ISSN: 2322 - 0902 (P)
ISSN: 2322 - 0910 (O)

International Journal of Ayurveda and Pharma Research

Research Article

FORMULATION AND IN VITRO EVALUATION OF GABAPENTIN CONTROLLED RELEASE TABLETS USING NATURAL POLYMERS

V. Sruthi[1], V. Alagarsamy[2], P. Subhash Chandra Bose[3], D. Saritha[4], P. Srikanth Reddy[3]*

[1]Department of Pharmacognosy, SSJ College of Pharmacy, Vattinagula Pally, Hyderabad.
[2]Department of Pharmaceutical Chemistry, *[3]Department of Pharmaceutics, MNR College of Pharmacy, Sangareddy,
[4]Department of Pharmaceutics, Sultan-ul-Uloom College of Pharmacy, Hyderabad, Telangana, India.

Article info

Article History:
Received: 11-05-2025
Accepted: 15-06-2025
Published: 07-07-2025

KEYWORDS:
Gabapentin, HPMC, MCC and DCP network.

ABSTRACT

This research set out to find the best way to use various grades of controlled-release polymer. To create a new one that would be just as effective as the original, but cheaper, and of better quality. The dosage form was designed using Hydroxypropyl Methyl Cellulose (HPMC K15MCR) as matrix builders. Research on the compatibility of medication and polymer was carried out. The flowability of the powder blend was optimized after studying the blend. Uniformity Compressing free-flowing powder directly into tablet form was the method of choice. They were successfully combined with the HPMC, MCC, and DCP networks. In order to compare different dissolution characteristics, we also presented the mean dissolving time. Clinical trials have shown that controlled-release gabapentin tablets are formulated by direct compression outperforms its immediate-release counterparts in terms of therapeutic efficacy.

INTRODUCTION

Modified release (MR) dosage forms are defined by the United States Pharmacopoeia (USP) as those for which the time course and/or location of drug release characteristics are selected to achieve therapeutic or convenient goals not provided by traditional dosage forms, like solutions, ointments, or rapidly dissolving dosage forms[1]. Extended release (ER) dosage forms are one type of MR dosage form that, when compared to those offered as a traditional dosage form (a solution or a prompt drug-releasing dosage form), enable at least a two-fold decrease in dosing frequency or a notable improvement in patient compliance or therapeutic performance. Extended-release medications are sometimes referred to as controlled release (CR), prolonged release, sustained or slow-release (SR), and long-acting (LA)[1].

Maintaining medication levels within the intended range, requiring fewer doses, promoting optimal use of the treatment, and improving patient compliance are all examples of controlled drug delivery systems[2].

Even though these benefits can be substantial, it is impossible to overlook the potential drawbacks, which include the potential toxicity or non-biocompatibility of the materials used, undesired degradation by products, the need for surgery to implant or remove the system, the possibility of patient discomfort from the delivery device, and the lower cost of controlled-release systems when compared to conventional pharmaceutical formulations[3,4]. Inertness, biocompatibility, mechanical strength, patient comfort, high drug loading capacity, safety from unintentional release, ease of administration and removal, and ease of fabrication and sterilization are all desirable qualities in a drug delivery system. Achieving a delivery profile of 1 would result in a high blood level of the drug over an extended period of time was the aim of many of the first controlled-release systems. With conventional medication delivery methods, the blood level of the drug increases with each dosage and then falls until the subsequent dosage. The crucial aspect of conventional drug administration is that the agent's blood level must stay between a minimum value, below which the medicine loses its effectiveness, and a

Access this article online

Quick Response Code

https://doi.org/10.47070/ijapr.v13i6.3748

maximum value, which could indicate a dangerous level.[5,6]

These challenges have led scientists to develop a medicine delivery method that can stay in the stomach for an extended and consistent amount of time. A controlled drug delivery device that can release the drug at a predetermined, predictable, and regulated rate7 is being developed. The main goal of an oral CDDS's de novo design should be to improve and anticipate the medications' bioavailability. The drug must be well absorbed throughout the GIT, ideally by passive diffusion, for oral CRDDS to be effective[7-9].

A controlled release dosage form delivers one or more medications either locally or systemically to a designated target organ over a predetermined length of time in a predefined pattern [10,11]. Because of the versatility in dosage form design, more focus is being placed on the development of oral controlled-release drug delivery systems. Modifying GI transit time, minimizing first-pass elimination, and delivering medication to the intended site at a therapeutically effective rate are the three primary problems facing oral drug delivery systems. Control release dosage forms reduce side effects and dosing frequency while maintaining an optimal and effective drug level for a longer period of time [11-14].

The main objective of the work is to formulate and evaluate the controlled release tablets of gabapentin using natural polymers such as acacia, agar, guar gum & xanthan gum with various ratios.

MATERIALS AND METHODS

Formulation of Gabapentin controlled release tablets

Method of preparation of tablets: Accurately weigh the active (Gabapentin) and all other ingredients, were individually passed through sieve no.60, and then all the ingredients were mixed thoroughly by triturating up to 15 min. The mixed powder was lubricated and the powder was again mixed thoroughly for punching to tablets by the Direct compression method[15]. The composition of different batch of tablets was given in table no.1.

