CODEN (USA): IAJPBB ISSN: 2349-7750

INDO AMERICAN JOURNAL OF
PHARMACEUTICAL SCIENCES

Available online at: http://www.iajps.com Research Article

FORMULATION AND EVALUATION OF ACECLOFENAC LOADED PRONIOSOMES FOR TOPICAL DELIVERY

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Abstract:
Proniosomes are one of the important novel drug delivery carriers of various drug molecules. Aceclofenac potent analgesic anti inflamatory agent used for the treatment of inflammation. The main objective of the study was to develop proniosomal containing aceclofenac for transdermal delivery using different ratios of cholesterol and non-ionic surfactants in order to achieve a sustained release of drug on topical administration. Proniosomes were prepared by using slurry method and evaluated for for angle of repose, entrapment efficiency, thickness, folding endurance, % moisture loss and absorption, drug content and in-vitro diffusion studies. As the concentration of the cholesterol decreases the entrapment efficiency decreases due to the low vescile size formation. The in-vitro diffusion and kinetic analysis were done for proniosomal patches. It showed the release of 51.28% at 8th hr and fitted into Zero order and follows non-fickian diffusion mechanism. The best formulation(F6) was composed of cholesterol and surfactant in the ratio of 1:2 showed the better sustain action. from the study it was observed that proniosomal transdermal patches are very stable and promising sustained delivery system for Aceclofenac.

Key Words: *Proniosomes, Aceclofenac, Cholesterol, Surfactant.*

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Please cite this article in press as ***V.Jayasankar Reddy and K.Ramesh Reddy, Formulation and Evaluation of Aceclofenac Loaded Proniosomes for Topical Delivery****, Indo Am. J. P. Sci, 2016; 3(6).*

INTRODUCTION:

Topical administration defined as application of a drug contained medicament to the surface of the skin to treat diseases as drug directly reaches systemic circulation [1,2]. The main advantage of topical delivery system is to bypass first pass metabolism. Avoidance of the invassiveness of *iv* treatment and the altered conditions like absorption are advantages of topical delivery.solid formulation in their assortment of dominating in the topical delivery, but foams, spray, semi-solids, solutions, and drug contained adhesive systems are in use.The formulations of topical dosage forms, attempts are being made to utilize drug carriers that ensure adequate localization or penetration of the drug within or through the skin in order to enhance the local and minimize the systemic effects, or to ensure adequate percutaneous absorption [3-6]. The application of proniosomes as drug carriers on the skin surface has been proven to be efficient in the delivery of proniosomes-entrapped drugs to and into the skin. Applied on the skin, proniosomes may act as a solubilizing matrix for poorly soluble drugs, penetration enhancers, as well as a local depot for sustained drug release, at the same time diminishing the side effects of these drugs. Summarily, topical proniosomal formulations could be more effective and less toxic than conventional formulations [7-12].

Type of Carrier System

Various types of transdermal drug delivery system include liposomes, erythrosomes, ethosomes, niosomes, and proniosomes.

Liposomes: small vesicles of bilayer of phospholipids encapsulating an aqueous space ranging from 0.03-10µm in diameter.

Nano- erythrosomes: An erythrocyte based new drug carrier, developed which is prepared by extrusion of erythrocyte ghosts to produce small vesicle having average diameter of 100µm.

Ethosomes: are vesicular systems with lipid-base immersed in ethanol relatively in high concentrations which improve the rate of delivery. vesicle having average diameter of 10-100 µm.

Niosomes: are non-ionic surfactants based multilamellar or unilamellar vesicles in which an aqueous solution of solute(s) is enclosed by a membrane resulted from the organization of surfactant macro-molecule as bilayer [13-20].

MATERIALS AND METHODS:

Aceclofenac (Bufna Pharma),Span 40 (SD fine chemicals mumbai,india), Span 60 (SD fine chemicals mumbai,india),Tween 6 (SD fine chemicals mumbai,india),Cholesterol (SD fine chemicals mumbai,india),HPMC (SD fine chemicals mumbai,india), Lactose (SD fine chemicals mumbai,india).

