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Research Article

DEVELOPMENT AND EVALUATION OF SUSTAINED RELEASE TABLET OF CEFIXIME USING BIOPOLYMER OBTAINED FROM *GLYCINE MAX*

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ABSTRACT

Cefixime is an antibiotic useful for the treatment of a number of bacterial infections. It is a third generationcephalosporin. The bactericidal action of cephalosporin is due to the inhibition of cell wall synthesis. It binds to one of the penicillin binding proteins (PBPs) which inhibit the final transpeptidation step of the peptidoglycan synthesis in the bacterial cell wall, thus inhibiting biosynthesis and arresting cell wall assembly resulting in bacterial cell death.

Recently biopolymer was used as material for conventional as well as novel dosage form development. The biopolymer was isolated from the seed of *Glycine max* (Soybean) by non solvent addition method. The merits of biopolymers have over synthetic polymers are low cost, natural origin, nontoxic, biocompatible, biodegradable, environmental friendly processing, local availability, better patient tolerance as well as public acceptance. The polymer were subjected to its physicochemical, phytochemical and micromeritic studies.

Keywords: Biopolymer, Sustained release tablet, Cefixime.

1. INTRODUCTION

A huge variety of natural polymers with growing interest has provided by nature.Biopolymers have been used for the preparation of dosage form.

The merits of biopolymers have over synthetic polymers are:

1. Low cost,
2. Natural origin,
3. Nontoxic,
4. Biocompatible,
5. Biodegradable,
6. Environmental friendly processing,
7. Local availability,
8. Better patient tolerance as well as public acceptance.

2. MATERIALS AND METHODS

2.1 Material

Cefixime was obtained as gift samples from Accacia Biotech Laboratories Ltd. All other reagents (magnesium stearate, talc, pvp) used were of analytical grade.

2.2 METHOD

2.2.1 Isolation of biopolymer

Soybean seeds were crushed and soaked in double distilled water. Solution was 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 25 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 60 and stored**.**

2.2.2. Characterization of Biopolymer

The biopolymer obtained from the seed of *Glycine max* was characterized for their physicochemical and phytochemical properties.

A. Physicochemical characterization

The isolated biopolymer was evaluated for 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

Biopolymer obtained from the seed of *Glycine max* was evaluated for phytochemical properties like test for alkaloids, test for carbohydrates, test for proteins, test for saponins and test for

mucilage.

2.2.3 Preparations of sustained release tablet

Sustained release tablets of cefixime were prepared by wet granulation method. The composition ofeach tablet is shown in table. All the components were screened and then mixed by further blending for 3 mins and finally talc was added to the blend.

2.2.4 Evaluation of granules

1. Angle of repose

Angle of repose was determined byNeumann's method and calculated using theformula, 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 using 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 using 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

Compressibility index of the powder wasdetermined by

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

using a mortal pestle. The powder mix was granulated with 5% w/v pvp solution. The wet mass was passed through sieve no.16 and the granules were dried at 50°C for 2 hrs in a hot air oven. The dried granules were passed through sieve no. 20 and lubricated with magnesium stearate

2.2.5 Evaluation of Sustained Release Tablets

1. Content uniformity

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

2. Weight variation

Twenty tablets were selected randomly andweighed. Average weight of the tablet was determined. These tablets were weighedindividually and the weight variation wasdetermined.

3. Tablet Hardness

The resistance of tablets to shipping orbreakage, under conditions of storage, transportation and handling before usages aredepends on its hardness. The hardness of tablet ofeach formulation was checked by using hardness tester.

4. Thickness

Thickness of tablet is important for uniformityof tablet size. Thickness was measured using Vernier Calipers. It was determined by checkingten tablets from each formulation.

5. Dissolution studies

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

3. RESULT AND DISCUSSION

3.1 Characterization of Biopolymer

Table 1: Solubility profile of biopolymer

S.No.	Solvent	Solubility
1	Cold water	Insoluble
2	Warm water	Soluble forming a viscous colloidal solution
3	Ethanol	Insoluble
4	Methanol	Insoluble
5	Acetone	Insoluble
6	Ether	Insoluble

Table 2: Organoleptic evaluation of Biopolymer

S.No	Parameters	Biopolymer (*Glycine max)*
1	Colour	Pale brown
2	Odour	Pungent
3	Taste	Mucilaginous
4	Shape	Crystaline

Table 3: Physicochemical characterization of Biopolymer

S.no.	Property	Result
1	Bulk Density (g/cc)	0 .50
2	Tapped Density (g/cc)	0.87
3	Carr's Index (%)	42.52
4	Hausner Ratio	1.74
5	Angle of Repose (°)	30.11
6	Loss on Drying	1%

Table 4: Phytochemical evaluation of Biopolymer

S.no.	Test	Observation
1.	Test for alkaloid	
	Mayer's test	(-)
	Dragandorff s test	(-)
2.	Test for carbohydrates	
	Fehling test	(-)
	Benedict s test	(-)
3.	Test for saponins	
	Foam test	(-)
4.	Test for proteins	
	Millon s test	(-)
	Ninhydrin test	(-)
5.	Test for mucilage	
	Ruthenium red test	(++)

