ISSN 0974-3618 (Print)
0974-360X (Online)
www.rjptonline.org

RESEARCH ARTICLE

Integration of Multivariate Data Analysis and composite desirability index to identify process and optimize formulation components in development of gel containing aceclofenac loaded nanoparticles

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ABSTRACT:
The purpose of the research was to identify the method of preparation and the composition of aceclofenac based nanoparticles using various multivariate data analysis methods. Top down and bottom up approaches were used for the preparation of the nanoparticles and polymers like hydroxylpropyl methylcellulose and polyvinyl pyrrolidone, surfactants like sodium lauryl sulphate and Tween 80 were screened for the purpose of formulation. Different combinations of these factors were used for designing of the experiments and the obtained products were evaluated for particle size, poly dispersibility index, zeta potential, drug content and entrapment efficiency. Principal component analysis, agglomerative hierarchical clustering, composite desirability index aided to identify the best possible combination. Nanoprecipitation along with sonication as process and poly vinyl pyrrolidone as stabilizer gave the highest values of desirability index. The formulation composition of nanosuspension was oscillated around the settings for the zeroing in on optimum quantitative formulation. The nanosuspension was gelled using Carbopol. The gel was studied for in vitro and ex vivo permeation characteristics. The optimized formulation was found to be stable and had acceptable levels of irritation as studied in wistar rats. Thus various data analysis methods could help identify the right combination of process and formulation composition.

KEYWORDS: Aceclofenac, agglomerative hierarchical clustering, principal component analysis, parallel coordinate plot, nanoparticles.

1. INTRODUCTION:
Musculoskeletal disorders like arthritis are a global threat to healthy ageing.[1] Pain is a hallmark feature of arthritis, significantly affecting quality of life.[2] Aceclofenac (ACF) is a nonsteroidal anti-inflammatory drug (NSAID) with analgesic and anti-inflammatory properties prescribed for alleviation of pain.

Received on 07.11.2024 Revised on 11.03.2025
Accepted on 18.05.2025 Published on 08.11.2025
Available online from November 13, 2025
Research J. Pharmacy and Technology. 2025;18(11):5438-5446.
DOI: 10.52711/0974-360X.2025.00784

NSAIDs primarily target an enzyme called cyclooxygenase (COX) specifically COX-2.[3,4] COX enzymes are involved in the production of prostaglandins, which cause inflammation, pain, and fever. ACF decreases prostaglandin synthesis, resulting in anti-inflammatory properties and pain relief, by inhibiting COX-2.[5,6,7] However, the long term used of ACF may cause gastrointestinal ulcers and anaemia due to gastrointestinal bleeding. Topical administration may therefore avoid the side effects associated with oral administration.

Aceclofenac is BCS class II drug and so has poor aqueous solubility.[8] Limited solubility of the drug may hinder the homogenity of the formulation and erratic penetration through skin, potentially compromising therapeutic efficacy. To overcome solubility issues, various strategies like incorporating ACF into nanocarriers or using solubility enhancers have been