WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 5.990
Volume 4, Issue 5, 1962-1969. Research Article ISSN 2277– 7105

ENHANCEMENT OF SOLUBILITY OF ACECLOFENAC BY SOLID DISPERSION USING BIOPOLYMER OBTAINED FROM *PRUNUS ARMENIACA*

Kamal Kishor Joshi*, D. K. Sharma and Arun Kumar Singh

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

Article Received on
06 March 2015,

Revised on 29 March 2015,
Accepted on 19 April 2015

***Correspondence for Author**
Kamal Kishor Joshi
Devsthali Vidyapeeth College of Pharmacy, Lalpur, Rudrapur, U.S.Nagar, Uttarakhand.

ABSTRACT

In the drug delivery system solubility plays a crucial factor for drug absorption and its bioavailability. Solubility is the main limiting factor for BCS class II category of drug. The objective of present study was to isolate and characterize biopolymer from the fruits of *Prunus armeniaca belonging to rosaceae* family. In the recent years the research in the biopolymer isolation and their use as pharmaceutical excipient become a core area for formulation scientist to develop safe and effective drug delivery system. The biomaterial was isolated by non solvent addition method and characterized their physiochemical, phytochemical and micromeritic properties. In the present study the attempt was made to enhance the solubility of aceclofenac by solid dispersion technique, using biomaterial as a hydrophilic carrier. Aceclofenac is a nonsteroidal anti-inflammatory drug acting by inhibition of the synthesis of prostaglandins by inhibiting the activity of the enzyme, cyclooxygenase-2(COX-2).Five different ratios of biopolymer and acelofenac(1:1, 1:1.5, 1:2, 1:2.5 and 1:3) were used and solid dispersion was prepared by fusion method. The aqueous solubility of each formulation was determined and compared with the solubility of pure aceclofenac. Result from study shows that by using biopolymer as carrier, the tremendous increase in the solubility was found as compared to the standard. So the biopolymer serves as a better alternative exicepient for the development of dosage form because of safe, non toxic, biocompatible and biodegradable and easily acceptable by regulatory bodies.

KEYWORDS: Biopolymer, Aqueous solubility Solid dispersion technique, *Prunus armeniaca*.

1. INTRODUCTION

Oral drug delivery is the easiest and simplest way of administering solid dosage form. Oral bioavailability of a drug depends on its solubility and/or dissolution rate. If these drugs are not completely released in the gastrointestinal tract, they will have a low bioavailability.[1,2] Solid – dispersion technology can be used to improve the invitro and invivo dissolution rate of slightly water soluble drugs and to control the dissolution rate of fully water soluble drugs. Solid dispersion systems have been considered over the last 20 years as a means of increasing the solubility dissolution and absorption of poorly water soluble drugs. Solid dispersions are molecular mixtures of poorly aqueous soluble solid drug with an inert hydrophilic carrier. Drug release profile from such mixtures is driven by the carrier properties.[3]

Solid dispersion is defined as the dispersion of one or more active ingredients in an inert carrier or matrix at solid state prepared by the melting, solvent or melting solvent method. The solid dispersion may also be called solid-state dispersion. Dispersion obtained through the fusion process is also called melts and those obtained by the solvent method are frequently referred to as co precipitates or co evaporates. The two basic procedures used to prepare solid dispersion are fusion and co solvent techniques.[4,5]

A huge variety of natural polymers with growing interest has provided by nature. This attributes to a number of factors which include their relative abundance, low cost, non-toxic, stable, biodegradable and eco-friendly profiles. Gum exudates are amongst the oldest natural polymers. They are already being used as thickening and stabilizing agents from last several years. The plant derived polymers comply with many requirements of pharmaceutical excipients. Another natural polysaccharide, bio material obtained from the fruit of *Prunus armeniaca*, possesses properties like high viscosity, broad pH tolerance, non-carcinogenicity, mucoadhesive nature, and biocompatible. Natural biopolymers are biodegradable and non toxic, which hydrate and swell on contact with aqueous media,and these have been used for the preparation of dosage form and as a carrier for the solubility enhancement of poorly soluble drugs.

2. MATERIAL AND METHOD

2.1. Materials: Aceclofenac was obtained as gift samples from Acacia Biotech Laboratories Ltd. Fruits of *Prunus armeniaca* were purchased from the local market of Haldwani (Uttarakhand). Methanol and other reagents were supplied from Loba Chemie.

