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Research

# Formulation and Evaluation of Sustained Release Matrix Tablets of Theophylline Using Natural Polymer

**Jagannath Das*, Pravat Ranjan Guru, Satya Ranjan Dalai, Rajat Kumar Kar**

*Department of Pharmaceutics, Dadhichi College of Pharmacy, Vidya-Vihar, Sundargram, Cuttack, Odisha-754 002.*

*Corresponding author: Jagannath Das
Email: pravatguru79@gmail.com

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## Abstract

The present study focuses on the formulation and evaluation of sustained release matrix tablets of Theophylline using natural polymers such as Guar Gum, Fenugreek, and Karya Gum. The aim was to develop a cost-effective and biocompatible drug delivery system that could provide prolonged therapeutic effects, reduce dosing frequency, and enhance patient compliance. A total of nine formulations were prepared using varying concentrations of the selected natural polymers by the Direct compression method.

All pre-compression and post-compression parameters, including hardness, friability, weight variation, thickness, and drug content, were found to be within acceptable limits as per IP standards, indicating the suitability of the formulations. *In-vitro* drug release studies were carried out for 12 hours, and the release profiles showed a sustained release pattern.

Among the nine formulations, F6 was identified as the optimized formulation as it exhibited a drug release of 99.72% at the end of 12 hours, following a controlled release mechanism. The results suggest that natural polymers can be effectively utilized for the formulation of sustained release tablets of Theophylline.

**Keywords:** Formulation And Evaluation of sustained release Tablets of Theophylline.

## 1. INTRODUCTION

Oral drug delivery has been known for decades as the most widely utilized route of administered among all the routes that have been employed for the systemic delivery of drug via various pharmaceutical products of different dosage forms. The reasons that the oral route achieved such popularity may be in part attributed to its ease of administration belief that by oral administration of the drug is well absorbed. All the pharmaceutical products formulated for systemic delivery via the oral route of administration irrespective of the mode of delivery (immediate, sustained or controlled release) and the design of dosage forms (either solid dispersion or liquid), must be developed within the intrinsic characteristics of GI physiology, pharmacokinetics, pharmacodymics and

formulation design is essential to achieve a systemic approach to the successful development of an oral pharmaceutical dosage form.[1,2]

Out of the many routes of administration available, the oral route remains the most popular dosage form among patients as it is easy to administer, carry around, formulation design flexibility, cost-effectiveness, causes minimal discomfort for many patients, and least sterility restrictions during manufacturing. Most of the newly discovered drugs are lipophilic in nature and have poor aqueous solubility, thereby posing problems in their formulation into delivery systems[3].

**SUSTAINED DRUG DELIVERY SYSTEM:**

Over the past 30 years, as the expense and complication involved in marketing new entities have increased with concomitant recognition of the therapeutics advantages of controlled drug delivery, greater attention has been focused on development of sustained or controlled drug delivery system. Sustained release technology is relatively new field and as a consequence, research in the field has been extremely fertile and has produced many discoveries. With many drugs, the basic goal is to achieve a steady state blood level that is therapeutically effective and non-toxic fir an extended period of time. The design of proper dosage form is an important element to accomplish this goal. Sustained release, sustained action, prolonged action, controlled release, extended action, timed release and depot dosage form are term used to identify drug delivery system that are designed to achieve prolonged therapeutic effect by continuously releasing medication over an extended period of time after administration of a single dose. In the case of oral sustained released dosage form, an effect is for several hours depending upon residence time of formulation in the GIT.

Physician can achieve several desirable therapeutics advantages by prescribing sustained release dosage form. Since, the frequency of drug administration is reduced, patient's compliances can be improved and the drug administration can be made more convenient as well. The blood level oscillation characteristics of multiple dosing form of conventional dosage form is reduced, because more even blood level is maintained in the design of sustained release dosage form. The total amount of drug administered, thus maximum availability with a minimum dose. In addition, the safety margin of high potency drug can be increased and the incidence of both local and systemic adverse effects can be reduced in sensitive patients. Overall, increased administration of sustained release dosage form gives increased reliability.

Not all the drugs are the suitable candidates for the sustained release dosage form. Ideal characteristic of the drug for the sustained release dosage form are;

- ✓ Drug should have a shorter half-life as drug with a longer half-life are inherently long acting drugs.
- ✓ Drug should be absorbed from large portion of gastrointestinal tract, since absorption must occur through the gut.
- ✓ Drug should be having a good solubility profile to be a good candidate for sustained release dosage form.
- ✓ Dose of the drug should not be too large, as a larger dose is to be incorporated into sustained release dosage form.[4,5]

**ADVANTAGES OF MATRIX SYSTEM:**

1.The interest awakened by matrix system in last few years is completely justified in view of the major advantages. Among these, the following stand out.