Table 1: Quantity of Raw Materials per Tablet (In mg)

Ingredients	F1 (mg)	F2 (mg)	F3 (mg)	F4 (mg)	F5 (mg)	F6 (mg)	F7 (mg)	F8 (mg)	F9 (mg)	F10 (mg)	F11 (mg)	F12 (mg)
Gabapentin	300	300	300	300	300	300	300	300	300	300	300	300
Acacia	125	150	175	_	-	-	-	-	-	-	-	-
Agar-agar	-	-	-	125	150	175	-	-	-	-	-	-
Guar gum	_	_	_	_	_	_	125	150	175	_	_	_
Xanthan gum	-	-	-	-	-	-	-	-	-	125	150	175
Magnesium stearate	25	20	15	25	20	15	25	20	15	25	20	15
Calcium carbonate	50	30	10	50	30	10	50	30	10	50	30	10
Total weight	500	500	500	500	500	500	500	500	500	500	500	500

i) Angle of repose: The frictional forces in loose powder or granules can be measured by the angle of repose. This is the maximum angle possible between the surface of a pile of powder or granules and the horizontal plane and is related to the density, surface area, and coefficient of friction of the raw material[16].

Method: The angle of repose was determined by using the funnel method. The height of the funnel was adjusted in such a way that the tip of the funnel just touches the heap of the blends. The accurately weighed blend is allowed to pass through the funnel freely on the surface. The height and diameter of the powder cone were measured and the angle of repose was calculated using the following equation[17].

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

Where, h = Height of heap, r = Radius of the heap, Θ = Angle of repose.

ii) Bulk density: Bulk density is defined as the mass of the powder divided by the bulk volume. Bulk density largely depends on particle shape, as the particle becomes more spherical, bulk density is increase. Also as the granule size increases bulk density decreases[18].

Method: The weighed quantity of active powder ingredient (API) was transferred into a 100 ml measuring cylinder without tapping during transfer. The volume occupied by the API was measured. Bulk density was measured by using the formula.

Bulk Density = Bulk Mass/Bulk Volume

iii) Tapped density: Tapped density is achieved by mechanically tapping a measuring cylinder containing a powder sample. After observing the initial volume, the cylinder is mechanically tapped and volume readings are taken until little further volume changes are observed the mechanical tapping is achieved by

raising the cylinder and allowing it to drop under its own weigh a specific distance. A device that rotates device during tapping may be preferred to minimize any possible separation of the mass during tapping down[19].

Cylinder dropping distance: 14±2mm at a normal rate of 300 drops/minute.

Unless otherwise specified, tab the cylinder 500 times initially and measure the tapped volume Va, the nearest graduated unit. Repeat the tapping an additional 750 times and measure the tapped volume, Vb, to the nearest graduated unit. If the difference between the two volumes is less than 2%, Vb is the final tapped volume, Vf. Repeat in increments of 1250 taps, as needed, unit the difference between succeeding measurements is less than 2%.

iv) Measurement of powder compressibility: The compressibility index and Hausner ratio are measures of the propensity of a powder to be compressed. As such, they are measures of the relative importance of inter particulate interactions. In a free-flowing power, such interactions are generally less and tapped densities will be closer in value. For poorer flowing materials, there are frequently greater interparticle interactions, and a greater difference between bulk and tapped densities will be observed[20].

v) Hausner Ratio: The Hausner ratio is a number that is correlated to the flowability of a powder or granular material. It is named after the engineer Henry H. Hausner. The Hausner ratio is calculated by the formula where is the freely settled bulk density of the powder and is the tapped bulk density of the powder[21].

Post Compression Parameters

Weight variation test: Twenty tablets were randomly selected from each batch and individually weighed. The average weight and standard deviation of 20 tablets were calculated. The batch passes the test for weight variation test if not more than two of the individual tablet weight deviates from the average weight by more than the percentage and none deviate by more than twice the percentage shown. Weight variation tolerance for tablet (USP).[22]

Hardness of tablet: The hardness of the tablets was determined by using Pfizer Hardness Tester. Twenty tablets from each batch were randomly selected. The force required to break the tablet is recorded. The unit is Newton[23]. The hardness of IP limits is NLT 5- 8 kg/cm^2.

Friability of tablet: Twenty (20) tablets were selected from each batch and weighed. Each group of tablets was rotated at 25 rpm for 4 minutes (100 rotations) in the Roche friabilator. The tablets were then dusted and re-weighed to determine the loss in weight. Friability was then calculated as percent weight loss from the original tablets[24].

Drug content: Five tablets of each formulation were weighed and powdered. The quantity of powder was the equivalent weight of gabapentin was transferred into 100ml volumetric flask and by using methanol as the extracting solvent and the samples were analyzed by spectrophotometrically[25].

***In vitro* dissolution of tablets:** 900ml of 0.1 HCl solution was placed in the vessel and the USP—II apparatus (paddle Method) was assembled. The medium was allowed to equilibrate to a temperature of 37±0.5°C. The tablets of each batch were placed in the vessels and the vessels are covered. The apparatus was operated for 2hrs and the medium, Phosphate buffer 6.8 was taken for the continued process from 3-12hrs at 50 rpm. At a definite time intervals of 5ml of the receptor fluid was withdrawn, filtered again 5ml of receptor fluid was replaced. Suitable dilutions were done with receptor fluid and analysed spectrophotometrically at 270nm using U.V-Spectrophotometer[26,27].

