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FORMULATION, OPTIMIZATION AND EVALUATION OF CEFPODOXIME PROXETIL SUSTAINED RELEASE MATRIX TABLETS BY COMBINATION OF THREE NATURAL GUMS FOUND IN NORTH MAHARASHTRA REGION.

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ABSTRACT

The most popular route of administration of a Drug is oral route, but some conventional dosage forms have its own problems like short gastrointestinal transit time, fluctuations in blood plasma levels, low bioavailability problems. Tablets are the most commonly and widely used dosage form. Cefpodoxime Proxetil is a class of medications called third generation Cephalosporin Antibiotics, it is used to treat certain infections caused by bacteria such as Bronchitis, Pneumonia, Gonorrhea and infections of the Skin, Ear, Sinuses, Throat, Tonsils and Urinary Tract. It has Minimum dose of 200 mg and 800 mg Maximum in a day. Many researchers developed Cefpodoxime Proxetil matrix dosage form which can give a prolonged therapeutic effect. But, in this formulation Cefpodoxime Proxetil is combined with three different Natural Gums [Karaya Gum, Acacia Gum and Guar Gum] they also act as Natural Binders in the dosage form due to their good binding abilities. The formulation was developed as a sustained release matrix dosage form in an oral tablet with a dose of 300 mg/tablet. Pre and Post- Compression parameters were done in the study, and In-Vitro drug dissolution study were conducted, but further In-Vivo study is Required/Recommended, And Future research is recommended.

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INTRODUCTION

[1,13,15,16,17,18,19] The drug Cefpodoxime Proxetil is an orally active ester prodrug of 3rd generation Cephalosporin, Cefpodoxime. In addition to being highly active against Enterobacteriaceae and Streptococci, it inhibits Staphylococcus Aureus. It is used mainly for Respiratory, Urinary, Skin and Soft tissue infections. It is sparingly soluble in water and slightly soluble in methanol. The drug inhibits mucopeptide synthesis in the bacterial cell wall, rendering it defective and osmotically unstable. The minimum dose of Cefpodoxime Proxetil is 200 mg a day and the maximum dose is 800 mg a day. Cefpodoxime Proxetil, as in tablet form has the frequency of a minimum of 1-2 tablets in a day and so, to reduce its frequency of dosing, there was a need to develop such type of dosage form which can provide a long therapeutic response in a single day dosing. So, Cefpodoxime sustained release matrix tablets by using a natural gum found in North Maharashtra region were formulated by using various excipients. In this study Cefpodoxime Proxetil was combined with Karaya Gum or "Gum Karaya" occurs in tears of variable size and in broke irregular pieces having a characteristic sei-crystalline appearance, pale yellow to pinkish brown, translucent and horny. It is soluble in ethanol, in water it swells to form a granular, stiff slightly opalescent gel. Karaya Gum is widely used in oral and topical pharmaceutical formulations, cosmetics and foods as a suspending and stabilizing agent. It is also used as a thickening and emulsifying agent. It is nontoxic, compatible with most of the other pharmaceutical ingredients, it also has good stability and viscosity properties over a wide pH and Temperature range. Karaya Gum gels show pseudoplastic behavior, the shear thinning being directly proportional to the shear rate, and the viscosity returns to normal immediately on release of its shear stress. Karaya Gum also has its therapeutic activities such as bulk-forming laxative to relieve constipation, it is also used to increase the sexual desire (as an aphrodisiac) and in manufacturing Karaya Gum is used as a thickener in medications, cosmetics and denture adhesives, and as a binder and stabilizer in foods and beverages and many other therapeutic uses, but in India it is not very well known, but the researchers from various parts in India are working on it.

Karaya Gum is particularly acetylated polysaccharide containing of about 8 % acetyl groups and about 37 % uronic acid residues. It undergoes hydrolysis in an acidic medium to produce D-Galactose, L-Rhamnose, D-Galacturonic acid and a Trisaccharide acidic substance. It contains a branched heteropolysaccharide moiety having a major chain of 1, 4-Linked α-D-Galacturonic acid along with 1, 2- Linked L-Rhamnopyranose units with a short D-Glucopyranosy-l uronic acid containing the side chains attached 1→3 to the main chain, that is D-Galactouronic acid moieties. In this study sustained release matrix tablets of Cefpodoxime Proxetil combined with Karaya Gum and other gums such as Guar Gum, Acacia Gum, excipients such as Magnesium stearate, Lactose, Talc were formulated but, further In-Vivo studies are required for the conformation of its therapeutic effect.

MATERIALS AND METHODS

Cefpodoxime Proxetil was the gift sample of pure active pharmaceutical ingredient by "Shree Swami Samarth Ayurvedic Pharmacy (Allopathic Division), Jalgaon", Acacia Gum, Karaya Gum and Guar Gum were the gift samples given by the tribal peoples of Barisurgas a small tribal village situated in the Satpuda Mountain ranges of the North Maharashtra region, Magnesium Stearate were purchased from "S.D. Fine chem, Ltd, Mumbai", Lactose and Talc were purchased from "Research Lab Fine Chem Industries, Mumbai", and all the chemicals used during the study were of analytical grade.

All the Gums were purified by washing with distilled water to remove the impurities and dried in an hot air oven at 40^0 C (Temperature should not exceed 50^0 C).

Design of Factorial Batches: -

All the batches i.e., F1-F9 were designed with the help of design expert software.

Table 1: Factorial Designed Tablet Batches.

INGREDIENTS (mg/tablet)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Cefpodoxime Proxetil	100	100	100	100	100	100	100	100	100
Karaya Gum	30	30	30	60	60	60	90	90	90
Acacia Gum	30	40	50	30	40	50	30	40	50
Guar Gum	20	20	20	20	20	20	20	20	20
Magnesium Stearate	10	10	10	10	10	10	10	10	10
Talc	10	10	10	10	10	10	10	10	10
Lactose	100	90	80	70	60	50	40	30	20
Total Weight	300	300	300	300	300	300	300	300	300

FTIR Analysis: -

FTIR spectra for pure drug and different polymers acquired at room temperature using an FTIR spectrophotometer in transmittance mode. The samples were ground in a mortar mixed with Nujol and placed between two plates of KBr and compressed to form a thin film. The sandwiched plates were placed in the infrared spectrophotometer and the spectra were obtained. scanning was performed between wave numbers 4000-400 cm^{-1}.