2.2. Methods

2.2.1. Isolation of Biopolymer[6]: Pulp of *Prunus armeniaca* fruit was collected in a beaker, than distilled water was added and stirred it for 1 hour. The solution of the pulp was filtered out with the help of muslin cloth. The filtrate was centrifuged and supernatant was collected. Acetone was added to the collected supernatant and allowed to be stand for24 hrs, so that the obtained polymer can be settled down in the form of precipitated. Supernatant was discarded and the polymer was filtered out with the help of whatmann filter paper. The polymer was collected in a china dish and kept for drying.

2.2.2. Characterization of Biopolymer[7, 8, 9]

The biopolymer obtained from the fruit of Prunus armeniaca 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 fruit of Prunus armeniaca 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. Spectrophotometric determination of Aceclofenac

Calibration curve of aceclofenac was prepared in methanol. Stock solution of aceclofenac (100µg/ml) was prepared. Aliquot from stock solution obtained was then serially diluted with methanol to get final concentrations in the range of 2-10µg/ml. The absorbance value of the resultant solutions were measured using methanol as blank at 274nm. The absorbance values were plotted against concentration (µg/ml) to obtain the standard calibration curve.

2.2.4. Preparations of Solid dispersion of Aceclofenac using biopolymer[10, 11]

Solid dispersion of aceclofenac with biopolymer was prepared by fusion method using 5 different ratio of biopolymer. (1:1, 1:.5, 1:2, 1:2.5, 1:3). Weighed quantities of aceclofenac and biopolymer in five different proportions were mixed respectively in a clean, dried china dish. The china dish was placed on a water bath and heated.

The drug carrier mixture was melted by increasing the temperature with constant stirring. The stirring was continued until a homogenous mass was resulted. Then the melt was poured on a clean, dried Petri dish and cooled in room temperature. The resulting solidified mass dried in desiccators. The dried material was pulverized and passed through sieve.no.80. The product was stored in an air tight container and kept in desiccators for further studies.

2.2.5. Comparison of solubility of solid dispersion with aceclofenac

The aqueous solubility of different ratios of solid dispersion were checked and compared with the solubility of pure aceclofenac.

3. RESULT AND DISCUSSION

3.1. Characterization of Biopolymer

A. Physicochemical Characterization

Table no. 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 no. 2. Organoleptic evaluation of Biopolymer

S.No.	Parameter	Observation
1	Colour	Brownish
2	Odour	Pungent
3	Taste	Sweet
4	Shape	Crystalline

Table no.3. Physicochemical characterization of Biopolymer

S.No.	Property	Result
1	True density (g/cc)	1.002
2	Tapped density (g/cc)	0.918
3	Bulk density (g/cc)	0.730
4	Angle of repose (°)	19.29
5	Compressibility index (%)	20.47
6	Swelling ratio	
	In Water In 0.1 N HCL (pH 1.2) In Phosphate Buffer (pH 7.4)	12% 15.0% 7..3%
7	pH	5.0
8	Loss on drying	0.8%
9	Melting point	115-120°C

Table no. 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. Spectrophotometric determination of Aceclofenac

Table no. 5. Calibration curve of aceclofenac in methanol

S. No.	Concentration (µg/ml)	Absorbance
1	**2**	**0.115**
2	**4**	**0.205**
3	**6**	**0.339**
4	**8**	**0.456**
5	**10**	**0.602**

