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FORMULATION AND IN VITRO EVALUATION OF CONTROLLED RELEASE MATRIX TABLETS OF GABAPENTIN

K. Durga Mounika*, R. Srujana[1], G. Manisha[2]

Vision College of Pharmaceutical Sciences and Research, Boduppal, Hyderabad, India, 500009.

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***Corresponding Author**

K. Durga Mounika

Vision College of Pharmaceutical Sciences and Research, Boduppal, Hyderabad, India, 500009.

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ABSTRACT

In the present study, an attempt has been made to develop controlled release tablets of Galantine by selecting different types of polymers Eudragit S 100, Ethyl Cellulose and Hydroponically Cellulose as retarding polymers. All the formulations were prepared by direct compression method. The blend of all the formulations showed good flow properties such as angle of repose, bulk density, tapped density. The prepared tablets were shown good post compression parameters and they passed all the quality control evaluation parameters as per I.P limits. Among all the formulations F8 formulation showed maximum % drug release i.e., 98.94 % in 12 hours. Hence it is considered as optimized formulation F8 which contains Hydroponically Cellulose (100 mg). Whereas the formulations with Eudragit S 100 showed more retarding with low concentration of polymer. The formulations with Ethyl Cellulose were unable to produce the desired drug release pattern. The results of the accelerated stability study of final formulation for 3 month revealed that storage conditions were not found to have made any significant changes infinal formulation.

KEYWORDS: Gabapentin, Eudragit S 100, Ethyl Cellulose, Hydroponically Cellulose and Controlled Release Tablets.

INTRODUCTION

The aim of the study was to formulate and in vitro evaluation of controlled release matrix tablets of gabapentin using diferent polymers. Gabapentin is a Anti-epileptic drug. It is a

white crystalline powder, soluble in water. It is used to treat neuropathic pain. Its biological half life 5-7 hours. Its protein binding is up to 97%. Formulate Controlled release Tablets Of Gabapentin for The Treatments Of partial seizures, neuropathic pain, hot flashes, and restless legs syndrome. The most common side effects of gabapentin include dizziness, fatigue, drowsiness, ataxia, peripheral edema. Its mechanism of action is its interacts with cortical neurons at auxiliary sub units of voltage-sensitive calcium channels. Gabapentin increases the synaptic concentration of GABA, enhances GABA responses at non-synaptic sites in neuronal tissues, and reduces the release of mono-amine neurotransmitters. To formulate sustained release tablets by using different types of polymers like Eudragit S 100, Ethyl Cellulose and Hydroponically Cellulose. To evaluate pre and post compression evaluation parameters . Controlled release tablets will help to reduce the dose dependency and improve patient compliance. The Purpose of this work was to design and formulate a novel oral controlled release matrix tablet dosage form for the Gabapentin .The drug that may be provide steady state drug release over a prolonged period.

MATERIAL AND METHODS

Gabapentin, Eudragit S 100, Ethyl Cellulose, Hydroponically Cellulose, Lactose, PVP K30, Magnesium stearate, Talc. All the formulations are direct compression method. Preparation of controlled release Matrix tablets of Gabapentin : Gabapentin and all other ingredients were individually passed through sieve no 60. All the ingredients were mixed thoroughly by triturating up to 15 min. The powder mixture was lubricated with talc. The tablets were compressed by using direct compression method.

Formulation composition for tablets

INGREDIENTS (mg)	FORMULATION CHART								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
Gabapentin	100	100	100	100	100	100	100	100	100
Ethyl Cellulose	50	100	150						
Eudragit S 100				50	100	150			
Eudragit S 100							50	100	150
Lactose	132	82	32	132	82	32	132	82	32
PVP K30	10	10	10	10	10	10	10	10	10
Magnesium stearate	4	4	4	4	4	4	4	4	4
Talc	4	4	4	4	4	4	4	4	4
Total Tablet Weight	300	300	300	300	300	300	300	300	300

