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FORMULATION AND EVALUATION OF SUSTAINED RELEASE MATRIX TABLETS OF THEOPHYLLINE USING NATURAL POLYMER

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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*

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

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.[3,4,5]

Recent trends in sustained drug delivery system:[6-9]

Sustained release dosage forms are categorized as:

- ➢ Single unit dosage form.
- ➢ Multiple unit dosage form.
- ➢ Mucoadhesive system.

Single unit dosage form:

These refer to diffusion system where the drug is uniformly distributed (dispersed / dissolved) throughout the solid matrix and the release of the drug is controlled or sustained either by incorporating hydrophilic or hydrophobic filler within the matrix or by coating the drug matrix with a swellable or non-swellable polymer film.

These systems can be classified as:

Monolithic system:

If the release rate is controlled or sustained by incorporating hydrophilic or hydrophobic filler within the matrix then the system is called as Monolithic device where the diffusion of drug through the matrix is rate- limiting step.

These are categorized as:

Hydrophobic/Swellable tablet:

Tablet prepared by mixing the drug with hydrophobic/hydrophilic filler appear to extend the release time of the drug from device within the GI tract after oral administration.

Floating tablet or capsule:

Designing of Floating tablet or capsule are called hydro-dynamically balanced drug delivery system is based on the principle that device with gravity lesser than that of the gastric juice of stomach and retain the drug in the proximal region of the GIT.

Semisolid matrix system:

In this system, the hydrophobic carrier occurs in an oily semisolid state where the drug is incorporated and the final mass is usually filled into gelatine capsule to prepare the dosage form.

Coated tablet and Similar Multilayer system:
Multilayer systems are designed in such a way that the drug has to cross a barrier or membrane on its way from the device to the physiological environment. The nature and the number of barriers control the release process. In the simplest form coated tablet comprised a core containing the drug and a coating layer, which surrounds the core. The core is usually the drug either alone or loaded on to an inert material (hydrophilic or hydrophobic).
Multilayered tablet having two or more distinct layers usually prepared by dry coating technique have also been used to formulate sustained or controlled preparations for water-soluble drugs. In this case, coating which controls the release process covers the core tablet containing the drug only partially.

Osmotic device:
In osmotic device usually an osmotic agent (often with an osmotic adjuvant) is contained within a rigid compartment that is separated from the osmotic compartment by a partition. In the physiological environment the aqueous fluid penetrates across the membrane and the increased volume within the osmotic compartment pushes the drug out of the device through a delivery orifice.

Multiple unit dosage forms:
It represents a combination of subnets of the dosage forms, the source of which may either be homogeneous or heterogeneous. It offers the advantages of releasing one of the drugs or part of the same drug immediately while remaining drug or parts of the same can be sustained release. These are useful where drug-excipients and drug-drug interactions are inevitable in a single unit dosage form. The various forms are as:

- Micro granules/Spheroids.
- Beads.
- Pellets.
- Microcapsules.

Mucoadhesive systems:
It utilizes principle of bioadhesion for optimum delivery of the drug from the device. Bioadhesion is definable as the occurrence in which one biological substance is adhered to another substance, which may either, be of biological or non-biological origin. If the substance is mucosal membrane the phenomenon is known as mucoadhesion. Conventional controlled release dosage forms described above are restrained localized in selected regions of GIT.Mucoadhesive systems are suitable to increase the contact time of drug with absorbing membrane and localization of delivery of drug at target sites.[3]

MATRIX SYSTEM [10-15]:
The matrix system is most often used for a drug-controlled release from a pharmaceutical dosage form. Among the innumerable method used in controlled release drug from pharmaceutical dosage form, the matrix system is the most frequently applied; it is release system for delay and control of the release of the drug that is dissolved or dispersed in a resistant-supports to disintegration. To define matrix, it is necessary to know the characters that differentiate it from other controlled release dosage forms. Hence the following must be considered:
The chemical nature of support (generally, the support are formed by polymeric net)

- ✓ The physical state of drug (dispersed under molecular or particulate form or both)
- ✓ The matrix shape and alteration in volume as a function of time.
- ✓ The route of administration (oral administration remains the most widely used but other route are adaptable)
- ✓ The release kinetic model.

