

Development of Oral Controlled Release Matrix Tablets for Antihypertensive Drugs Using Novel Natural and Synthetic form of Gum

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Abstract

Objective: The present work aimed to design and evaluate oral controlled-release matrix tablets using direct compression, with tamarind and fenugreek seed gums both in their natural and chemically modified forms serving as release-retarding agents.

Methodology: Eight formulations of propranolol hydrochloride were prepared, varying the proportions of natural and modified tamarind and fenugreek seed gums. The prepared matrix tablets were subjected to physicochemical and in-vitro release evaluations.

Results: The developed formulations exhibited satisfactory performance. In-vitro drug release profiles demonstrated similarity to marketed controlled-release tablets. Modified fenugreek seed gum (FSG) sustained drug release for approximately 18 hours at a 40% concentration, whereas modified tamarind seed gum (MSG) extended the release up to 24 hours.

Conclusion: The findings confirm that hydrophilic natural polymers and their modified derivatives are effective excipients for developing controlled-release matrix tablets of water-soluble drugs via direct compression.

Keywords: Natural gum, synthetic gum, controlled release tablets, tamarind seed gum, fenugreek seed gum, propranolol hydrochloride, and direct compression.

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1. Introduction

Millions of people worldwide are afflicted with hypertension, also referred to as high blood pressure. Given that it is associated with several adverse effects, including kidney damage, heart attacks, and stroke, it presents a significant risk

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to the public's health. As a result, controlling hypertension effectively is crucial to reducing the prevalence of cardiovascular diseases ("Maciel et al., 2006; Chivate et al., 2008; Nussinovitch, 2009; Vohra et al., 2012; Ali et al., 2013; Baviskar et al., 2013"). The use of antihypertensive medications is one of the main strategies for treating hypertension. By relaxing blood vessels and lowering blood pressure against arterial walls, these medications lower blood pressure. The effectiveness of antihypertensive therapy, however, primarily depends on sustaining steady blood levels of medicine (Thakkar et al., 2009; Thoorens et al., 2014)

Controlled release formulations promote therapeutic efficacy, lessen side effects, and enhance patient compliance by guaranteeing a consistent and continuous release of the active ingredient over an extended period of time (Aulton, 2007). Due to their biocompatibility, biodegradability, and availability, natural and synthetic gums have become viable excipients in pharmaceutical formulations. These gums can be employed in oral controlled release tablets as matrix-forming agents, offering a robust drug delivery platform that can customise the drug release kinetics to fit the necessary therapeutic profile. (Aulton, 2007, Thoorens et al., 2014, Hentzschel et al., 2012).

The physicochemical characteristics of the chosen natural and synthetic gums will be examined in this study, and their potential as matrix-forming agents will be assessed. We will evaluate the medication release profiles *in vitro* and then optimise the formulation to provide the required release kinetics. The findings of this study have great potential for enhancing pharmaceutical technology and hypertension therapy. If successful, the use of natural and synthetic gums in controlled release matrix tablets might revolutionise the distribution of antihypertensive drugs, offering a creative and patient-friendly solution to the difficulties associated with treating hypertension (Fung and Saltzman, 1997). "Controlled-release dosage forms provide a number of benefits including reduced dose frequency, higher compliance, improved therapeutic results, fewer side effects, increased acceptability, and cost-effective therapy," claim Das & Das (2003) and Kamboj et al. (2009). Blending different hydrophilic polymers can enhance their physicochemical and release-modifying properties, producing optimal controlled-release products. The primary objective of the study is to create better formulations of the model medication by modifying the properties of various mixtures of natural hydrophilic polymers to boost the drug's bioavailability.

2. Materials and methods

Materials

Propranolol hydrochloride, the chosen medication, was sent as a free sample by Hiral Labs Limited in Uttarakhand, India. Water-based extraction procedures were used to separate the gums from tamarind and fenugreek seeds. The current study was carried out in partnership with a number of prestigious organisations and focuses on the creation of oral controlled release matrix tablets for antihypertensive medications utilising unique natural and synthetic gum. Microcrystalline cellulose (ACCEL 101) was kindly donated by Indian company Lobacem Pharmaceuticals Pvt. Ltd. for inclusion in the formulation. This top-notch excipient played a significant role in the matrix formulation and helped ensure the regulated release of the active medication.

Separation method of fenugreek seed gum

Fenugreek seeds were gathered and properly cleaned with water to get rid of any impurities or dirt. Drying: After being thoroughly cleaned, the seeds were baked in a hot air oven until they were the right consistency of dry. Crushing: To make the extraction procedure easier, the dried seeds were crushed. The mixture was then cooked for 30 minutes to help completely remove the gum from the seeds after soaking. The boiling liquid was allowed to cool for an hour so that the gum could fully disintegrate into the water. Using a fourfold muslin cloth bag, the solution was purified of any leftover solids (marc) before the gum was extracted from it. In order to precipitate the gum, three times as much ethanol was added to the filtrate. The gum was once again separated into a pure form using a four-fold muslin cloth. In a hot air oven, the collected gum was dried at 40°C. The dried gum was crushed and passed through a #120 filter to produce a fine and uniform consistency. The separated fenugreek gum was stored in a desiccator at 30°C and 45% relative humidity until it was time to utilise it (Brummer et al., 2003, Reddy et al., 2012, Shukla et al., 2019).