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 400cm-1

RESULTS AND DISCUSSION

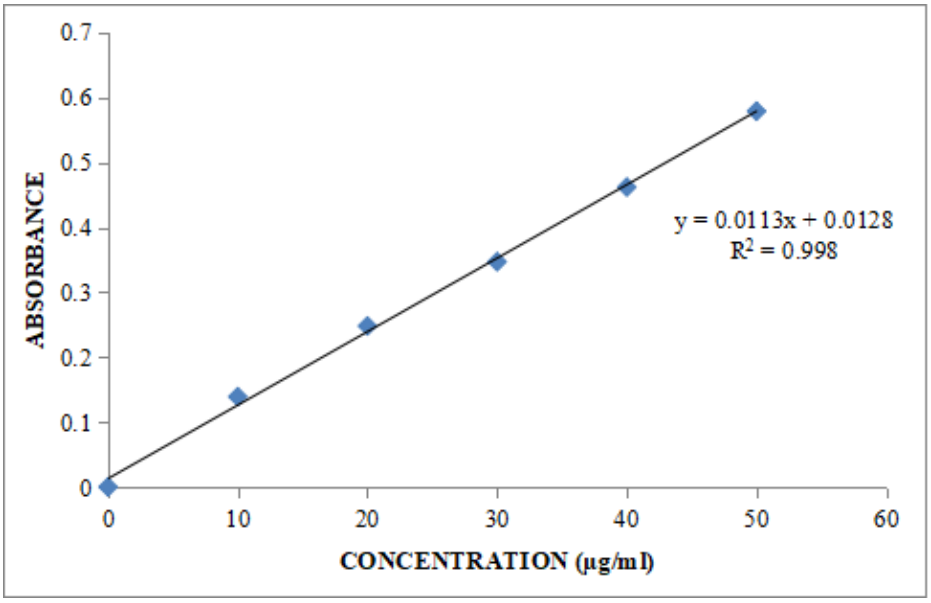
The present study was aimed to developing Controlled release tablets of Gabapentin using various polymers. All the formulations were evaluated for physicochemical properties and in vitro drug release studies.

10.1. Analytical Method

Graphs of Gabapentin was taken in Simulated Gastric fluid (pH 1.2) and in p H 6.8 phosphate buffer at 220 nm and 222 nm respectively.

Observations for graph of Gabapentin in 0.1N HCl

Concentration [µg/mL]	Absorbance
0	0
10	0.139
20	0.248
30	0.347
40	0.462
50	0.579

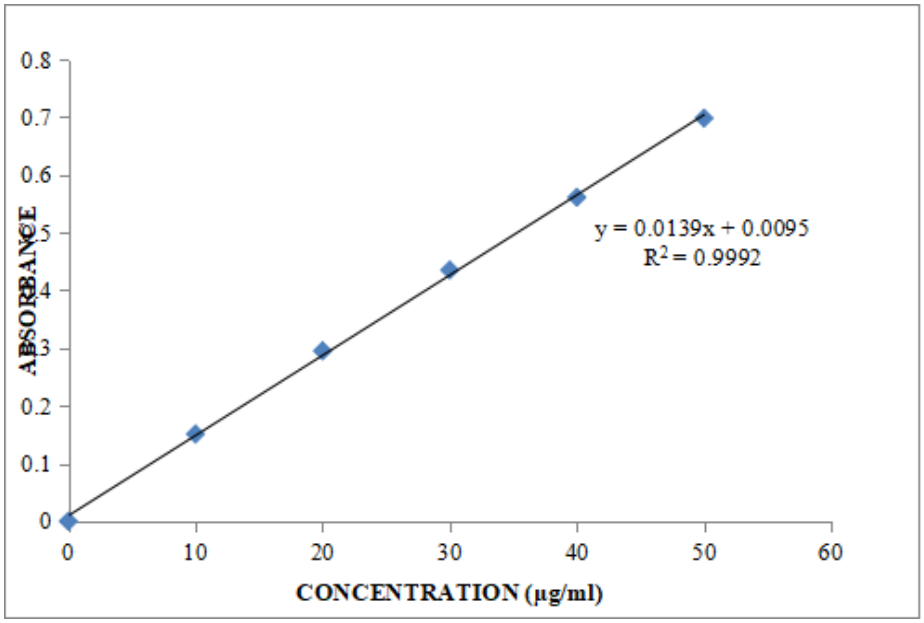


Standard Graph of Gabapentin in 0.1 HCL.

Observations for graph of Gabapentin in p H 6.8 phosphate buffer

Conc [µg/ml]	Abs
0	0
10	0.151
20	0.295
30	0.435
40	0.561
50	0.698

It was found that the estimation of Gabapentin by UV spectrophotometric method at λ_{max} 220 nm in 0.1N Hydrochloric acid had good reproducibility and this method was used in the study. The correlation coefficient for the standard curve was found to be closer to 1, at the concentration range, 10-50µg/ml. The regression equation generated was y = 0.011x+0.012.



