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Formulation and Evaluation of Azathioprine-Loaded Chitosan Microspheres for Controlled Drug Delivery

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ABSTRACT:
In the current study, AZA-loaded chitosan microspheres were formulated and characterized for sustained and targeted delivery in OA. The microspheres were developed by emulsification followed by heat-denaturation method. The prepared formulations were subjected to preformulation evaluation, drug-excipient compatibility, zeta potential analysis, and in vitro drug release studies. UV spectrophotometric analysis showed λmax at 276 nm with excellent linearity in the calibration curve. Compatibility studies confirmed the absence of chemical interaction between AZA and chitosan. In vitro dissolution studies revealed prolonged and sustained drug release following diffusion-controlled kinetics. Formulation F6 exhibited the best drug entrapment and release profile and was considered as the optimized batch. The findings indicate that AZA-loaded chitosan microspheres can provide extended therapeutic effect with reduced dosing frequency, thus enhancing efficacy and patient compliance in OA management. The proposed system may offer a viable alternative for improved clinical outcomes. Schematic representation is given in Figure 1..
Key words: Nanotechnology, Cosmeceuticals, Nanocarriers, Skin delivery, Anti-aging, Liposomes, Transfersomes, Nanoemulsions

I. INTRODUCTION

The introduction of cosmeceuticals has now become extremely important as an intermediary discipline between cosmetics and pharmaceuticals due to the ever-increasing demand for scientifically proven products for skin health. The term cosmeceutical was first coined by Kligman, referring to products containing biologically active ingredients that have pharmacological effects. [1-4].

The global cosmeceutical market, especially in the anti-aging category, is expected to cross USD 50 billion by 2027, fueled by aging demographics and rising consumer knowledge [5-8]. Cosmeceutical products contain active ingredients like retinoids, antioxidants, peptides, and plant extracts that affect collagen formation, oxidative damage, and skin healing processes [9-12].

Although successful in terms of sales, cosmeceuticals continue to be a grey area from a regulatory standpoint, with agencies such as the FDA considering them either drugs or cosmetics based on their claims [13-15].

Evolution from cosmetics to therapeutic skincare

Conventionally used cosmetic products were mainly concerned with superficial appearance improvement without altering skin physiology. Nonetheless, drawbacks like inefficient absorption, ineffective results, and non-permanent effects contributed to the rise of cosmeceutical products.

Modern cosmeceuticals incorporate active ingredients such as:

- Retinoids
- Antioxidants (Vitamin C, Vitamin E)
- Peptides
- Botanical extracts

These components affect oxidative stress reduction, skin healing, and collagen formation. This field has been further transformed by the incorporation of nanotechnology, which has improved clinical results and delivery efficiency. [16-19].

LIMITATIONS OF CONVENTIONAL FORMULATIONS

There are several shortcomings associated with conventional cosmeceutical preparations, which include poor absorption across the stratum corneum, instability of bioactives, decreased bioavailability, and limited site-specific drug delivery [20-25]. The stratum corneum serves as a significant barrier to the passage of most bioactive agents to the underlying dermal layer [26-34].

Moreover, some bioactives are susceptible to degradation owing to their exposure to external factors like sunlight, temperature, and oxygen, thereby decreasing their biological potency.

ROLE OF NANOTECHNOLOGY IN COSMECEUTICALS

Nanotechnology provides an ideal strategy to address the constraints of traditional formulations through improved delivery efficiency and stability. Nanoparticulate carriers increase permeability

through decreased particle size and increased surface area, thus providing better interactions with the biological membrane [35-40].
Nanotechnology allows for a controlled and sustained delivery system, targeting delivery to specific skin layers, and better solubility of insoluble drugs [41-52]. Furthermore, nanotechnology also offers improvements in formulation esthetics and increased spreadability.

Mechanism of Skin Permeation
It should be pointed out that the main way through which the effectiveness of nanocarriers in cosmeceuticals is achieved involves their contribution to increasing the skin penetration using several pathways. First of all, it should be noted that skin penetration is limited by the stratum corneum, the structure characterized by an organized matrix of lipids and thus limiting the penetration of most xenobiotics[53-58]. The penetration of nanoparticles through the stratum corneum occurs via three main pathways – the intercellular, transcellular, and follicular pathways. Namely, through the intercellular pathway, nanoparticles penetrate through the lipid matrix between corneocytes, while through the transcellular one, through the cells themselves. Finally, through the follicular pathway, nanocarriers reach the hair follicles and sebaceous glands, allowing for the storage of drug delivery systems there. Moreover, there are also such types of nanoparticles as ethosomes or transfersomes that disrupt or fluidize the lipid bilayer of the stratum corneum[59-61].

