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Review Article

NANOSTRUCTURED LIPID CARRIERS APPLICATIONS IN COSMECEUTICALS: STRUCTURE, FORMULATION, SAFETY PROFILE AND MARKET TRENDS

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ABSTRACT

Cosmeceuticals, a combination of medicines and cosmetics, provide therapeutic advantages using advanced drug delivery mechanisms. The products improve not only skin health but also beauty. Most of the cosmeceuticals used transdermal delivery systems, which have limitations in absorption and penetration. Advanced drug delivery systems, such as nanostructured lipid carriers (NLCs), have great potential in avoiding the epidermal barrier toward enhanced delivery and targeted distribution of active ingredients. Nanostructured Lipid Carriers are formed by mixing spatially incompatible long and short-chain lipids using various formulation techniques. Nanostructured lipid carriers can efficiently encapsulate active ingredients and ensure controlled release and targeted action. These benefits, combined with the properties of the encapsulated substances, contribute to improved skin hydration, moisturization, and anti-ageing effects when applied in cosmeceuticals. NLCs have shown potential in hair care, sunscreens, and UV protection applications because they enhance the delivery and stability of active ingredients. Despite these benefits, detailed information on the potential limitations of NLC systems remains underreported. Current research emphasizes the importance of conducting thorough in vitro toxicity studies per the Organization for Economic Co-operation and Development recommendations to assess their safety profiles and identify possible concerns. More research is also essential to close knowledge gaps and guarantee that the safety and effectiveness of NLC formulations are fully proven before moving on with clinical trials or regulatory evaluations.

KEYWORDS: Nanostructured Lipid Carriers, Cosmeceuticals, Transdermal Drug Delivery Systems, Skin Care, Hair Care.

1. Introduction

Cosmeceuticals are products applied topically. They contain bioactive ingredients. These offer cosmetic and therapeutic benefits. They improve skin health and appearance [1]. The cosmetics industry has made tremendous progress over the past decade, with new delivery methods becoming the foundation to increase the effectiveness of active ingredients in skin care formulations [2]. Among them, nanostructured lipid carriers (NLC) have emerged as a useful and efficient technology that overcome many limitations associated with traditional delivery methods [3].

One of the biggest challenges in skin care is managing the skin's natural barrier, especially the stratum corneum. This skin barrier prevents beneficial nutrients from being delivered to deeper layers of the skin [4,5]. Nanoscale size, lipid composition, and biocompatibility allow them to interact with the lipid matrix of the stratum corneum, thereby improving delivery and reducing systemic absorption [6].

NLCs increasingly offer bio-actives such as retinoids, antioxidants, peptides and vitamins [7, 8]. NLC offers many advantages over traditional carriers, including long shelf life, image stability, and superior image quality for surface applications [9]. Solid Lipid Nanoparticles (SLNs) and Nanostructured Lipid Carriers (NLCs) have emerged as promising carriers in cosmeceuticals [10]. Liposomes have been widely adopted because they enhance the skin's absorption of active ingredients [11,12].

Despite their potential efficacy, many aspects of NLC remain unexplored, including optimization of lipid composition, long-term stability, and safety by providing efficient encapsulation and targeted release of active ingredients [13] that make them susceptible to degradation [14-16]. Controlled-release formulations in cosmeceuticals are desired to provide sustained delivery of active ingredients, ensuring prolonged efficacy and enhancing skin hydration and protection over time [14]. Furthermore, SLNs have particle sizes ranging from 10-1000 nanometres and are composed of phospholipid layers enclosing a hydrophobic core of lipids, specifically triglycerides. Moreover, they are more resistant to coalescence than liposomes due to their solid nature [17].

These nanoparticles improve bioavailability significantly [18], which ultimately enhances skin hydration owing to their occlusive properties and have extended drug release profiles for active ingredients [19]. In addition, theses nano-formulations protect products from degradation through chemical and physical processes by providing stability against UV rays, acting as a physical sunscreen [20].

