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FORMULATION AND EVALUATION OF SUSTAINED RELEASE TABLET OF CEFEXIME TABLET BY USING BIOPOLYMER AS A RELEASE MODIFIER FROM DRIED SEED OF JACKFRUIT (*ARTOCARPUS HETEROPHYLLUS*)

Belwal Vijay*, Arya Vikram, Kumar Alok

Devsthali Vidyapeeth College of Pharmacy, Lalpur, Rudrapur, U.S.Nagar, Uttarakhand.

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***Correspondence for Author**
Belwal Vijay

Devsthali Vidyapeeth College of Pharmacy, Lalpur, Rudrapur, U.S.Nagar, Uttarakhand.

ABSTRACT

In the recent years the research in biomaterial science becomes a core area for the formulation scientist to develop a safe and effective drug delivery system. Recently biopolymer was used as material for conventional as well as novel dosage form development. biopolymer have advantage that they chemicaly inert, nontoxic, cost effective, ecofriendly, biodegerdable ,biocompatible and esaily accepted by reglulatory authority as compared to synthetic conterpart.The objective of present study was to develop sustained release tablets of cefexime by using novel isolated biopolymer as a release modifier ,obtained from dried seed of jackfruit (*Artocarpus heterophyllus*).The biopolymer was extracted by non solvent addition method and characterized their physiochemical ,phytochemical and micromeritic property. The sustained release tablet of cefexime were prepared through wet granulation methods by using different ratios (1:1,1:1.5,1:2,1:2.5 and 1:3) of drug and biopolymer. Further the tablet were evaluated for its weight variation, friability, hardness, drug content and in vitro dissolution study. The result obtained from the above study was found to under limit as pharmacopoeial standard. So the research from the study shows that the biomaterial obtained from the jackfruit (*Artocarpus heterophyllus*) serves as a better release modifier in the development of sustained release tablet . So jack fruit biopolymer can be used as a better alternative excipient for the development novel drug delivery system.

KEYWORDS: Biopolymer, sustained release tablet, *Artocarpus heterophyllus.*

1. INTRODUCTION

Bio material were isolated from the seed of jackfruit **(Artocarpus Heterophyllus)** posses properties like high viscosity, broad pH tolerance, non-carcinogenicity, mucoadhesive nature, and biocompatible. The biopolymer was extracted by non solvent addition method and characterized their physiochemical, phytochemical and micromeritic property. Natural polysaccharide gums - A group of polymers, swell to form highly viscous solutions or dispersions in aqueous media. They have advantages of biocompatibility, cost-effective, nontoxic, relatively wide spread availability and acceptable by the regulating authorities compared to their synthetic counterparts. Various polysaccharides used in drug delivery like cellulose ethers, xanthan gum, and guar gum.

2. MATERIALS AND METHODS

2.1 MATERIAL

Cefixime was obtained as gift samples from Accacia Biotech Laboratories Ltd. All other reaents (Magnesium Stearate, Talc, PVP) used were of analytical grade.

2.2 METHOD

2.2.1 Isolation of biopolymer

Artocarpus Heterophyllus seeds soaked in boiled double distilled water. Solution was cooled and kept in refrigerator overnight so that most of the undissolved portion was settled out. The upper clear solution was decanted off and centrifuged at 2000 rpm for 20 minutes. The Supernatant was separated, and poured into thrice the volume of acetone by continuous stirring. The precipitate was washed repeatedly with acetone and dried in decicator. Polymer was powdered, passed through sieve number 20 and stored**.**

2.2.2. Characterization of Biopolymer

Bio material were isolated from the seed of jackfruit **(Artocarpus Heterophyllus)** was characterized for their physicochemical and phytochemical properties.

A. Physicochemical characterization

Isolated biopolymer was evaluated for their physicochemical properties such as solubility behavior, organoleptic evaluation (colour, odour, taste and shape), melting point, density behavior, flow properties, pH, and swelling index.

B. Phytochemical characterization

The Biopolymer was obtained from the seed of jackfruit **(Artocarpus Heterophyllus)** was evaluated for phytochemical properties like test for alkaloids, test for carbohydrates, test for proteins, test for saponins and test for mucilage.

