therapeutic plasma concentration without reaching toxic levels. This sustained release further supports reduced dosing frequency, making the formulation more patient-compliant. The study also confirmed that increasing the polymer concentration significantly decreased the rate of drug release. Among all formulations, F3 displayed the most desirable extended-release characteristics. This highlights the importance of polymer selection and optimization in achieving controlled drug release. Release kinetics evaluation confirmed that the drug followed first-order release behavior and the mechanism of release fitted the Higuchi model, indicating diffusion as the primary drug release mechanism. These findings suggest that the proposed extended-release formulations could be a promising alternative to conventional Carbamazepine dosage forms and may offer improved therapeutic outcomes in clinical applications.

Keywords: Carbamazepine, Extended-Release Tablets, Carbopol, HPMCK₄M, HPMC K₁₅M, Drug Release Kinetics, First-Order Release, Higuchi Model, Controlled Drug Delivery, Direct Compression.

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1. Introduction

Oral drug delivery is the most preferred route due to its convenience, cost-effectiveness, and high patient compliance. It leverages the large surface area and rich blood supply of the gastrointestinal tract for efficient drug absorption. However, challenges such as pH variability, enzymatic degradation, and poor permeability for macromolecules limit its applicability for certain drugs.

Conventional dosage forms include liquids (solutions, suspensions, emulsions) and solids (tablets, capsules), with formulation factors like particle size and excipients influencing bioavailability. Sustained-release systems enhance therapeutic efficacy by maintaining consistent drug levels, though they are unsuitable for drugs with very short or long half-lives. Advanced mechanisms like diffusion-

controlled, dissolution-controlled, and osmotic pumps enable controlled drug release, while polymers play a key role in localized and stabilized delivery. Tablet evaluation involves hardness, friability, weight variation, and dissolution testing, with release kinetics analysed using models like zero-order, first-order, Higuchi, and Korsmeyer-Peppas to optimize drug delivery.

2. Materials and Methods

List of Materials and Suppliers:

The materials required for the study were procured from reliable suppliers to ensure high-quality formulation development. Carbamazepine, the active pharmaceutical ingredient, was supplied by Qulaychrome Research Labs. All other excipients, including Carbopol (a bioadhesive polymer), HPMC K4M and HPMC K15M (hydrophilic matrix-forming agents), PVPK30 (a binder), microcrystalline cellulose (MCC, a diluent), talc (a glidant), and magnesium stearate (a lubricant), were obtained from SD Fine Chemicals, Mumbai, a trusted supplier of pharmaceutical-grade materials. These excipients were carefully selected based on their functional properties to achieve optimal drug release, tablet integrity, and manufacturing feasibility in the development of sustained-release formulations.

List of equipments and Companies:

The study utilized various precision instruments to ensure accurate formulation and evaluation of the tablets. An Electronic Weighing Balance (Scale-tec) was used for precise measurement of ingredients. Tablet integrity was assessed using a Roche Friabilator (Electrolab, Mumbai) for friability testing and a Pfizer Hardness Tester (Mumbai) for mechanical strength. A Laboratory Oven (DTC-00R) facilitated controlled drying processes, while a Compression Machine (CMD, Cadmach) enabled uniform tablet compaction. Drug release studies were conducted using a Dissolution Apparatus (Electrolab TDT-08L), and UV Spectroscopy (Labindia UV 3000+) was employed for drug content analysis. Additionally, Vernier Calipers (CD-6"CS) were used to measure tablet dimensions, ensuring uniformity in size and thickness. All equipment played a critical role in maintaining quality and reproducibility throughout the study.

I. Analytical Method Development in 0.1N HCL:

Preparation of 0.1 N Hydrochloric Acid (pH 1.2)

8.5 ml of concentrate hydrochloric acid was taken and diluted with distilled water up to 1000 ml.

Determination of λ_{\max} of Carbamazepine in 0.1N HCL:

Procedure:

Working standard: 100mg of Carbamazepine was weighed and dissolved in 10ml methanol and then make up to the volume of 100ml with 0.1N HCL it give 1000 μ g/ml concentrated stock solution.

