IJFANS INTERNATIONAL JOURNAL OF FOOD AND NUTRITIONAL SCIENCES
ISSN PRINT 2319 1775 Online 2320 7876
 UGC CARE Listed (Group -I) Journal Volume 11, Iss 3, 2022

FORMULATION AND CHARACTERIZATION OF ZALTOPROFEN LOADED NANOVESICLE TRANSDERMAL PATCHES

Niranjan Babu Mudduluru[*1], Jyothi Basini[2], Vishnu Priya Kannedari[3]

[1]Department of Pharmacognosy, Seven Hills College of Pharmacy, Tirupati, A.P., India
[2,3]Department of Pharmacology, Seven Hills College of Pharmacy, Tirupati, A.P., India

Corresponding Author
Dr. M. Niranjan Babu
Professor, Department of Pharmacognosy, Seven Hills College of Pharmacy, Tirupati, A.P., India – 517561, Contact: 7702484513, Email: principal.cq@jntua.ac.in

ABSTRACT:
Rheumatoid arthritis (RA) presents a substantial global health challenge, impacting millions worldwide, with approximately 36 million affected individuals in India alone. This study focused on formulating nine batches of niosomes (Z1-Z9) with varying compositions of cholesterol and surfactants, aiming to develop an effective transdermal delivery system for RA treatment. Evaluation parameters such as polydispersity index (PDI), vesicle size, and entrapment efficiency were meticulously assessed. Results highlighted formulations Z6 and Z8 as demonstrating superior performance compared to other batches.
The optimized formulations (Z6 and Z8) exhibited high entrapment efficiencies of 84.4±1.53% and 87.6±1.46%, with particle sizes of 356±54.71 nm and 253±37.01 nm, respectively, along with acceptable PDI values. Transdermal patches were successfully developed using PEG 400 and HPMC K-100M from the Z6 and Z8 batches. Characterization of these patches revealed uniform thickness (0.332±0.001 mm and 0.328±0.001 mm), consistent weight (351.47±0.717 mg and 345.46±0.901 mg), and minimal moisture uptake (5.26±0.16 and 4.16±0.12). The Z8 batch patch emerged as particularly promising based on comprehensive evaluation criteria, suggesting its suitability for RA treatment.

Furthermore, the selected optimized transdermal patches exhibited drug release kinetics following zero order, Higuchi's kinetic, and Korsemeyer-Peppas models, further supporting their potential effectiveness in delivering RA treatment.

Keywords: Niosomal Transdermal patch, Zaltoprofen, RA, Non-ionic surfactant.

INTRODUCTION:

Arthritis, a term encompassing joint inflammation, ranks among the most prevalent chronic conditions and a leading cause of disability worldwide. It encompasses over 100 different conditions affecting joints, bones, and surrounding tissues [1]. Rheumatoid arthritis (RA), an autoimmune and inflammatory disease, involves the immune system mistakenly attacking healthy cells, leading to painful inflammation in affected areas [2]. RA primarily targets multiple joints simultaneously and affects approximately 25 million people globally, with a significantly higher prevalence among women compared to men.

ISSN PRINT 2319 1775 Online 2320 7876
 UGC CARE Listed (Group -I) Journal Volume 11, Iss 3, 2022

While symptoms like stiffness, swelling, and restricted joint movement are common across various types of arthritis, each condition is distinct and requires tailored treatment approaches[3]. In India, with a population of over 1.2 billion as per the 2011 census, the reported prevalence of RA ranges from 0.3% to 0.75%. Assuming an average prevalence of 0.5% among adults, the projected burden of RA in India stands at around 36 million individuals [4].

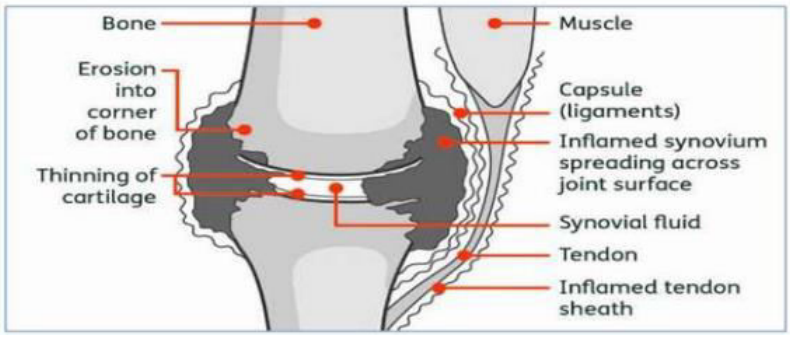

Figure:-1.1A joint badly affected by Rheumatoid Arthritis

1.2 Stages of Rheumatoid Arthritis:

Stage 1: The body mistakenly attacks its own joint tissue.

Stage 2: Antibodies are produced, leading to swelling in the joints.

Stage 3: Joints begin to deform and become bent. Fingers may become crooked, potentially causing nerve pain due to pressure on nerves.