NLCs, being second-generation nanoparticles, have been developed to overcome the limitations associated with SLNs [21]. Compared to SLNs, NLCs offer enchanced stability, higher loading capacity, and superior protection of active ingredients from chemical degradation [22]. The benefits of NLCs compared to other formulations are shown in Figure 1.

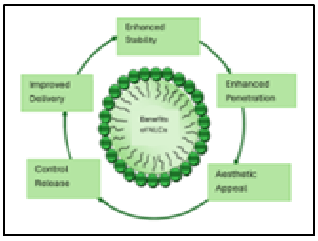

Fig 1. Benefits of Nano-structured Lipid Carriers

However, while NLCs excel in many areas, SLNs provide superior UV protection due to more stable and uniform structure of SLNs, which increases their ability to scatter and absorb UV light [23]. NLCs' nanosized structure gives them a high occlusion factor, preventing dehydration and promoting moisturization [24]. Additionally, NLCs are more appealing and have enhanced patient compliance due to their white colour instead of yellow [24-29]. This article provides a comprehensive review of the structure, and safety of NLCs with a focus on their cosmetic applications. Additionally, market trends and consumer attitudes supporting the adoption of NLC designs are also explored.

2. Structure of NLCs

A spatially incompatible mixture of Liquid lipid (LL) and Solid lipid (SL) is mixed to prepare NLCs [30]. In this mixture, the SL crystals do not dissolve in the LL, and the oil molecules, or LL, do not contribute to the crystalline matrix of SL. However, at a temperature lower than their melting point, this combination of lipids should be uniform and exhibit no phase separation; In this state, LL should be present as nanoscale compartments within the solid crystalline matrix of the SL, thus contributing to a non-crystalline lattice [31].

This non-crystalline structure significantly increases the solubility of pharmacologically active agents, thus increasing encapsulation efficiency. Furthermore, these nano-formulations have better drug stability and significant drug loading capacity, ultimately limiting drug leakage during storage [32]. There are three major categories of structures of NLCs disordered, amorphous, and multiple [25].

2.1. Disordered/ Imperfect Structure:

This imperfect structure is formed by mixing the SL and LP in a highly disordered form [33]. This lipid-based nano-formulation significantly improves the drug penetrating ability in the lipid layer as it forms an interface between liquid and crystalline lipids [34].

2.2. Amorphous Structure:

These lipid-based nano-formulations can keep the lipid matrix in a non-crystalline state, thus ultimately limiting drug leakage during storage of these formulations [35]. Furthermore, rapid chilling, performed by combining several lipids, assists in the required crystalline structure by preventing crystal formation [36].

2.3. Multiple Structures:

These have a higher concentration of liquid lipids, resulting in improved drug solubility and enhanced drug loading [37]. The structure allows for gradual drug release and prevents drug loss before the breakdown of the solid lipid [38].

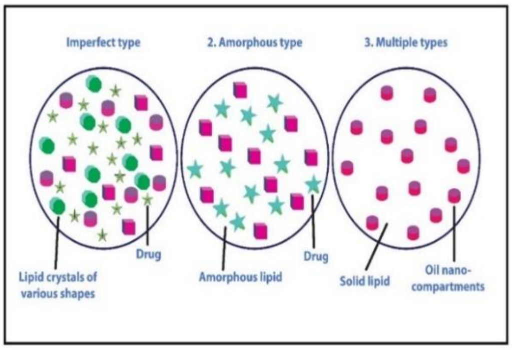

Fig 2. Schematic illustrations of structures of NLC (1, 2, and 3 are disorder, structure, amorphous structure, and multiple structures, respectively).

To prepare NLCs, an aqueous solution comprising water-soluble surfactants/emulsifiers is used to nano-emulsify a lipophilic phase consisting of a mixture of SL and LL, such as tripalmitin and squalene, respectively [39]. High-pressure homogenization (HPH), solvent emulsification/evaporation, micro emulsification, ultra-sonification or high-speed homogenization, spray drying, and microfluidic technology are some methods used to formulate NLC as shown in Table 1.