Drug release kinetics–Model fitting of the dissolution data drug release kinetics: Whenever a new solid dosage form is developed or produced, it is necessary to ensure that drug dissolution occurs appropriately (table no.2). Drug dissolution from solid dosage forms has been described by kinetic models in which the dissolved amount of drug (Q) is a function of the test time, t, or Q=f (t). Some analytical definitions of the Q (t) function are commonly used, such as Zero order, First order, and Higuchi and Korsmeyer–Peppas models[28].

Table 2: Drug release kinetics - Model fitting of the dissolution data drug release kinetics

Kinetic model	Relation	Systems Following the Mode
First-order	lnQt = lnQo + Kt (release is proportional to the amount of drug remaining)	Water-soluble drugs in porous matrix
Zero-order	Ft=Kot (independent of drug concentration)	Transdermal systems Osmotic systems
Higuchi	Ft=KHt1/2 (proportional to the square root of time)	Matrix formulations
Peppas –	Erodible isometric matrices	Ft= Fraction of dose

Korsmeyer Mt / Mα =		released at time 't'; KH, Ko, and Ks = releaserate
Kst		Constants characteristic of respective models; Qo= The drug amount remaining to be released at zero hours; Qt= The drug amount remaining to be released at time 't'; Mt= Initial amount of drug present in the matrix at time 't'. Mα= Amount of drug released at time _α'.

Mechanisms of the drug release

To find out the drug release mechanism due to swelling (upon hydration) along with gradual erosion of the matrix, first, 60% drug release data can be fitted in Korsmeyer–Peppas model which is often used to describe the drug release behaviour from polymeric systems when the mechanism is not well-known or when more than one type of release phenomenon is involved table no. 3.

Log (Mt / M∞) = Log KKP + n Log t

Where,

Mt is the amount of drug release at time t.

M∞ is the amount of drug release after infinite time.

KKP is a release rate constant incorporating structural and geometrical.

Characteristics of the tablet and n are the release exponent indicative of the Mechanism of drug release[29].

Table 3: Diffusion Exponent and Solute Release Mechanism for Cylindrical Shape

Diffusion exponent(n)	Overall solute diffusion mechanism
0.45	Fickian diffusion
0.45 < n < 0.89	Anomalous (non-Fickian) diffusion
0.89	Case-II transport
n > 0.89	Super case-II transport

Stability studies: The purpose of stability testing was to provide evidence on how the quality of a drug substance or drug product varies with time under the influence of a variety of environmental factors such as temperature, humidity, and light. And to establish shelf life for the drug product and recommended storage conditions. The storage conditions used for stability studies were accelerated condition (40°C±2°C/75% RH). A stability study was carried out for the optimized formulation. Tablets of optimized formulation were striped packed and kept in the humidity chamber for 90 days on above mention temperature[30,31].

The following tests were performed at a regular interval. Drug content 2. Dissolution profile 3. Test for other physical parameters (hardness, weight variation, friability)

RESULTS AND DISCUSSION

The overall objective of preformulation studies is to generate useful information to the formulator in developing stable and bioavailable dosage forms that can be mass produced.

The results indicating that the raw material had good flow property.

Table 4: Preformulation study results

Material	Bulk density	Tapped density	Carr's index (%)	Angle of repose	Hausner ratio (%)
Gabapentin raw material	0.33	0.36	16	27.57	1.23

Calibration Curve of Gabapentin

Preparation of standard curve in 0.1 N HCl

The calibration curve of gabapentin was determined by plotting concentration (µg/ml) versus absorbance (nm) at 270nm. The results were obtained as follows.

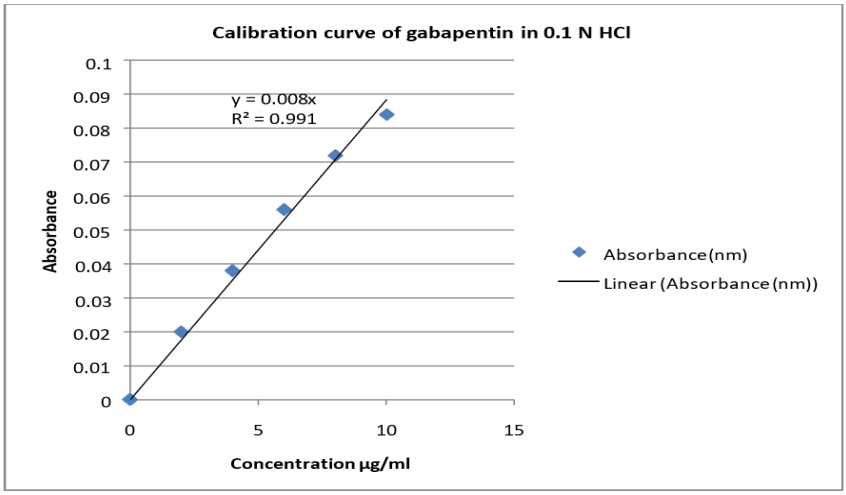

Figure 1: Calibration curve of gabapentin

The standard calibration curve of drug in 0.1 N HCl depicted. The data had a correlation co-efficient of 0.9917 and the equation of the regression line depicted in figure 1 R^2= 0.9917 shown in Figure 1.