2.With proper control of manufacturing process, reproducible release profiles are possible.

3.There is no risk of "dumping" of a large part of dose, through the structure makes the immediate release of a small amount of active principle unavoidable.

4. Their capacity to incorporate active principle is large, which suits them to delivery of large dosage.[6]

**Characteristics That Makes Drugs Suitable For Sustained Release Matrix DDS4-5 Biological characteristics [7-10]**

**Biological Half-Life**

The usual goal of an oral sustained-release product is to maintain therapeutic blood levels over an extended period. The elimination rate is quantitatively described by the half-life. Each drug has its own characteristic elimination rate, which is the sum of all elimination process, including metabolism, urinary excretion, and all other processes that permanently remove drug from the bloodstream. Therapeutic compound with short half-lives are excellent candidates for sustained release preparations, since this can reduce dosing frequency. However, this is limited, in that drug with very short half-lives may require excessively large amounts of drug in each dosage unit to maintain sustained effect, forcing the dosage form itself to become limitingly large. In general, drugs with half-lives shorter than 2 hours are poor candidates for sustained-release preparations. Compounds with long half-lives, more than 8 hours, are also generally not used in sustaining forms, since there effect is already sustained.

**Absorption**

The characteristics of absorption of a drug can greatly affect its suitability as a sustained-release product. Since the purpose of forming a sustainedrelease product is to place control on the delivery system, it is necessary that the rate of release much slower than the rate of absorption. If we assume that the transits time of most drugs and devices in the absorptive areas of the GI tract is about 8-12 hours, the maximum half-life for absorption should be approximately 3-4 hours; otherwise, the device

will pass out of the potential absorptive regions before drug release is complete. This corresponds to a minimum apparent absorption rate constant of 0.17-0.23 hours-1 to give 80-95% over this time period. The absorption rate constant is an apparent rate constant, and should, in actuality, be the release rate constant of the drug from the dosage form. Compounds that demonstrate true lower absorption rate constants will probably be poor candidates for sustaining system.

**Distribution**

The distribution of drugs into tissue can be an important factor in the overall drug elimination kinetics since it not only lowers the concentration of circulating drug but it also can be rate limiting in its equilibration with blood and extracellular fluid. One aspect of this distribution is binding of drug to tissue and proteins in blood. The apparent volume of distribution of a drug is frequently used to describe the magnitude of distribution, including binding, within the body. For design of sustained/controlled release products one would like to have as much information on drug disposition as possible but, in reality, decisions are usually based on only a few pharmacokinetic parameter, one of which is the apparent volume of distribution.

**Metabolism**

Drugs that are significantly metabolized before absorption, either in the lumen or tissue of the intestine, can show decreased bioavailability from slower-releasing dosage forms. Most intestinal wall enzyme systems are saturable. As the drug is released at a slower rate to these regions, less total drug is presented to the enzymatic process during specific period, allowing more complete conversion of the drug to its metabolites. Formulation of these enzymatically susceptible compounds as prodrugs is another viable solution.[7,8]

## MATERIALS

**Table 1: List of Materials Used**

| | |
|---|---|
| Theophylline | Procured from UniChem Laboratory, Mumbai, India. Provided by SURA LABS, Dilsukhnagar, Hyderabad. |
| Guar Gum | Elders Pharmaceuticals Pvt Ltd Dehradun |
| Fenugreek | Degussa India Ltd, Mumbai |
| Karya Gum | Elders Pharmaceuticals Pvt Ltd Dehradun |
| PVP K 30 | Merck Specialities Pvt Ltd, Mumbai, India |
| Talc | Shakti Chemicals, Mehsana, India |
| Mg Stearate | Signet Chemical Corp., Mumbai. |
| MCC | S. D. Fine Chemicals Ltd., Mumbai, India |

**Table 2: List of Equipment's used**

Weighing Balance - Sartourius

Tablet Compression Machine (Multistation) Lab Press

Hardness tester - Monsanto, Mumbai, India.

Vernier callipers - Mitutoyo, Japan.