Most frequently used lipids for NLCs are glyceryl monostearate and stearic acid as solid lipids, and squalene or medium-chain triglycerides as liquid lipids. Surfactants that stabilize the emulsions are Tween 80, lecithin, and sodium dodecyl sulfate, while co-surfactants that enhance stability and lower surface tension are ethanol, propylene glycol, and PEG. Such components are selected according to formulation requirements such as particle size and drug release.

Table 1.
Various techniques for preparing drug-loaded Nanostructured Lipid Carriers, highlighting their methodologies, advantages, and disadvantages. Each method is evaluated for suitability for different drug types, scalability, and safety considerations.

Technique	Description	Advantages	Disadvantages	Ref.
Hot High-Pressure Homogenization (HPH)	Drugs and lipids are dissolved in melted lipids and blended with a heated aqueous solution containing surfactants using a high-pressure homogenizer.	Suitable for large-scale manufacturing, no organic solvents are used.	Limits with drug thermolability, possibly lower efficiency.	[40]
Cold High-Pressure Homogenization	The drug and lipid mixture is dissolved in an organic solvent, emulsified in an aqueous phase, and evaporated under low pressure.	Suitable for heat-sensitive drugs.	Residual solvent may remain, posing potential toxicity; extra filtration may be needed, affecting yield.	[24]
Solvent Emulsification/ Evaporation	Drug and lipid mixture dissolved in a water-immiscible organic solvent, emulsified in aqueous phase, then solvent evaporated under low pressure.	Allows for heat-sensitive drug loading.	Risk of residual solvent; additional filtration may impact economic feasibility and yield.	[29]
Microemulsions	Molten lipids blended with hydrophilic aqueous phase (surfactant and co-surfactant) to form an emulsion; further dispersion in the chilled phase forms NLCs.	Cost-effective, simple, adaptable to various drug polarities; suitable for thermos-labile drugs	Requires substantial surfactants and large water volumes, impacting cost-effectiveness.	[41]
Ultrasonication/High -Speed Homogenization	By mixing the heated lipid phase with surfactant in the heated aqueous phase using ultrasonication or high-speed homogenization.	It is simple, has lower equipment costs than HPH, and has better availability.	Moderate stability, polydispersity issues, and contamination risks from probe-based sonicators.	[42]
Spray Drying	Induces particle agglomeration through heat and shear stress, causing melting and increased kinetic energy for particle collisions; solid lipids above 70°C used at 1% w/v in aqueous trehalose solution.	Cost-effective and suitable for high melting point lipids.	Risk of particle aggregation, structural changes in lipid core, surfactant alterations, and degradation at high temperatures.	[43]
Microfluidics	Controls flow rates of liquid reagents in a microfluidics chip, allowing rapid mixing and collision of nanolitre volumes under controlled pressure.	Enhances uniformity of nanoparticles, reduces production time, and eliminates organic solvents; efficient for large-scale production.	It requires sophisticated equipment, but scalability may still be a concern in some settings.	[44]

3. **NLCs application**

3.1. Skin hydration and moisturization

Skin, the human body's largest and most complex organ, plays crucial roles in vitamin synthesis, particularly vitamin D, thermal regulation, and protection against foreign bodies [45]. This highlights the importance of healthy skin for overall biological well-being. A key feature of healthy skin is hydration, prompting pharmaceutical companies to develop effective moisturizers for centuries [46]. Traditional products, including emulsions, lotions, and creams, often suffer from drawbacks like thick viscosity, grainy texture, which can lead to reduced patient compliance [47]. Nanotechnology has been introduced to the market as one of the new approaches aimed at improving the hydration of the skin. These nanoformulations have an occlusive effect, increasing the concentration of active ingredients in the skin. In addition, their formulation with biocompatible ingredients such as lipids inherent to the skin not only improves the safety profile but also alters the lipid membranes of skin to promote drug delivery. These changes take place through mechanisms such as fluidization, polarization alterations, or phase separation [48].