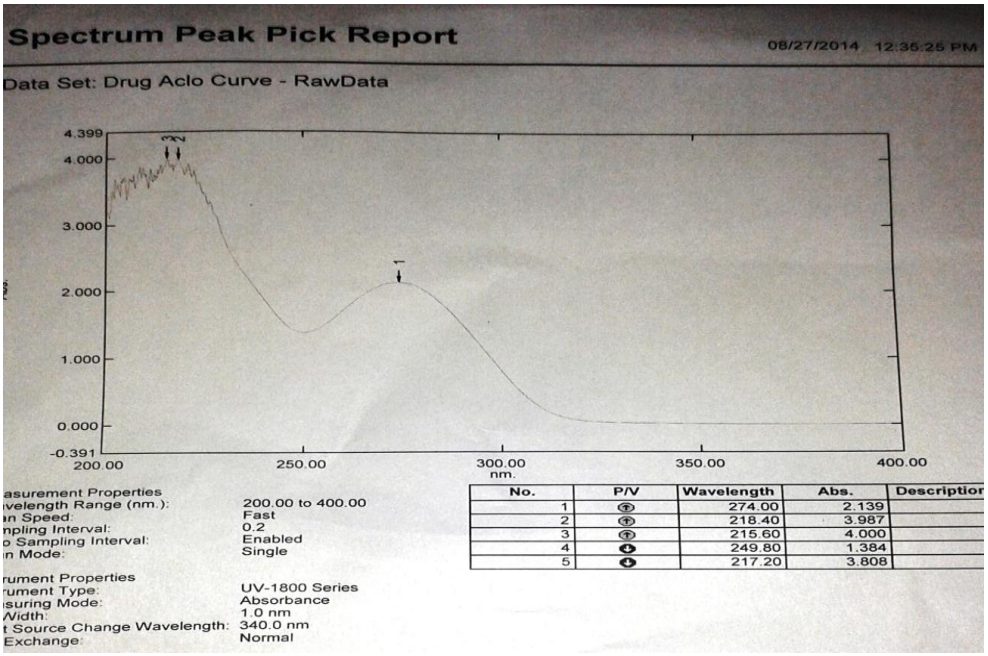

Figure 1. UV spectra of Aceclofenac

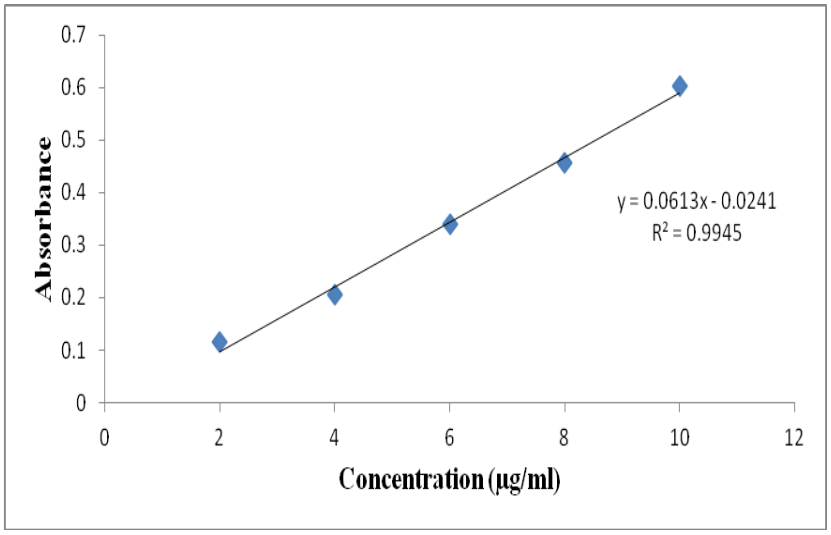

Figure 2. Calibration Curve of Aceclofenac in Methanol

3.3. Preparations of Solid dispersion of Aceclofenac using biopolymer

Table no. 5. Composition of Solid Dispersion of Aceclofenac

Formulation Code	Drug (mg)	Biopolymer (*Prunus armeniaca*) mg
F1	100	100
F2	100	150
F3	100	200
F4	100	250
F5	100	300

3.4. Comparison of solubility of Solid dispersion with aceclofenac

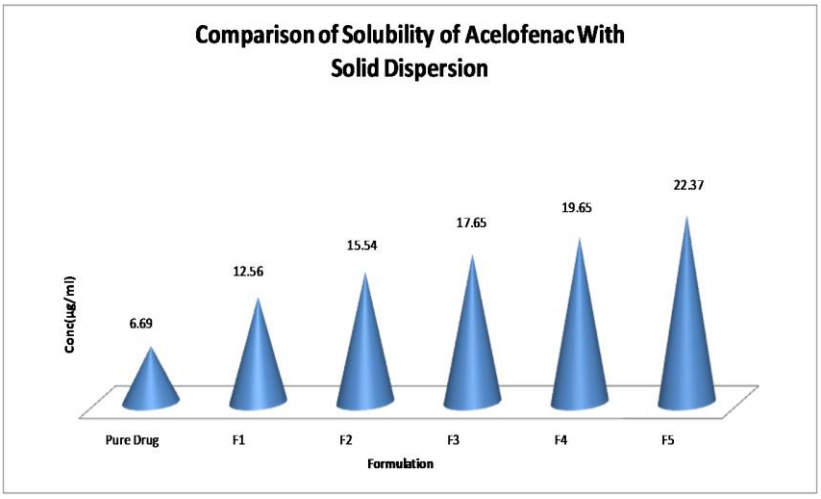

Figure 3. Solubility profile of Solid dispersion and pure Aceclofenac

3.5 RESULT: Result from study shows that by using biopolymer as carrier, the tremendous increase in the solubility was found as compared to the standard. So the biopolymer serves as a better alternative excipient for the development of dosage form because of safe, non toxic,