DSC Analysis: -

Method for estimating the physical interaction between drug and polymers used for the formulation of different dosage for its thermal analysis by DSC. In the present study the DSC analysis of the pure drug and polymers were carried out using a differential scanning calorimeter to evaluate any possible polymer drug thermal interaction exactly 5-6 gm of sample were weighed and sealed in aluminum crucible and heated at constant rate of 10^0 C/min over a temperature range of 40 to 300^0 C. inert atmosphere was maintained by purging nitrogen gas at a flow rate of 50 ml/min.

Preparation of Granules: -

The granules of the formulation were made by the wet granulation technique; water was used as a granulating agent, and after granulation the granules were passed through a 60 # mesh sieve.

Compression of Granules: -

The compression of Granules was performed on a 9-stationed tablet compression machine (Rimek Model: DL 09 stationed tablet compression machine, Karnavati engineering, (Mehsana, Gujrat, India) equipped with 9 mm of round shaped punches and further studied for post-Compression parameters.

RESULTS AND DISCUSSION

Determination of Melting point: -

The melting point of Cefpodoxime Proxetil API was determined by the Capillary Tube Method and the melting point was found within the standard range of 110-115^0 C and when compared with the official standards it was within its standard range.

Standard Calibration Curves of Cefpodoxime Proxetil (Pure Drug): -

Calibration Curve of Cefpodoxime Proxetil in 0.1N HCL and 6.8 pH Phosphate Buffer

A standard graph of Cefpodoxime Proxetil has shown good linearity of R^2 values 0.9963and 0.996 in 0.1 N HCL and pH 6.8 buffer respectively under λ max of 258 nm, which suggests that it obeys the "Beer-Labert's law"

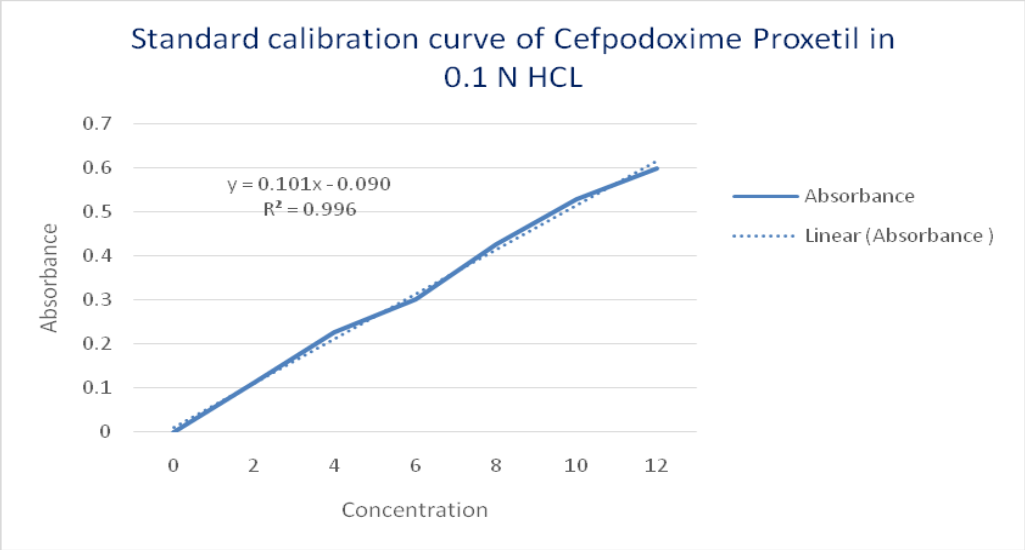

Fig 1: Standard Calibration curve of Cefpodoxime Proxetil in 0.1 N HCL.

Table 2: Standard Calibration curve of Cefpodoxime Proxetil in 0.1 N HCL.

CONCENTRATION (µg/ml)	ABSORBANCE
0	0
2	0.112
4	0.228
6	0.303
8	0.426
10	0.528
12	0.599

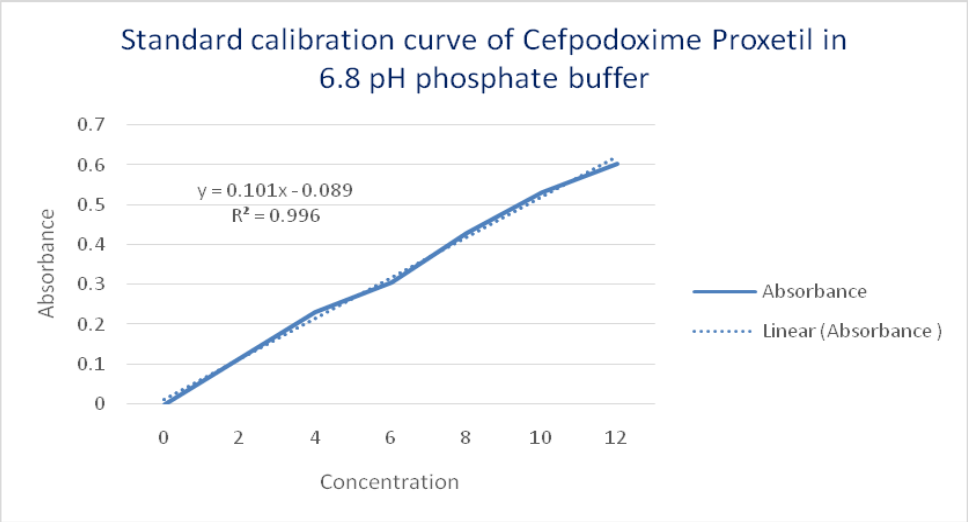

Fig 2: Standard Calibration curve of Cefpodoxime Proxetil in 6.8 pH Phosphate Buffer.

Table 3: Standard Calibration curve of Cefpodoxime Proxetil in 6.8 pH Phosphate Buffer.