To address that mostly includes low drug capacity, drug expulsion during storage, and limited stability [49]. Among the most promising developments in skin hydration are nano lipid gels, which incorporate lipid nanoparticles into a gel base. Typical gelling agents, such as xanthan gum, chitosan, hydroxyethyl cellulose, and acrylate polymers, enhance the stability and effectiveness of these formulations [50]. Before gel incorporation, SLNs and NLCs are carefully prepared and analyzed to ensure optimal performance [51,52].

3.2. Anti-aging

Aging is a natural process influenced by various environmental factors, such as sun exposure, smoking, and pollution, which can significantly accelerate its onset [53]. One of the primary mechanisms behind accelerated aging is the formation of reactive species, particularly free radicals [54]. These free radicals damage DNA and its structures, and may also oxidize proteins and lipids [55].

Under physiological conditions, the transcription factor, nuclear factor erythroid 2-related factor (Nrf2), binds to the antioxidant response element (ARE) in the promoter regulatory sequence, inducing the expression of genes that help protect cells against oxidative stress [56]. However, in basal conditions, Nrf2 binds to Keap1, resulting in its repression [57]. Disrupting the Nrf2-Keap1 complex could enhance protection against reactive chemical species [58,59].

NLCs present cost-effective formulations for delivering active ingredients to skin cells. These vehicles can effectively encapsulate and transport active compounds [60]. NLCs can be utilized to prepare cosmeceuticals with active ingredients at their core. These carriers possess unique features, such as nanoscale size, which facilitates penetration through anatomical barriers, high drug loading capacity, controlled release, and enhanced encapsulation efficiency [61]. Folic acid, an essential member of the B-complex family, is known for its anti-aging properties. It promotes DNA synthesis and helps regenerate skin cells in mitotically active tissues [62]. Incorporating NLCs to enhance the topical delivery of folic acid allows for the controlled release of this active ingredient to skin cells [63]. Folic acid-loaded NLCs protect the skin and reduce lipid peroxidation formation in the stratum corneum. After one hour of application of the folic acid formulation, a remarkable 90.1% inhibition of lipid peroxidation is achieved. Aloe vera-based nano-emulsions showed a 50% enhancement in wound healing compared to conventional ointments, and Collagen-infused hydrogels improved skin elasticity by 72% in clinical trials over six weeks [64].

3.3. Hair Care Innovations

The influence of nanoparticles in hair care is primarily attributed to their unique properties, which significantly enhance the effectiveness of active ingredients i.e increasing the effectiveness and performance of active ingredient to give best results in products [65]. However, understanding hair fiber and follicular targeting mechanisms is helpful in the development of customized products and new techniques capable of achieving improved hair care results [66]. Nanocarriers are used to deliver different molecules to the follicle and shaft [67].

Nanomaterials, particularly NLCs, are increasingly used in hair care products, such as shampoos and conditioners, to enhance their effectiveness [68]. In shampoos, these nanomaterials increase the contact time with the scalp and hair follicles, allowing active agents to form a protective layer that seals moisture within the cuticles [69]. As shown in Figure 3, using NLCs significantly reduces the damage caused by external stressors like UV exposure and thermal treatments, as indicated by the lower colour change values in NLC-treated hair compared to untreated hair. This protective film formed by NLCs prevents severe damage, allowing the hair to maintain its integrity and appearance [70].