Standard graph of Gabapentin pH 6.8 phosphate buffer (222nm)

Preformulation parameters of powder blend

Formulations	Bulk Density(gm/cm^2)	Tap Density (gm/cm^2)	Carr's Index (%)	Hausner ratio	Angle Of Repose(Ɵ)
F1	0.46±0.001	0.54±0.005	14.81±0.10	1.19±0.011	28.36±0.14
F2	0.42±0.003	0.63±0.003	30.15±0.07	1.50±0.007	5.64±0.20
F3	0.44±0.004	0.54±0.004	18.05±0.09	1.22±0.011	7.02±0.13
F4	0.52±0.004	0.57±0.005	8.77±0.28	1.09±0.010	4.22±0.13
F5	0.57±0.003	0.63±0.002	9.52±0.09	1.10±0.009	31.38±0.24
F6	0.46±0.002	0.57±0.002	19.29±0.11	1.23±0.011	4.22±0.22
F7	0.42±0.004	0.52±0.003	19.23±0.050	1.23±0.010	0.11±0.23
F8	0.52±0.006	0.60±0.005	13.33±0.08	1.15±0.010	2.29±0.07
F9	0.48±0.003	0.57±0.002	18.75±0.12	1.08±0.007	7.02±0.16

Quality Control Parameters For tablets

Tablet quality control tests such as weight variation, hardness, and friability, thickness, and drug release studies in different media were performed on the compression coated tablet.

***In vitro* quality control parameters for tablets**

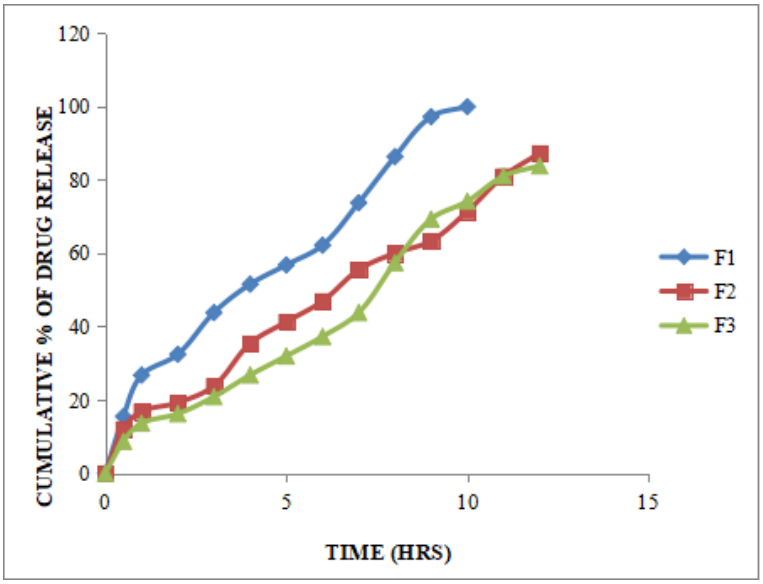
Formulation Codes	Average Weight (mg)	Hardness(kg/cm^2)	Friability (% lose)	Thickness (mm)	Drug content (%)
F1	298.32	5.3	0.39	4.01	99.33
F2	297.54	5.8	0.58	4.12	97.42
F3	297.22	5.1	0.12	4.75	99.10
F4	299.15	5.9	0.75	4.31	97.59
F5	298.10	5.4	0.15	4.52	98.25
F6	295.48	5.7	0.68	4.76	97.43
F7	298.39	5.2	0.34	4.19	99.21
F8	297.56	5.4	0.28	4.28	99.12
F9	300.02	5.8	0.33	4.43	98.74

All the parameters such as weight variation (295.48 to 300.02**)**, friability (0.12 to 0.75), hardness**(**5.1 **to** 5.8) Kg/cm^2, thickness (4.19) and drug content **(**96.62 **to** 99.33**)** were found to be within IP limits.