CONCENTRATION (µg/ml)	ABSORBANCE
0	0
2	0.115
4	0.232
6	0.305
8	0.429
10	0.531
12	0.603

FTIR Studies

FTIR of Cefpodoxime Proxetil (Pure Drug)

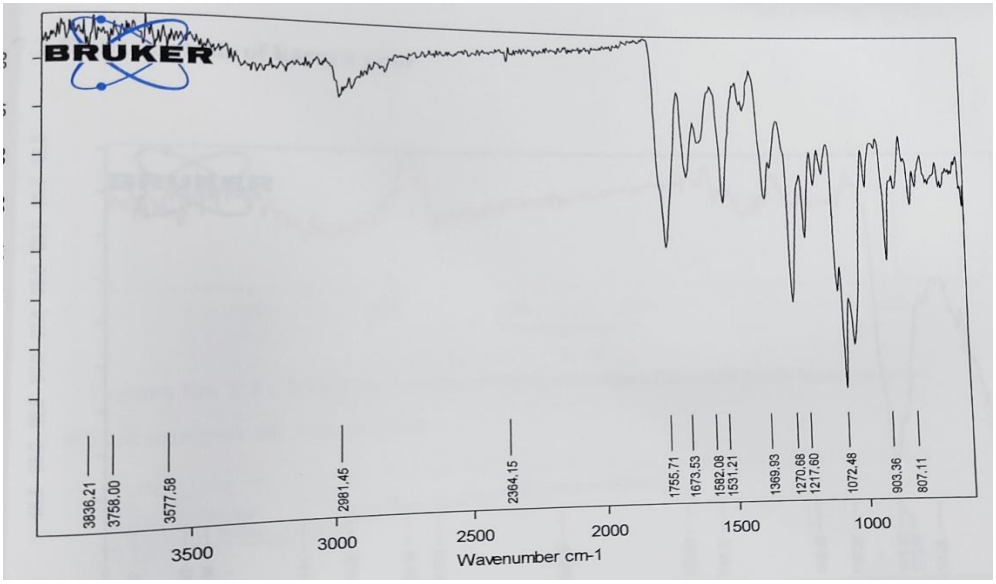

Fig 3: FTIR analysis of Cefpodoxime Proxetil (Pure Drug).

Table 4: Interpretation of FTIR of Cefpodoxime Proxetil (Pure Drug).

FUNCTIONAL GROUP	CHARACTERISTIC PEAKS cm^{-1}
C-H Stretching (Aliphatic)	2937.04
C-H Stretching (Aromatic)	2984.39
N-H Stretching	3330.81
N-H Bending	1618.01
C=N Stretching	1638.04
C-O Stretching	1074.15, 1099.46
C=O Stretching	1761.84
C-S-C Stretching	674.20
C-N Stretching	1274.25
C-H Bending	1375

FTIR of Karaya Gum

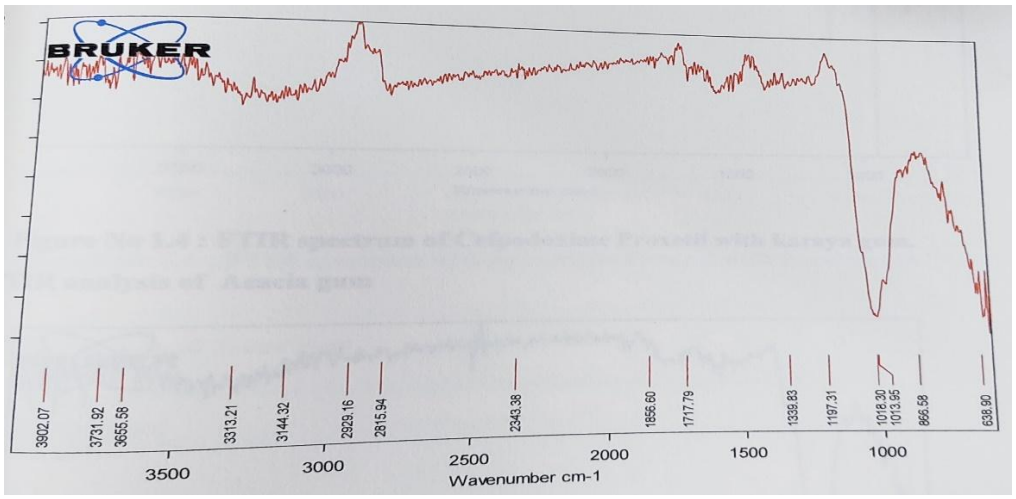

Fig 4: FTIR analysis of Karaya Gum.

FTIR of Cefpodoxime Proxetil with Karaya Gum

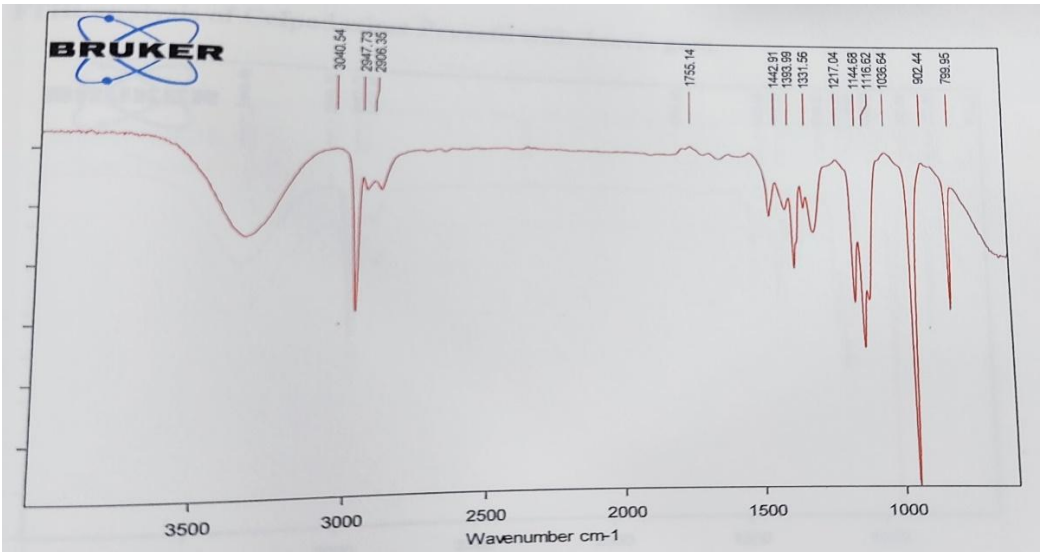

Fig 5: FTIR analysis of Cefpodoxime Proxetil with Karaya Gum.