Preparation of standard curve in 6.8 pH buffer

The calibration curve of gabapentin was determined by plotting concentration (µg/ml) versus absorbance (nm) at 270 nm. The results were obtained as follows.

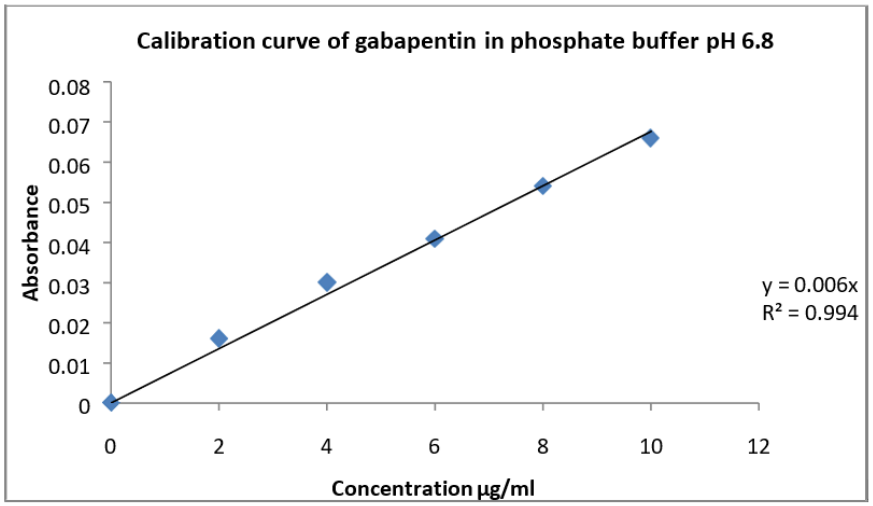

Figure 2: Calibration curve of Gabapentin with phosphate buffer pH 6.8

The standard calibration curve of drug in phosphate buffer pH 6.8 depicted as Figure 2. The data had a correlation coefficient of 0.9941 and the equation of a regressed line with R^2= 0.9941.

Drug and Excipient Compatibility Study

Compatibility study of drug with the excipients was determined by FTIR Spectroscopy (FTIR) using Bruker spectrometer**.** The FTIR spectra of the pure drug, excipient and physical mixture of drug and excipients used in controlled release tablet formulations shown in table no. 5 were recorded in between 400- 4000 wave number (cm^{-1}).

Table 5: Characteristic peaks of drug and physical mixture

S.No.	Pure drug (wave number cm^{-1})	Physical mixture (wave number cm^{-1})	Types of vibration	Functional groups
1	2931.4 cm^{-1} (2850-2960)	2922.92 cm^{-1}	C-H stretch	Alkanes
2	2151.45 cm^{-1} (2100-2140)	2150.48 cm^{-1}	-C=C- stretch	Alkynes
3	1545.84 cm^{-1} (15001700)	1625.27 cm^{-1}	N-H bend	Amines
4	1399.26 cm^{-1} (1300-1500)	1399.26 cm^{-1}	C-H bend	Alkanes
5	1299.93 cm^{-1} (1300-800)	1274.86 cm^{-1}	C-C stretch	Alkanes
6	1091.63 cm^{-1} (-1100cm^{-1})	1080.60 cm^{-1}	C-O stretch	Secondary alcohol
7	617.18 cm^{-1} (610-650)	617.18 cm^{-1}	C-H bend	Alkynes

Formulation of Gabapentin Controlled Release Tablets

Acacia, Agar-agar, Xanthan gum, Guar gum polymers were used in different ratios for controlled release systems to find out the effect of different drug polymer ratio and the different batches of tablets were formulated as per procedure given in 6.4.

Evaluation of Gabapentin Controlled Release Tablets

Precompression Parameters

Precompression parameters were evaluated as per the procedure given in 6.5.1 and the results were given in table no.6.

Table 6: Evaluation of precompression parameters of F1-F12 Formulations

Formulation code	Angle of repose (degree ± SD)	Bulk Density (gm/ml±SD)	Tapped Density (gm/ ml±SD)	Carr's index (%± SD)	Hausner ratio (%± SD)
F1	26.42±0.04	0.311±0.02	0.337±0.02	14.35±0.06	1.03±0.05
F2	27.17±0.01	0.325±0.04	0.359±0.04	15.61±0.07	1.23±0.04
F3	29.01±0.03	0.339±0.06	0.361±0.07	14.64±0.04	1.14±0.02
F4	27.57±0.07	0.307±0.04	0.317±0.06	13.46±0.01	1.13±0.06
F5	26.77±0.09	0.287±0.03	0.321±0.05	12.29±0.05	1.25±0.03
F6	25.61±0.06	0.271±0.01	0.345±0.01	16.35±0.03	1.15±0.01
F7	26.16±0.03	0.297±0.04	0.357±0.03	14.46±0.07	1.20±0.03
F8	29.11±0.09	0.307±0.05	0.366±0.02	13.61±0.04	1.19±0.05
F9	28.05±0.02	0.320±0.06	0.359±0.04	13.85±0.09	1.21±0.00
F10	25.61±0.03	0.271±0.02	0.345±0.01	16.35±0.02	1.15±0.01
F11	29.57±0.07	0.307±0.03	0.317±0.04	15.46±0.01	1.13±0.05
F12	27.17±0.02	0.325±0.04	0.359±0.04	15.61±0.06	1.23±0.04

The powders were evaluated for various flow properties. The powders of all batches showed good flow properties evident from the results shown in table-15. The angle of repose values were ranged from 25.61±0.06 to 29.11±0.09. The results were found to be below 30; hence they have good flow ability. The Carr's index value ranged from 12.29±0.05 to 16.35±0.03 and Hausner's ratio value ranged from 1.03±0.05 to 1.25±0.03 hence they have good flow and free flowability.

