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Method Development & Evaluation of gabapentin Modified Release Tablets

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Abstract: Using polymers such as Carbopol 934 and polyvinyl acetate to produce a matrix type tablet, a modified release Gabapentin tablet was effectively developed in this work. The formulation was tested in vitro and fitted using pharmacokinetic models including Zero order kinetics, First order kinetics, Higuchi Plot, and Korsmeyer Peppas plot. The tablets have enough mechanical strength, which is an important property of any tablet dosage form. The tablet was made using a variety of polymers, with the formulation comprising a larger proportion of polyvinyl acetate and a smaller amount of Carbopol proving to be the most stable and effective in terms of release profile. This research lays the door for more research into cost-effective and viable polymers for the creation of long-acting and modified-release dosage forms.

INTRODUCTION

Monolithic matrix and reservoir types of controlled-release systems are the most common. The medicine is dispersed across a polymer matrix in monolithic matrix systems.

The hardness, palatability, strength, and stability of tablets containing Carbopol 934 as an excipient are all advantages. Furthermore, the Carbopol residue is not absorbed by the body and passes unchanged through the digestive tract. The study's main goals were to design and assess modified release tablet methods in order to obtain the necessary target product profile during a 12-hour period, so that the starting recommended dose for diabetic peripheral neuropathy could be fixed at 82.5 mg once a day.

The purpose of developing sustained delivery systems is to reduce dosage frequency, increasing treatment effectiveness by localizing the drug at the site of action, lowering the amount necessary, or delivering uniform drug delivery. So, a sustained release dosage form is one that releases one or more drugs continuously in a predetermined pattern for a predetermined period of time, either systemically or to a specific target organ, and it also provides better control of plasma drug levels, less dosage frequency, fewer side effects, increased efficacy, and consistent delivery.

METHODOLOGY

Preparation of Modified Release Tablets:

Preparation of Blends:

To eliminate any lumps, the medication and excipients were run through sieve number 10. The medication, together with excipients such as the polymers Carbopol 934 and Poly vinyl acetate, were weighed correctly in a digital electronic balance and mixed for 15 minutes to create a homogeneous blend, which was then submitted to flow property analysis.

Preparation of Tablets:

The mixture was sieved, and the appropriate hardness was determined in the Rotary tablet press. The tooling's dies were carefully cleaned and inspected for any signs of abrasion. The mixture was then crushed in a Type-B Tooling rotary tablet press (Rimek 10 station small tablet press) using 9 mm concave punches to generate tablet. The punches were chosen based on the weight of each individual pill, which is 200 mg in weight.

Table 1: Formulation Table of Modified Release Gabapentin Tablet

Ingredient	Formulation Code				
	F-1	F-2	F-3	F-4	F-5
Drug (Gabapentin) (mg)	82.5	82.5	82.5	82.5	82.5
Polyvinyl acetate (mg)	50	75	25	100	-
Carbopol 934 (mg)	50	25	75	-	100
Microcrystalline cellulose (mg)	9.5	9.5	9.5	9.5	9.5
Talc (mg)	4	4	4	4	4
Magnesium Stearate (mg)	4	4	4	4	4
Total (mg)	200	200	200	200	200

Evaluation of Tablets:

Weight Variation, Tablet Thickness, Hardness, and Friability tests were carried

Determination of Drug Content:

The weight of the crushed tablet powder corresponding to the weight of 82.5 mg was derived from ten tablets crushed and weighed in mortar. The drug content was estimated after successive dilutions were produced to reach an appropriate concentration and examined under UV double beam spectrophotometer.

Dissolution Test:

Drug release studies are carried out for the produced tablets, and they were performed in a dissolution test USP apparatus, Type 2 (Paddle) with Phosphate buffer pH 6.8 at 37°C.

Stability:

The stability of the drug formulation was tested at room settings with an average temperature of around 28 C, as well as in the refrigerator for 60 days, with no noticeable changes in physical appearance or drug content.