The Following are the Rationale of Developing SR Matrix DDS To extend the duration of action of the drug

- ✓ To reduce the frequency of dosing
- ✓ To minimize the fluctuations in plasma
- ✓ level Improved drug utilization
- ✓ Less adverse effects

METHODOLOGY:

Analytical method development:

a) Determination of absorption maxima:
100 mg of Theophylline pure drug was dissolved in 100ml of Methanol (stock solution)10ml of above solution was taken and make up with100ml by using 0.1 N HCl (100µg/ml). From this 10ml was taken and make up with 100 ml of 0.1 N HCl (10µg/ml). and pH 6.8 Phosphate buffer UV spectrums was taken using Double beam UV/Visible spectrophotometer. The solution was scanned in the range of 200 – 400 nm.

b) Preparation calibration curve:
100 mg of Theophylline pure drug was dissolved in 100ml of Methanol (stock solution) 10ml of above solution was taken and make up with100ml by using 0.1 N HCl (100µg/ml). From this 10ml was taken and make up with 100 ml of 0.1 N HCl (10µg/ml). The above solution was subsequently diluted with 0.1N HCl to obtain series of dilutions Containing 10,20,30,40 and 50 µg/ml of Theophylline per ml of solution. The absorbance of the above dilutions was measured at 274 nm by using UV-Spectrophotometer taking 0.1N HCl as blank. Then a graph was plotted by taking Concentration on X-Axis and Absorbance on Y-Axis which gives a straight- line Linearity of standard curve was assessed from the square of correlation coefficient (R^2) which determined by least-square linear regression analysis. The above procedure was repeated by using pH 6.8 phosphate buffer solutions.

Preformulation parameters

The quality of tablet, once formulated by rule, is generally dictated by the quality of physicochemical properties of blends. There are many formulations and process variables involved in mixing and all these can affect the characteristics of blends produced. The various characteristics of blends tested as per Pharmacopoeia.

Angle of repose:

The frictional force in a loose powder can be measured by the angle of repose. It is defined as, the maximum angle possible between the surface of the pile of the powder and the horizontal plane. If more powder is added to the pile, it slides down the sides of the pile until the mutual friction of the particles producing a surface angle, is in equilibrium with the gravitational force. The fixed funnel method was employed to measure the angle of repose. A funnel was secured with its tip at a given height (h), above a graph paper that is placed on a flat horizontal surface. The blend was carefully pored through the funnel until the apex of the conical pile just touches the tip of the funnel. The radius (r) of the base of the conical pile was measured. The angle of repose was calculated using the following formula:

$\tan \theta = h / r$

$\tan \theta$ = Angle of repose

h = Height of the cone,

r = Radius of the cone base

Bulk density:

Density is defined as weight per unit volume. Bulk density, is defined as the mass of the powder divided by the bulk volume and is expressed as gm/cm^3. The bulk density of a powder primarily depends on particle size distribution, particle shape and the tendency of particles to adhere together. Bulk density is very important in the size of containers needed for handling, shipping, and storage of raw material and blend. It is also important in size blending equipment. 10 gm powder blend was sieved and introduced into a dry 20 ml cylinder, without compacting.

The powder was carefully leveled without compacting and the unsettled apparent volume, Vo, was read.

The bulk density was calculated using the formula:

$\text{Bulk Density} = M / V_o$

Where, M = weight of sample

V_o = apparent volume of powder

Tapped density:

After carrying out the procedure as given in the measurement of bulk density the cylinder containing the sample was tapped using a suitable mechanical tapped density tester that provides 100 drops per minute and this was repeated until difference between succeeding measurement is less than 2 % and then tapped volume, V measured, to the nearest graduated unit. The tapped density was calculated, in gm per L, using the formula:

$\text{Tap} = M / V$

Where, Tap= Tapped Density

M = Weight of sample

V= Tapped volume of powder

Measures of powder compressibility:

The Compressibility Index (Carr's Index) is a measure of the propensity of a powder to be compressed. It is determined from the bulk and tapped densities. In theory, the less compressible a material the more flowable it is. As such, it is measures of the relative importance of interparticle interactions. In a free- flowing powder, such interactions are generally less significant, and the bulk and tapped densities will be closer in value.