FTIR of Acacia Gum

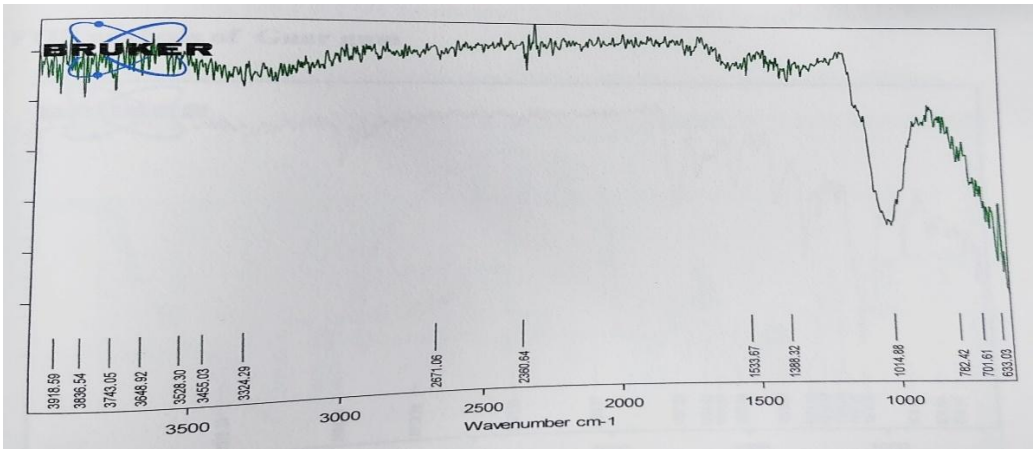

Fig 6: FTIR analysis of Acacia Gum.

FTIR of Cefpodoxime Proxetil with Acacia Gum

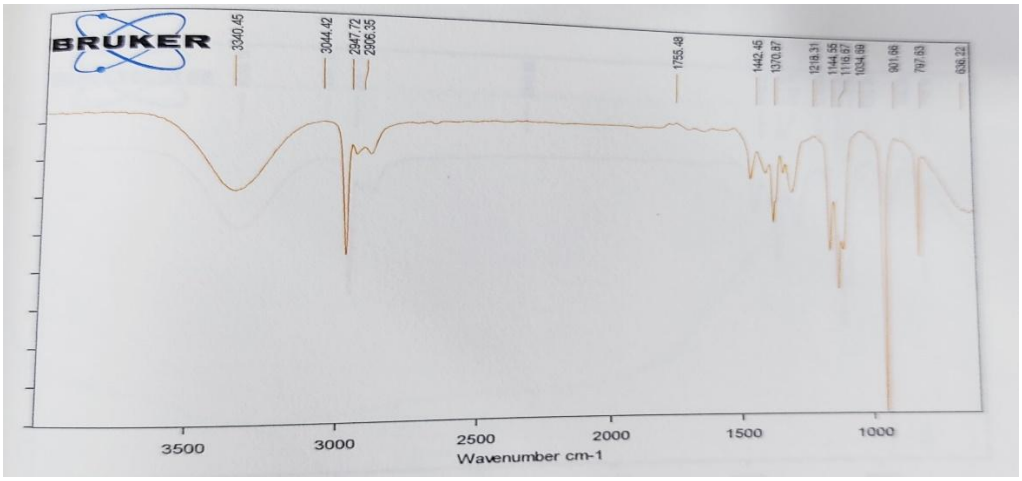

Fig 7: FTIR analysis of Cefpodoxime Proxetil with Acacia Gum.

FTIR of Guar Gum

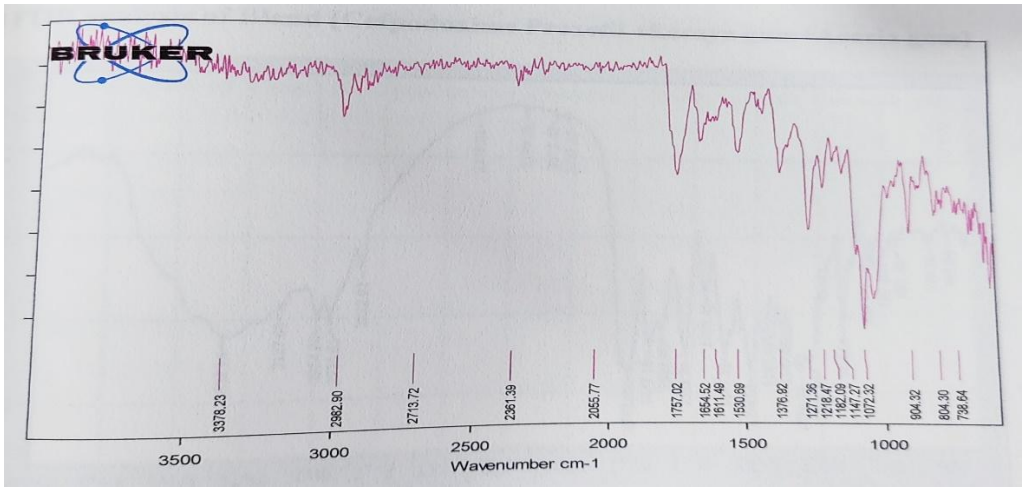

Fig 8: FTIR analysis of Guar Gum.

FTIR of Cefpodoxime Proxetil with Guar Gum

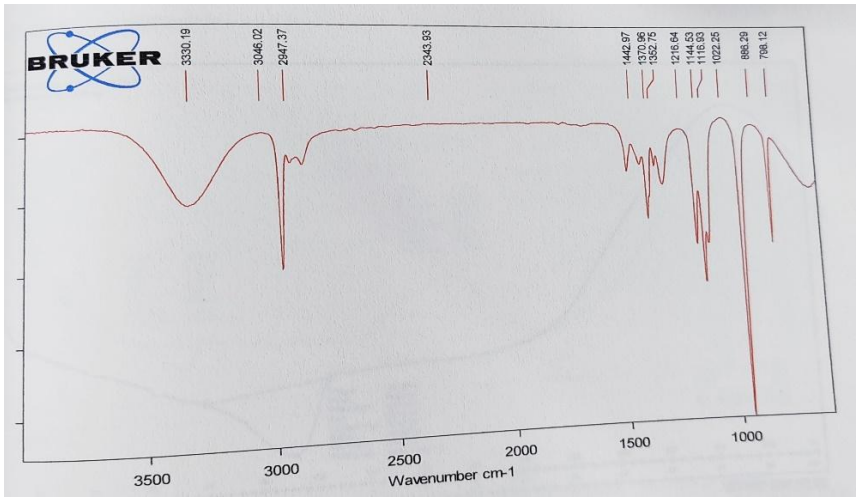

Fig 9: FTIR analysis of Cefpodoxime Proxetil with Guar Gum.