Roche Friabilator - Lab India, Mumbai, India

Dissolution Apparatus- Lab India, Mumbai, India

UV-Visible Spectrophotometer- Lab India, Mumbai, India

pH meter- Lab India, Mumbai, India

FT-IR- Spectrophotometer Bruker

## METHODOLOGY

**Formulation development of Tablets:**

All the formulations were prepared by direct compression. The compositions of different formulations are given in Table 7.3. The tablets were prepared as per the procedure given below and aim is to prolong the release of Theophylline Total weight of the tablet was considered as 250mg.

**Procedure:**

1) Theophylline and all other ingredients were individually passed through sieve no ≠ 60.
2) All the ingredients were mixed thoroughly by triturating up to 15 min.
1) The powder mixture was lubricated with talc.
2) The tablets were prepared by using direct compression method.

**Table 3: Formulation composition for tablets**

| Ingredients | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 | F9 |
|---|---|---|---|---|---|---|---|---|---|
| Theophylline | 25 | 25 | 25 | 25 | 25 | 25 | 25 | 25 | 25 |
| Guar Gum | 25 | 50 | 75 | - | - | - | - | - | - |
| Fenugreek | - | - | - | 25 | 50 | 75 | - | - | - |
| Karya Gum | - | - | - | - | - | - | 25 | 50 | 75 |
| PVP K 30 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 |
| Talc | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| Mg Stearate | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 |
| MCC | QS | QS | QS | QS | QS | QS | QS | QS | QS |
| Total weight | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 |

All the quantities were in mg

**Evaluation of post compression parameters for prepared Tablets**

The designed formulation 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

**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 |

***In vitro* drug release studies**

**Dissolution parameters:**

Apparatus -- USP-II, Paddle Method

Dissolution Medium -- 0.1 N HCl, p H 6.8 Phosphate buffe

RPM -- 50

Sampling intervals (hrs) -- 1,2,3,4,5,6,7,8,9,10,11,12

Temperature -- 37°c $\pm$ 0.5°c

**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 apparatus was operated for 2 hours and then the media 0.1 N HCl was removed and pH 6.8 phosphate buffer was added process was continued from up to 12 hrs at 50 rpm. At definite time intervals withdrawn 5 ml of sample, filtered and again 5ml media was replaced. Suitable dilutions were done with media and analyzed by spectrophotometrically at 274 and 256 nm using UV-spectrophotometer.

**Drug – Excipient compatibility studies**

**Fourier Transform Infrared (FTIR) spectroscopy:**

The physical properties of the physical mixture were compared with those of plain drug. Samples was mixed thoroughly with 100mg potassium bromide IR powder and compacted under vacuum at a pressure of about 12 psi for 3 minutes. The resultant disc was mounted in a suitable holder in Agilent spectrophotometer and the IR spectrum was recorded from 4000 $cm^{-1}$ to 500 $cm^{-1}$. The resultant spectrum was compared for any spectrum changes.

## RESULTS & DISCUSSIONS

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

**Analytical Method**

Graphs of Theophylline were taken in 0.1N HCl and in pH 6.8 phosphate buffer at 271nm and 274 nm respectively.

**Table 5: Observations for graph of Theophylline in 0.1N HCl**

| Concentration (µg/ml) | Absorbance |
|---|---|
| 0 | 0 |
| 10 | 0.168 |
| 20 | 0.355 |
| 30 | 0.537 |
| 40 | 0.728 |
| 50 | 0.909 |

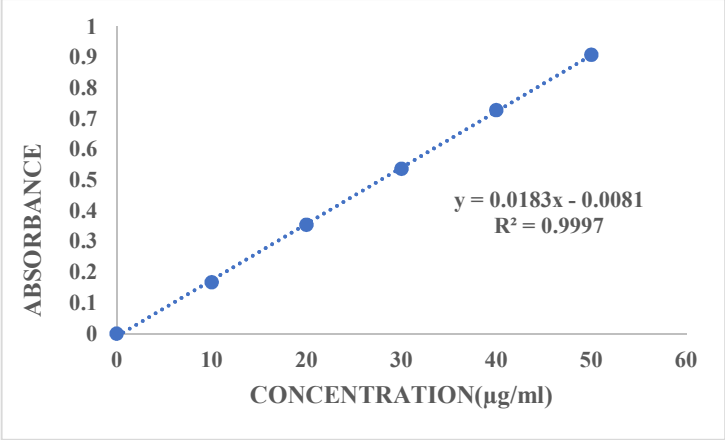


**Fig 1: Standard curve of Theophylline**

**Table 6 : Standard graph values of Theophylline pH 6.8 phosphate buffer**

| Concentration (µg/ml) | Absorbance |
|---|---|
| 0 | 0 |
| 10 | 0.153 |
| 20 | 0.312 |
| 30 | 0.486 |
| 40 | 0.649 |
| 50 | 0.816 |