Separation method of tamarind seed gum

The tamarind seeds were soaked in water for 12 hours. To encourage the release of gum into the water after soaking, boil the crushed seeds in water for 30 minutes. To guarantee that the gum is completely released into the water, let the mixture remain for an hour. To filter the mixture and separate the gum from the marc (solid residue), use a four-fold muslin cotton bag. "To precipitate the gum, add ethanol to the filter at a ratio of three times the volume of the filtrate. To separate the precipitated gum from the liquid, filter the mixture once again using a four-fold muslin towel. On a tray, spread out the gathered gum and dry it in a hot air oven at 40°C. Use a #120 sieve to grind the dry gum into a fine powder. Until it is time to utilise it, keep the ground gum in a desiccator at 30°C and 45% relative humidity. You may effectively separate tamarind seed gum from tamarind seeds by following these methods." was stated by (Brummer et al., 2003, Reddy et al., 2012, Shukla et al., 2019).

The process for creating a synthetic version of isolated gum with sodium trimetaphosphate (STMP) was as follows:

Separately, 50 ml of distilled water was added to each beaker to dissolve one gramme of STMP and one gramme of natural gum. The natural gum solution was first made, and then 5 ml of 0.1 N NaOH was added while stirring. Two hours were

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spent stirring the 100 ml reaction solutions in each of the two beakers. The mixtures were stirred, then put into petri dishes and dried at 60°C for 24 hours. The dried compound (synthetic gum) was then ground into a fine powder and put through a #120 aperture sieve. Utilising this synthetic gum powder, controlled release matrix tablets were created. (Brummer et al., 2003, Reddy et al., 2012, Shukla et al., 2019).

FTIR analysis of separated gums and their synthetic form

A potent analytical method used to examine the chemical make-up and molecular structure of many compounds, including natural gums and their synthetic varieties, is Fourier Transform Infrared (FTIR) spectroscopy. FTIR analysis is essential for identifying the chemical alterations that take place during gum modification and formulation for creating oral controlled release matrix tablets for antihypertensive medications.

X-ray diffraction analysis (XRD) of separated gums and their synthetic form

Another effective analytical method for examining the crystallographic structure and crystallinity of materials is X-ray Diffraction Analysis (XRD). In the context of researching natural gums and their changed forms for the creation of oral controlled release matrix tablets, XRD analysis can offer insightful data regarding the modifications to the gums' physical structure. The crystalline makeup of native and synthetic gums was evaluated using X-ray diffraction (XRD). The X-ray diffraction spectra were compared. The XRD spectra of natural and synthetic gums are shown in Figure No. for FSG 6, TSG 7, MFSG 8, and MTSG 9, respectively (Reddy et al., 2012; Shukla et al., 2019).

Drug and excipients interaction studies

Studies on the interactions between drugs and excipients are essential for pharmaceutical development, particularly when creating pharmacological formulations like tablets, capsules, or other dosage forms. These studies evaluate how well the formulation's excipients and active pharmaceutical ingredient (API) get along. To guarantee the final pharmaceutical product's safety, stability, and effectiveness, it is crucial to comprehend drug-excipient interactions. Here are some crucial elements of research on how drugs and excipients interact: It was determined and analysed if various pharmacological peaks existed in the excipients' FTIR spectra, both singly and in combination. Figs. 1 to 5 display the FTIR spectra of the PRPL medicine both with and without excipients. The DSC thermogram of the medication propranolol HCl is depicted in Figure (DSC spectra of PRPL 12–13) in both its pure and excipient-containing forms as reported by Reddy et al. (2012) and Shukla et al. (2019).

Formulation of controlled release matrix tablets

In the formulations, fenugreek gum and tamarind seed gum are both utilised in various proportions. A number of medications and polymer ratios use it. The ratios of each diluent, including lactose, gum, and medicine, are shown in Table No. 1. The powder mixtures made it through a sieve with a 100-size opening. The blends mixture :1 was mixed for 20 minutes. After blending, mixtures were run through sieve number 12. After that, talc and magnesium stearate were added to the bulk of the mixed goods. The final blended mixed material was compressed into tablets using a 12mm die single tablet punching machine. The typical weight of a pill was set at 500 mg.[10-12].

Evaluations of powder blend

The flow characteristics of a powder mix were assessed using the angle of repose, the Carr's index, the Hausner's ratio, and other metrics. The results are shown in Table.

Evaluation of controlled release matrix tablets formulation

The produced controlled release matrix tablets were evaluated for the drug content, weight variation, hardness, thickness, and friability in accordance with official protocols. Table 3 displays the results.

In Vitro Dissolution study

An in-vitro drug release experiment was conducted using a six station USP XXVII type II (paddle) equipment for the produced SRMT. At a temperature of 37.0°C plus 0.5°C, the tests were conducted for 12 hours. For the first two hours, 0.1N HCL and a paddle speed of 50 rpm were used. After then, Phosphate Buffer Solution, pH (PBS) was used as a simulated dissolving medium till the end of the investigation. There were three different in-vitro drug release dissolution studies carried out. A 10 ml sample of the material was obtained and filtered over a predetermined period of time using filter paper. It was then properly diluted with a fluid-like media before being spectro-photometrically UV scanned at 248 nm. Cumulative percent cumulative drug release rate for the formulation and medication. The formulation and medication's cumulative percent cumulative drug release rate. The outcomes are displayed in Figure 5.