FTIR of Blend (Cefpodoxime Proxetil + Karaya Gum + Acacia Gum + Guar Gum)

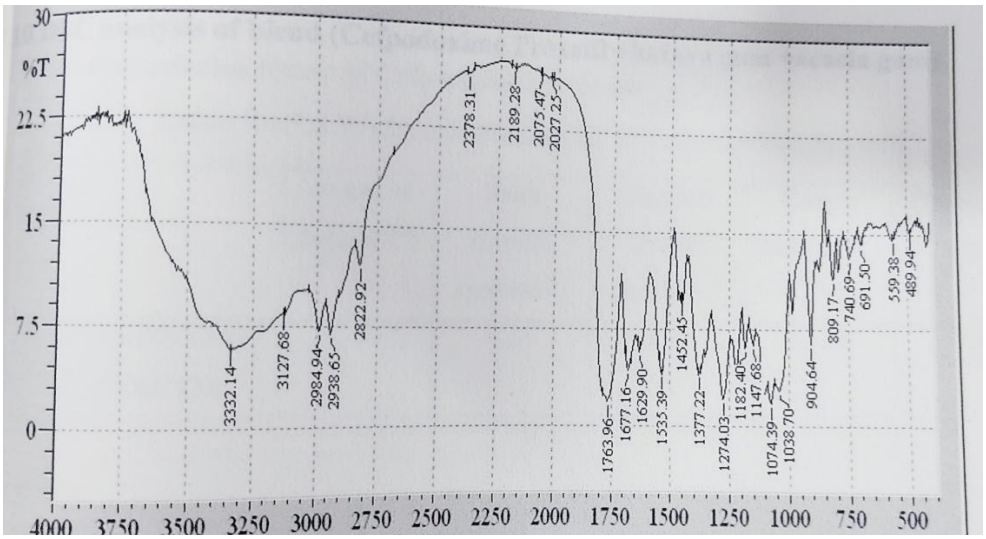

Fig 10: FTIR analysis of Blend (Cefpodoxime Proxetil + Karaya Gum + Acacia Gum + Guar Gum).

DSC Studies

DSC Graph of Cefpodoxime Proxetil (Pure Drug)

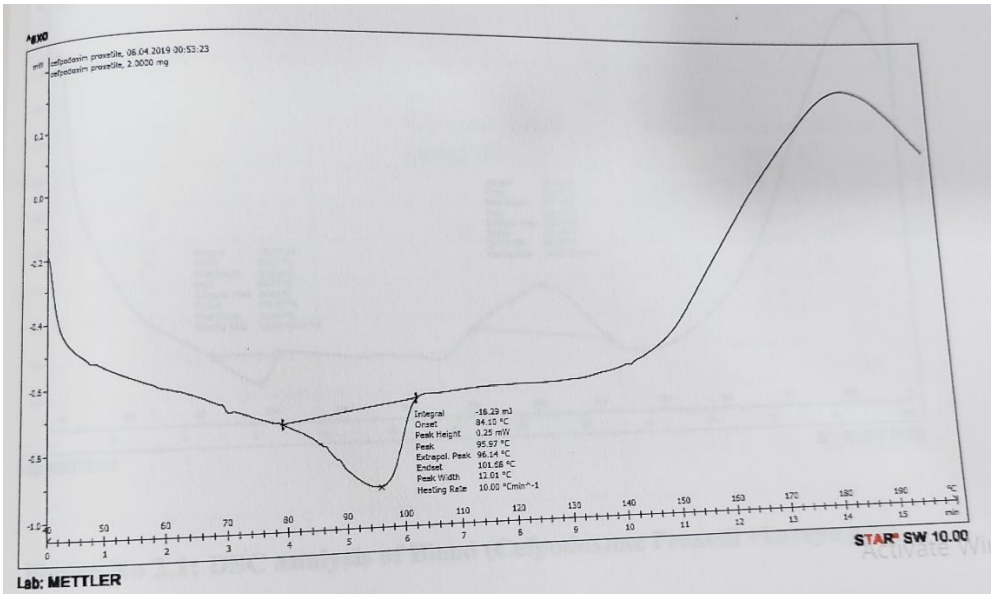

Fig 11: DSC analysis of Cefpodoxime Proxetil (Pure Drug).

DSC Graph of Blend (Cefpodoxime Proxetil + Karaya Gum + Acacia Gum + Guar Gum)

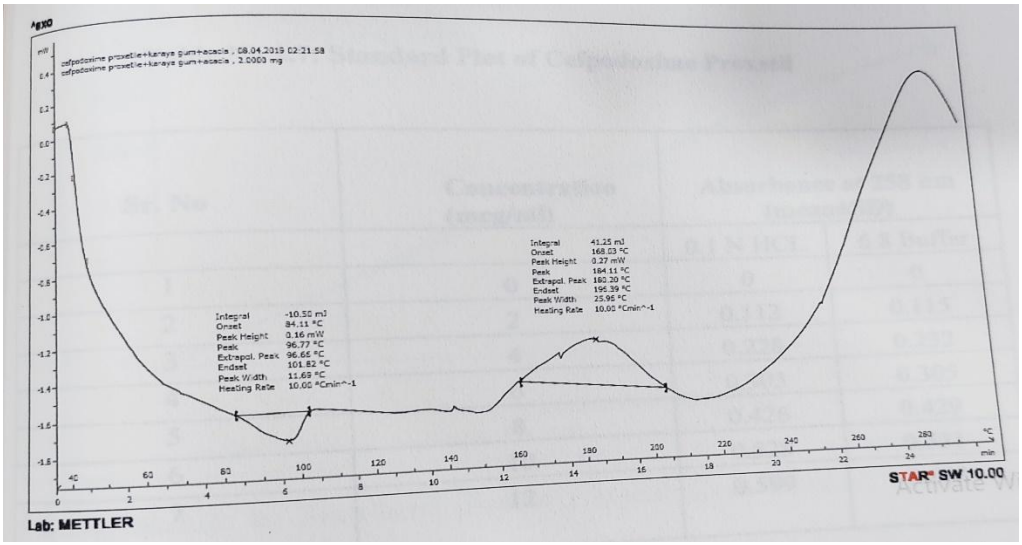

Fig 12: DSC analysis of Blend (Cefpodoxime Proxetil + Karaya Gum + Acacia Gum + Guar Gum).