biocompatible and biodegradable and easily acceptable by regulatory bodies.

4. CONCLUSION: This study investigated that optimized (F5) Solid dispersion was prepared successfully by fusion method using the combination of aceclofenac and biopolymer in 1:3. It was observed that the concentration of the biopolymer enhanced the solubility of aceclofenac.

5. ACKNOWLEDGEMENT: It's my sincere privilege to express my thanks to my esteemed research guide Assistant Prof. Mr. Arun Kumar Singh, My senior Mr. Vikas Bhatt and my batch mate Swati Devsthali Vidyapeeth College of Pharmacy, Rudrapur. It gives me great pleasure to acknowledge my immense respect and gratitude to my esteemed Principal Dr. D. K. Sharma, for the facilities provided. I sincerely thank Devsthali Vidyapeeth Collage of Pharmacy for providing me all the facilities for my research work.

6. REFERENCES

1. Sugawara M., Kadomura S., He X., Takekuma Y., Kohri N., Miyazaki K.," The use of an invitro dissolution and absorption system to evaluate oral absorption of two weak bases in pH-dependent controlled-release formulations", Eur. J. Pharm. Sci., 2005; 26: 1-8.
2. Kumar S., Malviya R., Sharma P.K., "Solid Dispersion: Pharmaceutical Technology for the Improvement of Various Physical Characteristics of Active Pharmaceutical Ingredient", Afr. J. Basic. Appl. Sci., 2011; 3: 116-125.
3. Vasconcelos T.F., Sarmento B., Costa P., "Solid dispersions as strategy to improve oral bioavailability of poor water soluble drugs", Drug Discov. Today. 2007; 12: 1068-1075.
4. Ratnaparkhi M. Dhomse R, "Formulation development and evaluation of fast dissolving aceclofenactablets prepared by solid dispersion by using mannitol", International Journal of Pharmaceutical, Chemical and Biological Sciences, 2012; 2(3): 325-334, ISSN: 2249-9504 325-328.
5. Senthilkumar K. L., Sirisha Y, "Enhancement of dissolution rate studies on solid dispersion of aceclofenac", International Journal of Pharma and Bio Sciences, Vol.2/Issue 2/Apr-Jun 2011, page no- 70-75.
6. Bidkar Jayant, Bidkar Shital, Baheti Jagdish, Navale Sampat, Badhe Sachin," Isolation and Characterization of mucilage from aegle marmelos linn. fruit pulp", Deccan J. Natural Products, Jan-March 2011; 2(1): 23-28.

7. X Fatima Grace, S Latha., S Shanthi., N Lakshmi., D Chamundeeswari, "Isolation and preliminary evaluation of *Portulaca quadrifida* mucilage", Journal of Pharmacy Research, 2012; 5(1): 505-507.
8. H Pawar, P M D Mello, "Isolation of seed gum from Cassia tora & preliminary studies of its application as a binder for tablets", Indian drugs, 2004; 41(8): 465-468.
9. Narkhede Sachin B, Vidyasagar G, Jadhav Anil G., Bendale Atul R, Patel Kalpen N, "Isolation and evaluation of mucilage of Artocarpus heterophyllus as a tablet binder", J. Chem. Pharm. Res., 2010; 2(6): 161-166.
10. Kumar Shobhit, Gupta Satish Kumar, Sharma Pramod Kumar, "Dissolution rate enhancement of aceclofenac by solid dispersion technique", Asian Journal of Pharmacy and Life Science ISSN 2231 – 4423., Oct-Dec, 2011; 1(4): 396-399.
11. Mahaparale P.R., Gudsoorkar V.R., Gajeli G.B., Kuchekar B.S," Studies on solid dispersions of meloxicam", Ind. J. Pharm. Educ. Res., 2006; 40: 241-244.