For poorer flowing materials, there are frequently greater interparticle interactions, and a greater difference between the bulk and tapped densities will be observed. These differences are reflected in the Compressibility Index which is calculated using the following formulas:

$\text{Carr's Index} = [(\text{tap} - b) / \text{tap}] \times 100$

Where, b = Bulk Density

Tap = Tapped Density

Formulation development of Tablets:

All the formulations were prepared by direct compression. The compositions of different formulations are given in Table 1. 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 no: 1 Formulation compositions 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

Hardness:

Hardness of tablet is defined as the force applied across the diameter of the tablet in order to break the tablet. The resistance of the tablet to chipping, abrasion or breakage under condition of storage transformation and handling before usage depends on its hardness. For each formulation, the hardness of three tablets was determined using Monsanto hardness tester and the average is calculated and presented with deviation.

Thickness:

Tablet thickness is an important characteristic in reproducing appearance. Tablet thickness is an important characteristic in reproducing appearance. Average thickness for core and coated tablets is calculated and presented with deviation. The thickness of tablets is measured by using screw gauge.

Friability:

It is measured of mechanical strength of tablets. Roche friabilator was used to determine the friability by following procedure. Reweighed tablets were placed in the friabilator. The tablets were rotated at 25 rpm for 4 minutes (100 rotations). At the end of test, the tablets were re weighed, loss in the weight of tablet is the measure of friability and is expressed in percentage as

% Friability = [(W1-W2) / W] × 100

Where, W1 = Initial weight of three tablets

W2 = Weight of the three tablets after testing

Determination of drug content:

Tablets were tested for their drug content. Ten tablets were finely powdered quantities of the powder equivalent to one tablet weight of drug were accurately weighed, transferred to a 100 ml volumetric flask containing 50 ml water and were allowed to stand to ensure complete solubility of the drug. The mixture was made up to volume with media. The solution was suitably diluted and the absorption was determined by UV –Visible spectrophotometer. The drug concentration was calculated from the calibration curve.

***In vitro* drug release studies**

Dissolution parameters:

Apparatus -- USP-II, Paddle Method

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

RPM -- 50

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

Temperature -- 37°c ± 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 ± 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 are 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 & DISCUSSION:

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 No:2 Standard 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

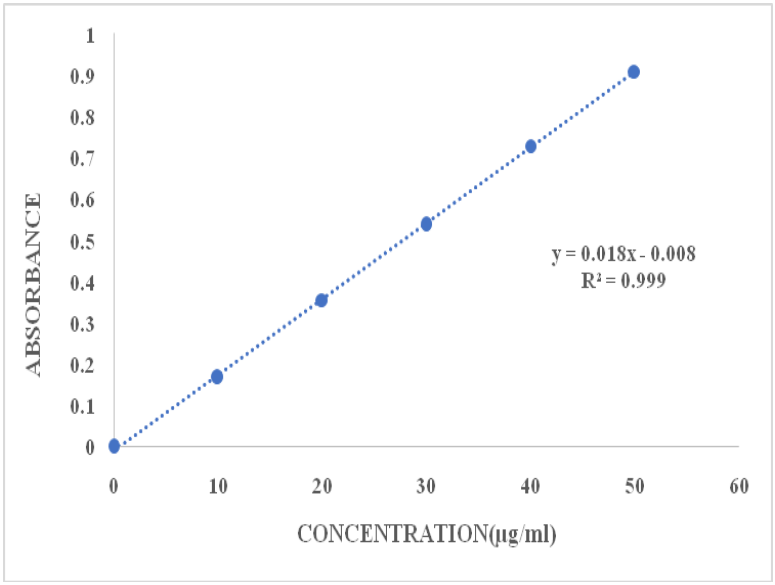

Figure no:1 Standard curve of Theophylline

Table no 3: 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

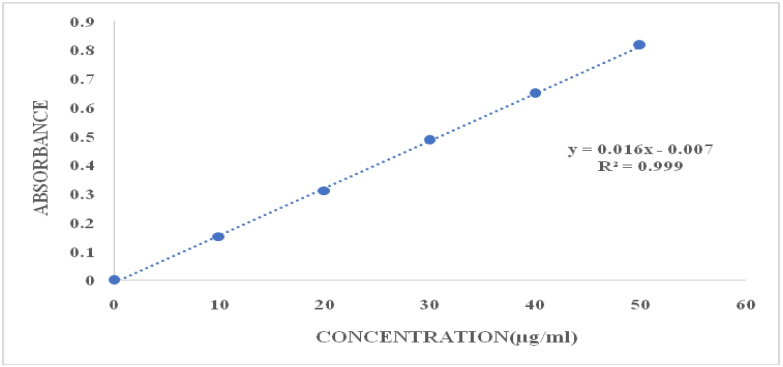

Figure no:2 Standard curve of Theophylline

Preformulation parameters of powder blend

Table no:4 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 no 5:*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

Weight variation test:

Tablets of each batch were subjected to weight variation test, difference in weight and percent deviation was calculated for each tablet and was shown in the Table. The average weight of the tablet is approximately in range of 196.31 to 200.05 mg, so the permissible limit is ±7.5% (>200 mg). The results of the test showed that, the tablet weights were within the pharmacopoeia limit.