Evaluation of Sustained release matrix tablets

Appearance: - The tablets were observed visually and did not shown any defects such as Overlapping, Chipping and Lamination.

Post-Compression Parameters: -

Parameters such as Thickness, Hardness, Friability, Weight Variation and Drug Content were conducted on finalized sustained release matrix tablets and all the parameters observed within the standard ranges.

Table 5: Post-Compression parameters of sustained release matrix tablets.

FORMULATION	THICKNESS (n=3) (mm) (SD)	HARDNESS (Kg/cm^2) (n=3) (SD)	FRIABILITY (%) (n=10)	WEIGHT VARIATION (n=20) (mg) (SD)	DRUG CONTENT (%)
F1	2.88 ± 0.1	5.93 ± 0.03	0.78	286 ± 0.4	95.50 ± 0.2
F2	3.96 ± 0.3	8.10 ± 0.04	0.50	288 ± 0.3	97.50 ± 0.4
F3	2.62 ± 0.3	6.02 ± 0.06	0.62	289 ± 0.7	94.51 ± 0.6
F4	2.08 ± 0.2	6.93 ± 0.10	0.67	291 ± 0.1	96.50 ± 0.2
F5	3.47 ± 0.3	9.01 ± 0.06	0.64	289 ± 0.2	93.48 ± 0.8
F6	2.02 ± 0.4	7.53 ± 0.07	0.78	291 ± 0.5	90.49 ± 0.7
F7	3.97 ± 0.3	8.60 ± 0.02	0.50	290 ± 0.2	91.51 ± 0.2
F8	2.76 ± 0.3	6.00 ± 0.02	0.62	287 ± 0.1	92.53 ± 0.2
F9	2.53 ± 0.2	6.99 ± 0.05	0.41	290 ± 0.4	94.51 ± 0.4

In-Vitro Drug release study of optimized batches: -

The In-Vitro dissolution studies of the factorially designed sustained release matrix tablet batches were studied for 12 Hr. and the results obtained were given in the table below.

Table 6: In-Vitro drug release (0-12 Hr.) of optimized formulations (F1-F9).

TIME (Hrs.)	CUMULATIVE % DRUG RELEASE (% CDR)								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
1	1.35	4.50	3.60	4.50	4.50	0.90	2.70	1.80	1.82
2	13.50	11.70	15.30	8.10	9.90	10.80	7.20	8.10	13.50
3	19.80	27.00	20.70	18.90	22.50	17.10	17.10	18.90	17.10
4	38.70	37.80	24.30	25.20	26.10	23.40	22.50	24.30	24.30
5	44.10	43.20	34.20	36.90	34.20	33.30	31.50	32.40	31.50
6	45.90	45.00	40.50	45.00	40.50	36.90	39.60	37.80	40.50
7	61.20	51.30	53.10	49.50	50.40	52.20	44.10	43.20	50.40
8	68.40	62.10	55.80	62.10	61.20	54.00	61.20	59.40	62.10
9	76.50	65.70	71.10	71.10	70.20	67.50	66.60	67.50	66.60
10	84.60	77.40	75.60	79.20	76.50	72.90	77.40	74.70	80.10
11	89.82	89.10	87.30	84.60	88.20	83.70	82.80	85.50	85.50
12	97.20	96.30	95.40	94.50	98.10	93.60	92.70	91.80	90.09

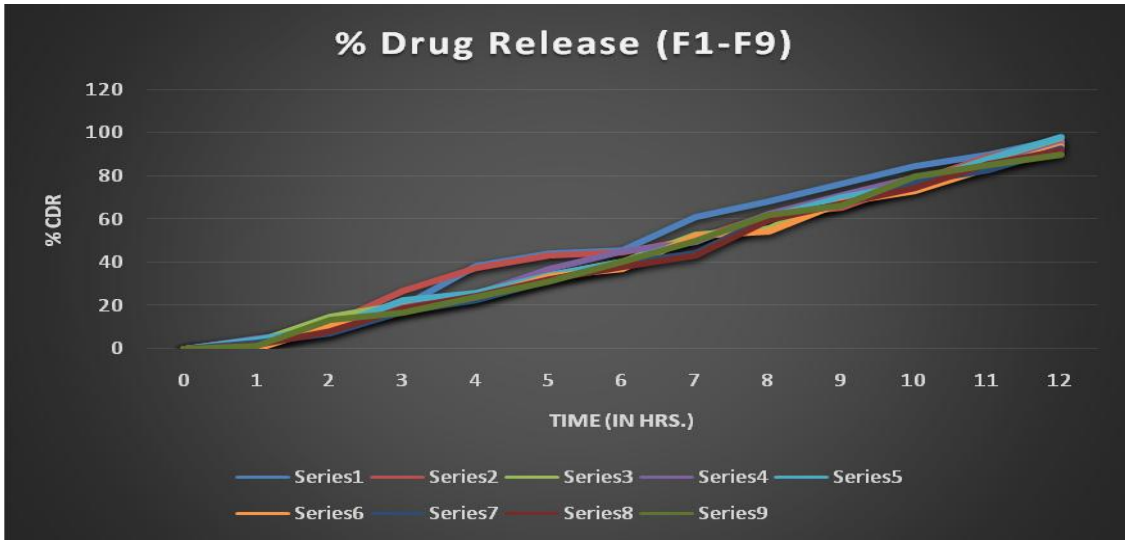

Fig 13: In-Vitro drug release (0-12 Hr.) of optimized formulation (F1-F9).

The release of all formulations was companied and evaluated. The results showed that the formulations give more drug release were considered optimized and further studied for stability studies.

Stability Studies: -

Stability Study is carried out on formulation batch (F5) according to ICH guidelines. The tablet did not show any physical changes during the study period. The drug content was found to be 99.48 ± 1.23 at the end of 3rd month on stability conditions shown in the table below.

Table 7: Stability Study of optimized batch (F5).