Stage 4: Without treatment, the disease progresses to the final stage where joints are completely destroyed and fused.

NIOSOMES:

Niosomes are nonionic surfactant vesicles known for their potential to enhance stability and solubility of pharmaceutical compounds. These innovative drug delivery vehicles are designed to provide targeted and controlled release of medicinal agents.

Structure of Niosomes

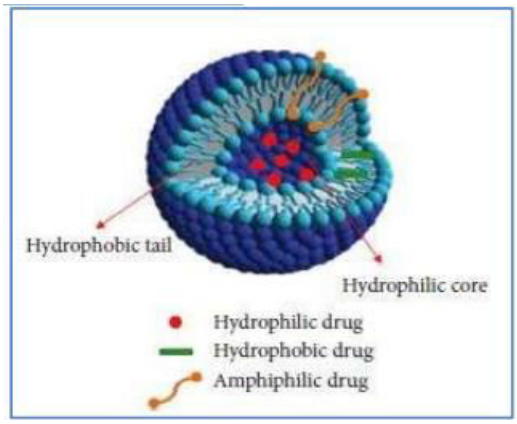

Figure:- 2.1 niosomes

ISSN PRINT 2319 1775 Online 2320 7876
 UGC CARE Listed (Group -I) Journal Volume 11, Iss 3, 2022

2.1. Advantages of Niosomes:

1. Niosomes exhibit low toxicity, are non-immunogenic, biodegradable, biocompatible, and enhance patient compliance [5].
2. Niosomes facilitate enhanced drug penetration through the skin [6].
3. Encapsulation within niosomes enhances the stability of medications.
4. There is precise control over the properties of vesicle formulation such as size, lamellarity, surface charge, concentration, and drug encapsulation efficiency [7].

2.2. Limitations of Niosomes Drug-Delivery System:

1. Niosomes in aqueous solutions may have a short shelf life due to drug aggregation, permeability issues, and hydrolysis of encapsulated drugs [8].

2.3. Preparation Methods of Niosomes:

1. Transmembrane pH Gradient Method
2. Reversed-Phase Evaporation
3. Ether Injection
4. Bubbling of Nitrogen
5. Sonication
6. Enzymatic Method
7. Single-Pass Method
8. Microfluidization
9. Formation of **niosomes from proniosomes**

TRANSDERMAL PATCH

Transdermal drug delivery systems, commonly known as "patches," are designed to administer an effective dose of medication through the patient's skin. This method offers significant advantages over oral and injectable approaches by potentially bypassing first-pass metabolism and enhancing patient compliance. Transdermal delivery enables continuous drug distribution, particularly beneficial for medications with short biological half-lives, while preventing the sudden spikes in systemic circulation that often cause adverse effects.

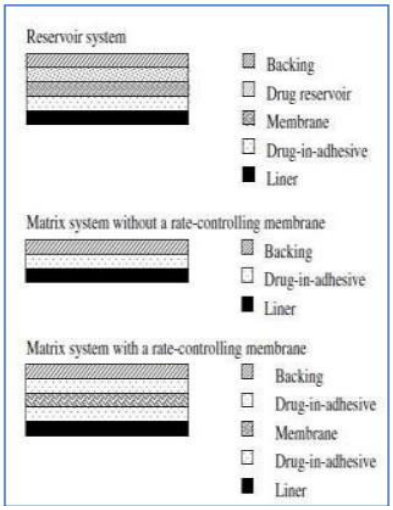

Figure:-3.1 TDDS Types

ISSN PRINT 2319 1775 Online 2320 7876
 UGC CARE Listed (Group -I) Journal Volume 11, Iss 3, 2022

MATERIALS & METHODS:

Preparation of Zaltoprofen-loaded Niosomes:

Step 1: Dissolve the drug, surfactant, and cholesterol in a selected organic solvent.

Step 2: Remove the organic solvent at room temperature using a vacuum rotary evaporator.

Step 3: Form a thin, dry layer on the surface of the flask.

Step 4: Rehydrate the dry surfactant film with 15 ml of phosphate buffer saline (pH 6.8), containing the drug, using a rotary evaporator without vacuum at 60°C to ensure removal of any residual organic solvent.

Step 5: Store the final niosomal suspension in the refrigerator for further investigation.

DSC analysis of pure drug Zaltoprofen:

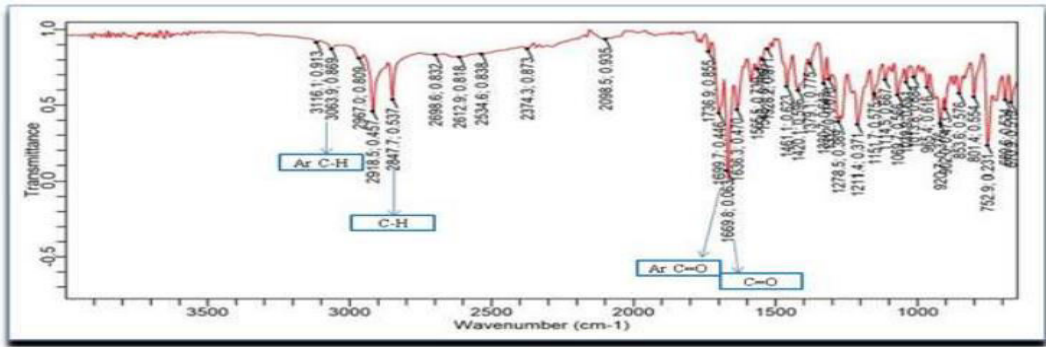

Figure:- 5.1 Identification of drug by FT-IR study

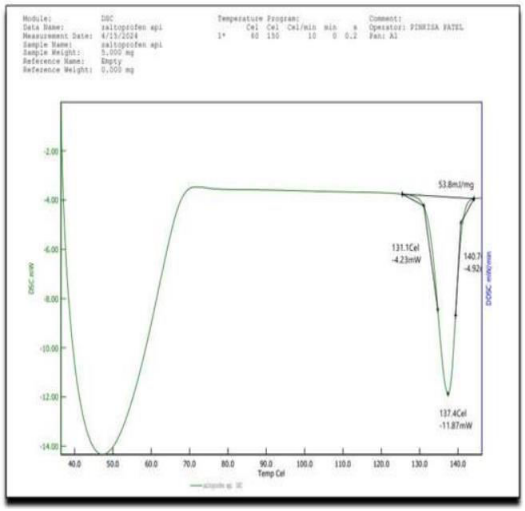

Figure:5.2 DSC Thermal analysis results of Zaltoprofen.

Morphology of Niosomes: -

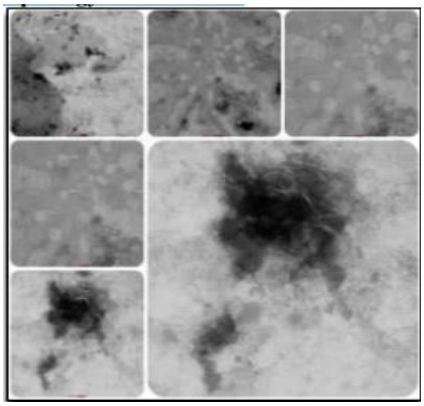

Figure :- 5.3 TEM of Niosomes

ISSN PRINT 2319 1775 Online 2320 7876
 UGC CARE Listed (Group -I) Journal Volume 11, Iss 3, 2022

CONCLUSION:

The development of Zaltoprofen-loaded niosomal transdermal patches represents a significant breakthrough in sustained drug delivery for managing rheumatoid arthritis (RA). Through meticulous optimization and rigorous evaluation, we have achieved a highly efficient and stable drug delivery system. The integration of optimized niosomes into transdermal patches has resulted in formulations exhibiting excellent drug release profiles and robust stability, meeting ICH guidelines. This innovative approach holds promise for enhancing RA treatment modalities, highlighting its potential for clinical application and further research in transdermal drug delivery and RA management.

REFERENCE:

[1]. Dunlop DD, Manheim LM, Yelin EH, Song J, Chang RW. The costs of arthritis. Arthritis Care & Research: Official Journal of the American College of Rheumatology. 2003 Feb 15;49(1):101-13.

[2]. Centers for Disease Control and Prevention (CDC. Arthritis prevalence and activity limitations--United States, 1990. MMWR. Morbidity and mortality weekly report. 1994 Jun 24;43(24):433-8. 2011 Census. Censusindia.gov.in.

[3]. Gharbavi M, Amani J, Kheiri-Manjili H, Danafar H, Sharafi A. Niosome: a promising nanocarrier for natural drug delivery through blood-brain barrier. Advances in Pharmacological and Pharmaceutical Sciences. 2018 Dec 11;2018

[4] AdlinJinoNesalin J. Niosome as a novel rug delivery system-review. International Research Journal of Pharmaceutical and Applied Sciences. 2015 Jun 30;5(3):1-7.

[5]. Sambhakar S, Paliwal S, Sharma S, Singh B. Formulation of risperidone loaded proniosomes for effective transdermal delivery: An in-vitro and in-vivo study. Bulletin of faculty of pharmacy, Cairo University. 2017 Dec 1;55(2):239-47.

[6]. Azeem A, Anwer MK, Talegaonkar S. Niosomes in sustained and targeted drug delivery: some recent advances. Journal of drug targeting. 2009 Nov 1;17(9):671-89.

[7]. Nasr M, Mansour S, Mortada ND, Elshamy AA. Vesicular aceclofenac systems: a comparative study between liposomes and niosomes. Journal of microencapsulation. 2008 Oct 1;25(7):499-512.

[8]. Gharbavi M, Amani J, Kheiri-Manjili H, Danafar H, Sharafi A. Niosome: a promising nanocarrier for natural drug delivery through blood-brain barrier. Advances in Pharmacological and Pharmaceutical Sciences. 2018 Dec 11;2018.