Dissimilarity and Similarity Factors

The formulation and medication's cumulative percent cumulative drug release rate. The outcomes are displayed in Figure 5.

$$f1 = 100*(Rt-Tt)/ Rt$$

Where Rt and Tt are the average percent of the reference and test products' dissolution, respectively.

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The logarithmic reciprocal square root conversion of one is added to the mean squared difference in the percentage of dissolved matter between the test sample and the reference products to arrive at the similarity factor (f_2). The computation is used to compare the test sample to the reference release profile.

$$f_2 = 50 \times \log_{10} \left\{ 100 / \left[1 + 1/n \times \sum (R_t - T_t)^2 \right] \right\}$$

Where n = number of sampling points release data were curve fitted using PCP disso software.

Stability studies

The produced 100 mg propranolol controlled release tablet was kept in bottles and kept at two different temperatures and relative humidity levels: 250°C and 60% and 400°C and 75%. The physical features of the tablets, such as their thickness, hardness, friability, percentage of drug content, and drug release profile, were evaluated after three months.

3. Results and discussions

“The gum produced from tamarind seeds (TSG) and fenugreek seeds (FSG) yielded 18.90% and 25% w/w gum, respectively, after the hot water extraction and ethanol treatment. Rutinium red identification tests on the separated gum samples were performed, and they were then dissolved in hot distilled water. The particles dyed pink when stained with ruthenium red, and a gelatinous mass resulted, demonstrating the presence of a polysaccharide in nature. All additional assays also supported the polysaccharide identity of the separated gums.

The chemical nature of isolated natural gum was studied using infrared spectroscopy on the separated gums (FSG and TSG). The major peaks at “1036 cm^{-1} (representing the C-O-C ether group), 1637–1655 cm^{-1} (CH OH stretching vibration), 2924 cm^{-1} (C-H aliphatic stretching), 3356 cm^{-1} (O-H glucan backbone), and 1053 cm^{-1} (CH stretching vibration). In Fig. 1, 2 and 3, the FTIR spectra of FSG and TSG are shown.”

For (MFSG), “infrared spectroscopy tests were carried out. The main MFSG peaks were located at 3923.98 and 3819.08 cm^{-1} , 3731.70–3564.26 cm^{-1} , 2931.57–2863.56 cm^{-1} , 1848.09 cm^{-1} , 1687.44–1634.38 cm^{-1} , 1549.39–1516.11 cm^{-1} , 1097.07 cm^{-1} , 1279.78 cm^{-1} , and 1279.78 cm^{-1} . 989.52 cm^{-1} , 689.98–647.0 cm^{-1} . O-H free hydroxyl alcohol, N-H stretching, OH alcohol free, C-H stretching, C=O stretching, C=C stretching, C-H methyl stretching, C-O alkyl aryl ether, C-O primary alcohol, C=C bending Alkenes, and C-H of alkenes are all present in the range of 92 cm^{-1} , respectively.

The synthetic tamarind seed gum (MTSG) “was the subject of experiments using infrared spectroscopy. The extended peak that appeared at 3564 cm^{-1} may be recognised because the O-H stretching band in synthetic gum and the N-H stretching band of the amide group overlap. Acetyl groups of peaks were seen to disappear in synthetic TSG and FSG gum. As seen in Figure 5's FTIR spectra of MTSG, the existence of new peaks lacking in the natural gum is related to Phosphate-II (-C-O bending) of the phosphate group of STMP, demonstrating the occurrence of the cross-linking reaction. The outcomes are displayed in Fig. 4 and 5.”

The surface characteristics of both naturally occurring and artificially produced tamarind and fenugreek gum were investigated using X-ray diffractogram (XRD) analysis. The XRD of the natural material displays a noticeably rough surface as compared to synthetic natural gum with holes and cracks. The fact that the particle sizes of the powders were not uniform and that their size distribution did not fall inside a particular range is clear. The gum powder contains a range of particle sizes. This could explain why the gum particles are “heavy.” Gum granules are packed in a ‘closet’ pattern to minimise bulk, with the smaller particles filling in the crevices between the larger ones. The low porosity values also point to this packing structure. The poor flow properties of the FSG and TSG might possibly be attributed to the tight packing. The surface characteristics of natural (FSG, TSG), synthetic (MFSG, MTSG), and synthetic gums were studied using the gum's XRD spectrum. In contrast to natural gum that had been altered to have cracks and fissures on it, the XRD spectra of natural FSG and TSG exhibited very rough surfaces. These XRD spectra are shown in Fig. 6, 7, 8, and 9.

On pure medicines PRP, studies utilising infrared spectroscopy were conducted. The four main peaks of propranolol HCl are located at 3274 cm^{-1} , 2803 cm^{-1} , 1265 cm^{-1} , and 823 cm^{-1} , and they represent the secondary hydroxyl group, secondary amine group, aryl alkyl ether, and substituted naphthalene, respectively. The FTIR spectra of propranolol HCl are shown in Table No. 10. Infrared spectroscopy tests were performed on pure medicines PRP, pure polymers, and combinations of medications and excipients to ensure compatibility. Peaks at 2979 cm^{-1} , 3279 cm^{-1} , 1265 cm^{-1} , and 799 cm^{-1} were seen in the FTIR tests, indicating that there was no chemical interaction between propranolol HCl and the excipients.”

