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Development And Characterization Of Diacerin Loaded Niosomes For Improved Transdermal Delivery In Osteoarthritis

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Abstract

General Background: Osteoarthritis is a chronic degenerative joint disease, while oral diacerein has limited dissolution and low bioavailability. **Specific Background:** Niosomes may provide a vesicular approach for transdermal diacerein delivery while addressing limitations associated with oral administration. **Knowledge Gap:** An optimized diacerein niosomal formulation requires appropriate surfactant, cholesterol ratio, and sonication conditions. **Aims:** This study aimed to develop and optimize diacerein-loaded niosomes using the thin film hydration method. **Results:** Formulation F8 showed a vesicle size of 164.92±0.41 nm, entrapment efficiency of 91.52±1.0%, PDI of 0.16±0.015, and zeta potential of −33.94 mV. Increasing Span 60 reduced vesicle size and increased entrapment efficiency, whereas higher cholesterol increased vesicle size and reduced entrapment efficiency. Longer sonication reduced vesicle size but decreased entrapment efficiency. **Novelty:** F8 combined favorable vesicle characteristics with high drug entrapment. **Implications:** F8 may serve as a candidate for further transdermal development, requiring ex vivo permeation and in vivo anti-inflammatory studies.

Key Findings Highlights

Span 60 increased drug entrapment while reducing vesicle size.

Higher cholesterol produced larger vesicles with lower entrapment.

Extended sonication reduced vesicle size but lowered drug entrapment.

Keywords : Diacerein, Niosomes, Transdermal Drug Delivery, Osteoarthritis, Nanovesicles

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Introduction

One of the most prevalent degenerative joint diseases, osteoarthritis (OA) is a major contributor to global impairment, especially among the elderly. This is a complex, multifaceted disease that causes articular cartilage to steadily worsen, subchondral bone to change, osteophytes to grow, and the synovial membrane to become inflamed [1].

Gender, obesity, musculoskeletal trauma, athletic participation, and occupation are some of the primary reasons of OA [2]. Although paracetamol and NSAIDs are often used to relieve OA symptoms, they are ineffective in halting the illness's progression [3]. Because OA is a chronic condition, using these medications for a long time has a number of negative effects, including kidney and gastrointestinal issues with nonselective COX inhibitors and cardiovascular problems with selective COX-2 inhibitors [4]. Diacerein (DCN) is a non-steroidal anti-inflammatory medication derived from anthraquinone. It is safe and efficient for treating osteoarthritis. It has anti-catabolic and pro-anabolic actions on cartilage, serves as an antioxidant, and protects subchondral bone remodeling. Recent studies have found that it has beneficial effects [5].

Through deacetylation, diacerein is transformed into Rhein, its active metabolite [6]. Diacerein's active metabolite and chemical structure are depicted in Figure 1 [7]. The medication operates by obstructing the enzyme IL-1 converting enzyme, which transforms Pro-IL-1 into IL-1, therefore preventing the IL-1 biosynthetic route. Therefore, diacerein inhibits IL-1's negative effects on osteoarthritis. Additionally, diacerein indirectly blocks the formation of inflammatory cytokines like tumor necrosis factor-alpha (TNF-) and interleukin-6 (IL-6) by decreasing IL-1 activity [8].

Because of its poor dissolving in the GIT fluid, Diacerein, a BCS class II medication, has a low oral bioavailability of 35-50% [9]. In addition, colonic microorganisms convert unabsorbed rhein into rhein-9-anthrone, which results in soft stools or diarrhea and promotes poor compliance and treatment termination [10]. Transdermal delivery appears to be a good technique. For the treatment of osteoarthritis, a transdermal delivery device that crosses the stratum corneum needs to be created [11].