TEMPERATURE	TIME (In months)	HARDNESS (Kg/cm^2)	FRIABILITY (%)	DRUG CONTENT (%)	% DRUG RELEASE
40^0 C ± 2^0 C, 75% RH ± 5%RH	0	5.67	0.26	99.55 ± 1.10	98.15 %
40^0 C ± 2^0 C, 75% RH ± 5%RH	3	5.63	0.21	99.48 ± 1.23	98.10 %

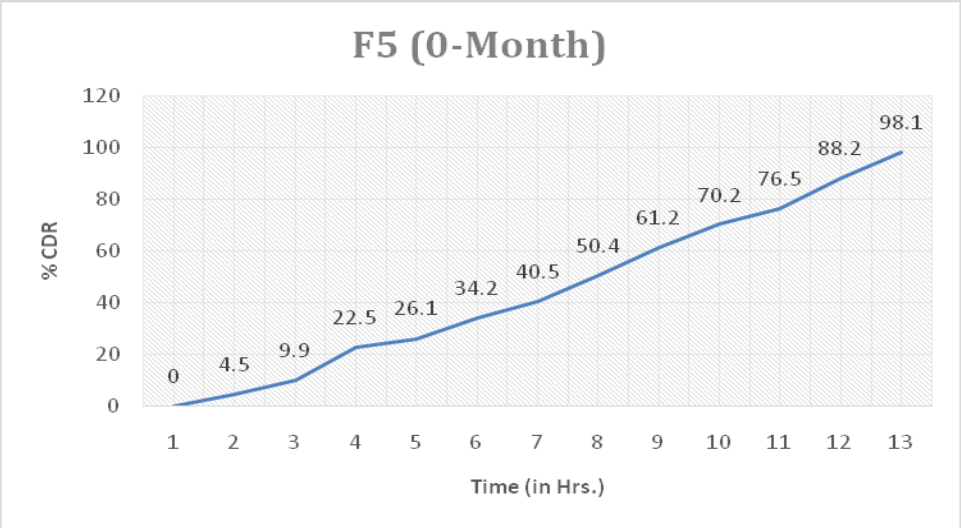

Fig 14: Dissolution profile of Optimized batch (F5) after 0-Month under stability period.

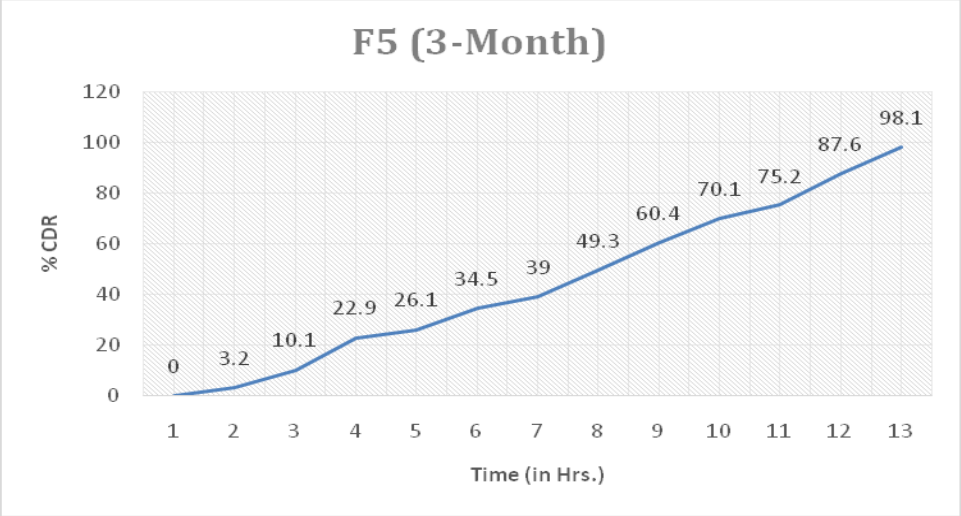

Fig 15: Dissolution profile of Optimized batch (F5) after 3-Month under stability period

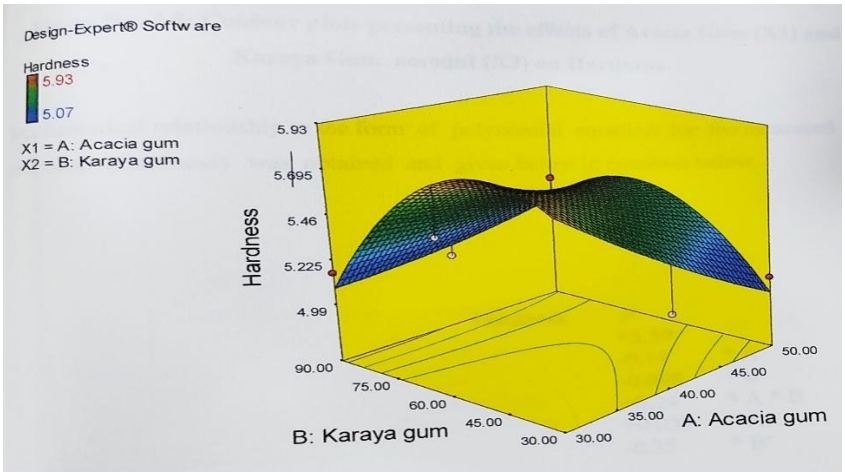

Fig 16: Response surface plots presenting the effects of Acacia Gum (X1) and Karaya Gum (X2) on Hardness.

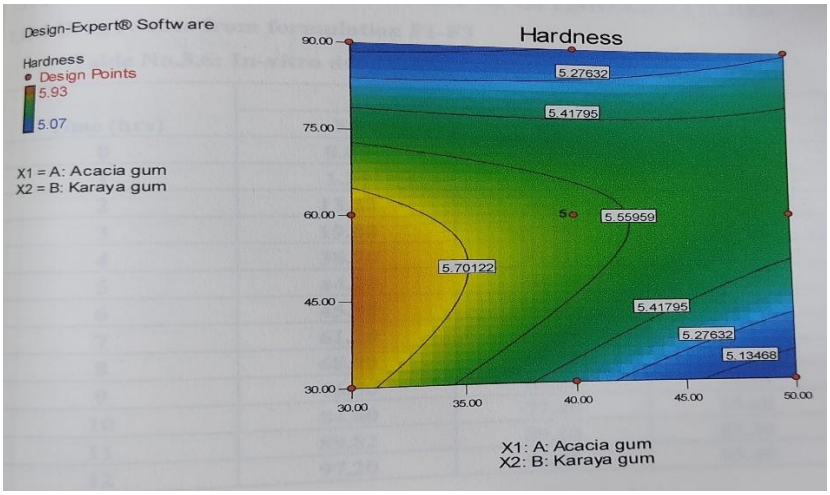

Fig 17: Contour plots presenting the effects of Acacia Gum (X1) and Karaya Gum (X2) on Hardness.