Drug Release Kinetic Studies:

A mathematical model is useful for predicting drug release mechanisms and for providing more general recommendations for the creation of additional systems. A wide variety of models have been created to characterise the drug release rate from various drug delivery systems. The following are some of the most important models:

- Zero order kinetic model
- First order kinetic model
- Higuchi model
- Korsmeyer-peppas model

RESULTS AND DISCUSSION

Evolution of modified release tablets of gabapentin

Evaluation of Flow Property:

The following are the findings of the Hausner's ratio and the compressibility index, both of which are significant parameters in direct compression:

Table 2: Hausner's Ratio and Compressibility Index

Formulation Code	Hausner's Ratio	Compressibility Index (%)	Flow Property	Angle of Repose	Flow Property
F-1	1.152	13.7	Good	33°51'	Good
F-2	1.177	14.9	Good	34°26'	Good
F-3	1.132	12.4	Good	32°66'	Good
F-4	1.111	10.1	Excellent	30°21'	Excellent
F-5	1.22	17.6	Fair	37°11'	Fair

The formulation mixes had sufficient flow properties, but the blend with solely Carbopol 934 as a polymer had a lower flow property.

Angle of repose values, on the other hand, imply a comparable flow characteristic that ranges from acceptable to outstanding.

Evaluation of Tablets:

Weight variation, tests were carried out, and deviations were calculated in relation to each formulation's average weight. The greatest variation permitted from the average weight is 7.5 percent since the tablet's weight falls between 130 and 324 mg.

Table 3: Weight Variation of Tablets

Formulation Code	Average Weight (mg)	Friability (%)	Hardness Average (Kg/Cm ²) ± S.D	Thickness (mm)	Drug Content (mg)
F-1	200.7	0.79	5.37	3.64	95.73
F-2	201.6	0.90	5.77	3.74	97.04
F-3	200.5	0.91	4.74	3.54	95.64
F-4	201.3	0.68	6.42	3.74	92.16
F-5	200.9	0.91	4.56	3.64	95.30

All of the formulations are within the required range, and 18 of the 20 pills are inside the limit.

Dissolution Studies:

Time (hrs)	Conc.(mcg/ml)	Cumulative % Drug Release
1	7.3	9.3
2	23.2	25
3	32	34.7
4	39.3	42.8
5	54.7	59.76
6	65.3	74.3
7	75	80.61
8	78.5	85.6
9	83.2	90.2
10	88	95.13
11	89.3	96.9
12	89.3	96.9

The formulation F-2 shows its maximum drug release of 96.9 % at 11 hours.

Selection of Best Formulation:

The foregoing data demonstrate that the formulation F-2 has a longer period of drug release than predicted, and it releases the medication in a more consistent manner. Higher amounts of polyvinyl acetate and smaller proportions of carbopol 934 are found in the aforementioned composition.

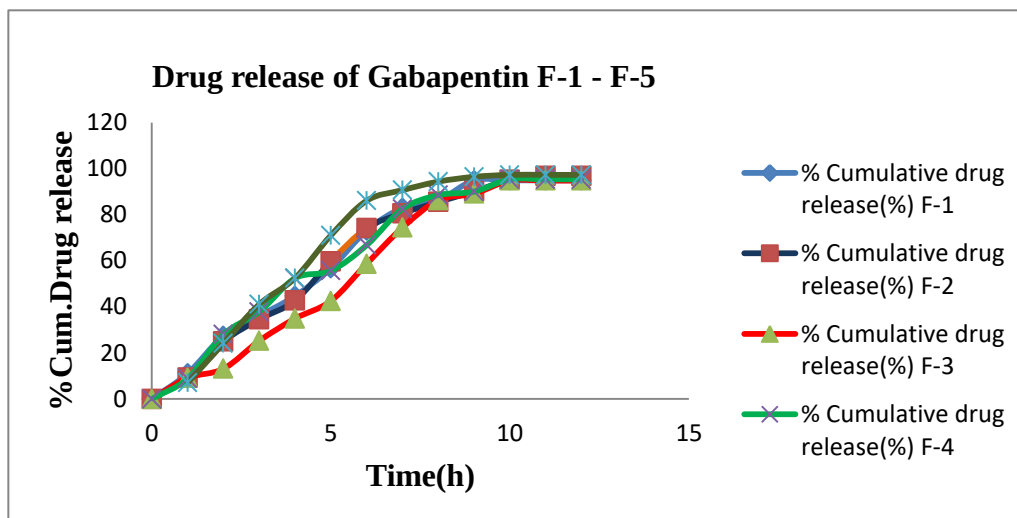


Fig 1: Cumulative Drug Release of Formulations F-1 to F-5

Stability Study:

The assessment and findings of the stability study of the formulation F-2 is as follows,

Table 4: Stability Study of Formulations

Time Interval (Days)	Room Condition		Refrigerator	
	Appearance	Drug Content	Appearance	Drug Content
15	White	97%	White	96.9%
30	White	96.6%	White	96.6%
45	White	95.9%	White	96.1%
60	White	95.6%	Off-white	95.7%

Drug Release Kinetic Studies:

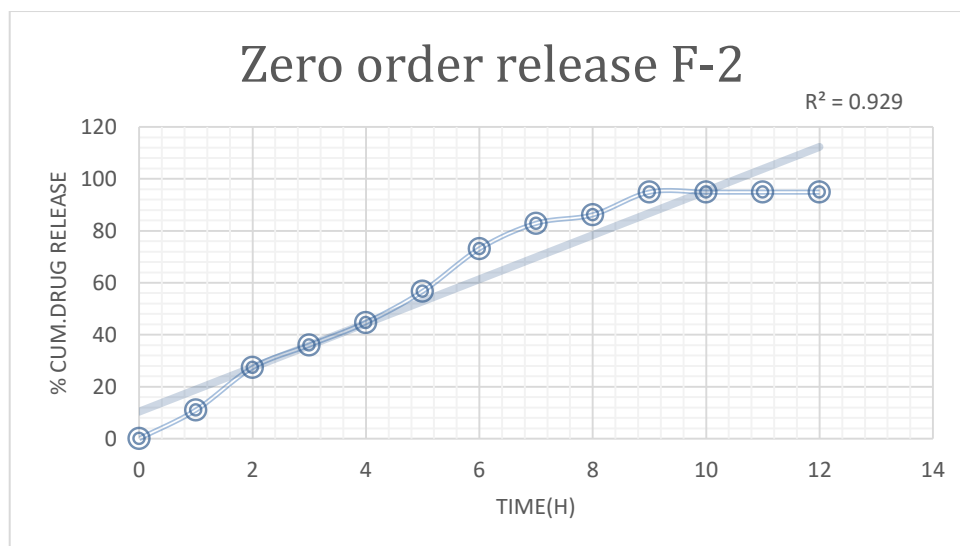


Fig 2: Zero Order Plot of Formulation F-2

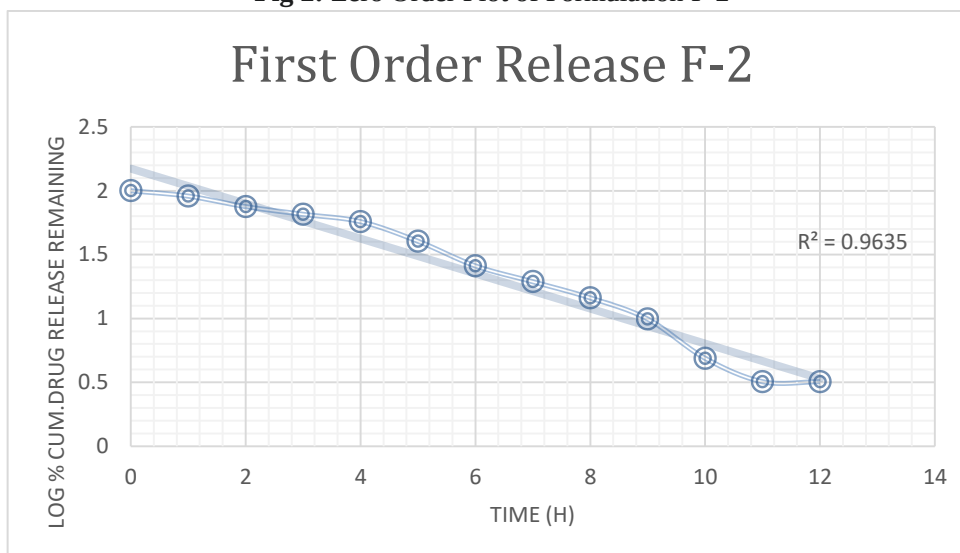


Fig.3: First Order Release of Formulation F-2

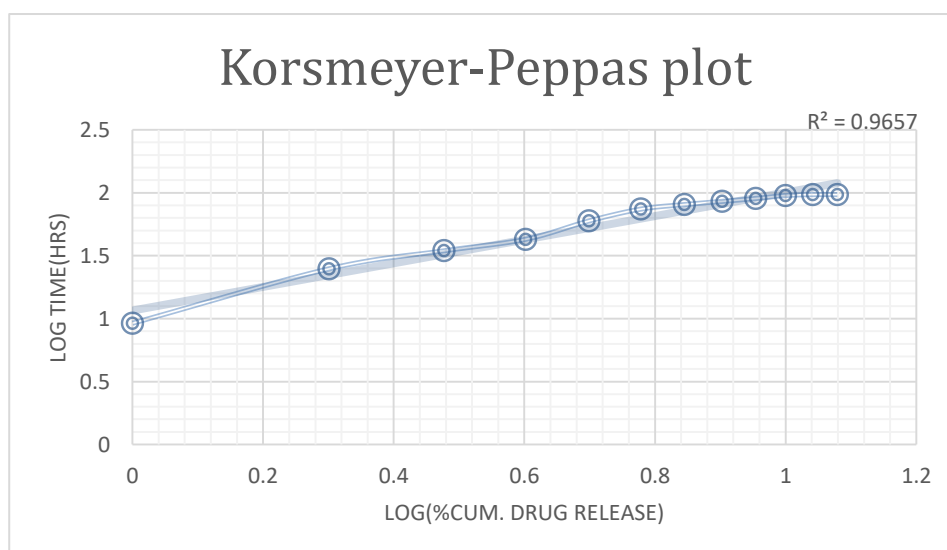
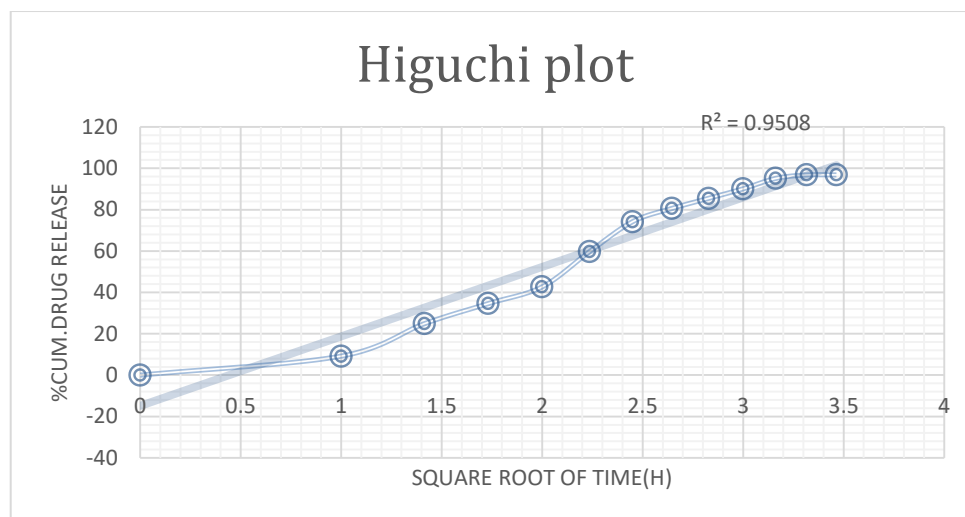


Fig 4: First Order Release of Formulation F-2

**Fig 5:** Higuchi Plot of Formulation F-2**Table 5:** Drug Release Kinetics

Release Kinetic Model	R ² Values
Zero order Kinetics	0.930
First order Kinetics	0.964
Korsmeyer Peppas plot	0.966
Higuchi Plot	0.951

In the case of a zero-order release profile, a lower correlation coefficient value of 0.93 indicates that the formulation does not follow zero order release. The first order, higuchi, and korsmeyer peppas models had higher correlation coefficients of 0.964, 0.951, and 0.966, respectively. Because the drug release profile has a coefficient of 0.964, the release of the medication follows first order kinetics theories. The coefficient of 0.966 in relation to the Korsemeyer-Peppas model suggests that drug release from the formulation is diffusion regulated, as does Higuchi's plot ($R^2=0.951$).

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