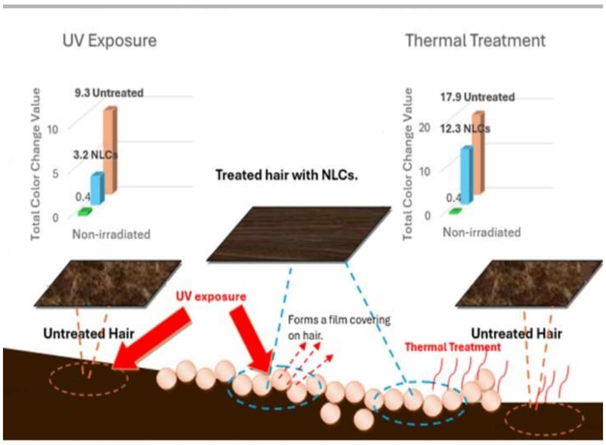

Fig 3. This illustration shows the protective effects of NLCs on hair under UV exposure and thermal treatment. Untreated hair shows significantly higher color change (9.3 units for UV exposure and 17.9 units for thermal treatment) than NLC-treated hair (3.2 units for UV and 12.3 units for thermal treatment), highlighting the damage reduction provided by NLCs. Non-irradiated hair exhibits minimal color change (0.4 units). The illustrations show that NLCs form a protective film over the hair, preventing damage from external stressors and preserving the hair's appearance and structure.

Unlike traditional formulations, where silicone tends to accumulate on the scalp due to its hydrophobic nature [71]. In NLC-based preparations, silicone oil is incorporated into nanomaterials. Due to its smaller particle size, it diffuses more easily into the hair fibers. A significant advantage of such formulations is their ability to penetrate deeper into the hair's hydrolipid layer without damaging the cuticle [72]. While shampoo is primarily used to cleanse the hair, conditioners play a crucial role in reintroducing essential materials that support hair growth, texture, and overall health [73]. One novel development in conditioning agents is the use of sericin, a material derived from silkworms, incorporated as cationic nanoparticles [74]. These nanoparticles are effective in repairing damaged hair [75]. The use of NLCs and other nanomaterials in hair care represents a significant advancement, as their smaller size enables more profound and more efficient penetration of beneficial ingredients, enhancing the overall health and appearance of the hair [76].

3.4. Sunscreen and UV Protection

Skin exposure to harmful UV rays is a significant factor in causing various skin problems, such as hyperpigmentation and skin cancer [77]. The rising incidence of skin cancer has led to an increase in sunscreen sales [78]. Sunscreens protect the skin by reflecting or absorbing UV rays [79,80].

As shown in Figure 4, NLCs in sunscreens provide significant advantages by delivering active molecules more profoundly into the skin while forming a protective barrier against UV rays and pollutants [81]. NLCs allow for greater skin coverage, improving both protection and skin hydration. Nanomaterials like zinc oxide and titanium oxide in nanoform provide better protection than conventional UV filters due to their stability and deeper penetration into the skin [82].

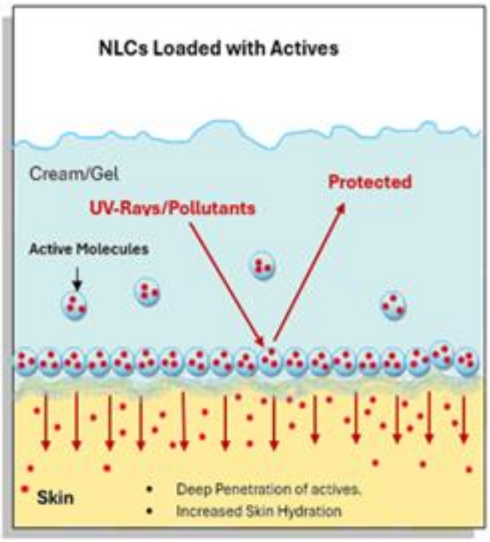

Fig 4. The diagram shows how these NLC-based sunscreens create a shield on the skin's surface, reducing UV damage while increasing active ingredients' hydration and effectiveness.

Mineral-based filters that contain nanoparticles, such as zinc oxide and titanium oxide, are more stable and provide better protection than conventional UV filters [83]. Zinc oxide is the most commonly used due to its superior reflective properties. Additionally, NLC-based formulations help address aesthetic concerns, providing a non-white finish, a key benefit in modern sunscreens [84]. This makes NLCs a valuable advancement in sunscreen cosmetics, combining enhanced protection with improved user satisfaction [85].