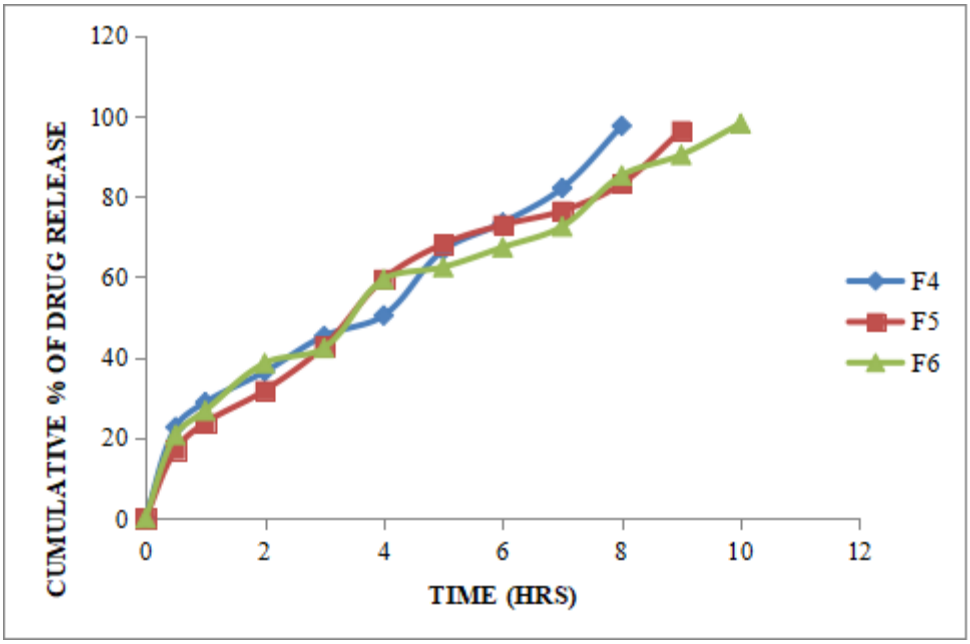
***In Vitro* Drug Release Studies**

The formulations prepared with different polymers by direct compression method. The tablets dissolution study was carried out in paddle dissolution apparatus using 0.1N HCL for 2 hours and 6.8 pH phosphate buffers for remaining hours as a dissolution medium.

Dissolution Data of Gabapentin Tablets

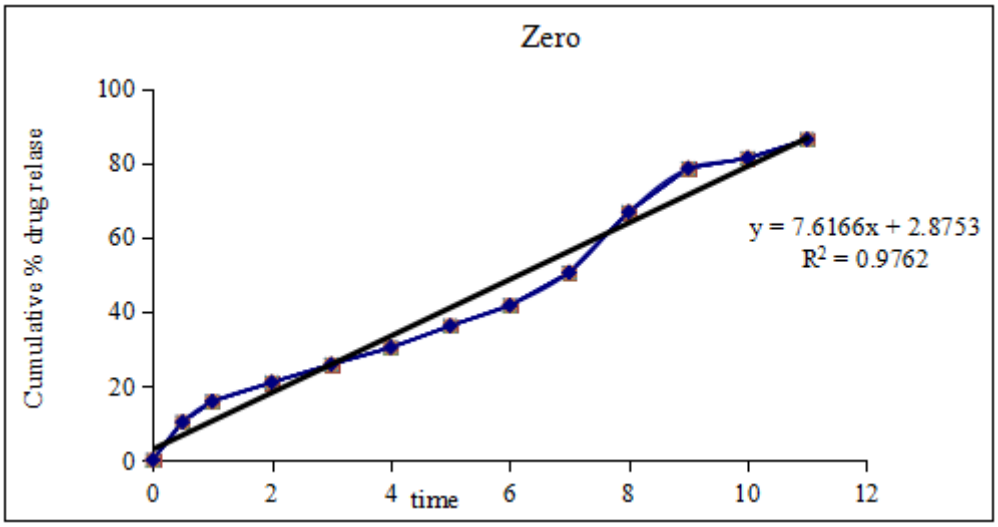


Dissolution profile of Gabapentin (F1, F2, F3 formulations).



Dissolution profile of Gabapentin (F4,F5,F6 formulations)