All the formulations were shown good flow properties which suggested that the blend was suitable for direct compression.

Post compression parameters

Post compression parameters were evaluated as per the procedure given in 6.5.2 and the results were given in Table no.7.

Table 7: Evaluation of post compression parameters of F1-F12 Formulations

Formulation code	Weight variation (n=20) (mg ± SD)	Hardness (kg/cm²±SD)	Friability (%)	Drug content (%± SD)	Thickness (%± SD)
F1	502±0.29	6.6±0.1	0.69	99.13±0.04	5.2±0.007
F2	501±0.67	6.4±0.2	0.67	98.19±0.01	5.3±0.006
F3	498±0.45	7.0±0.3	0.74	99.09±0.12	5.2±0.011
F4	504±0.71	6.7±0.5	0.71	98.19±0.09	5.3±0.008
F5	499±0.15	7.2±0.2	0.65	99.17±0.07	5.2±0.009
F6	501±0.31	6.8±0.4	0.63	98.61±0.03	5.2±0.013
F7	496±0.04	6.5±0.3	0.76	99.13±0.17	5.3±0.004
F8	497±0.71	7.3±0.3	0.70	98.11±0.14	5.2±0.012
F9	503±0.52	7.4±0.5	0.68	98.21±0.05	5.3±0.05
F10	499±0.34	6.5±0.4	0.78	99.13±0.07	5.3±0.008
F11	501±0.71	6.7±0.5	0.73	99.19±0.11	5.3±0.006
F12	502±0.68	6.4±0.2	0.69	98.19±0.02	5.3±0.002

The formulated controlled release tablets were then evaluated for various physical characteristics like thickness, weight variation, hardness, friability, drug content. The weight variation of tablets was uniform in all formulations and ranged from 496±0.04 to 503±0.32. The **%** deviation was coming within 5**%** range. For 500mg tablet the accepted **%** deviation should be 5**%**. F1to F12 batches came within limit and passed the test. The hardness of the prepared tablets was ranged from 6.4±0.2 to 7.4±0.3. Friability values were ranged from 0.63 to 0.76 which fallen with in the limit of standard (0.1 to 0.9%). Drug content of tablets was ranged from 98.11±0.03 to 99.91±0.14, F11 showed maximum drug contene. Thickness of tablets was uniform and values are ranged from 5.2±0.013 to 5.3±0.006.

In vitro dissolution study of gabapentin-controlled release tablets

The formulated controlled released tablets were then subjected to *in vitro* dissolution test for evaluating drug release from the formulation. The *in vitro* dissolution test was carried out in 900ml of 0.1N Hcl in USP-II paddle type apparatus at 50 rpm and 37±0.5°C for first 2 hrs followed by 900ml of phosphate buffer pH 6.8 up to 12hrs. The results of dissolution study was depend on polymer concentration. Among all 12 formulations, Formulation F11 containing Xanthan gum had given drug release 99.88% in 12 hrs. Formulations F1 to F3 and F4 to F6 which contain acacia and agar-agar respectively release the drug within 8 hrs due to the less binding nature and controlled release property. Then the formulations containing guar gum and Xanthan gum was given better release profiles when compared with formulations containing acacia, agar-agar. Even compared with guar gum xanthan gum showed better release profile. So, formulation F11 which contains xanthan gum was selected as best formulation and the results shown in figure 3.