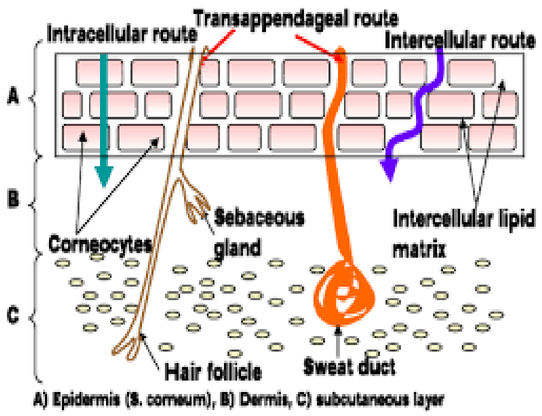

Fig:1 Mechanism of skin permeation

Need for nanotechnology
The use of conventional cosmeceutical products is limited by various factors that can affect their efficacy. Among these are inadequate skin permeability, instability of active compounds, poor bioavailability, and lack of targeted drug delivery. Due to the high density of the stratum corneum – the outermost layer of the skin – only a few molecules can penetrate into the deeper layers, where they perform their biological activity. As a consequence, conventional preparations do not exhibit significant or sustainable therapeutic effects.
Nano-based technology provides an efficient way of overcoming all these obstacles. Nanoparticles have an increased surface-to-volume ratio and interact more effectively with active substances, resulting in their better penetration into the skin and targeted delivery [62-65]. Another important benefit of nano-based cosmeceuticals is that they deliver active components in a sustained manner and thus increase the duration of treatment while decreasing its frequency. Moreover, nanocontainers ensure the stability of preparations and protect them from external environmental factors such as light, oxygen, and temperature fluctuations.
Moreover, nanotechnology facilitates targeted delivery of active ingredients into specific layers of the skin or even specific structures like hair follicles and sebaceous glands. This can be advantageous in the treatment of disorders such as acne, hyperpigmentation, and anti-aging. In addition, enhanced solubility of poorly soluble ingredients leads to increased bioavailability and efficacy.
It is also crucial to consider aesthetics improvements, including better spreadability and non-greasy characteristics that promote compliance and product acceptability[66-70].
It is thus imperative that nanotechnology be incorporated in cosmeceuticals to establish a link between traditional cosmetics and dermatology treatment.

II. FUNDAMENTALS OF NANOTECHNOLOGY IN COSMECEUTICALS

Nanotechnology can be described as the science and technology of manipulating matter at the nanoscale level between 1-100 nm. These materials display different physicochemical characteristics due to their small size and special physicochemical properties, such as high surface area, high reactivity, and optical, mechanical, and biological characteristics that differ from their bulk counterparts[71-75].
In the fields of pharmaceuticals and cosmeceuticals, the use of nanotechnology includes the development, design, and implementation of nanoparticles, including liposomes, nanoparticles, and nanoemulsions, which improve the transport of the active ingredient within the nanoscale range of 1-100 nm.

Therefore, nanotechnology plays an important role in the application of drugs and cosmetics through the effective and efficient transport of active molecules within the 1-100 nm size range[76-80].

Advantages:

- Enhanced penetration
- Controlled release
- Targeted delivery
- Improved stability

Mechanism of skin permeation (stratum corneum interaction)

III. TYPES OF NANOCARRIERS USED IN COSMECEUTICALS

The most common of all these types is liposomes, which are widely used owing to their lipid bilayer composition that allows them to encapsulate both water-soluble and fat-soluble substances; hence their applicability in moisturizing and anti-aging purposes.

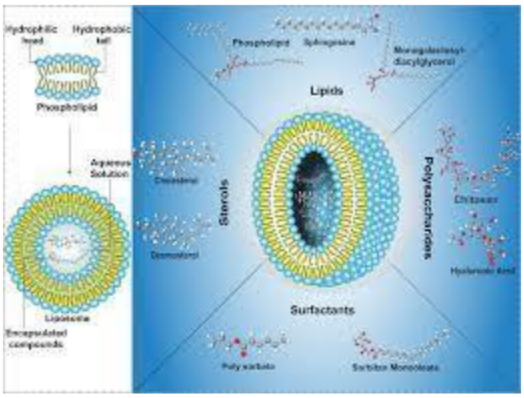

Fig: 2 Structure of Liposome

3.2 Niosomes

Niosomes are a possible substitute for liposomes in topical medication delivery since they are made of non-ionic surfactants and provide better physicochemical stability and cost-effectiveness.