3.5. Customized Beauty Products

Each individual's skin is unique, requiring personalized treatment based on specific conditions [86]. While consumers were limited to using generic products in the past, today's consumers are much more demanding, seeking personalized cosmetics that address their unique skin concerns [87]. In this evolving field, nanoformulations, particularly NLCs, have played a significant role by offering greater customization and targeted benefits according to the specific needs of each user [88]. NLCs allow for the delivery of active ingredients more efficiently, ensuring that products can be tailored to address distinct skin issues such as hydration, anti-aging, or UV protection [89]. As personalization continues to gain popularity, we can expect further innovations in NLC-based cosmetics to facilitate even more customized beauty solutions in the future [90].

4. Safety of NLCs Cosmeceuticals

When using NLCs, especially in cosmeceuticals, their safety and toxicity profile are crucial factors to consider [91]. Current research indicates that NLCs are typically safe and effective for cosmetic applications, even if their full safety and toxicity profiles are yet unknown [92]. Because they are biodegradable and include physiological lipids that the body can tolerate, oral NLCs, in particular, are thought to be comparatively safer [93]. Additionally, NLC formulations usually have a better safety profile than other delivery methods like emulsions since they contain fewer chemicals, such as surfactants and co-surfactants [94]. However, certain chemotherapeutic drugs delivered by NLCs may have cationic components or linkers that bind ligands for targeted administration, raising certain issues [95]. These components may elicit immune responses, an area of concern requiring further research [96]. Evaluating the safety of NLCs requires a diversified approach, considering the formulation components and how they interact with the skin and body [97].

4.1. Potential toxic effects of NLCs

NLCs are perfect for cosmeceutical applications because of their tiny particle size, allowing for improved skin layer penetration [98]. Their nanoscale size, meanwhile, may potentially have harmful consequences. Because of their increased surface area, smaller nanoparticles interact more strongly with biological constituents such as proteins, fatty acids, and nucleic acids [99]. Concerns regarding the possible toxicity are raised by the possibility of prolonged retention in the body due to NLCs' capacity to permeate cell membranes and elude cellular clearance processes [100]. The generation of reactive oxygen species (ROS) is one of the most extensively researched mechanisms of NLC toxicity. Oxidative stress from ROS can result in DNA damage, gene transcription changes, and cellular signaling pathways disruption [101]. This oxidative stress, if prolonged, may lead to significant cellular damage depending on the duration of ROS exposure and external factors such as oxygen pressure, nutrient depletion, and temperature [102].

4.2. Cytotoxicity of lipid-based nanomaterials

When evaluating the safety of NLC, cytotoxicity, the ability of a chemical to harm or destroy the cells, is a crucial element to consider [103]. NLCs and other lipid-based nanomaterials can cause complement activation in cosmeceuticals, resulting in hypersensitivity responses and inflammation. Although the exact mechanisms underlying this immune activation remain unclear, it is widely known that medications made with nanotechnology can cause acute hypersensitivity reactions in patients, which can show up as respiratory, hemodynamic, and cutaneous symptoms [1044].

Their surface charge significantly influences the cytotoxic potential of NLCs. Because they adhere to the cell surfaces non-specifically and increase the inflammatory and immunological reactions, cationic liposomes, which have a positive surface charge, are often inappropriate for therapeutic usage [105]. Systemic toxicity may develop from early release or aggregation of active substances [106]. Additionally, the particle concentration affected the cytotoxicity of NLCs on lymphocytes; 2.1×10^{11} particles/ml reduced cell viability by around 55% [32]

5. Future Aspects

NLCs in cosmeceuticals have much potential but also call for stricter laws and international collaboration [107]. Strict regulations must be made for the manufacture, storage, importation, and marketing of NLC-based cosmeceuticals as they develop to guarantee their safety and uniformity [108]. Researchers, businesses, and regulatory agencies must collaborate globally to develop uniform rules for using nanosystems in cosmetics. This partnership will improve consumer safety and fill data gaps [109].