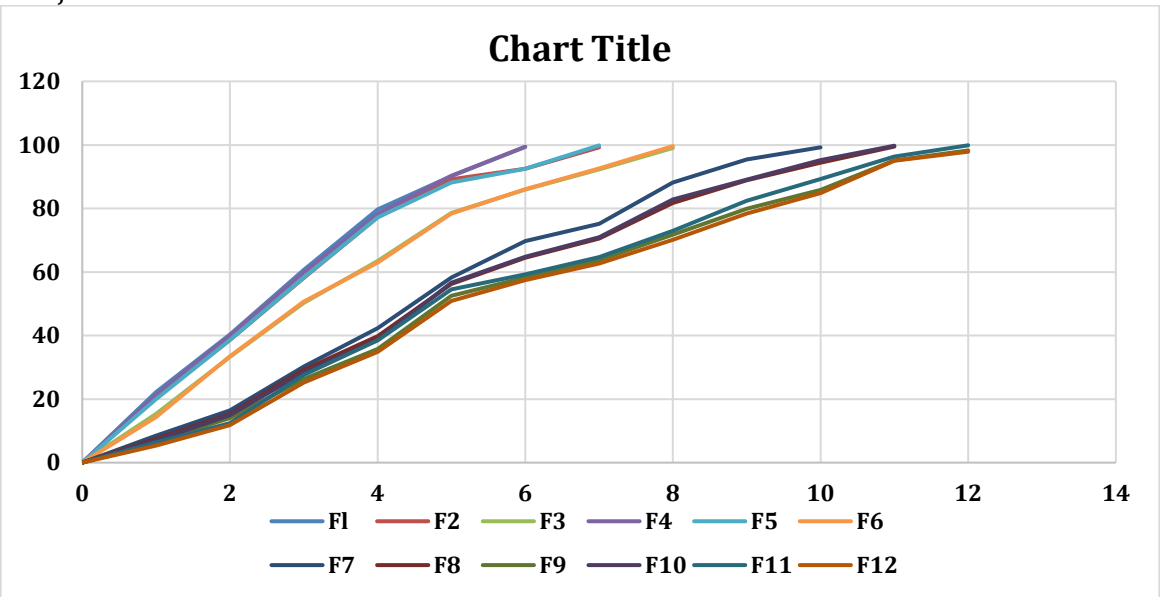

Figure 3: *In vitro* drug release data (F1-F12)

Drug release kinetics–Model fitting of the dissolution data drug release kinetics

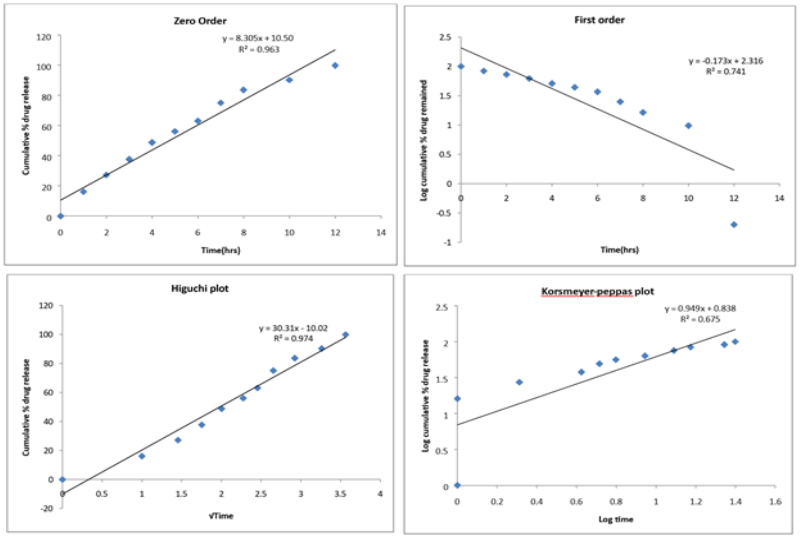

Figure 4: Zero order plot, First order plot, Higuchi plot and Korsmeyer- peppas plot

In order to determine the mechanism of drug release form the formulations, the *in vitro* dissolution data was fitted to zero order, first order, Higuchi plot and Korsmeyer-peppas plot was drawn and interpretation of release exponent value (n) was calculated and results are shown in figure 4. The results of R^2 for zero and first order were obtained as 0.963, 0.741. Based on that confirmed the best formulation followed zero order release.

The drug release was diffusion controlled as the plot of optimized formulation F11 was found 0.974 as regression coefficient in Higuchi plot. From Korsmeyerpeppas plot the release exponent value n was found as 0.675 and it was confirmed as the release of drug from the formulation was founded as anomalous non-fickian transport of diffusion.

Stability Studies

Gabapentin formulation F11 was subjected to accelerated stability studies for a period of 3 months. The samples were withdrawn after periods of 30 days, 60 days and 90 days and were analyzed for their appearance, hardness, friability, drug content and *in vitro* drug release. The results revealed that F11 had no significant changes in appearance, drug content, hardness, friability, and *in vitro* release. Thus, it could be concluded that the formulation was stable storage condition at 40°C±2°C/ 75% RH±5% table 8.

Table 8: Stability data

Test	F11	30 days	60 days	90 days
Weight Variation	501±0.71	501±0.55	501±0.22	501±0.12
Hardness	6.7	6.7	6.7	6.7
Friability	0.73	0.73	0.73	0.72
Drug content	99.19±0.11	99.19±0.05	99.19±0.04	99.19±0.01

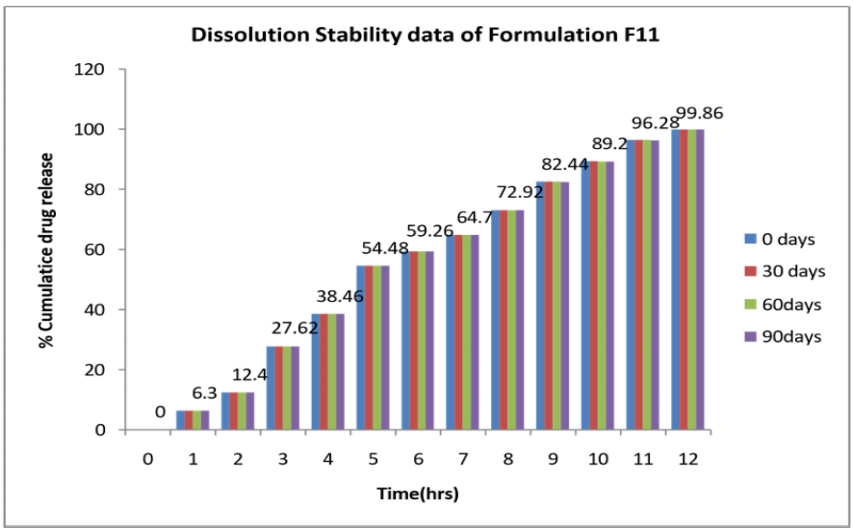

Figure 5: Dissolution stability data for sample F11

The stability studies for optimized formulation F11 was carried out based accelerated stability conditions and study of various parameters carried out at 0, 30, 60, 90 days of intervals and the results found satisfactorily and that reveals that the selected best formulation was stable under accelerated condition Figure 5.