Application of Release Rate Kinetics to Dissolution Data

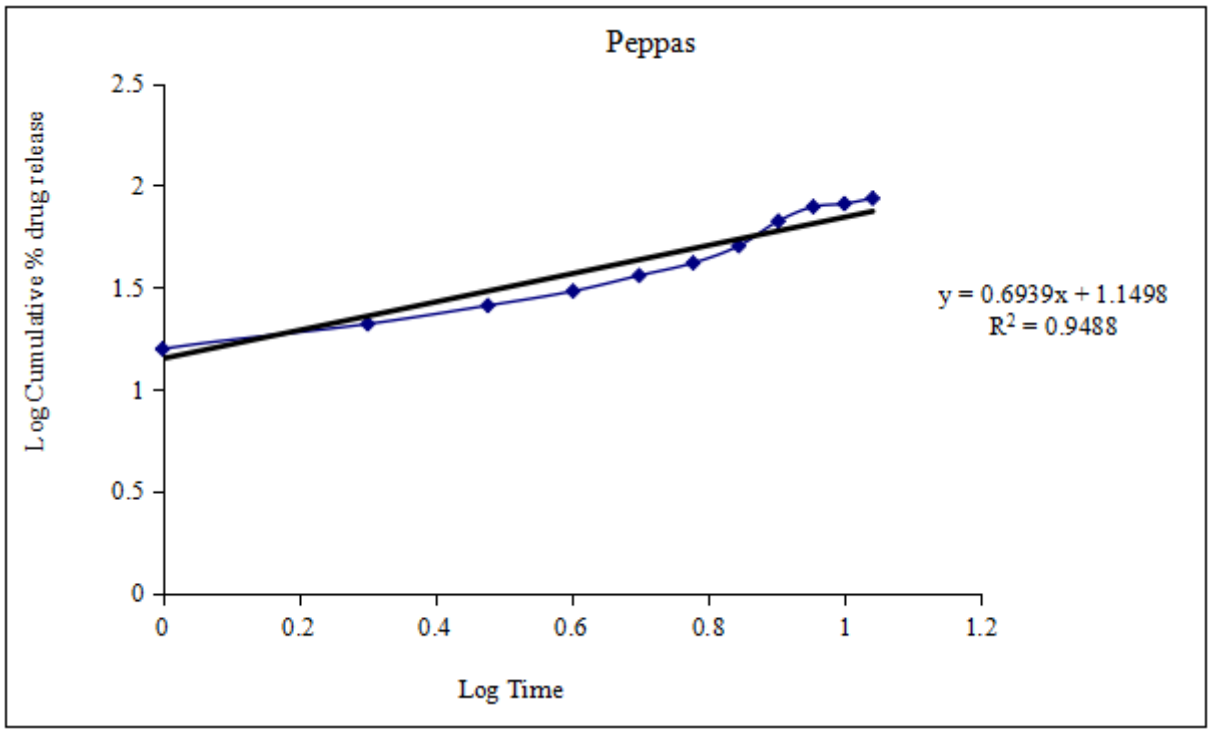


Zero order release kinetics

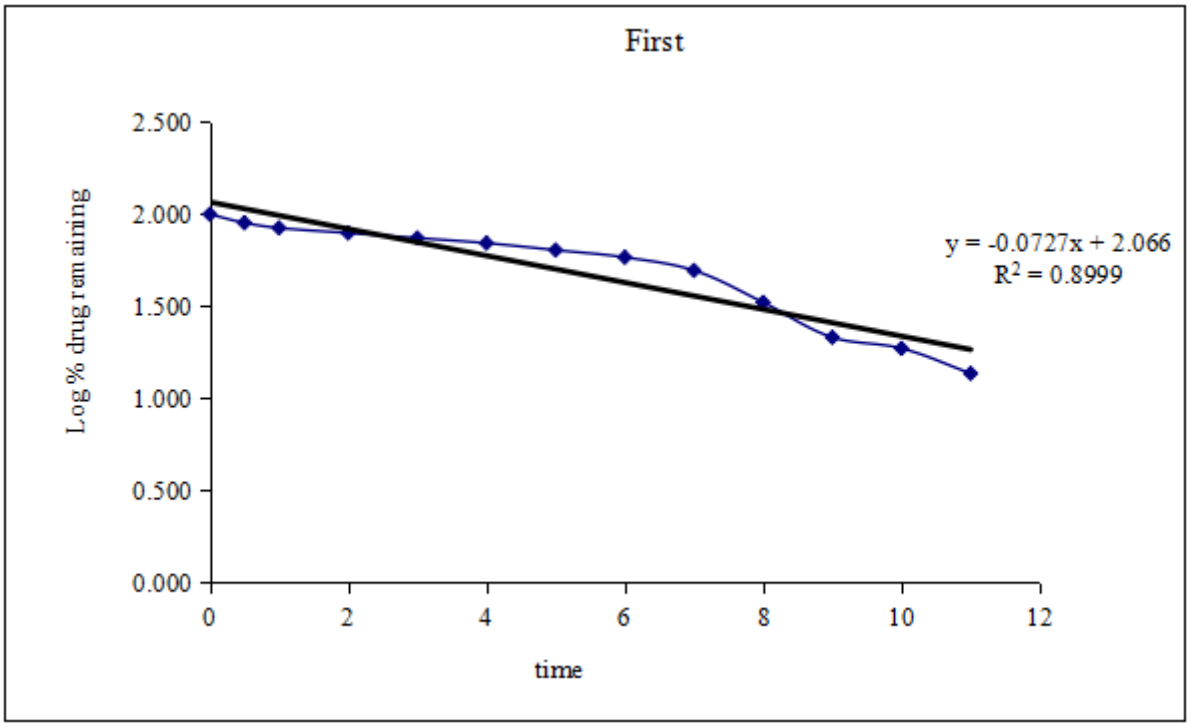
Release kinetics data for optimised formulation