Dilution 1:

From the working standard, 10ml solution was diluted to 100ml with 0.1NHCl it will give 100 μ g/ml concentrated solution.

Dilution 2:

From the dilution1, 10ml solution was diluted to 100ml with 0.1NHCl it will give 10 μ g/ml concentrated solution. This solutions was scanned at range of 200-400nm wavelength light corresponding scan spectrum curve was

noted .the corresponding wavelength having highest absorbance is noted as λ_{\max}

Construction of calibration curve of Carbamazepine in 0.1N HCL:

Procedure:

Working standard:

100mg of Carbamazepine was weighed and dissolved in 10ml methanol and then make up to the volume of 100ml with 0.1N HCL it give 1000 μ g/ml concentrated stock solution.

Dilution 1: From the working standard, 10ml solution was diluted to 100ml with 0.1NHCl it will give 100 μ g/ml concentrated solutions. From dilution 1, take 0.2, 0.4, 0.6, 0.8, and 1ml of solution was diluted up to mark in 10ml volumetric flask to obtain 2, 4, 6, 8 and 10 μ g/ml concentrated solutions. This solutions absorbance was noted at 280nm.

III. Analytical Method Development in 6.8 phosphate buffer:

Preparation of 6.8 phosphate buffer:

6.8gms of potassium di hydrogen ortho phosphate was taken in a 1000ml volumetric flask and dissolved with distilled water and make up to 1000 ml with distilled water and adjust pH upto 6.8 with Sodium hydroxide solution.

Determination of λ_{\max} of Carbamazepine in 6.8 phosphate buffer:

Procedure:

Working standard:

100mg of Carbamazepine was weighed and dissolved in 10ml methanol and then make up to the volume of 100ml with 6.8 phosphate buffer it give 1000 μ g/ml concentrated stock solution.

Dilution 1: From the working standard, 10ml solution was diluted to 100ml with 6.8 phosphate buffer it will give 100 μ g/ml concentrated solution.

Dilution 2:

From the dilution-1, 10ml solution was diluted to 100ml with 6.8 phosphate buffer it will give 10 μ g/ml concentrated solution. This solution was scanned at range of 200-400nm wavelength light corresponding scan spectrum curve was noted .the corresponding wavelength having highest absorbance is noted as λ_{\max} .

Construction of calibration curve of Carbamazepine 6.8 phosphate buffer:

Procedure:

Working standard: 100mg of Carbamazepine was weighed and dissolved in 10ml methanol and then make up to the volume of 100ml with 6.8 phosphate buffer it give 1000 μ g/ml concentrated stock solution.

Dilution 1:

From the working standard, 10ml solution was diluted to 100ml with 6.8 phosphate buffer it will give 100 μ g/ml concentrated solution. From dilution 1, take 0.2, 0.4, 0.6, 0.8 and 1ml of solution and was diluted up to mark in 10ml volumetric flask to obtain 2,4,6,8 and 10 μ g/ml concentrated solutions. This solutions absorbance was noted at $\lambda_{\max}=270$

II. Formulation of Extended release tablets of Carbamazepine by direct compression method

processing steps involved in direct compression method: The matrix tablets were prepared by following the General Methodology as given below:

1. All ingredients (Carbamazepine + MCC + polymer + PVP K30) were weighed accurately and co sifted by passing through #22 sieve, blended in a Poly Bag for 5 min.
2. The above blend were lubricated with # 40 Sieves passed Talc and Magnesium stearate.
3. The final blend was then compressed into tablets using 16 station tablet compression machine with an average hardness of 5.0 - 7.0Kg/cm², by using 8-12mm die.

Iv. Evaluation of tablets

The formulated tablets were evaluated for the following Pre and Post compression quality control studies

A) Pre Compression studies:

1. Angle of Repose: It is defined as the maximum angle possible between the surface of a pile of powder and the horizontal plane.