2.3 Preparations of sustained release tablet

Sustained release tablet of cefexime were prepared by wet granulation method. In this Drug and biopolymer were mixed together in different ratio into a mortar pestle then 5% PVP solution was added as a binder. Then formation of lump were passes through sieved no 16/22 mesh. Afterwards the granules dried at 50ºC for 30 min in hot air oven, then Talc and magnesium stearate were added as glidant and lubricant for each batch of granules. Finally the tablets was compressed using ten station tablet punching machine.

2.2.4 Evaluation of granules

1. Angle of repose

Angle of repose was determined by the Neumann's method and calculated using the formula, for unlubricated as well as lubricated granules.

$\tan \theta = h/r$

$\theta = \tan^{-1} (h/r)$

Where, h = height of pile, r = radius of the pile base

2. Bulk density

The bulk density was calculated by the following equation,

$\rho b = M/V$

Where, ρb = Bulk density

M = Mass of the granules in grams

V = Final untapped volume of granules in ml.

3. True density

The true density was calculated by using following equation,

$\rho t = M/Vp$

Where, ρt = true density

M= Mass of granules in grams

Vp= Final tapped volume of granules in ml.

4. Hausner ratio

Hausner ratio was calculated as follow

$$\text{Hausner ratio} = \frac{\text{Tapped Density}}{\text{Bulk density}}$$

5. Compressibility index

The compressibility index of powder wasdetermined by the follow

$$\text{Carr's index (\%)} = \frac{\text{Tapped density} - \text{bulk density} \times 100}{\text{Tapped density}}$$

2.2.5 Evaluation of Sustained Release Tablets

1. Content uniformity

Three tablets of each type of formulation were weighed and crushed into a mortar pistal and was dissolved in 100ml distil water. This was the stock solution from which l ml sample was withdrawn and diluted to 100 ml with 0.1N HCl. The absorbance were measured by using a double beam UV-Visible spectrophotometer.

2. Weight variation

20 tablets were selected randomly and then average weighed was determined. Then individual weight of each tablets were determined and then the weight variation were calculated out.

3. Tablet Hardness

The resistance of tablets to shipping or breakage, under conditions of storage, transportation and handling before usages are depends on its hardness. The hardness of tablet of each formulation was checked by using hardness tester.

4. Thickness

The thickness of tablet is important for the uniformity of tablet size. Thickness was measured using Vernier Calipers. It was determined by checking 10 tablets from each formulation.

5. Dissolution studies

Tablets of each formulation were subjected to dissolution rate studies. In-vitro dissolution studies were carried out to determine the drug release from various formulations. The release characteristic studies included the amount of drug released per hour up to 12 hours.

1. RESULT AND DISCUSSION

3.1 Characterization of Biopolymer

Table 1: Solubility profile of biopolymer

SOLVENT	SOLUBILITY BEHAVIOR
Cold Water	Sparingly Soluble
Warm Water	Quickly soluble forming a viscous colloidal solution
Ethanol	Soluble
Methanol	Soluble
Acetone	Insoluble
Ether	Insoluble

Table 2: Organoleptic evaluation of Biopolymer

PARAMETERS	BIOPOLYMER (Artocarpus Heterophyllus)
Colour	Brownish
Odour	Pungent
Taste	Mucilaginous
Shape	Amorphous
Melting Point	145-150

Table 3: Physicochemical characterization of Isolated Biopolymer

PROPERTY	RESULTS
True Density (g/cc)	1.201
Tapped Density (g/cc)	0.904
Bulk Density (g/cc)	0.76
Angle Of Repose (°)	22.32
Compressibility Index(%)	18.69
Sweeling Ratio	

In Water In 0.1 N HCL (pH 1.2) In Phosphate Buffer (pH 7.4)	12% 8.2% 5%
pH	5.2
Loss On Drying	4.35%

Table 4: Phytochemical evaluation of Isolated Biopolymer

S.no.	Test	Observation
1	**Alkaloids**	
	Mayer's test	**(--)**
	Dragandorff s test	**(--)**
2	**Carbohydrates**	
	Fehling test	**(++)**
	Benedict s test	**(++)**
3	**Saponins**	
	Foam test	**(++)**
4	proteins	
	Millon s test (-)	**(--)**
	Ninhydrin test (-)	**(--)**
5	mucilage	
	Ruthenium red test	**(++)**