Calibration Curve of Aceclofenac

A calibration curve of Aceclofenac was constructed in phosphate buffer pH 6.8 at a wave length of 274nm. The linearity of the curve was found in the range of 5-30 µg/ml. A regression coefficient value of 0.998 was noticed for Aceclofenac.

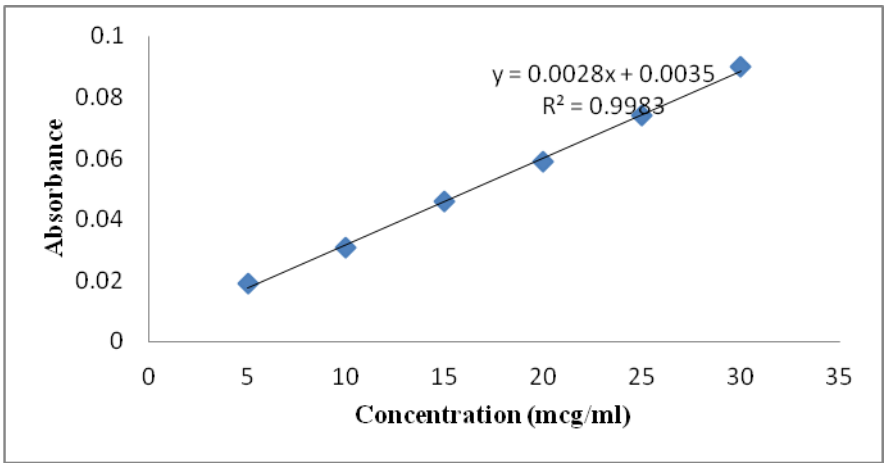

Fig1: Calibration Curve of Aceclofenac

Drug – polymer compatibility studies by FTIR:
Drug polymer compatibility studies were performed by FTIR (Fourier Transform Infrared Spectroscopy) . Infrared (IR) spectra were obtained using the KBr disk method (2 mg sample in 200 mg KBr). The scanning range was 400 to 4000 cm^{-1} and the resolution was 1 cm^{-1}.

Table No.1 Formulation Table of Proniosomes

Formulation code	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
Drug (mg)	**80**	**80**	**80**	**80**	**80**	**80**	**80**	**80**	**80**	**80**	**80**	**80**
Cholesterol(mg)	**1000**	**1000**	**500**	**250**	**1000**	**1000**	**500**	**250**	**1000**	**1000**	**1000**	**1000**
Span 40 (mg)	**1000**	**2000**	**2000**	**2000**	-	-	-	-	-	-	-	-
Span 60 (mg)	-	-	-	-	**1000**	**2000**	**2000**	**2000**	-	-	**2000**	-
Tween 60 (mg)	-	-	-	-	-	-	-	-	**1000**	**2000**	-	**2000**
Lactose (mg)	**1000**	**1000**	**1000**	**1000**	**1000**	**1000**	**1000**	**1000**	**1000**	**1000**	**1000**	**1000**
Diethyl ether (ml)	**10**	**10**	**10**	**10**	**10**	**10**	**10**	**10**	**10**	**10**	**10**	**10**
Methonal (ml)	**5**	**5**	**5**	**5**	**5**	**5**	**5**	**5**	**5**	**5**	**5**	**5**

RESULTS AND DISCUSSION:

Drug –polymer compatibility studies by FTIR

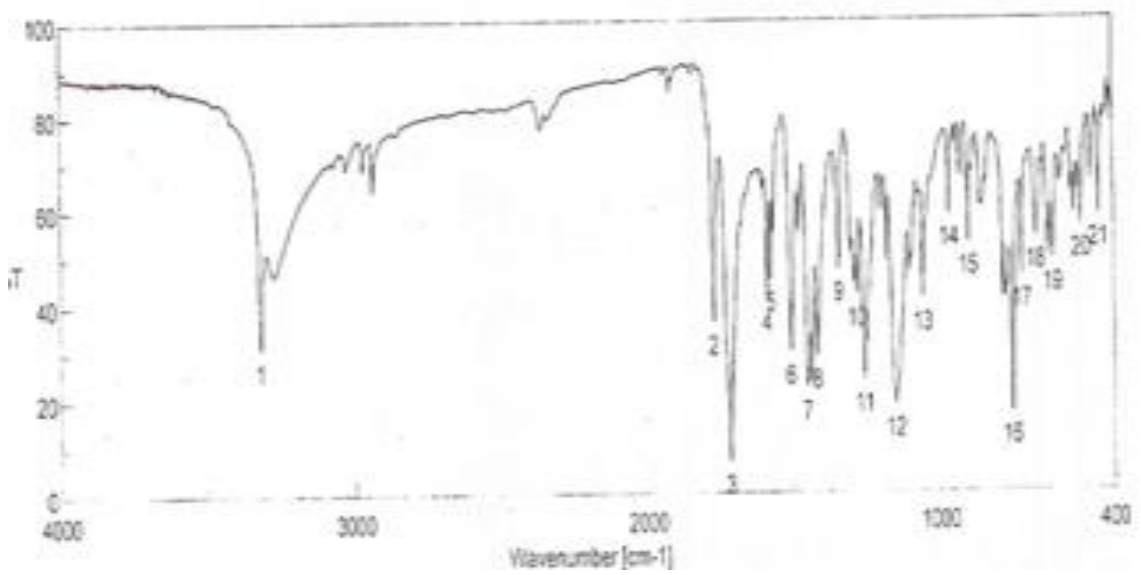

Fig 2: FTIR spectra for pure drug

SEM Analysis

The formulated proniosomal derived niosomes vesicles were confirmed by scanning electron microscopy. The vesicles are spherical in shape and smooth.

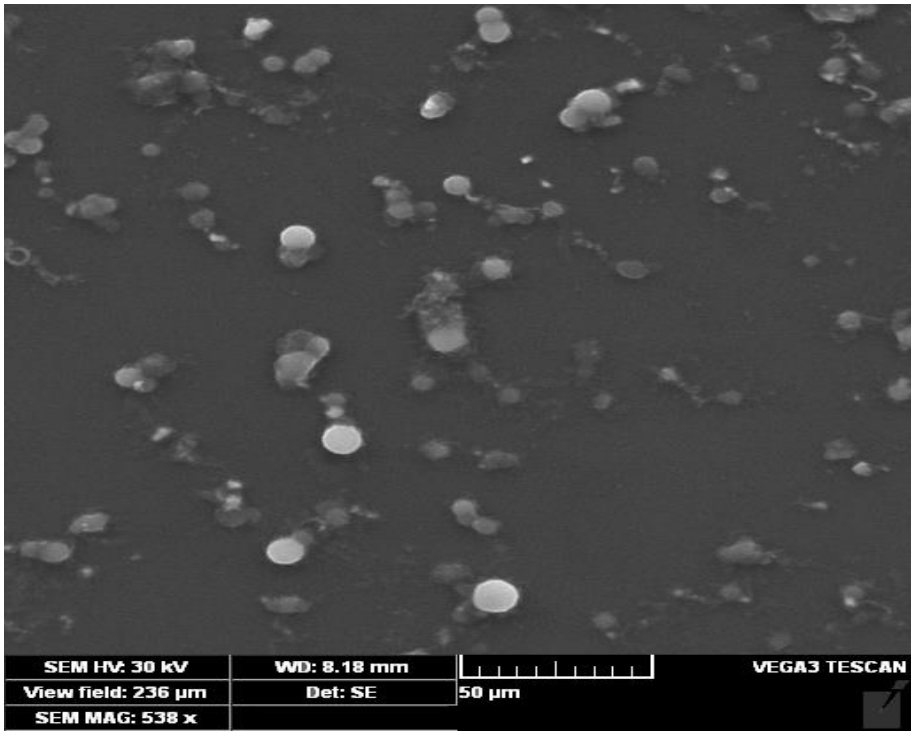

Fig 3: Scanning electron microscope image of Aceclofenac loaded proniosomal derived niosomes

Entrapment Efficiency:

Table 2: Entrapment Efficiency of proniosomal formulation

FORMULATION CODE	PERCENTAGE ENTRAPMENT EFFICIENCY
F1	70.45
F2	72.33
F3	73.29
F4	75.28
F5	77.06
F6	82.13
F7	80.21
F8	79.57
F9	78.38
F10	73.83
F11	72.36
F12	81.16

In-vitro drug release studies of proniosomes formulations

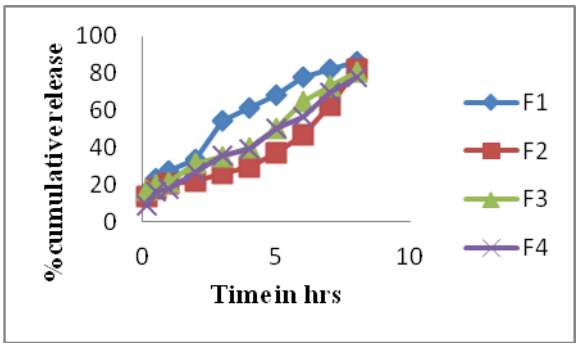

Fig 4: *In-vitro* drug release studies of proniosomes formulations (F1-F4)

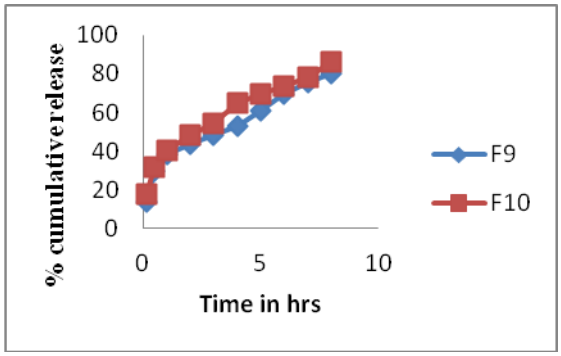

Fig 6: *In-vitro* drug release studies of proniosomes formulations (F9-F10)

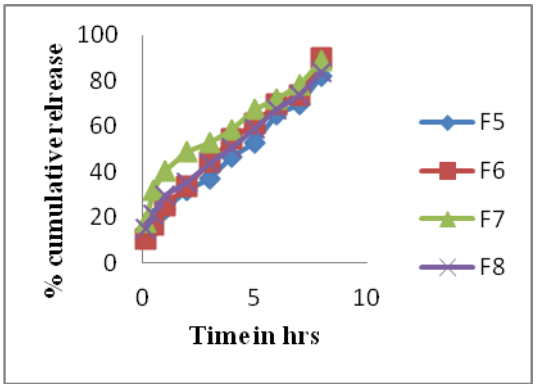

Fig 5: *In-vitro* drug release studies of proniosomes formulations (F5-F8)

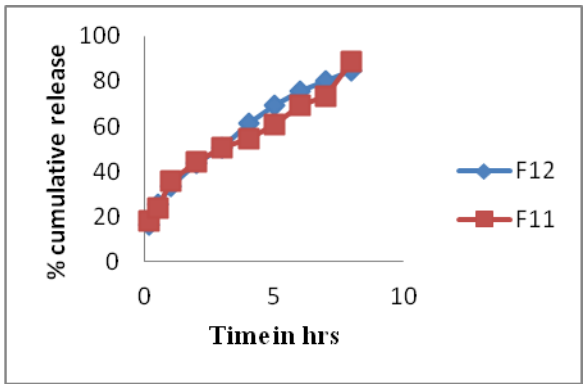

Fig 7: *In-vitro* drug release studies of proniosomes formulations (F11-F12)