Angle of Repose of granules was determined by the funnel method. Accurately weighed powder blend was taken in the funnel. Height of the funnel was adjusted in such a way the tip of the funnel just touched the apex of the powder blend. Powder blend was allowed to flow through the funnel freely on to the surface. Diameter of the powder cone was measured and angle of repose was calculated using the following equation¹⁷.

$$\theta = \tan^{-1} (h/r)$$

Where: θ = angle of repose

h = height in cms

r = radius in cms

The angle of repose has been used to characterize the flow properties of solids. It is a characteristic related to inter particulate friction or resistance to movement between particles.

2. Density:

a. Bulk density (BD): It is the ratio of total mass of powder to the bulk volume of powder Weigh accurately 25 g of granules, which was previously passed through 22#sieve and transferred in 100 ml graduated cylinder. Carefully level the powder without compacting, and read the unsettled apparent volume. Calculate the apparent bulk density in gm/ml by the following formula¹⁸.

Bulk density = weight of powder/ Bulk volume.

$$D_b = \frac{M}{V_0}$$

M = mass of the powder

V₀ = bulk volume of the powder.

b. Tapped density (TD):

It is the ratio of total mass of powder to the tapped volume of powder Weigh accurately 25 g of granules, which was previously passed through 40# sieve and transferred in 100 ml graduated cylinder of tap density tester which was operated for fixed number of taps until the powder bed volume has reached a minimum, thus was calculated by formula¹⁸.

Tapped density = Weigh of powder / Tapped volume

$$Dt = (M) / (V_f)$$

M = mass of the powder

V_f = tapped volume of the powder.

3. Carr's Index:

Compressibility index of the powder blend was determined by Carr's compressibility index. It is a simple test to evaluate the BD and TD of a powder and the rate at which it packed down¹⁹. The formula for Carr's index is as below:

$$\text{Compressibility index} = 100 \times \frac{\text{Tappeddensity} - \text{Bulk density}}{\text{Tappeddensity}}$$

4. Hausner's Ratio:

Hausner's Ratio is a number that is correlated to the flow ability of a powder¹⁹.

$$\text{Hausner's Ratio} = \frac{\text{TappedDensity}}{\text{Bulk Density}}$$

B) Post compression studies:

1. General appearance:

The formulated tablets were assessed for its general appearance and observations were made for shape, colour, texture and odour.

2. Average weight/Weight Variation:

20 tablets were selected and weighed collectively and individually. From the collective weight, average weight was calculated. Each tablet weight was then compared with average weight to assure whether it was within permissible limits or not. Not more than two of the individual weights deviated from the average weight by more than 7.5% for 300 mg tablets and none by more than double that percentage.

$$\text{Average weight} = \text{weight of 20 tablets}/20$$

$$\% \text{ weight variation} = \frac{\text{Average weight} - \text{weight of each tablet}}{\text{Average weight}} * 100$$

3. Thickness: Thickness of the tablets (n=3) was determined using a Vernier calipers

4. Hardness test: Hardness of the tablet was determined by using the Monsanto hardness tester (n=3) the lower plunger was placed in contact with the tablet and a zero reading was taken. The plunger was then forced against a spring by turning a threaded bolt until the tablet fractured. As the spring was compressed a pointer rides along a gauge in the barrel to indicate the force.

5. Friability test: This test is performed to evaluate the ability of tablets to withstand abrasion in packing, handling and transporting. Initial weight of 20 tablets is taken and these are placed in the Friabilator, rotating at 25rpm for 4min. The difference in the weight is noted and expressed as percentage. It should be preferably between 0.5 to 1.0%.

$$\% \text{Friability} = [(W_1 - W_2)/W_1] \times 100$$

Where, W₁ = weight of tablets before test,

W₂ = weight of tablets after test

6. Content uniformity test

Ten tablets were weighed and powdered, a quantity of powder equivalent to 100 mg of Carbamazepine was transferred to a 100 ml volumetric flask and 10 ml methanol is added. The drug is dissolved in methanol by vigorously shaking the volumetric flask

for 15 minutes. Then the volume is adjusted to the mark with distilled water and the liquid is filtered. From prepared solution take 0.1ml solution in 10ml volumetric flask and make up to mark with distilled water. The Carbamazepine content was determined by measuring the absorbance at 270nm after appropriate dilution. The drug content was calculated using the standard calibration curve. The mean percent drug content was calculated as an average of three determinations. Calculate the quantity in mg of drug in the portion taken by the formula

$$\text{Assay} = \frac{\text{Test Absorbance}}{\text{Standard Absorbance}} \times \frac{\text{Standard Concentration}}{\text{Sample Concentration}} \times \frac{\text{Average Weight}}{\text{Label Claim}} \times \frac{\text{Purity of drug}}{100} \times 100$$