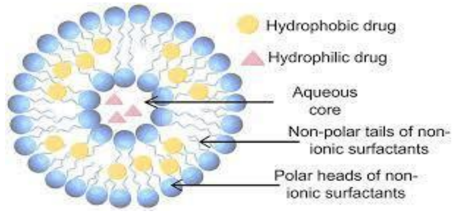

Fig: 3 Structure of Niosome

3.3 Transfersomes

As a result of their exceptional flexibility and ultra-deformable vesicular structure, transfersomes can penetrate deeper epidermal layers, improving the transdermal administration of active ingredients.

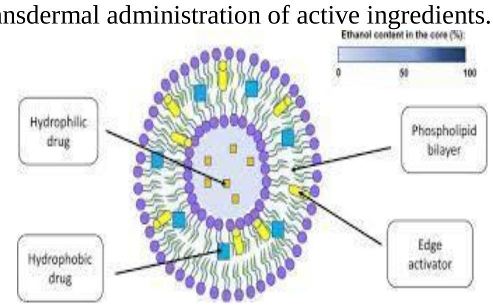

Fig: 4 Structure of Transferosome

3.4 Ethosomes

Ethosomes, because of their ability to incorporate large amounts of ethanol, have been shown to enhance the penetration ability through the fluidization of the stratum corneum lipid bilayer. Together, the nanocarrier system plays an important role in improving the therapeutic efficiency of cosmeceuticals by overcoming the inadequacies in the traditional formulations[81-85].