In-vitro diffusion studies of transdermal patches

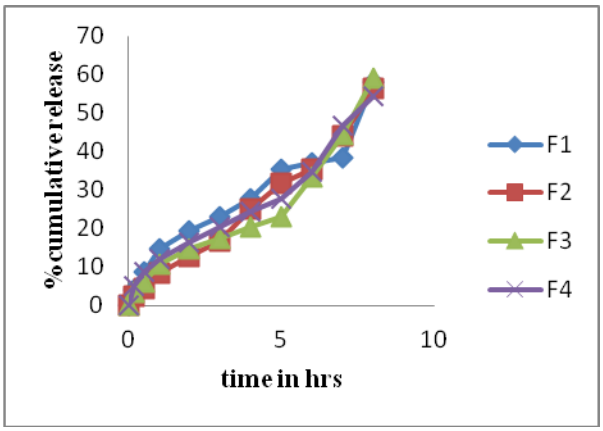

Fig: 8: *In-vitro* diffusion studies of transdermal patches (F1-F4)

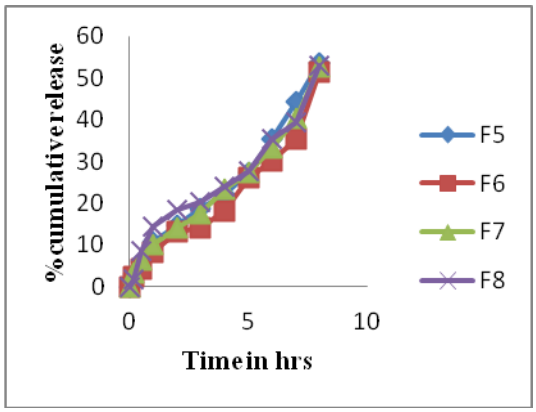

Fig 9: *In-vitro* diffusion studies of transdermal patches (F5-F8)

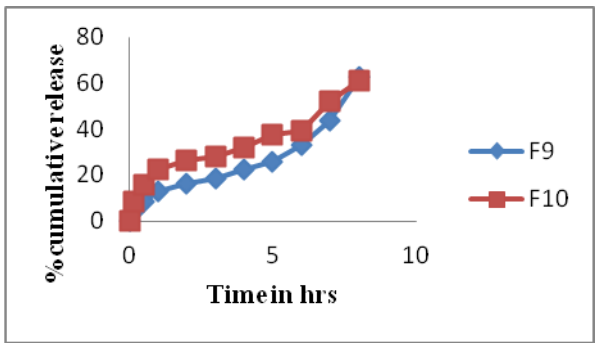

Fig10*: In-vitro* diffusion studies of transdermal patches (F9-F10)

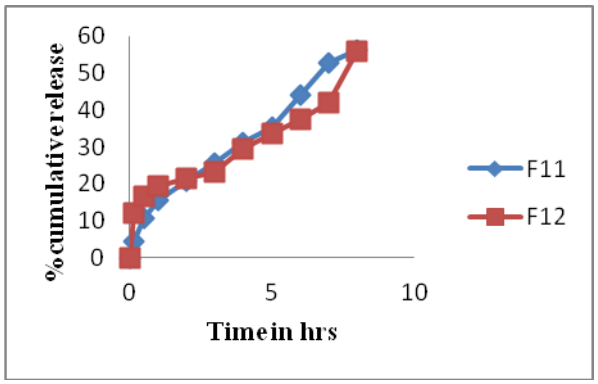

Fig11: *In-vitro* diffusion studies of transdermal patches (F11-F12)

CONCLUSION:

The present study revealed that Slurry method followed by evaporation in rotary evaporator produced Aceclofenac loaded proniosomes. The formulation containing non-ionic surfactant and cholesterol with 1:2 ratios is found to be better when it's characterized for various pharmaceutical characters. The entrapment study also showed that the significant amount of drug was entrapped in proniosomal powder. The optimized proniosomes formulation showed maximum release at 8th hr. The formulations was incorporated into HPMC transdermal patch respectively. The incorporation of powder into patches showed more suatained release in the formulation with ratio of 1:2 of cholesterol and non-ionic surfactant. The release kinetics analysis indicated that most of the formulations fit into Zero order & release mechanism was based on non-fickian diffusion. In conclusion, the noval proniosomal formulations of Aceclofenac Sodium could be used for transdermal delivery in better treatment of rheumatoid arthritis .The results of stability study showed no significant alteration in physical and chemical parameters. Further studies using animal model will throw more light on the effectiveness of the formulation.

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