7. In vitro Dissolution Study:

900 ml of 0.1N HCl was placed in the vessel and the USP-II apparatus (Paddle method) was assembled. The medium was allowed to equilibrate to temperature of $37^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$. A tablet was placed in the vessel and was covered; the apparatus was operated up to 2hours at 50 rpm. After completion of 2hours remove the 0.1N HCL and add 6.8 phosphate buffer then continue the apparatus up to 24hours. At definite time intervals, 5 ml of dissolution medium was withdrawn; filtered and again replaced with 5 ml of fresh medium to maintain sink conditions. Suitable dilutions were done with dissolution medium and were analysed spectrophotometrically at $\lambda_{\text{max}} = 280$ nm using a UV-spectrophotometer (Lab India).

C) In vitro Release Kinetics Studies:

The analysis of drug release mechanism from a pharmaceutical dosage form is important but complicated process and is practically evident in the case of matrix systems. The order of drug release from ER was described by using zero order kinetics or first order kinetics. The mechanism of drug release from ER was studied by using Higuchi equation and the Peppas's-Korsmeyer equation.

1. Zero Order Release Kinetics:

It defines a linear relationship between the fractions of drug released versus time.

$$Q = k_0 t$$

Where, Q is the fraction of drug released at time t and k_0 is the zero order release rate constant. A plot of the fraction of drug released against time will be linear if the release obeys zero order release kinetics.

2. First Order Release Kinetics:

Wagner assuming that the exposed surface area of a tablet decreased exponentially with time during dissolution process suggested that the drug release from most of the slow release tablets could be described adequately by the first-order kinetics. The equation that describes first order kinetics is

$$\text{Log } C = \text{Log } C_0 - kt/2.303$$

Where C is the amount of drug dissolved at time t, C_0 is the amount of drug dissolved at $t=0$ and k is the first order rate constant.

A graph of log cumulative of log % drug remaining Vs time yields a straight line. Will be linear if the release obeys the first order release kinetics.

3. Higuchi equation:

It defines a linear dependence of the active fraction released per unit of surface (Q) and the square root of time.

$$Q = K_2 t^{1/2}$$

Where K_2 is release rate constant. A plot of the fraction of drug released against square root of time will be linear if

the release obeys Higuchi equation. This equation describes drug release as a diffusion process based on the Fick's law, square root time dependent²⁰.

4. Peppas's-Korsmeyer equation (Power Law):

In order to define a model, which would represent a better fit for the formulation, dissolution data was further analysed by Peppas's-Korsmeyer equation (Power Law).

$$M_t / M_{\infty} = K.t^n$$

Where, M_t is the amount of drug released at time t

M_{∞} is the amount released at time ∞ ,

M_t / M_{∞} is the fraction of drug released at time t,

K is the kinetic constant and n is the diffusion exponent.

To characterize the mechanism for both solvent penetration and drug release n can be used as abstracted. A plot between log drug release up to 60% against log of time will be linear if the release obeys Peppas's-Korsmeyer equation and the slope of this plot represents "n" value²¹. the kinetic data of the formulations were included. Nature of release of the drug from the designed tablets was inferred based on the correlation coefficients obtained from the plots of the kinetic models. The data were processed for regression analysis using MS EXCEL

Drug release kinetics mechanism:

The drug release mechanism from the formulation was interpreted based on the Korsmeyer-Peppas model, where the diffusion exponent (n) determines the release behavior. A value of $n = 0.45$ indicates Fickian diffusion, where drug release is primarily governed by molecular diffusion through the polymer matrix. When $0.45 < n < 0.89$, the mechanism follows anomalous (non-Fickian) diffusion, suggesting a combination of diffusion and polymer relaxation. At $n=0.89$, the release exhibits Case II transport, where drug release is controlled by polymer swelling and relaxation. If $n > 0.89$, the mechanism transitions to Super Case II transport, indicating a strong influence of polymer erosion/ swelling-dominated release. These interpretations help optimize the formulation for controlled and sustained drug delivery.