The only peaks that could be seen in the FTIR spectra of propranolol HCl with excipients were functional groups of distinguishable peaks. The mixing spectra showed a single recognisable peak. It demonstrates that the excipient compatibility of the medicine (propranolol HCl) was satisfactory. FTIR spectra are shown in Fig. 10 and 11.

Another DSC was performed to look for any possible drug-gum interactions. Drug-excipient interactions were not detected in thermograms. The DSC curve for the pure drug propranolol HCl was obtained using a DSC at a heating rate of 1000°C/min from 30 to 350 °C in a nitrogen atmosphere (30 mL/min). Analysing the collected thermograms allowed us to determine the temperature required to melt both the pure substances and the physical mixtures. There was no transition of the thermogram from an endothermic to an exothermic condition. The DSC results provide assurance that drugs and excipients are compatible.”

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PRP with excipients' DSC thermogram is shown in Figure (DSC spectra of PRP, 12–13). “Controlled release propranolol HCl matrix tablets produced by the direct compression technique were evaluated for a variety of parameters, including angle of repose, bulk density, tapped density, Carrs index, and hausner ratio. The values of these characteristics were the angle of repose (°) 24.4-29.410.12, bulk density (g/cm³) 0.510-0.6060.05, tapped density (g/cm³) 0.612-0.7530.04, Carrs index (%) 17.88-24.320.22, and Hausner ratio 1.18-1.280.01.” The results of the parameter evaluation mirrored the characteristics of blends. They were found to be within acceptable limits. The results are shown in Table 2.

The controlled release matrix tablets containing water soluble model medications were produced using the direct compression technique. Eight different powder formulations of controlled release propranolol HCL were created by varying the ratios of TSG, FSG, MTSG, and MFSG. Following assessment criteria, including thickness, hardness, weight fluctuation, friability, and drug content, were used to assess compressed sustained release matrix tablets. The sustained release matrix tablets formulation has a hardness value that ranged from 4.1.±0 0.06 to 5.6 0.08 kg/cm². The hardness value rises as the concentration of mucilage, both natural and synthetic, does. Friability is another indicator of tablet strength; in the current study, it was less than 1%, which indicates that it was within pharmacopoeia limits. The results are shown in Table 3.

The swelling profile for several batches of controlled release propranolol HCL matrix tablets is shown in Table 4. “The swelling state of the polymer (in the formulation) has been hypothesised to be crucial for its bioadhesive activity. After swelling begins, adhesion develops quickly, but there isn't a particularly strong bond formed between the mucosal layer and the polymer. The amount of hydration increases adhesion up to a certain extent before disentanglement at the polymer/tissue interface produces a sudden fall in adhesive strength. The swelling index increases together with the concentration of natural gum polymer, the findings show. The swelling index of the bilayer matrix tablets was found to be maximum for formulations F, E, G, and H, respectively.” Table 4 presents the findings. A 20% gum concentration of tamarind and fenugreek clearly controlled the drug release for up to 14 hours and 10 hours, respectively, according to the in-vitro drug release experiment.

Tamarind and fenugreek prevented the release for 17 hours and 12 hours, respectively, at greater gum concentrations, i.e. 40%. When applied at a 20% gum concentration, synthetic tamarind seed gum and fenugreek seed gum controlled release for up to 8 hours in the case of the former and up to 12 hours in the case of the latter.

For up to 24 hours, the discharge was under control. The results of studies on release rates are shown in image number 14 and table number 7.

Stability studies

Accelerated stability tests proved that the produced tablets' quality might change over time as a result of environmental factors including temperature and humidity. According to this classification, the accelerated stability research was conducted for six months in a chamber with humidity levels of 40% and 25% at 25°C. The results that were acquired are shown in Table 7.

4. Conclusion

The results of the investigation have shown that “the light tamarind and fenugreek seed gum powder possesses the required physicochemical properties to be employed as a direct compression excipient.” It was successful to combine three hydrophilic polymers in various ways to create controlled release matrix tablets that contained propranolol HCL. Drug release from water-soluble propranolol HCL has been investigated. The study emphasises the complexity of pharmacological formulations, the lack of a universal formulation, and the necessity of assessing each medicine individually.

Authors Contribution

This article's primary author, Ajay Kumar Shukla, conducted the research for it. The remaining writers each made an equal contribution, including formatting and drafting

Ethics Approval Statement

Not required

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Nil

Conflict of interest

Nil

Table: 1: “Formulation Table

S.N.	Bat.	Propranolol	TSG	FSG	MTSG	MFSG	Lactose	Mg. Stearate	Total
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1	A	65	80				150	5	300
2	B	65		80			150	5	300
3	C	65			80		150	5	300
4	D	65				80	150	5	300
5	E	65	160				70	5	300
6	F	65		160			70	5	300
7	G	65			160		70	5	300
8	H	65				160	70	5	300

“All the quantities were taken in mg”

Table: 2 Evaluation of blend for controlled release propranolol HCl matrix tablets