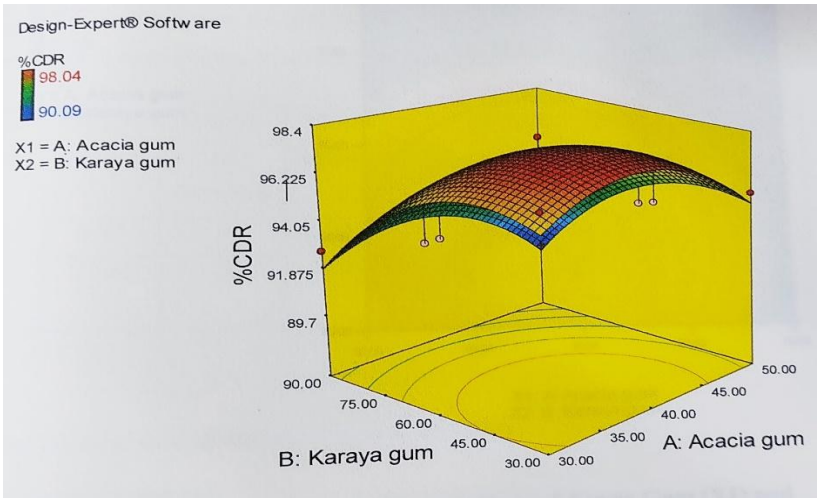

Fig 18: Response surface plots presenting the effects of Acacia Gum (X1) and Karaya Gum (X2) on % CDR.

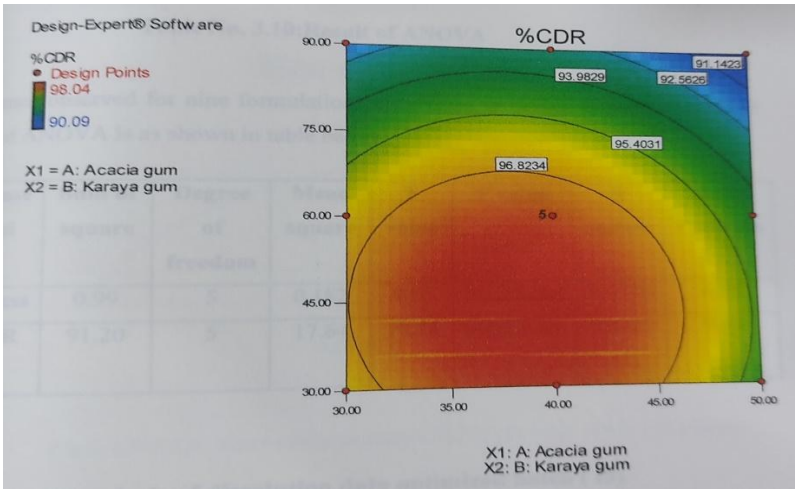

Fig 19: Contour plots presenting the effects of Acacia Gum (X1) and Karaya Gum (X2) on % CDR.

CONCLUSION

The main aim of the study was to formulate, optimize and evaluate sustained release matrix tablets of Cefpodoxime Proxetil by combination of three natural gums found in North Maharashtra Region. The matrix tablets were formulated by using the active pharmaceutical ingredient (Cefpodoxime Proxetil), Karaya Gum, Acacia Gum and Guar Gum in combination and excipients such as Magnesium Stearate, Talc and Lactose were used.

In the study formulation F5 showed satisfactory results in the release of drug in a linear form and so, from the formulations F1-F9 formulation F5 was selected as an optimized formulation because it showed maximum drug release i.e., 98.10 % in 12 Hrs. the studies of FTIR shows that all of the above characteristic peaks of Cefpodoxime Proxetil were observed near their respective standard values. So, it has been concluded that there is no incompatibility between polymers and pure drugs. The preliminary examination of Cefpodoxime Proxetil like its Melting Point obtained in the range from 110-115^0 C by Capillary Tube Method using Thiele's Tube and Liquid Paraffin to check the Melting Point. Calibration curves were taken in 0.1 N HCL pH 1.2 and 6.8 pH Phosphate Buffer at 258 nm by using a dual beam U.V Spectrophotometer. The Post-Compression parameters of formulation like its Hardness, Friability, Thickness, Weight Variation, Drug content uniformity, Surface pH, In-Vitro drug release study have been performed.

The Hardness of Optimized formulation i.e., F5 after 3 months of Accelerated stability studies observed were 5.63, the Friability were 0.21, the Drug Content were 99.48 ± 1.23 and the % Drug release were found 98.10 % at the end of 3rd month accelerated stability studies of optimized batch i.e., F5 and it can be concluded that from the above FTIR and DSC study and Physical observation it can be conclude that there is no significant drug-excipient interaction. So, drug and other excipients are compatible with each other, matrix tablets of Cefpodoxime Proxetil were formulated well in terms of Hardness, Thickness, Weight Variation, Content Uniformity, etc. the matrix tablet of Cefpodoxime Proxetil was prepared by wet granulation technique using different natural polymers such as Karaya Gum, Acacia Gum and Guar Gum in different concentrations. Among all formulations, containing Karaya Gum, Acacia Gum and Guar Gum as natural polymers is fulfilling all the parameters satisfactorily. It has shown excellent, In-Vitro dissolution time. In-Vitro release studies that almost 98.10 % of drug was release from all the formulation were within 12 Hrs. formulation F5 showed sustained drug release within 12 Hrs. compared to other formulations. Drug release rate of best formulation F5 was increase with increasing the rotation speed (50 rpm, 75 rpm, 100 rpm) and also increasing the concentration in dissolution media. Stability Studies were conducted for the F5formulation at 40^0 C ± 2^0 C / 75% RH ± 5% RH for 3 months. Various parameters like Disintegration time, Hardness, Thickness, Drug Content and Dissolution rate were analyzed at a time interval of 1-Month till the period of 3-Months not much variation or change was observed in any parameters throughout the study period. Best formulation batch F5 found to be stable.

Recommended future research.

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