3. Results and Discussion

1. Construction of Standard calibration curve of Carbamazepine in 0.1N HCL:

The absorbance of the solution was measured at 280nm, using UV spectrometer with 0.1N HCL as blank. The values are shown in table. A graph of absorbance Vs Concentration was plotted which indicated in compliance to Beer's law in the concentration range 2 to 10 $\mu\text{g/ml}$.

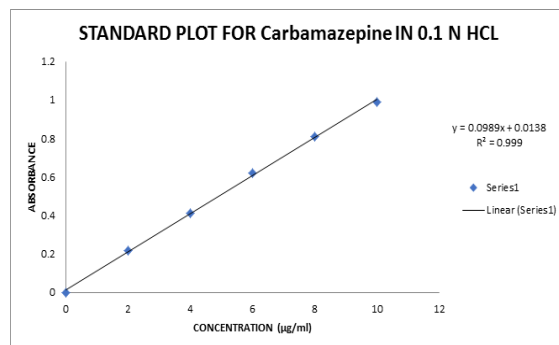


Figure 1: Standard calibration curve of Carbamazepine in 0.1N HCL

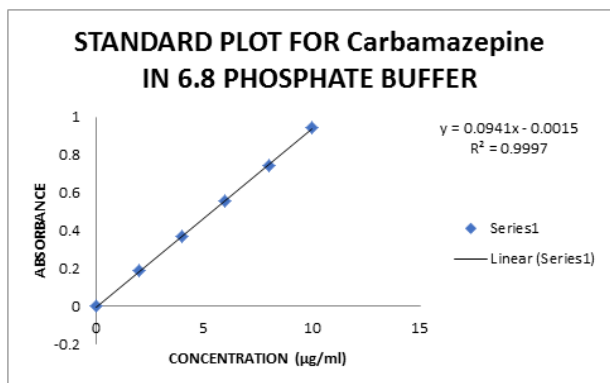


Figure 2: Standard calibration curve of Carbamazepine in 6.8 phosphate buffer

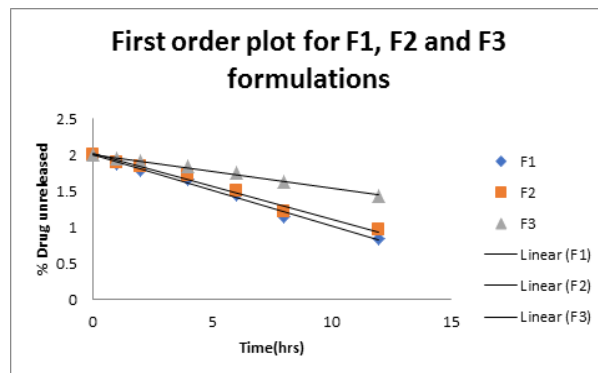


Figure 6: First order plot for F1, F2 and F3 formulations