CONCLUSION

The main objective of the present study was to develop controlled-release tablets containing 300 mg of gabapentin for epilepsy therapy by using polymers like acacia, agar-agar, guar gum, xanthan gum. The controlled release of the drug delivery system improves the bioavailability and therapeutic efficiency of the drug.

In the pre-formulation FTIR study was carried out for pure drug (Gabapentin), gabapentin, and excipients. It has not shown any interaction. Construction of the calibration curve was done using 0.1N HCl and phosphate buffer p^H 6.8.

The formulations F1 o F12 were prepared by the direct compression method. The angle of repose values for formulations range from 25.61±0.03 to 29.57±0.07. Bulk and tapped densities are used for the measurement of the compressibility index. The bulk and tapped values for formulations range from 0.271 ±0.01 to 0.339±0.06 and 0.317±0.04 to 0.366±0.02 respectively. The carr‘s index and Hausner's ratio values for formulations range from 12.29±0.05 to 16.35±0.03 and 1.03±0.05 to 1.25±0.03 respectively. Thus, all formulations exhibited good flow characteristics.

The prepared controlled-release tablets were evaluated for various parameters like thickness,

weight variation, hardness, friability, and drug content uniformity. The thickness of tablets in all formulations was ranged from 5.2±0.007 to 5.3±0.008.

The weight variation of tablets in all formulations were ranged from 496±0.04 to 503±0.32.

The hardness and friability of all the formulations F1-F12 were found to be 6.4±0.2 to 7.4±0.5 and 0.63 to 0.78 respectively. The drug content of all the formulations were ranging from 98.11±0.14 to 99.19±0.12.

In vitro drug release study was carried out for formulations F1 to F12 containing different ratios of natural polymers like acacia, agar-agar, guar gum, and xanthan gum. Among 12 formulations F11 was selected as best formulation based on in vitro drug release. The cumulative percentage drug release of F11 was 99.88% after 12hrs.

The kinetic study was carried out for F11 formulation which showed that the drug release follows zero-order kinetics.

The stability studies were carried out for F11 formulation at 40^{o}C ± 2^{o}C/75% RH± 5% for 3 months. Data revealed that there was no considerable difference and the product was stable.

From the above study, it can be concluded that F11 is the best formulation which has shown better drug release 99.88%. However, further *in vivo* studies can be carried out to support the results.

REFERENCES

1. Harish Gopinath, B. Pragati Kumar, S. Duraivel, K. P. Sampath Kumar, D., Debjit Bhowmik et.al., Controlled Release Drug Delivery Systems. Nimra College of Pharmacy, Vijayawada, Andhra Pradesh, India: 2012.
2. Doddayya Hiremath., Formulation and Evaluation of controlled release matrix tablets of Ambroxol Hydrochloride. Journal of Pharmacy Research. 2010; 3(8), 1810- 1813.
3. Brahmankar DM, Jaiswal SB. Biopharmaceutics and Pharmacokinetics: Pharmacokinetics. 2nd ed. Vallabh Prakashan, Delhi: 2009; 399-401.
4. John C, Morten C, The Science of Dosage Form Design, Aulton: Modified release peroral dosage forms. 2nd ed. Churchill Livingstone.2002; 290-300.
5. Mamidala R, Ramana V, Lingam M, Gannu R, Rao MY. Review Article Factors Influencing the Design And Performance of Oral Sustained/Controlled Release Dosage Form. Journal of Pharmaceutical Science and Nanotechnology. 2009; 2: 583.
6. Allen LV, Popvich GN, Ansel HC. Ansel‘s Pharmaceutical dosage form and drug delivery system. 8th ed. 2004; 260-263.
7. Mamidala R, Ramana V, Lingam M, Gannu R, Rao MY. Review article factors influencing the design and performance of oral sustained/controlled release dosage form. Journal of pharmaceutical science and nanotechnology. 2009; 2: 583.
8. Gupta S, Singh RP, Sharma R, Kalyanwat R, Lokwani P. Osmotic pumps: A review. Journal of comprehensive pharmacy. 2011; 6: 1-8.
9. Kamboj S, Gupta GD. Matrix Tablets: An important tool for the oral controlled release dosage form. Pharma info. Net. 2009; 7: 1-9.
10. Mahore JG, Wadher J, Umekar MJ, Bhoyar PK. Ion exchange resins: Pharmaceutical application and recent advancement. Journal of Pharmaceutical. Science Review. Research. 2010; 1(2): 8-13.
11. Javed Ali, RK Khar, Alka Ahuja. Dosage form design. 4th ed. Birla Publication Pvt. Ltd; 2009; 181-194.
12. Cristina M, Aranzazu Z, Jose ML. Review: Critical factors in the release of drugs from sustained release hydrophilic matrices. Journal of Research in Ayurveda and Pharmacy.2011; 21: 1701-08.
13. Gupta RN, Gupta R, Basniwal PK, Rathore GS. Osmotically controlled oral drug delivery systems; A Review. Journal of Pharmaceutical. Science. 2009; 1(2): 75-269.
14. Srikanth MV,Sunil SA, Rao NS, Uhumwangho MU, Ramana Murthy KV. Ion exchange resins as controlled drug delivery carriers. Journal of Science Research. 2010; 2(3): 11-597.
15. Kornblau DH, Conway Jr EE, Caplen SM. Neurologic Disorders. In: Marx JA, ed. Rosen's Emergency Medicine: Concepts and Clinical Practice. 7th ed. Philadelphia, PA: Mosby Elsevier. 2009; chap 173.
16. Swati jagdale, Bhanudas Kuchekar, Pharmaceutical equivalence of Gabapentin tablets with various extra granular binders. Rev Ciênc Farm Básica Apl. 2010; 31(1): 25-31.
17. Lin, Hong-Liang & Lin, Shan-Yang & Lin, Chih-Cheng & Hsu, Cheng-Hung & Wu, Tieh-Kang & Huang, Yu-Ting, et, al., Mechanical grinding effect on thermodynamics and inclusion efficiency of loratadine-cyclodextrin inclusion complex formation. Carbohydrate Polymers. 2012.87.512517.10.1016/j.
18. Yari, Abdollah, FatemehPapi, and Said Farhadi. "Voltammetric Determination of Trace Antiepileptic Gabapentin with a Silver_Nanoparticle Modified Multiwalled Carbon Nanotube Paste Electrode." Electroanalysis 23.12 2011; 2949-2954.
19. KuKanich, B., and Cohen, R. Pharmacokinetics of oral gabapentin in greyhound dogs. The Veterinary Journal, 2011, 187(1), pp. 133-135.
20. Achrai, Ben & Libster, Dima & Aserin, Abraham & Garti, Nissim. Solubilization of Gabapentin into H-II Mesophases. The journal of physical chemistry. 2011; 115: 825-35.