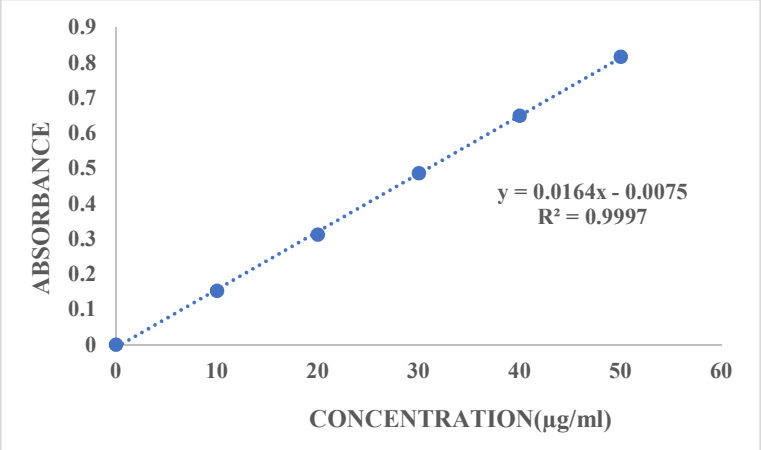


**Fig 2: Standard curve of Theophylline**

**Pre formulation parameters of powder blend**

**Table 7: Pre-formulation parameters of Core blend**

| Formulation code | Angle of repose (Ɵ) | Bulk density (gm/cm$^3$ | Tapped density(gm/cm$^3$) | Carr's index (%) |
|---|---|---|---|---|
| **F1** | 27.12±1.64 | 0.289±0.003 | 0.317±0.012 | 9.779±1.35 |
| **F2** | 27.35±1.79 | 0.278±0.005 | 0.309±0.010 | 11.15±1.34 |
| **F3** | 25.78±1.54 | 0.268±0.006 | 0.304±0.015 | 11.84±1.31 |
| **F4** | 27.25±1.56 | 0.282±0.004 | 0.312±0.011 | 9.615±1.37 |
| **F5** | 28.47±1.72 | 0.272±.0005 | 0.301±0.013 | 9.634±1.34 |
| **F6** | 25.67±1.84 | 0.250±0.005 | 0.285±0.012 | 12.28±1.29 |
| **F7** | 26.86±1.49 | 0.291±0.003 | 0.316±0.011 | 7.911±1.36 |
| **F8** | 27.21±1.25 | 0.262±0.004 | 0.292±0.014 | 10.27±1.39 |
| **F9** | 25.20±1.31 | 0.287±0.003 | 0.308±0.016 | 6.818±1.37 |

All the values represent n=3

Tablet powder blend was subjected to various pre-formulation parameters. The angle of repose values indicates that the powder blend has good flow properties. The bulk density of all the formulations was found to be in the range of 0.250±0.005 to 0.291±0.003 (gm/cm3) showing that the powder has good flow properties. The tapped density of all the formulations was found to be in the range of 0.285±0.012 to 0.317±0.012 showing the powder has good flow properties. The compressibility index of all the formulations was found to be below 12.28 which show that the powder has good flow properties.

**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.

**Table 8: *In-vitro* quality control parameters for tablets**

| Formulation codes | Weight variation(mg) | Hardness(kg/cm2) | Friability (%loss) | Thickness (mm) | Drug content (%) |
|---|---|---|---|---|---|
| F1 | 197.22 | 4.6 | 0.24 | 2.26 | 99.12 |
| F2 | 198.45 | 4.8 | 0.31 | 2.28 | 98.26 |
| F3 | 196.31 | 4.2 | 0.28 | 2.19 | 97.35 |

| | | | | | |
|---|---|---|---|---|---|
| F4 | 199.84 | 4.5 | 0.19 | 2.22 | 99.22 |
| F5 | 194.36 | 4.7 | 0.22 | 2.34 | 99.19 |
| F6 | 200.05 | 4.2 | 0.15 | 2.18 | 100.05 |
| F7 | 199.63 | 4.4 | 0.17 | 2.31 | 98.56 |
| F8 | 198.37 | 4.9 | 0.26 | 2.24 | 99.37 |
| F9 | 199.41 | 4.5 | 0.22 | 2.26 | 97.28 |

**Drug content:**

Drug content studies were performed for the prepared formulations. From the drug content studies it was concluded that all the formulations were showing the % drug content values within 97.28 - 100.05 %.