Hardness test:

Hardness of the three tablets of each batch was checked by using monsanto hardness tester and the data's were shown in Table 8.4. The results showed that the hardness of the tablets is in range of 4.2 to 4.9 kg/cm^2,which was within IP limits.

Thickness:

Thickness of three tablets of each batch was checked by using screw gauge and data shown in Table no -5. The result showed that thickness of the tablet is raging from 2.18 to 2.34 mm.

Friability:

Tablets of each batch were evaluated for percentage friability and the data were shown in the Table 8.4. The average friability of all the formulations was less than 1% as per official requirement of IP indicating a good mechanical resistance of tablets.

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 no 6: 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

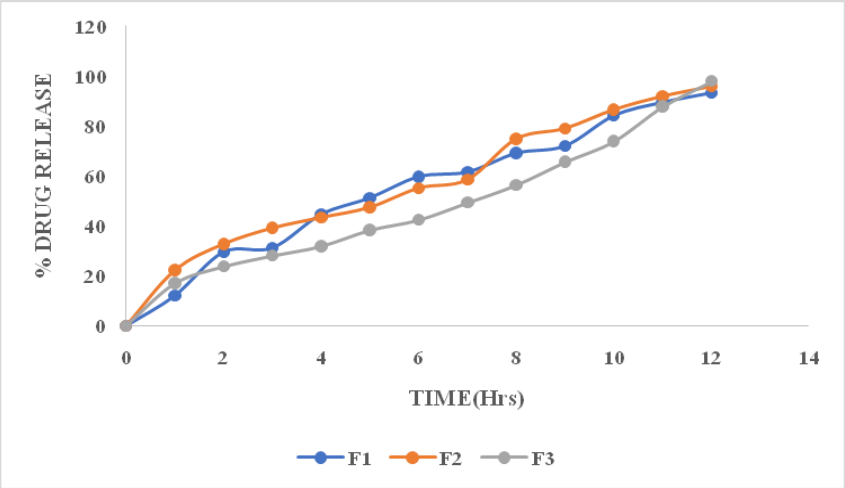

Figure no 3: Dissolution profile of Theophylline (F1, F2, F3 formulations).

Table no 7: Dissolution Theophylline Tablets Prepared usingFenugreek

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

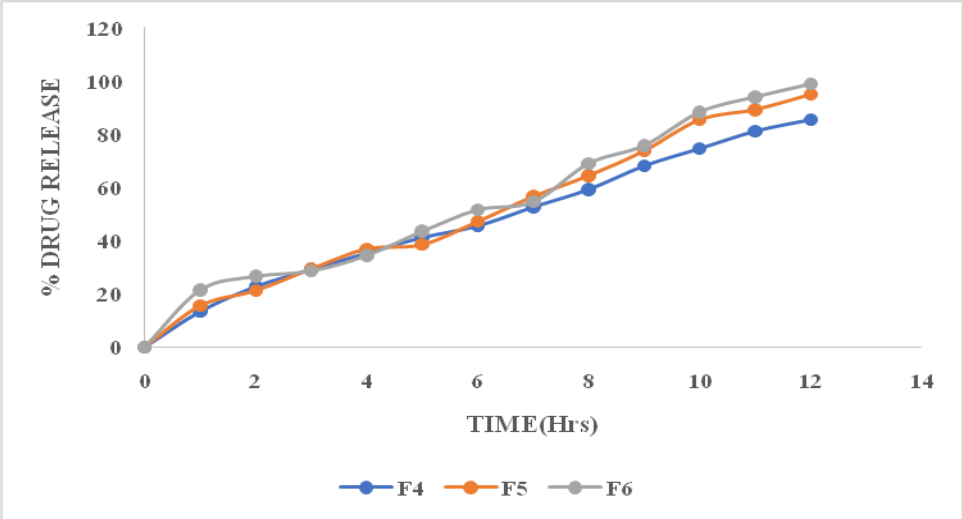

Figure no:4 Dissolution profile of Theophylline(F4, F5, F6 formulations)