CUMULATIVE (%) RELEASE Q	TIME (T)	ROOT (T)	LOG (%) RELEASE	LOG (T)	LOG (%) REMAIN	RELEASE RATE (CUMULATIVE % RELEASE / t)	1/CUM% RELEASE	PEPPAS log Q/100	% Drug Remaining	Q01/3	Qt1/3	Q01/3-Qt1/3
0	0	0			2.000				100	4.642	4.642	0.000
10.22	0.5	0.707	1.009	-0.301	1.953	20.440	0.0978	-0.991	89.78	4.642	4.478	0.164
15.75	1	1.000	1.197	0.000	1.926	15.750	0.0635	-0.803	84.25	4.642	4.384	0.258
20.89	2	1.414	1.320	0.301	1.898	10.445	0.0479	-0.680	79.11	4.642	4.293	0.349
25.73	3	1.732	1.410	0.477	1.871	8.577	0.0389	-0.590	74.27	4.642	4.203	0.438
30.27	4	2.000	1.481	0.602	1.843	7.568	0.0330	-0.519	69.73	4.642	4.116	0.526
36.1	5	2.236	1.558	0.699	1.806	7.220	0.0277	-0.442	63.9	4.642	3.998	0.644
41.61	6	2.449	1.619	0.778	1.766	6.935	0.0240	-0.381	58.39	4.642	3.880	0.762
50.46	7	2.646	1.703	0.845	1.695	7.209	0.0198	-0.297	49.54	4.642	3.673	0.969
66.75	8	2.828	1.824	0.903	1.522	8.344	0.0150	-0.176	33.25	4.642	3.216	1.426
78.51	9	3.000	1.895	0.954	1.332	8.723	0.0127	-0.105	21.49	4.642	2.780	1.861
81.28	10	3.162	1.910	1.000	1.272	8.128	0.0123	-0.090	18.72	4.642	2.655	1.986
86.31	11	3.317	1.936	1.041	1.136	7.846	0.0116	-0.064	13.69	4.642	2.392	2.249
98.94	12	3.464	1.995	1.079	0.025	8.245	0.0101	-0.005	1.06	4.642	1.020	3.622