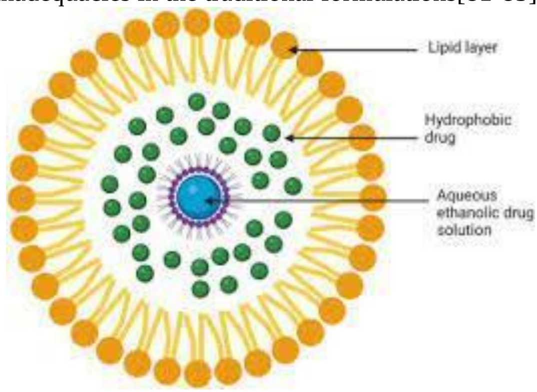

Fig: 5 Structure of Ethosome

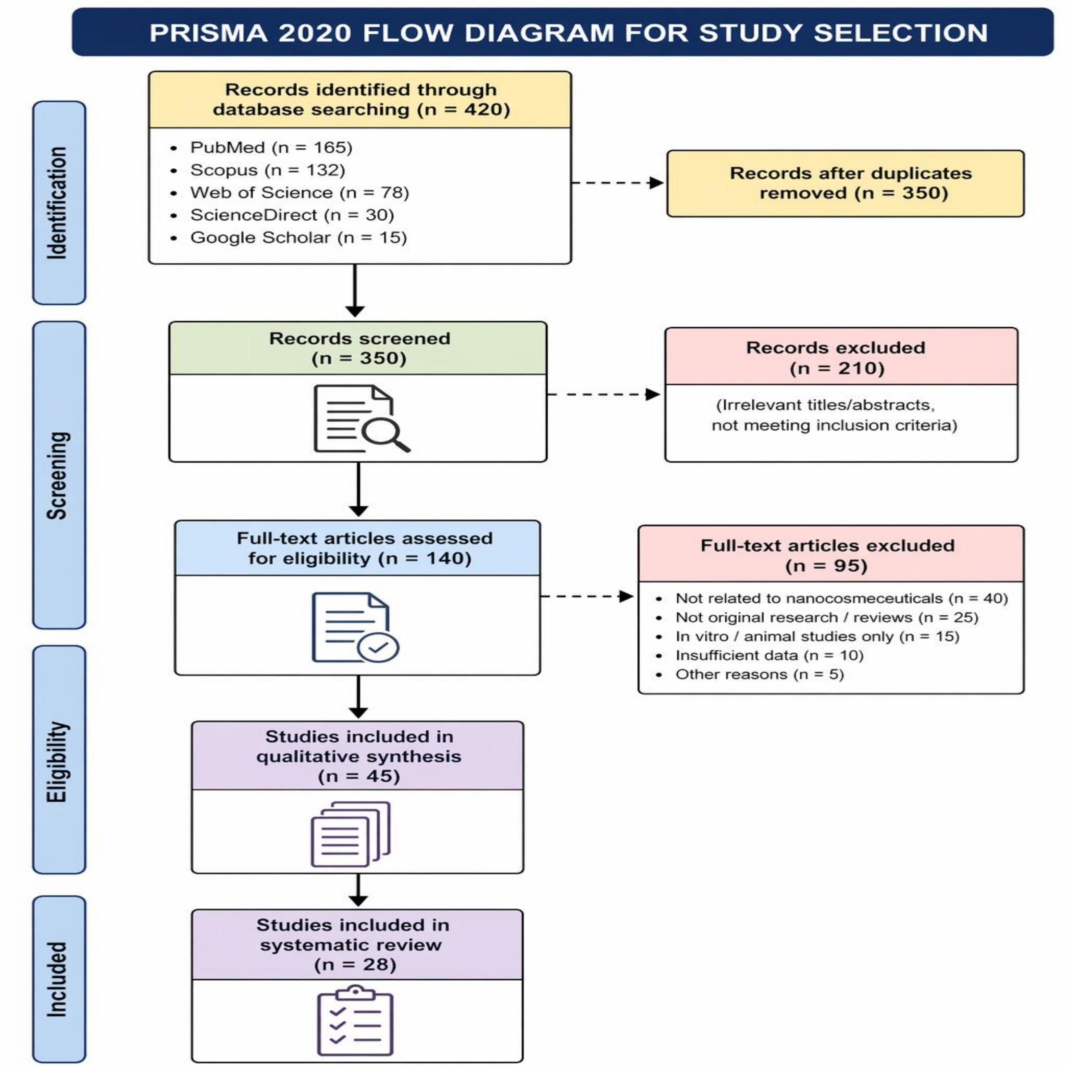

Table: 1 COMPARISON OF NANOCARRIERS

Nanocarrier	Composition	Key Features	Advantages	Limitations	Cosmeceutical Applications
Liposomes	Phospholipids	Bilayer vesicles encapsulating hydrophilic & lipophilic drugs	Biocompatible, enhances skin hydration, good penetration	Low stability, high cost	Anti-aging, moisturizers
Niosomes	Non-ionic surfactants	Vesicular system similar to liposomes	More stable, cost-effective, easy storage	Lower penetration than transfersomes	Anti-aging, drug delivery
Transfersomes	Phospholipids + edge activators	Ultra-deformable vesicles	Excellent transdermal delivery, high flexibility	Expensive, formulation complexity	Transdermal therapy, deep skin delivery
Ethosomes	Phospholipids + high ethanol	Soft vesicles with high ethanol content	Enhanced skin permeation, improved drug solubility	Skin irritation (due to ethanol), stability issues	Acne, pigmentation treatment

SLNs (Solid Lipid Nanoparticles)	Solid lipids	Solid matrix system	Controlled release, protects sensitive drugs	Limited drug loading, drug expulsion	Sunscreens, anti-aging
NLCs (Nanostructured Lipid Carriers)	Solid + liquid lipids	Imperfect lipid matrix	Higher drug loading, better stability than SLNs	Complex formulation	Anti-aging, dermal delivery
Nanoemulsions	Oil + water + surfactants	Thermodynamically stable dispersions	Transparent, high solubilization, good spreadability	Requires high surfactant concentration	Moisturizers, topical delivery
Polymeric Nanoparticles	Natural/synthetic polymers	Matrix or reservoir system	Sustained release, targeted delivery	Possible toxicity, high cost	Anti-aging, targeted therapy

IV. CONCLUSION

Nanotechnology has transformed cosmeceuticals by solving inherent problems associated with traditional cosmeceutical formulations such as poor permeability, lack of stability, and inadequate targeting. Nanocarriers have facilitated significant improvements in bioavailability, controlled drug delivery, and efficacious dermatological treatments in areas like anti-aging, treatment of acne, and photoprotection [85-97].

Despite the aforementioned benefits, issues of nanotoxicology, safety, and uncertainty about regulations are some of the challenges associated with nanotechnology that need to be sorted out via extensive clinical trials and proper guidelines [98-100].

In the future, advancements in nanocosmeceutics tailored to individuals, application of AI for cosmeceutical formulations, and environmentally friendly nanotechnology are anticipated in this field. In general, nanotechnology plays a vital role as a link between cosmetics and medicine.

CRediT authorship contribution statement

Dr. H. Gayathri was solely responsible for the conceptualization, design, data collection, analysis, visualization, and preparation of the manuscript.

Consent to participate

None.

Data availability

No data was used for the research described in the article.

Ethical approval

This review is only a summary of the existing literature and does not refer to any human or animal experiments.

Declaration of generative AI and AI-assisted technologies in the writing process

During the preparation of this work the author(s) used Paperpal and Quillbot for language corrections and flow. After using this tool/service, the author(s) reviewed and edited the content as needed and take(s) full responsibility for the content of the publication.

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