Table no 8: 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

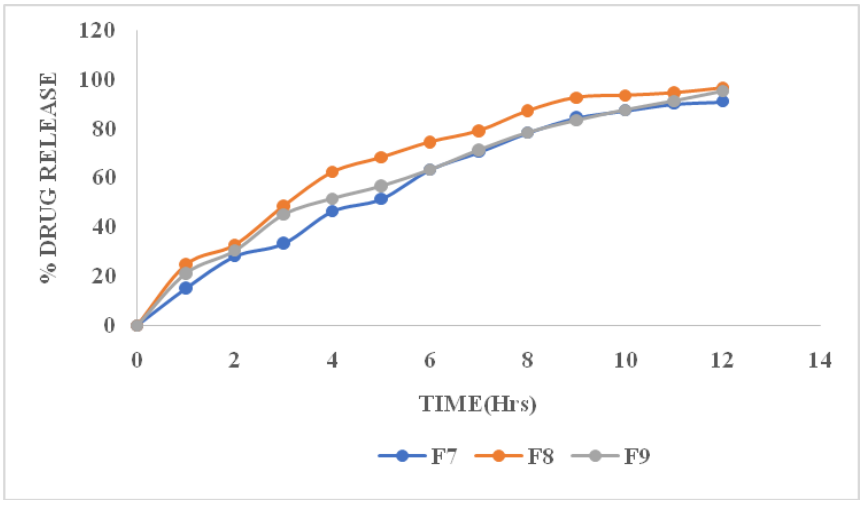

Figure no 5: Dissolution profile of Theophylline (F7, F8, F9 formulations)

Formulations prepared with Guar Gumretarded 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 Fenugreekretarded 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 Gumretarded 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.