Parameter s	A-TSG	B-FSG	C-MTSG	D-MFSG	E-FSG	F-TSG	G-MFSG	H-MTSG
Angle of repose (θ)	28.98 \pm 0.3	28.05 \pm 0.3	26.6 \pm 0.12	24.60 \pm 0.7	28.7 \pm 0.10	29.41 \pm 0.1	23.9 \pm 0.21	24.4 \pm 0.4
Bulk density (g/cm ³)	0.510 \pm 0.0	0.601 \pm 0.0	0.578 \pm 0.0	0.550 \pm 0.0	0.540 \pm 0.0	0.560 \pm 0.0	0.600 \pm 0.0	0.606 \pm 0.0
Tap density (g/cm ³)	0.656 \pm 0.0	0.753 \pm 0.04	0.718 \pm 0.0	0.648 \pm 0.01	0.680 \pm 0.0	0.740 \pm 0.0	0.742 \pm 0.0	0.738 \pm 0.0
Carrs index (%)	22.25 \pm 0.1	20.18 \pm 0.3	19.49 \pm 0.2	15.12 \pm 0.1	20.58 \pm 0.1	24.32 \pm 0.2	19.13 \pm 0.3	17.88 \pm 0.4
Hausner ratio	1.28 \pm 0.01	1.25 \pm 0.01	1.24 \pm 0.05	1.2 \pm 0.09	1.26 \pm 0.01	1.32 \pm 0.02	1.23 \pm 0.02	1.21 \pm 0.06

“(Mean \pm SD, n = 3)”

Table: 3 Evaluation of controlled release propranolol HCl matrix tablets

Parameter s	A-TSG	B-FSG	C-MTSG	D-MFSG	E-FSG	F-TSG	G-MFSG	H-MTSG
Hard. (Kg/cm²)	5.5 \pm 0.3	4.5 \pm 0.3	4.4 \pm 0.2	4.1 \pm 0.6	5.2 \pm 0.3	5.62 \pm 0.8	5.0 \pm 0.7	5.3 \pm 0.3
Friability (%)	0.33 \pm 0.02	0.37 \pm 0.01	0.36 \pm 0.09	0.38 \pm 0.0	0.31 \pm 0.01	0.30 \pm 0.0	0.38 \pm 0.07	0.33 \pm 0.07
Average Weight (mg)	401.72 \pm 0.	397.04 \pm 0.	403.75 \pm 0.	386.4 \pm 0.3	401.88 \pm 0.5	402.2 \pm 0.	413.64 \pm 0.	401.64 \pm 0.
Drug content	96.60 \pm 0.5	96.41 \pm 0.1	97.30 \pm 0.2	98.18 \pm 0.	97.70 \pm 0.5	97.82 \pm 0.	98.47 \pm 0.2	99.82 \pm 0.5

(Mean \pm SD, n = 3)

Table: 4 Swelling Index of controlled release propranolol HCl matrix tablets

Time	A	B	C	D	E	F	G	H
2	81.8%	64.7%	67.34%	74.59%	95.7%	99.57%	89.9%	77.01%
4	97.35%	98.8%	74.39%	89.4%	144.93%	198.98%	105.90%	84.08%
6	123.6%	119.1%	93.31%	152.10%	189.27%	343.84%	131%	1411.48%
8	167.4%	136.03%	106.1%	105.51%	201.66%	301.08%	175.03%	188.0%

Table: 5 Cumulative % drugs released from controlled release propranolol HCl matrix tablets

HRS	A-TSG	B-FSG	C-MTSG	D-MFSG	E-FSG	F-TSG	G-MFSG	H-MTSG	I-MRK
0	0	0	0	0	0	0	0	0	0
1	21.26±0.8	28.8±0.9	23.81±0.1	57.37±0.1	22.5±0.6	19.12±0.	22.94±0.8	18.14±0.8	4.75±0.34
2	29.99±0.1	41.25±0.	49.87±0.1	66.32±0.7	41.12±0.	25.87±0.	29.91±0.11	23.25±0.7	6.9±0.15
4	41.54±0.9	62.95±0.	57.04±0.6	81.25±0.8	70.03±0.	32.5±0.7	38.26±0.10	31.12±0.3	14.81±0.8
6	58.75±0.1	76.70±0.	73.15±0.6	94.5±0.6	86.3±0.2	58.62±0.	47.4±0.6	38.62±0.10	29.5±0.8
8	68.62±0.8	84.17±0.	88.8±0.7	95.11±0.2	91.1±0.1	67.40±0.	56.96±0.15	46.93±0.12	34.43±0.7
10	81.57±0.1	89.3±0.2	93.70±0.5	96.7±0.8	96.82±0.	71.6±0.3	68.92±0.14	57.81±0.9	49.56±0.11
12	95.19±0.1	99.5±0.6	97.49±0.1	96.7±0.8	97.38±0.	78.95±0.	75.53±0.12	65.10±0.11	57.12±0.13
14	97.17±0.8	99.5±0.6	99.81±0.9		99.25±0.	84.32±0.	86.66±0.14	72.5±0.6	63.75±0.16
16	98.13±0.4		99.81±0.9		99.25±0.	88.27±0.	97.98±0.16	81.62±0.7	71.5±0.4
17	98.13±0.					90.35±0.	98.82±0.10	91.17±0.18	78.11±0.11

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18						96.7±0.9	98.82±0.10	95.62±0.9	80.62±0.2
19						99.41±0.5		97.62±0.8	86.37±0.3
20						99.41±0.5		98.03±0.17	90.62±0.7
22								98.79±0.17	94.68±0.8
24								98.79±0.17	97.8±0.7