Higuchi release kinetics graph



Kars mayer peppas graph



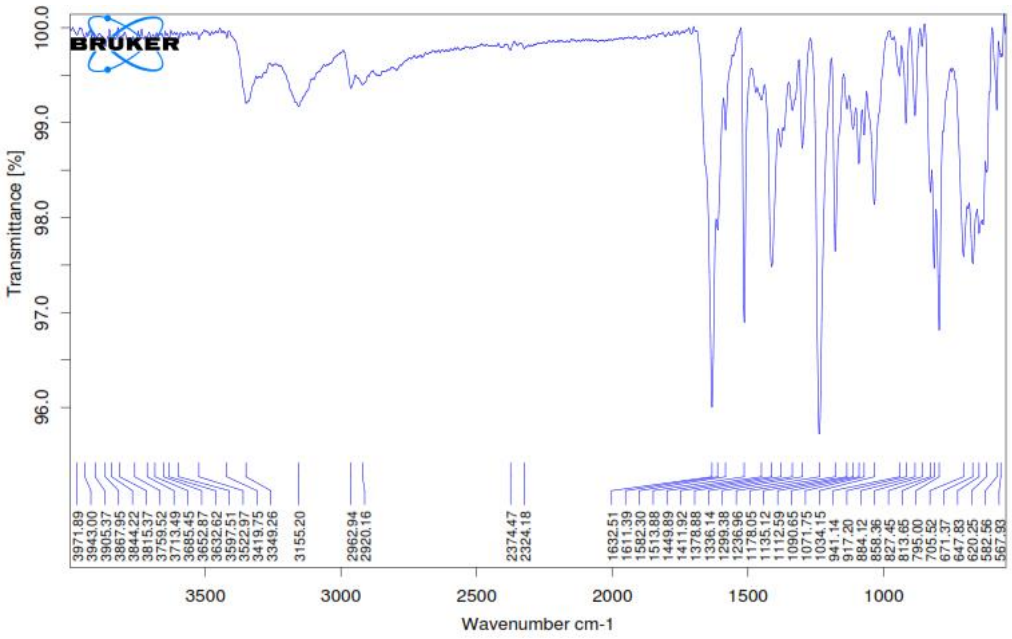
First order release kinetics graph

Kinetics Correlation Coefficient Values

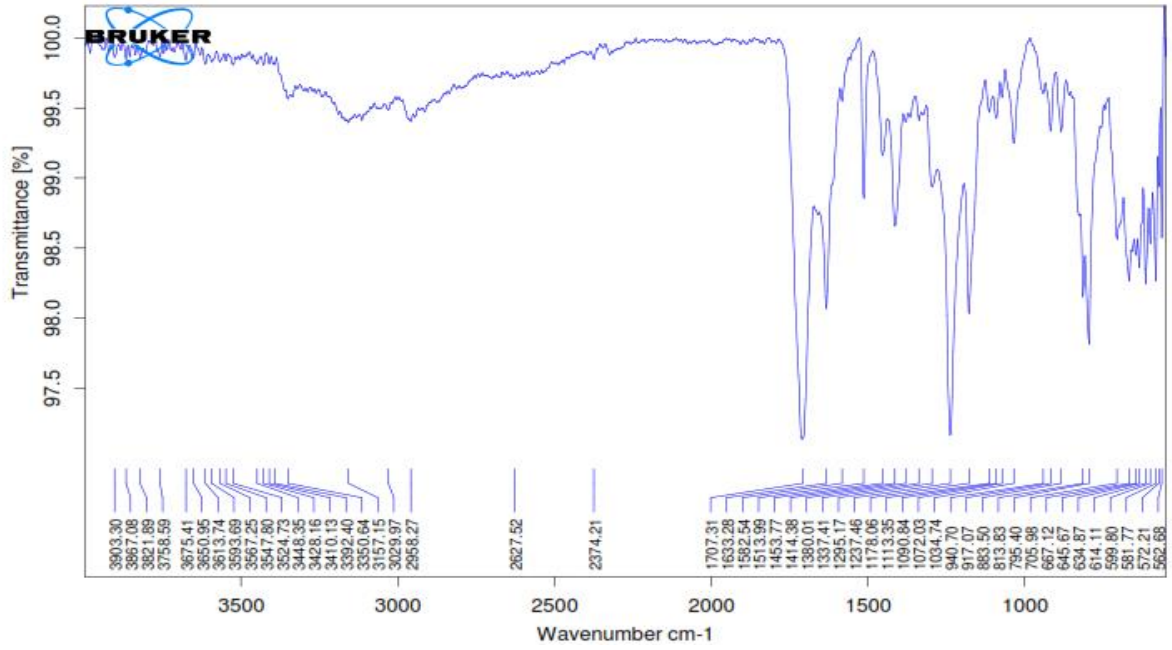
Release Kinetics	Correlation coefficient values
Zero order release kinetics	$R^2 = 0.976$
Higuchi release kinetics	$R^2 = 0.898$
Peppas release kinetics	$R^2 = 0.948$
First order release kinetics	$R^2 = 0.899$

Drug – Excipient compatability studies

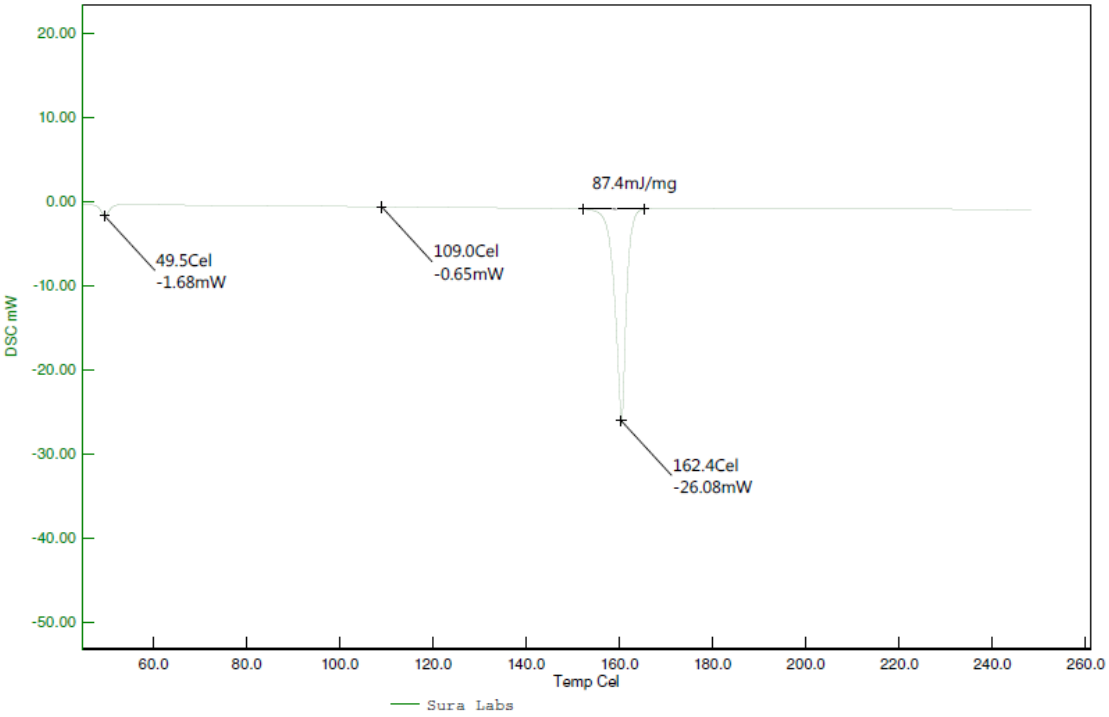
Fourier Transform-Infrared Spectroscopy



FT-IR Spectrum of Gabapentin pure drug.



FT-IR Spectrum of Optimise formulation.