Furthermore, it is impossible to overestimate the importance of governments and non-governmental groups in consumer education [110]. The main focus of efforts should be creating and distributing instructional resources via various venues, such as seminars, multimedia platforms, films, and textual information [111]. To ensure that users benefit from the innovation without running the danger of unintended consequences, such programs will assist consumers in understanding the appropriate and safe use of cosmeceuticals incorporating nanoparticles [112].

Lastly, the global cosmeceutical industry requires unified regulations to enhance product safety, efficacy, and marketing. Harmonized international standards will offer a stronger regulatory framework for manufacturers and retailers alike, benefiting consumers through higher product safety standards [113].

6. Market Growth

The cosemectieuticals market is driven by innovations such as NLC-based products, is experiencing robust growth [114]. It is valued at USD 56.08 billion in 2022 and is projected to exceed USD 128.54 billion by 2032, growing at a compound annual growth rate (CAGR) of 8.7% from 2023 to 2032[115].

This growth is fueled by rising consumer demand for innovative, effective, and personalized cosmetic products that offer more than just superficial benefits, aligning with the potential of NLC-based formulations [116]. Globally, the United States and China are significant markets, with the U.S. cosmeceuticals sector expected to reach $15.3 billion by 2020 and China forecasted to achieve a market size of $14.3 billion by 2027, growing at a 6.4% CAGR [117].

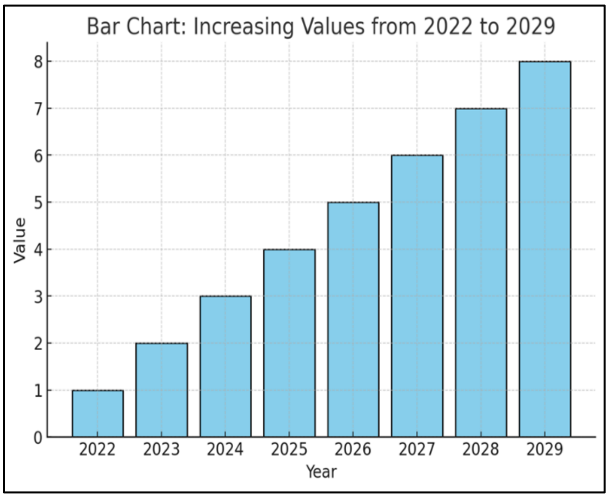

Fig 5. Asia Pacific Cosmeceutical Market Size, 2022-2030.

Other key markets, such as Japan, Canada, and Germany, are also projected to see steady growth rates between 2020 and 2027, ranging from 5.5% to 6.4%, as shown in graph 1, further highlighting the expanding global demand for advanced cosmeceutical products [119].

7. Conclusion

Nanostructured Lipid Carriers, a recent innovation in drug delivery systems, provide promising and versatile formulations in cosmeceutical products. NLCs are composed of a blend of SL and LL that provide enhanced stability, offer high encapsulation efficiency, and prevent lipophilic substances from degradation. Their properties, including biodegradability and targeted drug delivery, make them versatile for various administration routes. NLCs, nanoscale in size, are the best candidates to improve skin penetration and retention for use in the transdermal route of cosmeceuticals. While conventional drug delivery and offer promising applications in dermatology, bio-medics, and cosmetics. NLCs have the potential to fulfill and satisfy increased customer demand, but their use is limited due to various controversies. European cosmetic regulations made it necessary to safely test nanomaterials before using them. Some highly toxic materials are used in sunscreens raise potential health concerns.

In conclusion, even though there is a need for further clinical trials to develop a suitable safety profile for NLCs in cosmeceuticals, they are still being used in nano-formulations. Their unique properties in maintaining skin integrity and retention on the skin make them potential candidates for revolutionizing the pharmaceutical drug delivery system and ultimately benefiting humankind.

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