Table: 6 In-vitro drug release kinetic studies of controlled release propranolol HCl matrix tablets

Batches	Zero-order	First-order	Higuchi	Korsmeyer-Peppas	Hixson-Crowell
Regression values	R0	R1	RH	RK	RH
A	0.934	0.937	0.776	0.982	0.978
B	0.792	0.801	0.691	0.962	0.910
C	0.794	0.880	0.674	0.960	0.959
D	0.530	0.779	0.585	0.800	0.723
E	0.722	0.977	0.682	0.922	0.933
F	0.913	0.991	0.786	0.973	0.980
G	0.968	0.790	0.768	0.975	0.921
H	0.975	0.971	0.973	0.793	0.988
I	0.991	0.978	0.958	0.905	0.988

Table: 7 Stability studies of controlled release propranolol HCl matrix tablets

S. No.	Stability parameter	At 25°C/60% RH			At 40°C/75% RH		
		Initial	3 month	6 month	Initial	3 month	6 month
1	Drug content	96.2±0.09	95.7±1.4	95.9±1.2	97.0±1.2	96.3±0.5	95.8±1.0
2	Hardness	6.00±0.2	5.7±0.4	5.1±1.2	5.2±1.15	4.7±0.5	4.2±0.5
3	Friability	0.24±0.3	0.41±0.4	0.53±0.25	0.40±0.5	0.52±0.4	0.61±0.5

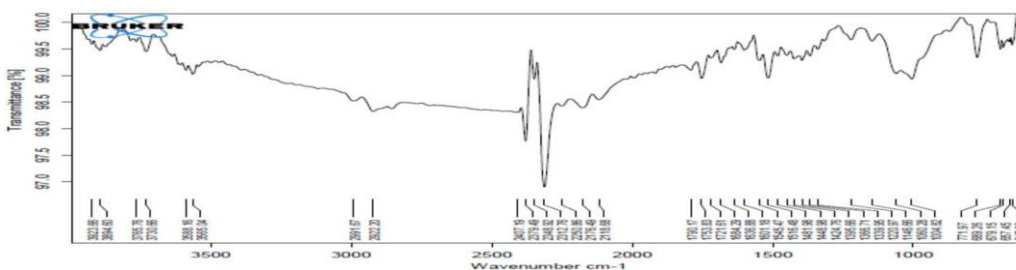


Figure: 1 FTIR analysis of fenugreek gum

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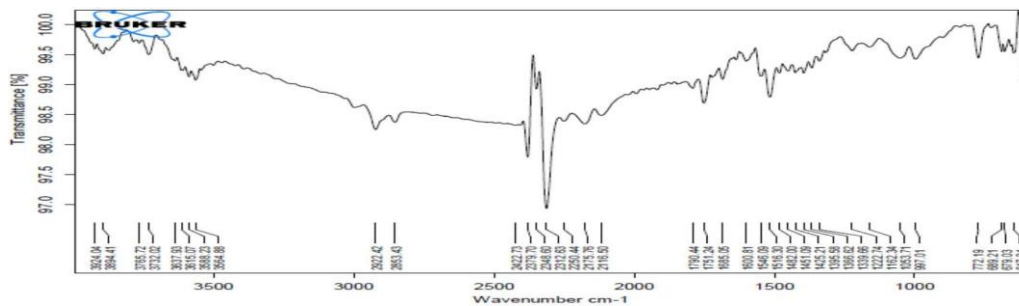