All the parameters such as weight variation, friability, hardness, thickness and drug content were found to be within limits.

***In-Vitro* Drug Release Studies**

**Table 9: Dissolution Data of Theophylline Tablets Prepared with Guar Gum**

| TIME (HRS) | % DRUG RELEASE | | |
|---|---|---|---|
| | F1 | F2 | F3 |
| 0 | 0 | 0 | 0 |
| 1 | 12.12 | 22.24 | 16.94 |
| 2 | 29.57 | 32.82 | 23.69 |
| 3 | 31.24 | 39.21 | 27.99 |
| 4 | 44.64 | 43.45 | 31.84 |
| 5 | 51.25 | 47.54 | 38.27 |
| 6 | 59.72 | 55.24 | 42.37 |
| 7 | 61.57 | 58.65 | 49.25 |
| 8 | 69.11 | 74.94 | 56.33 |
| 9 | 72.02 | 79.14 | 65.53 |
| 10 | 84.14 | 86.64 | 73.79 |
| 11 | 89.45 | 92.01 | 87.68 |
| 12 | 93.22 | 97.73 | 95.94 |

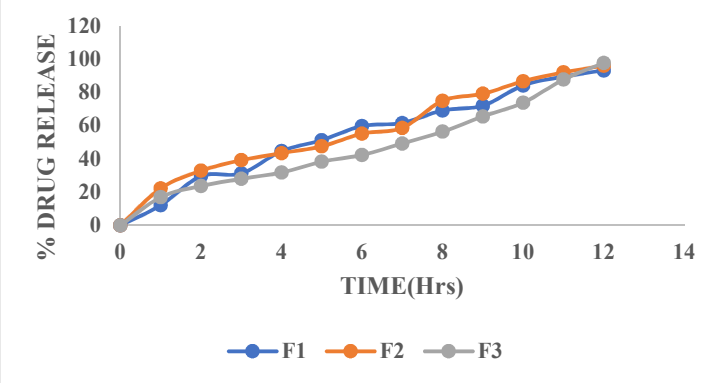


**Fig 8: Dissolution profile of Theophylline (F1, F2, F3 formulations).**

**Table 10: Dissolution Theophylline Tablets Prepared With Fenugreek**

| TIME(MIN) | % DRUG RELEASE | | |
|---|---|---|---|
| | F4 | F5 | F6 |
| 0 | 0 | 0 | 0 |
| 1 | 13.41 | 15.57 | 21.42 |
| 2 | 22.76 | 21.24 | 26.56 |
| 3 | 29.25 | 29.36 | 28.58 |
| 4 | 35.35 | 36.86 | 34.43 |
| 5 | 41.21 | 38.45 | 43.42 |
| 6 | 45.58 | 47.12 | 51.53 |
| 7 | 52.69 | 56.51 | 54.52 |
| 8 | 59.34 | 64.36 | 68.94 |
| 9 | 68.18 | 73.67 | 75.65 |
| 10 | 74.67 | 85.31 | 88.21 |
| 11 | 81.21 | 89.12 | 93.89 |
| 12 | 85.51 | 94.81 | 99.72 |

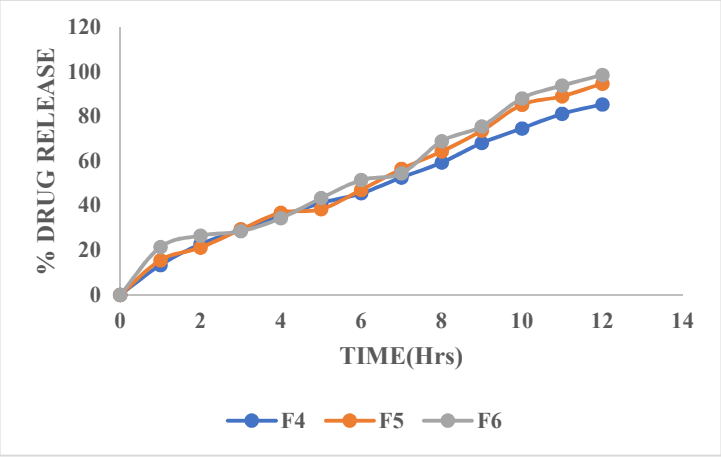


**Fig 4: Dissolution profile of Theophylline (F4, F5, F6 formulations)**

**Table 11: Dissolution Data of Theophylline Tablets Prepared with Karya Gum**

| TIME(MIN) | % DRUG RELEASE | | |
|---|---|---|---|
| | F7 | F8 | F9 |
| 0 | 0 | 0 | 0 |
| 1 | 15.12 | 24.78 | 21.22 |
| 2 | 28.12 | 32.85 | 30.42 |
| 3 | 33.39 | 48.72 | 45.12 |
| 4 | 46.52 | 62.52 | 51.68 |
| 5 | 51.54 | 68.52 | 56.74 |
| 6 | 63.46 | 74.86 | 63.42 |
| 7 | 70.61 | 79.42 | 71.45 |