21. Argoft CE, Clinical development of a once-daily gastro rententive formulation of Gabapentin tablets for the treatment of post-therapeutic neuralgia. 2012.
22. Sandercock, D., Cramer, M., Wu, J., Chiang, Y., Biton, V. and Heritier, M., Gabapentinet, al., Extended Release for the Treatment of Painful Diabetic Peripheral Neuropathy: Efficacy and tolerability in a double-blind, randomized, controlled clinical trial. Diabetes Care, 2009; 32(2), pp. e20-e20.
23. Mohana, K. and Ramdas Bhandarkar, P., Oxidation of 2-Phenylethylamine with N- Bromosuccinimide in Acid and Alkaline Media: A Kinetic and Mechanistic Study. Journal of the Chinese Chemical Society, 2007; 54(5), pp.1223-1232.
24. Taksande, Formulation, and pharmacodynamic investigations of lamotrigine microspheres. Asian Journal of Pharmaceutics, Jan-Mar 2017 (Suppl), 2017; 11(1): S215.
25. Narasimha s. managoli, Crosslinked chitosan hydrogelmatrix tablets for controlled release of gabapentin. FARMACIA -BUCURESTI; 2012; 60; 272-286.
26. Issam B. Rimawi, Ramzi H. Muqedi, Development of Gabapentin Expandable gastroretentive Controlled Drug Delivery System. 2019; 9: 11675 |
27. Dembla NM, Maniyam AP, Agarwal S, Formulation Development, and Evaluation of Gabapentin Controlled-Release Tablets. Pharmacy & Pharmacology International Journal, 2015; 2(3): 00021. DOI: 10.15406/ppij.2015.02.00021.
28. Samar M. Abouelatta, Ahmed A. Aboelwafa, Gastroretentive raft liquid delivery system as a new approach to release extension for carrier-mediated drug, Drug Delivery, 2018; 25: 1, 1161-1174.
29. Raymond C Rowe, Paul J Sheskey and Marian E Quinn, Handbook of pharmaceutical excipients, 6th edition, Pharmaceutical press; America acolInt J. 2015; 2(3): 75–81. DOI: 10.15406/ppij.2015. 02.00021.
30. Dembla NM, Maniyam AP, Agarwal S. Formulation development and evaluation of gabapentin controlled-release tablets. Pharmacy & Pharmacology International Journal. 2015; 2(3): 75–81. DOI: 10.15406/ppij.2015.02.00021
31. Lal, R., Sukbuntherng, J., Luo, W., Tovera, J., Lassauzet, M., and Cundy, K. Population Pharmacokinetics and Pharmacodynamics of Gabapentin After Administration of Gabapentin enacarbil. The Journal of Clinical Pharmacology. 2013; 53(1), pp.29-40.

Cite this article as:
V. Sruthi, V. Alagarsamy, P. Subhash Chandra Bose, D. Saritha, P. Srikanth Reddy. Formulation and In Vitro Evaluation of Gabapentin Controlled Release Tablets Using Natural Polymers. International Journal of Ayurveda and Pharma Research. 2025;13(6):1-10.
https://doi.org/10.47070/ijapr.v13i6.3748
Source of support: Nil, Conflict of interest: None Declared

***Address for correspondence**
P. Srikanth Reddy
Department of Pharmaceutics,
MNR College of Pharmacy,
Sangareddy, Telangana, India
Email:
srikanthreddyporeddy@gmail.com