3.2 Preparation of sustained release tablets

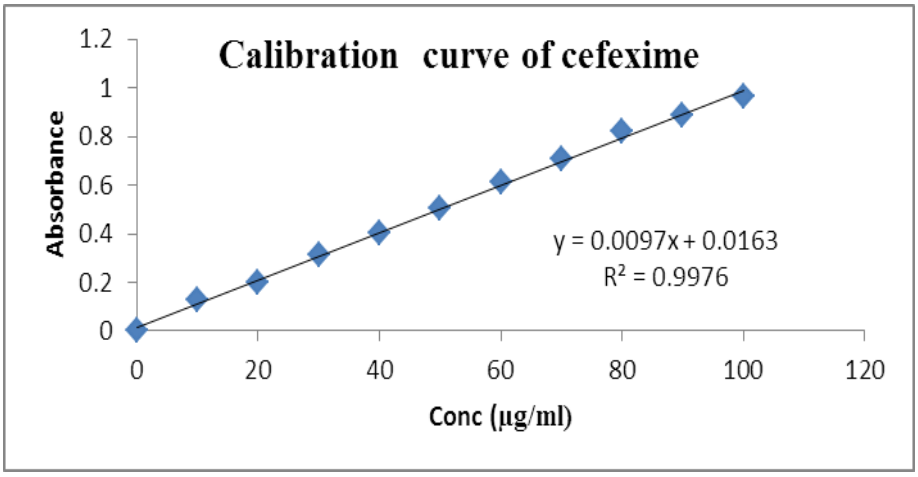
Table 5: Composition of sustained release tablets

Formulation Code	Drug (mg)	Polymer (Artocarpus Heterophyllus)	Magenesium stearate (mg)	Talc (mg)	PVP (%w/v)
F1	200	100	25	50	5
F2	200	200	25	50	5
F3	200	300	25	50	5
F4	200	400	25	50	5
F5	200	500	25	50	5

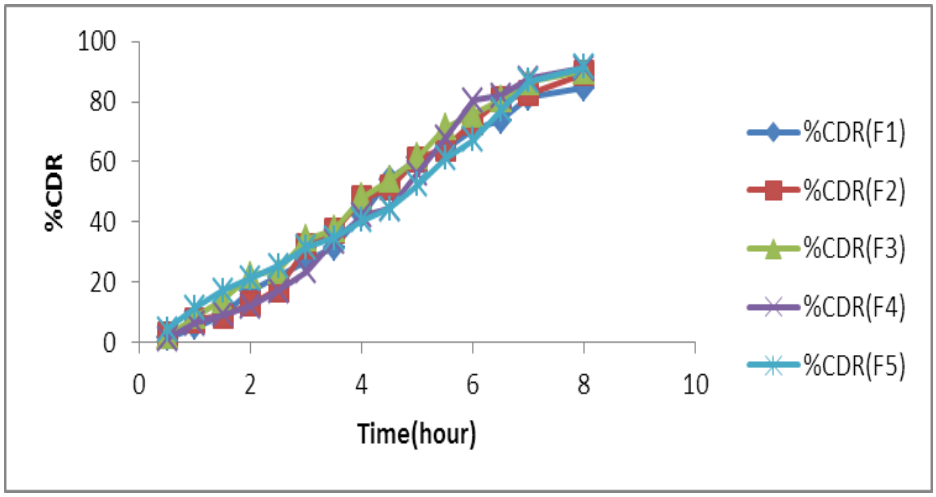
3.3 Evaluation of sustained release tablets

Table 6: Evaluation of sustained release tablets

Formulation code	Friability%	Hardness	%Drug content	%Drug release
FI	0.57	5.09	80.2	84.41
F2	0.59	5.13	85.7	89.28
F3	0.63	5.8	88	90.089
F4	0.73	4.74	89.5	91.16
F5	0.64	5.23	94	91.45



3.4 Calibration curve of cefexime



3.5 Cumulative release of sustained release tablet

RESULT AND CONCLUSION

The result obtained from the above study was found to under limit as pharmacopoeial standard. So the research from the study shows that the biomaterial obtained from the jackfruit (*Artocarpus heterophyllus)* serves as a better release modifier in the development of sustained release tablet, from the release studies it was observe that as the polymer ratio increases the release will be prolonged. So jack fruit biopolymer can be used as a better alternative excipient for the development novel drug delivery system.

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