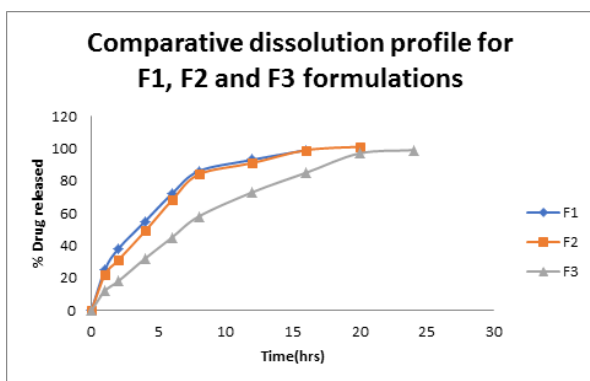


Figure 3: Comparative dissolution profile for F1, F2 and F3 formulations

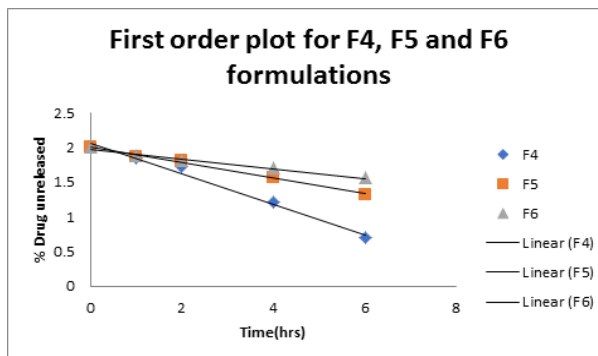


Figure 7: First order plot for F4, F5 and F6 formulations

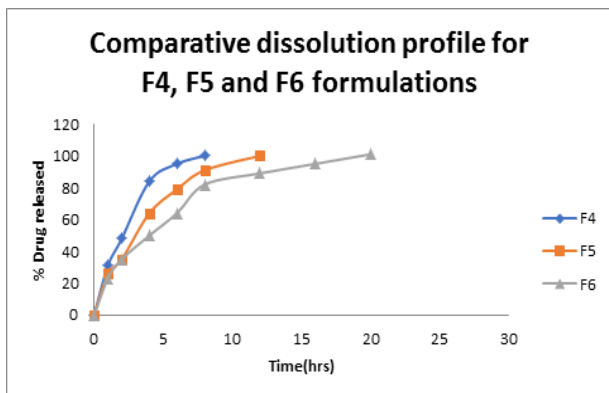


Figure 4: Comparative dissolution profile for F4, F5 and F6 formulations

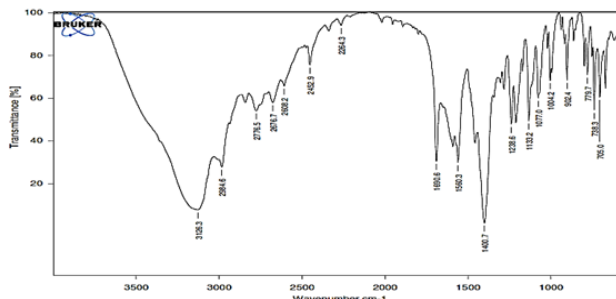


Figure 20: FTIR graph for Carbamazepine

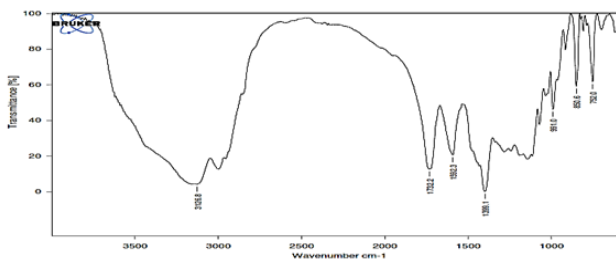


Figure 21: FTIR graph for Carbopol

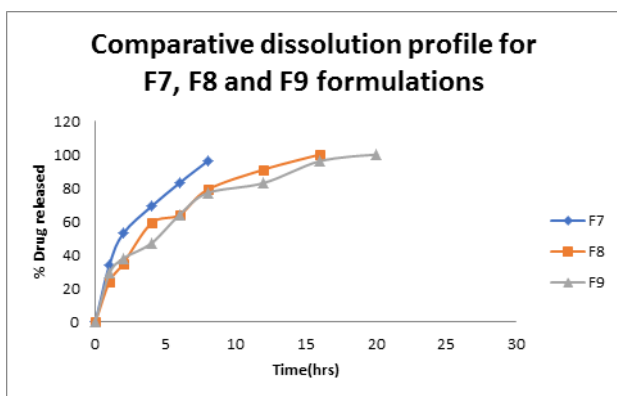


Figure 5: Comparative dissolution profile for F7, F8 and F9 formulations

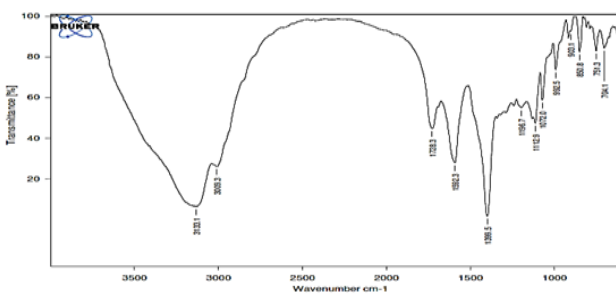


Figure 22: FTIR graph for Best formulation(F3)