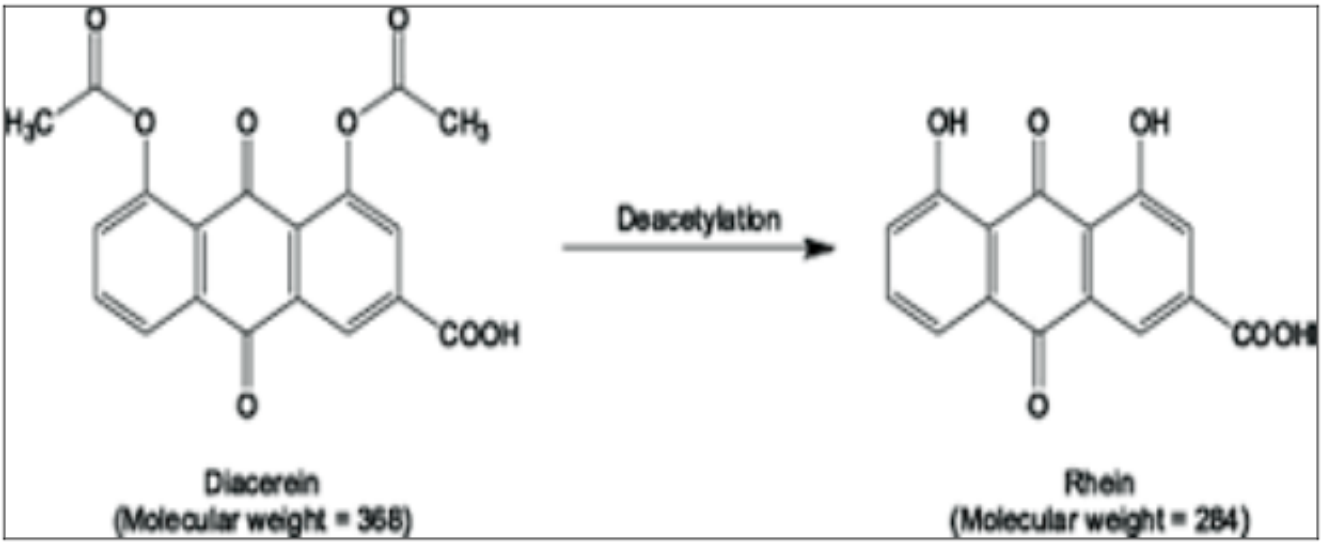


Figure 1.

Figure (1): Structure of rhein and diacerein [7]

Some limitations of transdermal delivery systems include the stratum corneum's (the skin's outermost layer) poor permeability, which can make it harder for bigger or hydrophilic molecules to be absorbed. To promote drug absorption, this barrier frequently requires the usage of penetration enhancers or specialized delivery systems. Several hypotheses have been put forth to account for niosomes' ability to improve permeation. Niosomes can either enter the stratum corneum intact or undergo structural changes to create smaller vesicles within the skin, depending on the amount of local hydration [12]. Through activities like adsorption or fusion, they might also talk with the stratum corneum directly. Adsorption can allow substances to pass directly from the vesicle to the skin either by forming receptor-ligand bonds or by physically interacting nonspecifically [12]. The self-assembly of nonionic surfactants that produce lipid bilayers around an aqueous core creates colloidal carriers called niosomes, which may contain medications with a variety of solubilities. Their makeup and characteristics, including their size, lamellarity, and surface charge, may be modified to suit a specific goal [13].

The present study aimed to create an ideal DCN niosomal carrier that could deliver DCN across the skin while minimizing oral administration's issues of bad dissolution and diarrhea.

Materials and Methods

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Lee Chemicals, China, provided the diacerin. Direvo Industrial Biotechnology in Germany provides cholesterol. Tween 60, Tween 40, Span 60, and Span 40 were bought from Himedica Laboratories in India. Other chemicals and other solvents, including water, were purchased from various sources and were of analytical quality.

Preparation of Diacerin Niosomes

Using the thin film hydration technique described in the literature, niosomes of DCN were synthesized for this investigation with minor changes. Drug, cholesterol, and surfactant were dissolved in 10 mL of chloroform in the round bottom flask. After that, the chloroform was rotary evaporated (100 rpm, 60 ◦C) in 25 minutes or when a thin film appeared. Using 15 ml of phosphate buffer saline (pH 7.4), the dried thin films were hydrated about 30 minutes at 100 rpm, 60 ◦C, with no vaccum vacuum. Finally, the niosomal suspension was sonicated for the predetermined time with 4-second breaks at 30-second intervals after being vortex mixed for 5 minutes. For further research, niosomal suspension was refrigerated overnight at 4°C [14, 15]. The compositions of the Diacerin niosome formulations are shown in Table 1.

Table (1): Composition of different niosomal formulations.

Formula number	Surfactant: cholesterol	Span 40	Span 60	Tween 40	Tween 60	Cholesterol amount	Sonication time
F1	1:1	90					

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