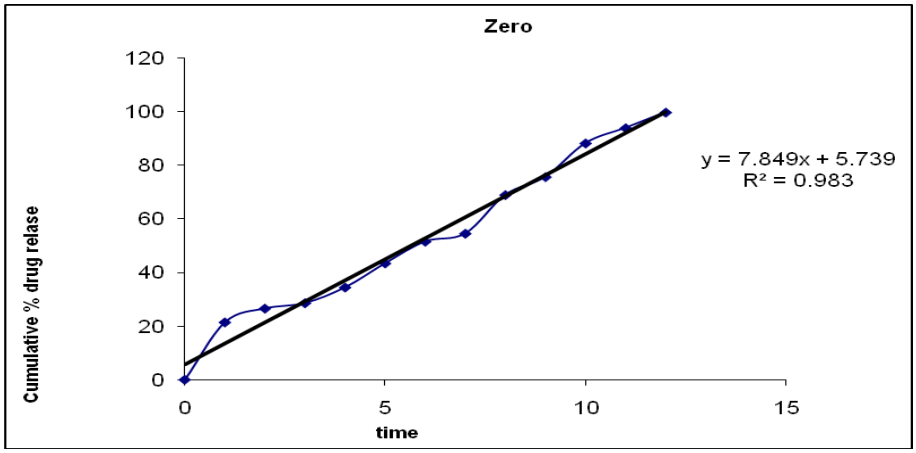

Figure no 6: Zero order release kinetics graph

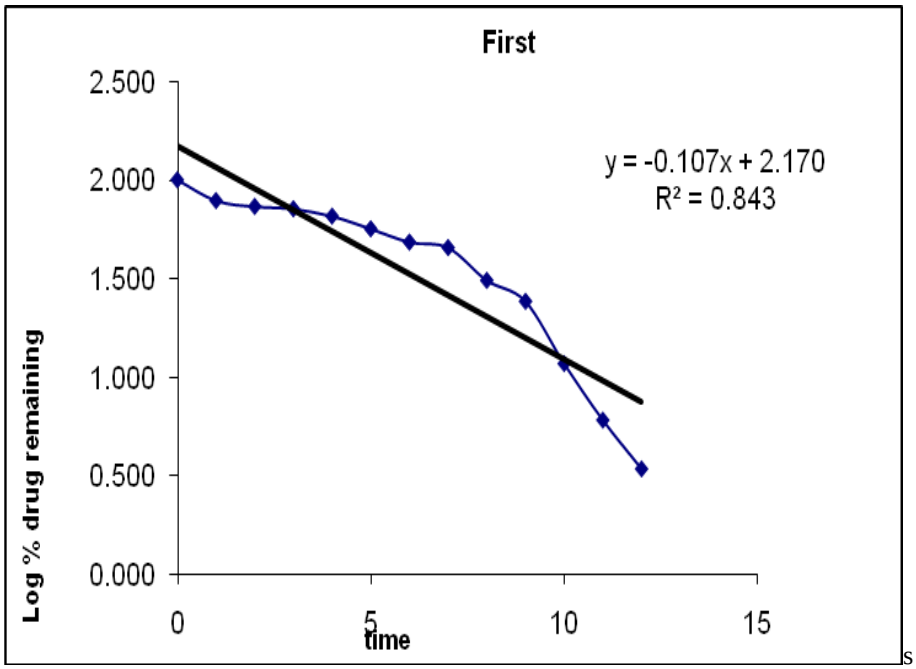

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Figure no 7:First order release kinetics graph

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:

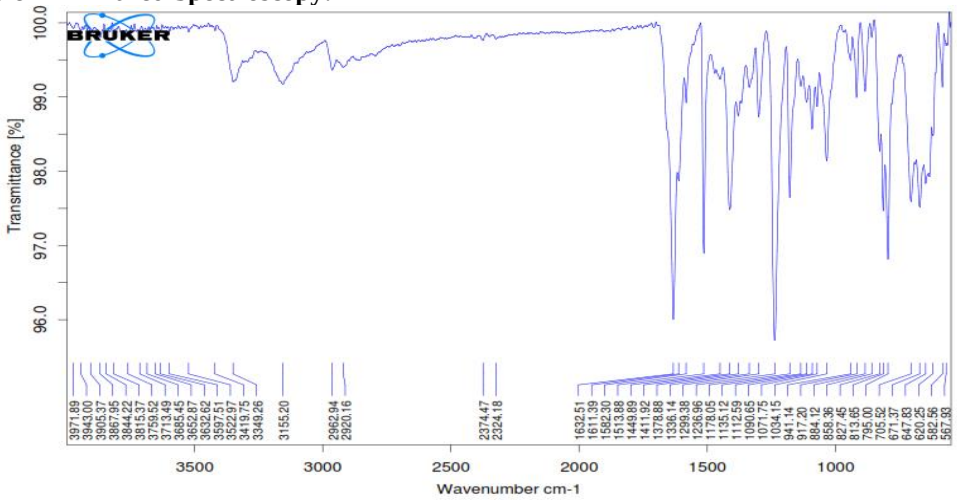

Figure 8.: FT-TR Spectrum of Theophylline pure drug.

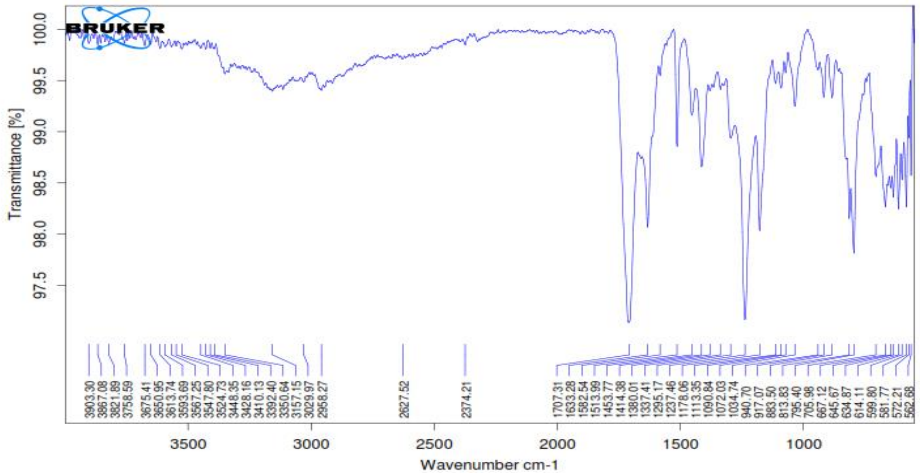

Figure 9: FT-IR Spectrum of Optimized Formulation

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 gumin 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 optimizedformulation 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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