3.2 Preparation of sustained release tablets

Table 5: Composition of sustained release tablets

Formulation code	Drug (mg)	Polymer *(Glycine max)*	Magnesium stearate (mg)	Talc (mg)	PVP (% w/v)
FI	200	200	25	50	5
F2	200	400	25	50	5
F3	200	500	25	50	5
F4	200	600	25	50	5

3.3 Evaluation of sustained release tablets

Table 6: Evaluation of sustained release tablets

Formulation code	Friability (%)	Hardness	Drug release	% drug content
FI	0.59	5.10	93.96	189.25
F2	0.61	5.12	83.70	184.45
F3	0.66	5.8	75.12	195.23
F4	0.69	4.82	81.96	196.62
F5	0.57	5.28	82.95	165.33

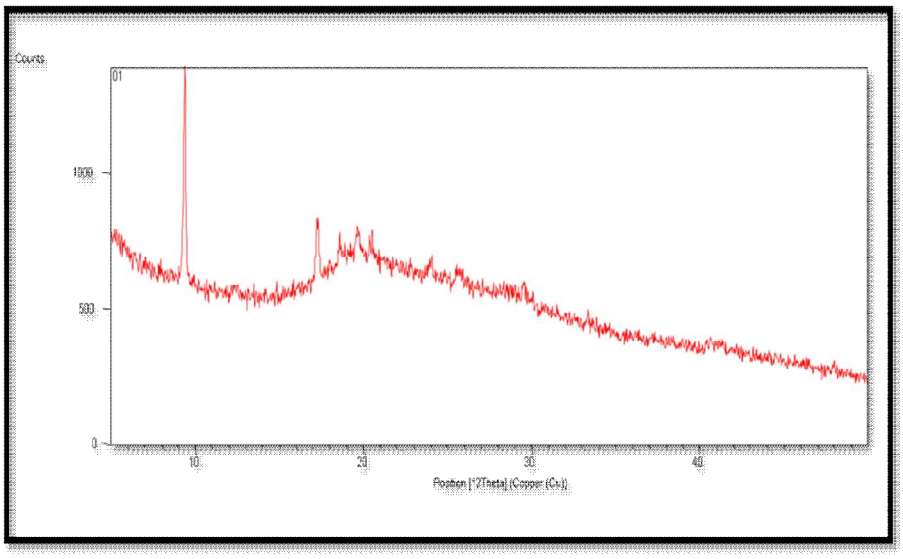

Fig. 1: XRD study of biopolymer

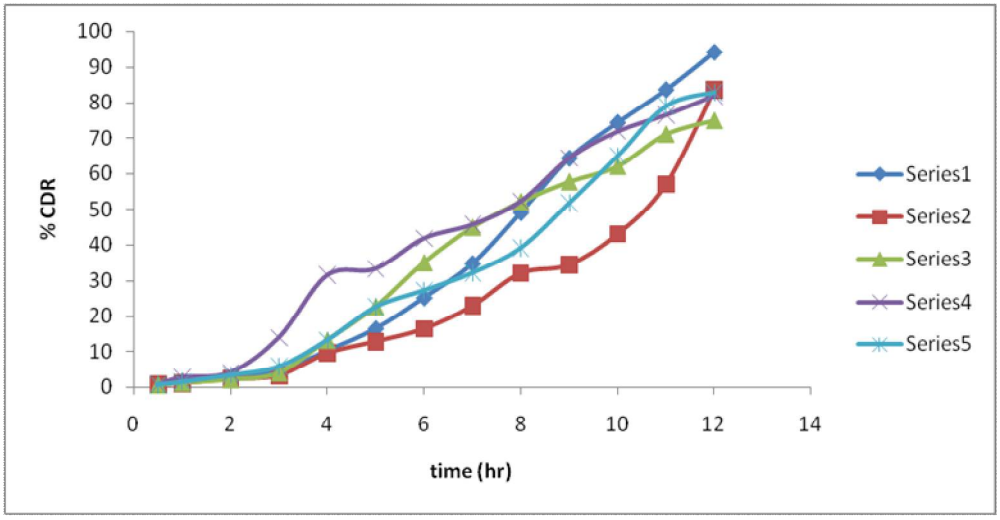

Fig. 2: Cumulative release of sustained release tablet

3.4 RESULT

The present study indicates that formation of sustained release tablet of cefixime using biopolymer enhance drug release in comparison to previous works and the biopolymer serves as a better alternative excipient for the development of dosages forms.

4. CONCLUSION

This study investigated that sustained release tablet of cefixime were prepared successfully by wet granulation method using the biopolymer in different ratios. It was observed that the concentration of the biopolymer can be control the hardness and the drug release properties of the tablets. Thus, sustained release tablets of cefixime could be developed for controlled drug delivery.

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