Table 1: Formulation of Carbamazepine SR tablets by direct compression method

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Carbamazepine	100	100	100	100	100	100	100	100	100
Carbopol	30	60	90	-	-	-	-	-	-
HPMC K4M	-	-	-	30	60	90	-	-	-
HPMC K15M	-	-	-	-	-	-	30	60	90
PVP K30	10	10	10	10	10	10	10	10	10
MCC	126	96	66	126	96	66	126	96	66
Talc	2	2	2	2	2	2	2	2	2
Mg.stearate	2	2	2	2	2	2	2	2	2
Total Weight(mg)	270	270	270	270	270	270	270	270	270

Table 2: Scale of Flow ability (USP29-NF34)

Compressibility Index (%)	Flow Character	Hausner's Ratio
≤ 10	Excellent	1.00-1.11
11-15	Good	1.12-1.18
16-20	Fair	1.19-1.25
21-25	Passable	1.26-1.34
26-31	Poor	1.35-1.45
32-37	Very Poor	1.46-1.59
> 38	Very, very Poor	> 1.60

Table 3: Dissolution parameters

Parameter	Details
Dissolution apparatus	USP -Type II (paddle)
Medium	0.1N HCl and 6.8 Phosphate buffer
Volume	900 ml
Speed	50rpm
Temperature	37± 0.5 °C
Sample volume withdrawn	5ml
Time points	1, 2, 4, 6, 8, 12, 16, 20 and 24 hours
Analytical method	Ultraviolet Visible Spectroscopy
λmax	270nm

Table 4: Standard Calibration graph values of Carbamazepine in 0.1N HCL

Concentration (µg/ml)	Absorbance
0	0
2	0.218
4	0.413
6	0.621
8	0.81
10	0.988

Table 5: Standard Calibration graph values of Carbamazepine in 6.8 phosphate buffer

Concentration (µg/ml)	Absorbance
0	0
2	0.191
4	0.372
6	0.558
8	0.744
10	0.948

Table 10: In-vitro Dissolution results for Carbamazepine ER tablets

Time (hrs)	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
1	25	22	12	31	26	23	34	24	29
2	38	31	18	48	35	35	53	35	38
4	55	49	32	84	64	50	69	59	47

6	72	68	45	95	79	64	83	64	64
8	86	84	58	100	91	82	96	79	77
12	93	91	73	-	100	89	-	91	83
16	99	99	85	-	-	95	-	100	96
20	-	101	97	-	-	101	-	-	100
24	-	-	99	-	-	-	-	-	-

Table 6: R² value and n result table

Formulation code	R ² values				"n" values
	Zero order	First order	Higuchi	Peppas	
F1	0.840	0.991	0.976	0.978	0.515
F2	0.832	0.985	0.964	0.979	0.579
F3	0.938	0.996	0.984	0.995	0.737
F4	0.886	0.986	0.976	0.970	0.593
F5	0.883	0.994	0.980	0.985	0.634
F6	0.839	0.987	0.973	0.995	0.592
F7	0.892	0.950	0.996	0.990	0.482
F8	0.872	0.978	0.988	0.986	0.574
F9	0.855	0.971	0.982	0.970	0.457

4. Conclusion

This study have been showed that Carbamazepine could be used in extended release drug delivery system by formulating it has extended drug delivery system, provides extend duration of action in therapeutic range without reaching toxic levels as in the case of conventional dosage forms. These dosage forms have the ability to reduce the dosing frequency. By increasing the polymer, release rate of the drug decreases. Formulations F3 gave better release when compared to all formulations. By the results we can confirm that order of drug release first order and the mechanism of drug release from extended release tablets is Higuchi model.

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