Figure: 2 FTIR analysis of tamarind gum

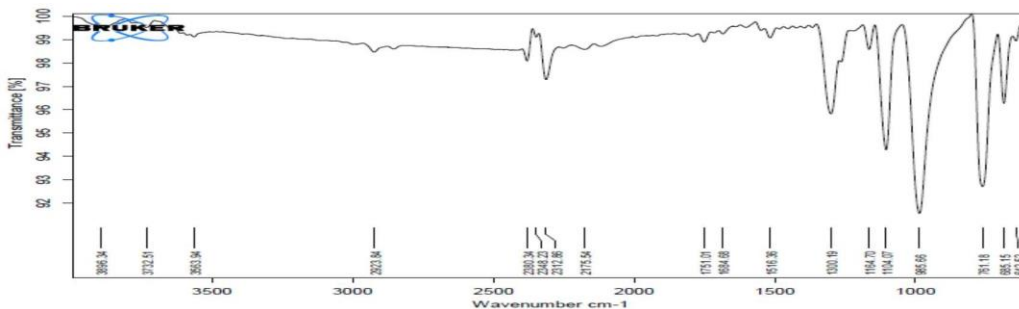


Figure: 3 FTIR analysis of STMP

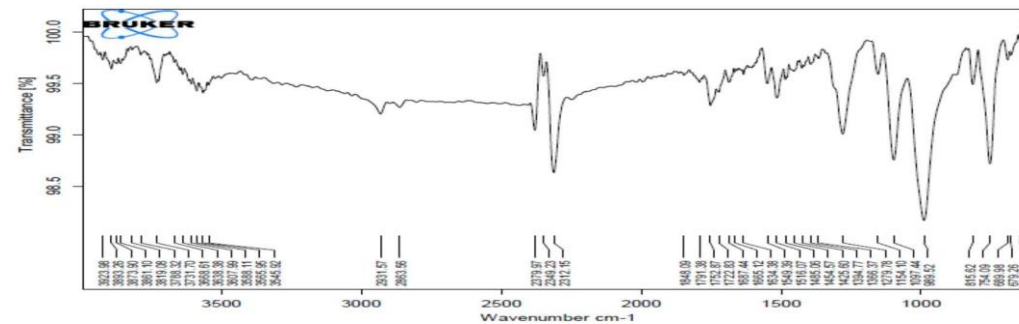


Figure: 4 FTIR analysis of synthetic form of fenugreek seed gum

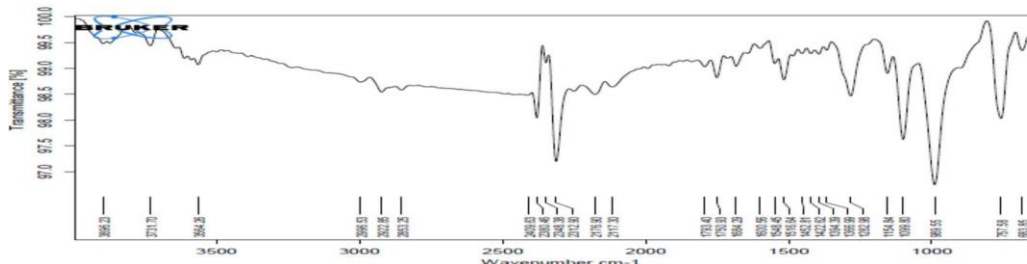


Figure: 5 FTIR analysis of synthetic form of tamarind seed gum

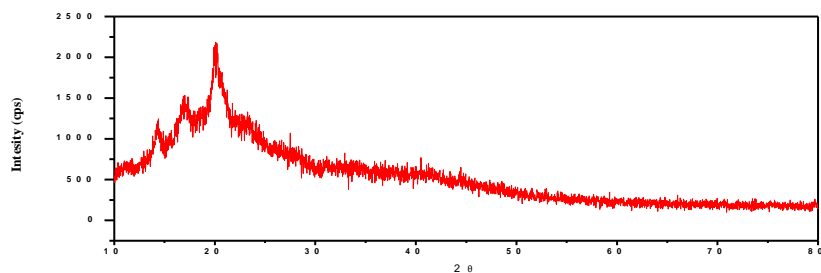


Figure 6. XRD analysis of fenugreek seed gum

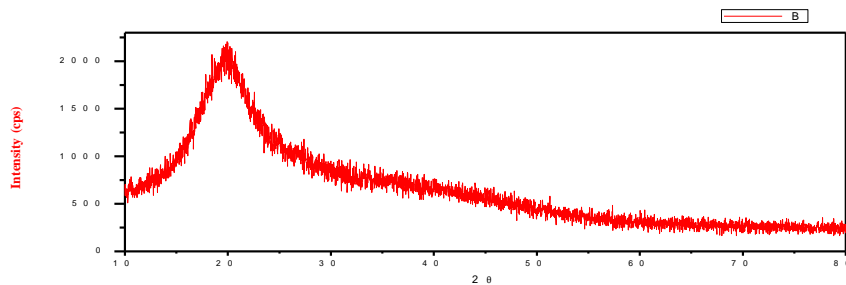


Figure 7. XRD study of tamarind seed gum

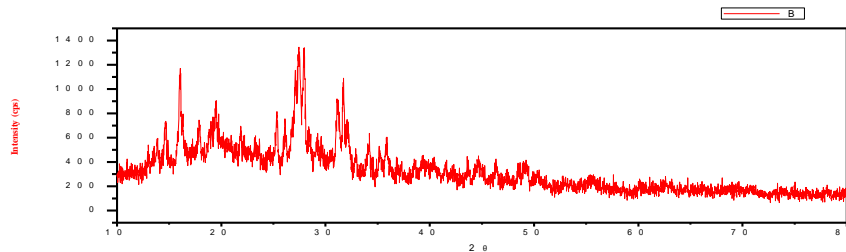


Figure 8. XRD study of fenugreek seed gum in synthetic form

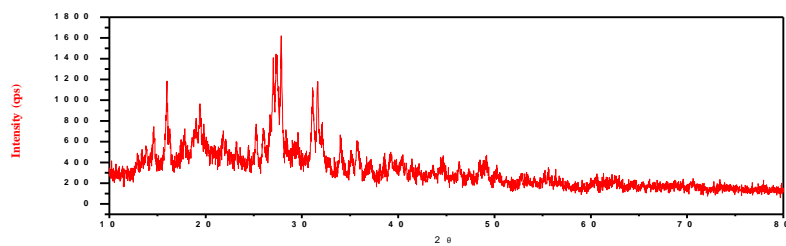


Figure 9. XRD study of tamarind seed gum in synthetic form

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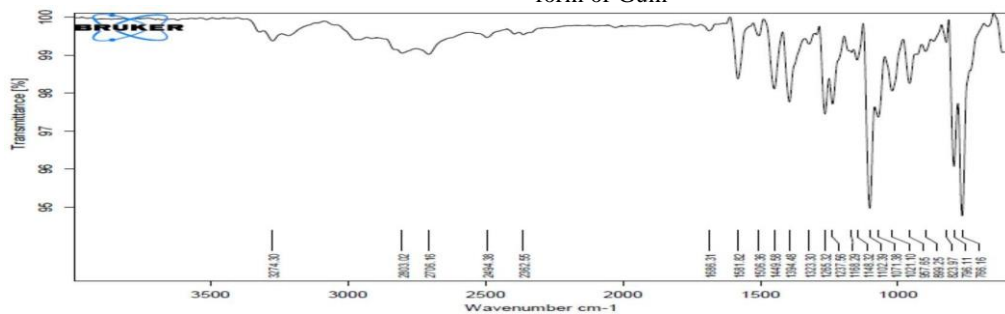