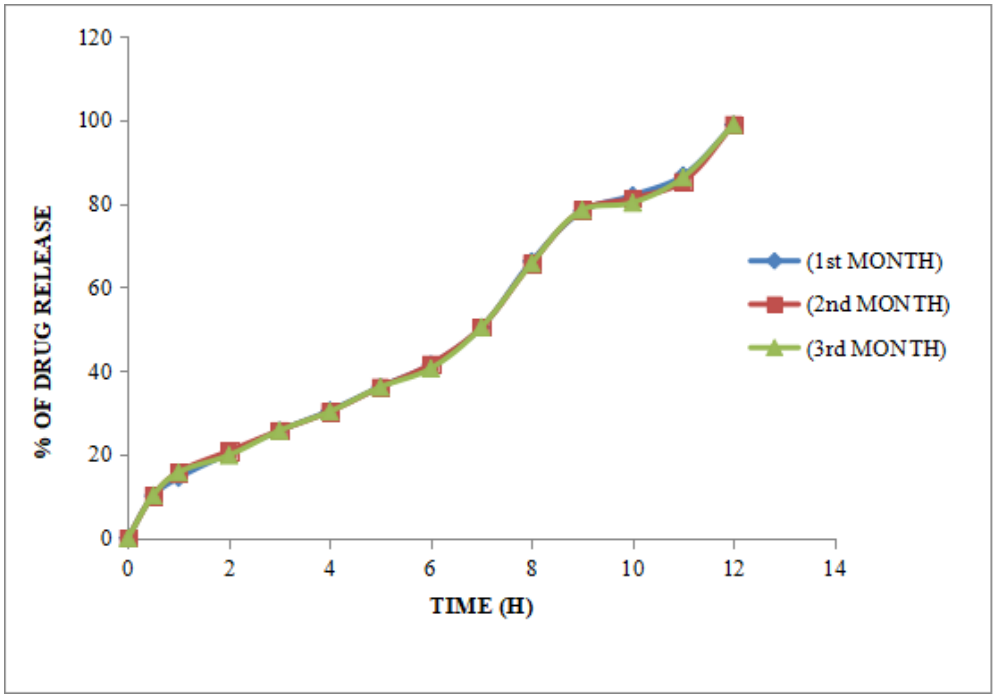
DSC Gabapentin pure formulation

ACCELERATED STABILITY STUDIES

Stability dissolution profile of F7 for 1st, 2nd & 3rd months

Dissolution Profile

S. NO	TIME (HOURS)	F8 (1st MONTH)	F8 (2nd MONTH)	F8 (3rd MONTH)
1	0	0	0	0
2	0.5	10.12	10.20	10.18
3	1	14.39	15.76	15.70
4	2	20.25	20.80	19.82
5	3	25.68	25.71	25.68
6	4	30.47	30.25	30.26
7	5	36.16	36.09	36.10
8	6	41.51	41.60	40.57
9	7	50.40	50.44	50.41
10	8	66.19	65.74	65.72
11	9	78.21	78.50	78.47
12	10	81.96	81.27	80.23
13	11	86.73	85.28	86.30
14	12	98.85	98.93	98.90



Drug release profile of formulation F8 during stability

Physicochemical parameters of most satisfactory formulation during stability studies for optimised formulation

Time Period (Month)	Hardness (kg/cm^2)	Drug Content (%)
1	54	99.12
2	5.4	99.11
3	5.3	99.11

There was no major change in the various physicochemical parameters evaluated like hardness, drug content, *in vitro* dissolution pattern at the various sampling points. There was no statistically significant difference between the initial values and the results obtained during stability studies.

CONCLUSION

The aim of the present study was to develop controlled release formulation of Gabapentin to maintain constant therapeutic levels of the drug for over 12 hrs. Eudragit S 100, Ethyl Cellulose and Hydroxypropyl Cellulose were employed as polymers. Total weight of the tablet was considered as 300 mg. Polymers were used in the concentration of 50, 100 and 150 mg concentration. Compatibility study revealed that there was no interaction between the drug and the excipients in the formulation. The pre-compression and the post compression parameters are found to be within the limits. All the formulations were passed various physicochemical evaluation parameters and they were found to be within limits. Whereas from the dissolution studies it was evident that the

formulation (F8) showed better and desired drug release pattern i.e., 98.94 % in 12 hours. It contains the polymer Hydroxy propyl cellulose as sustained release material. It followed Zero order release kinetics mechanism. When the stability results of best formulation was studied at 40±2oC/75±5% RH for 3 months were compared with their initial results it was found that there was no significant difference in hardness, drug content and drug release of optimized formulation.

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Conflict of interest

The authors declares that there is no conflict of interest.

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