| | | | |
|---|---|---|---|
| 8 | 78.51 | 87.51 | 78.52 |
| 9 | 84.59 | 92.98 | 83.54 |
| 10 | 87.52 | 93.83 | 87.76 |
| 11 | 90.24 | 94.86 | 91.42 |
| 12 | 96.88 | 91.12 | 95.37 |

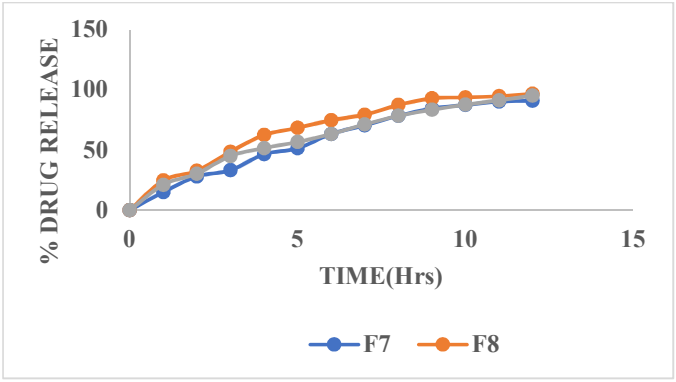


**Fig 5: Dissolution profile of Theophylline (F7, F8, F9 formulations)**

Formulations prepared with Guar Gum retarded the drug release in the concentration of 50mg (F2Formulation) showed required release pattern i.e., retarded the drug release up to 12 hours and showed maximum of 97.73% in 12 hours with good retardation

Formulations prepared with Fenugreek retarded the drug release in the concentration of 75 mg (F6 Formulation ) showed required release pattern i.e., retarded the drug release up to 12 hours and showed maximum of 99.72% in 12 hours with good retardation.

Formulations prepared with Karya Gum retarded the drug release in the concentration of 25mg (F7 Formulation ) showed required release pattern i.e., retarded the drug release up to 12 hours and showed maximum of 96.88% in 12 hours with good retardation

From the above results it was evident that the formulation F6 is best formulation with desired drug release pattern extended up to 12 hours.

**Application of Release Rate Kinetics to Dissolution Data:**

Various models were tested for explaining the kinetics of drug release. To analyse 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 mode

**Table 12: Release kinetics data for optimised formulation**

| CUMULATIVE (%) RELEASE Q | TIME (T) | ROOT (T) | %) REL | 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 |
| 21.42 | 1 | 1.000 | 1.331 | 0.000 | 1.895 | 21.420 | 0.0467 | -0.669 | 78.58 | 4.642 | 4.283 | 0.358 |
| 26.56 | 2 | 1.414 | 1.424 | 0.301 | 1.866 | 13.280 | 0.0377 | -0.576 | 73.44 | 4.642 | 4.188 | 0.454 |
| 28.58 | 3 | 1.732 | 1.456 | 0.477 | 1.854 | 9.527 | 0.0350 | -0.544 | 71.42 | 4.642 | 4.149 | 0.493 |
| 34.43 | 4 | 2.000 | 1.537 | 0.602 | 1.817 | 8.608 | 0.0290 | -0.463 | 65.57 | 4.642 | 4.032 | 0.609 |
| 43.42 | 5 | 2.236 | 1.638 | 0.699 | 1.753 | 8.684 | 0.0230 | -0.362 | 56.58 | 4.642 | 3.839 | 0.803 |
| 51.53 | 6 | 2.449 | 1.712 | 0.778 | 1.685 | 8.588 | 0.0194 | -0.288 | 48.47 | 4.642 | 3.646 | 0.996 |
| 54.52 | 7 | 2.646 | 1.737 | 0.845 | 1.658 | 7.789 | 0.0183 | -0.263 | 45.48 | 4.642 | 3.569 | 1.072 |
| 68.94 | 8 | 2.828 | 1.838 | 0.903 | 1.492 | 8.618 | 0.0145 | -0.162 | 31.06 | 4.642 | 3.143 | 1.498 |
| 75.65 | 9 | 3.000 | 1.879 | 0.954 | 1.386 | 8.406 | 0.0132 | -0.121 | 24.35 | 4.642 | 2.898 | 1.743 |
| 88.21 | 10 | 3.162 | 1.946 | 1.000 | 1.072 | 8.821 | 0.0113 | -0.054 | 11.79 | 4.642 | 2.276 | 2.366 |
| 93.89 | 11 | 3.317 | 1.973 | 1.041 | 0.786 | 8.535 | 0.0107 | -0.027 | 6.11 | 4.642 | 1.828 | 2.813 |
| 99.72 | 12 | 3.464 | 1.999 | 1.079 | 0.540 | 8.310 | 0.0100 | -0.001 | 0.28 | 4.642 | 0.654 | 3.987 |