Figure: 10 FTIR analysis of propranolol HCl

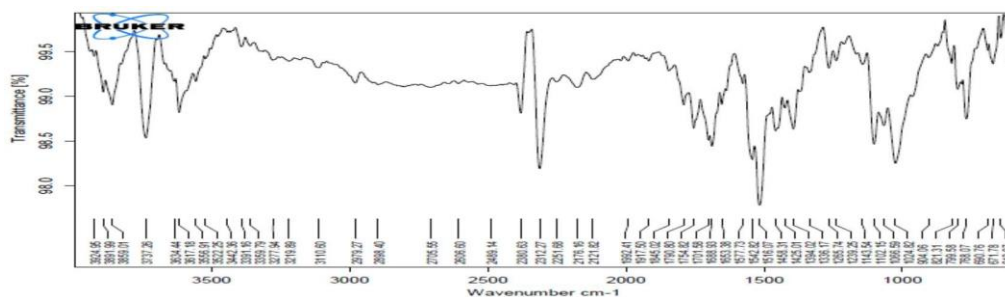


Figure: 11. FTIR analysis of propranolol HCl and excipients

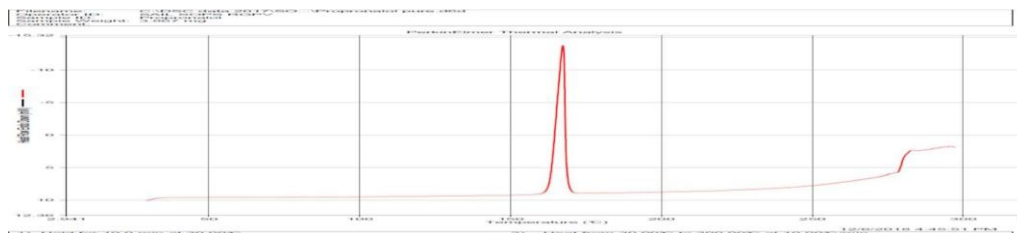


Figure: 12. DSC analysis of propranolol HCl pure

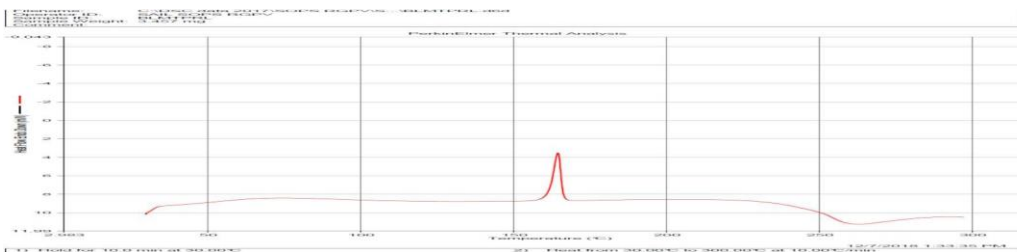


Figure: 13. DSC analysis of propranolol HCl with excipients

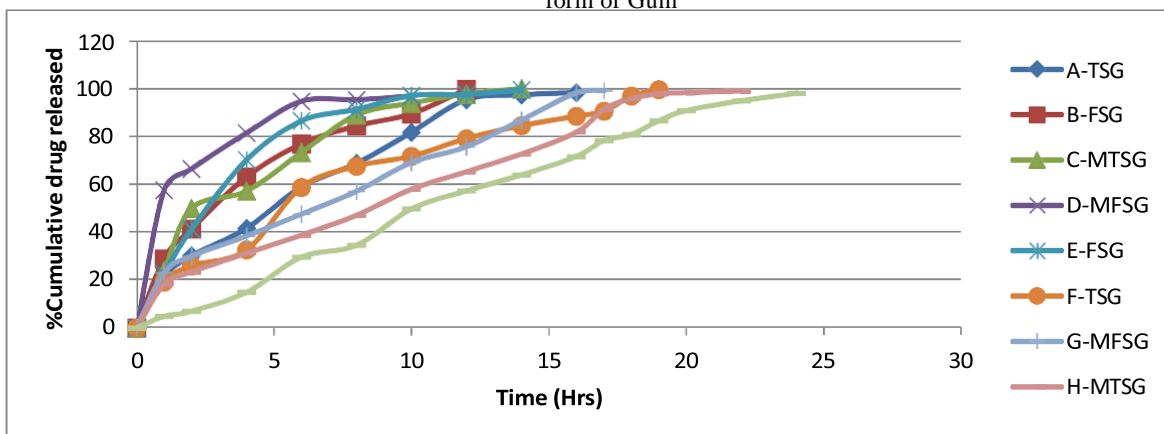


Figure 14. Cumulative % drug released from controlled release propranolol HCl matrix tablets

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