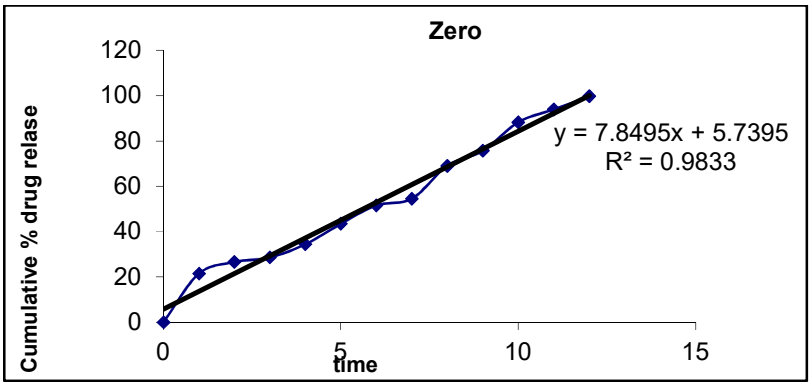


**Fig 6: Zero order release kinetics graph**

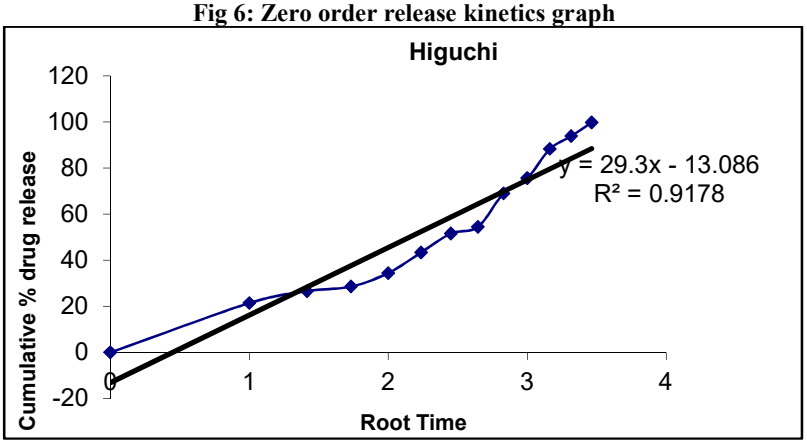


**Fig 7: Higuchi release kinetics graph**

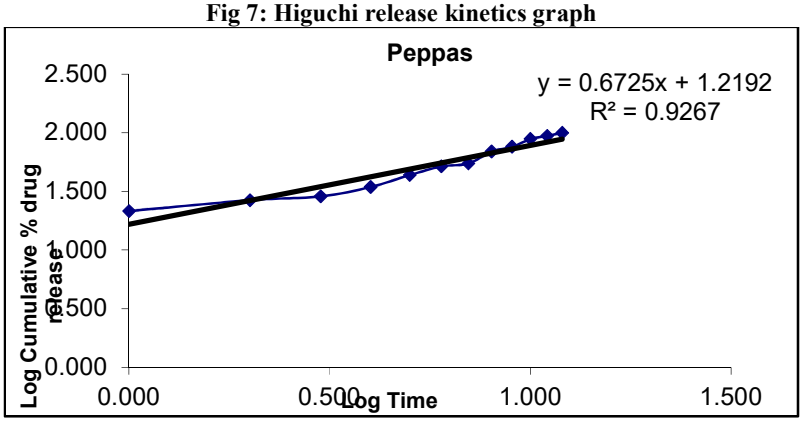


**Fig 8: Kars mayer peppas graph**

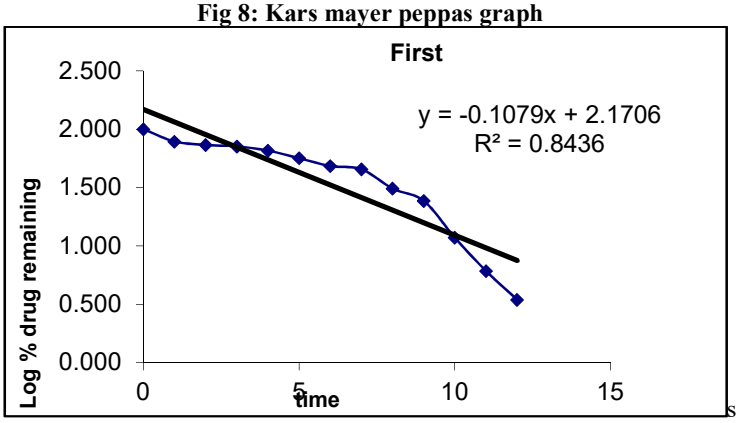


**Fig 9: First order release kinetics graph**

From the above graphs it was evident that the formulation F6 was followed Zero order release kinetics mechanism.

**Drug – Excipient compatibility studies**
**Fourier Transform-Infrared Spectroscopy:**

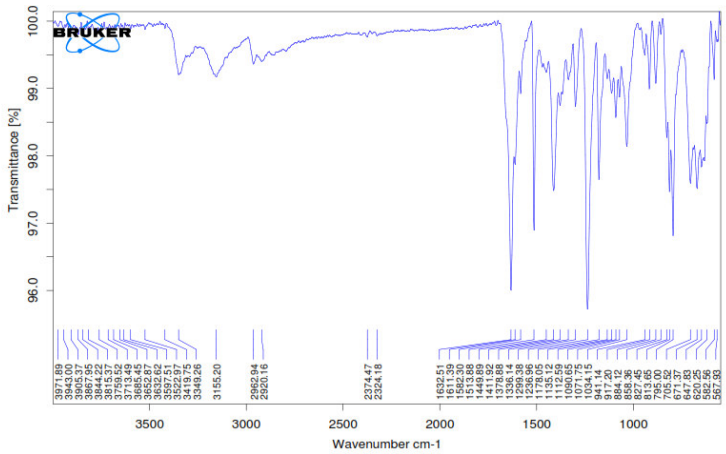


**Figure 10 : FT-TR Spectrum of Theophylline pure drug.**

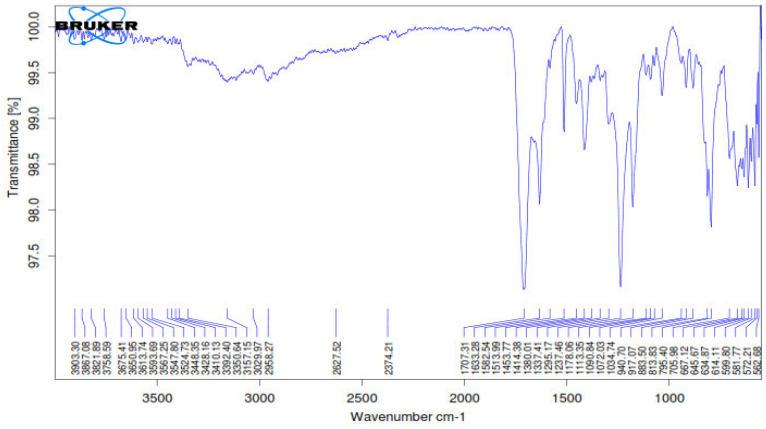


**Figure 11: FT-IR Spectrum of Optimized Formulation**

## CONCLUSION

The present study was successfully carried out for the formulation and evaluation of sustained release matrix tablets of Theophylline using natural polymers. Various formulations were prepared by employing natural polymers like Guar Gum, Fenugreek and Karya gum in different concentrations to sustain the drug release over an extended period. All the pre-compression and post-compression parameters such as hardness, friability, thickness, weight variation, and drug content were found to be within acceptable Pharmacopoeial limits, indicating good formulation characteristics.

Among all the formulations, the optimized formulation F6 demonstrated a sustained drug release profile, achieving approximately 99.72% drug release over 12 hours, which closely matched the theoretical release pattern. The drug release kinetics followed a controlled release mechanism, confirming the role of natural polymers in modulating the release rate effectively.

Thus, it can be concluded that natural polymers can be efficiently used to develop cost-effective, biocompatible, and environmentally safe sustained-release matrix tablets of Theophylline, enhancing patient compliance and therapeutic efficacy.

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