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Review Article

Niosomal Drug Delivery System used in Tuberculosis

Oma Shanker, *Arsh Chanana, Pooja Gupta, Aditya Narayan, Yukta R. Kulkarni, Akhilesh Patel, Ujwal havelikar, Bhabesh Mahato, Ravindra Pal Singh, Himmat Singh Chawra, Anurag Mishra

Department of Pharmaceutics, NIMS Institute of Pharmacy, NIMS University Rajasthan, India

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*Address for Correspondence:

Arsh Chanana, Department of Pharmaceutics, NIMS Institute of Pharmacy, NIMS University Rajasthan, India

Abstract

Niosomes are artificially manufactured vesicles made of Cholesterol and Non-ionic surfactant. Their capacity to encapsulate a broad variety of pharmaceuticals and shield them from deterioration has piqued interest in drug delivery. Niosomes have demonstrated a possible use in the administration of anti-tuberculosis medications. Worldwide, tuberculosis is a serious public health concern. Even with advances in science and technology, tuberculosis remains a persistent problem.Niosomes can encapsulate anti-TB drugs, protecting them from enzymatic degradation and allowing for sustained release. Research in this field is on-going, with scientists working on optimizing niosomal formulations for tuberculosis treatment. It's important to consult current scientific literature for the latest advancements. Some anti-tubercular drugs face challenges in terms of absorption and bioavailability. Niosomal delivery systems can help address these issues. While niosomal drug delivery systems show promise, it's crucial to note that they are still an area of active research and specific formulations and protocols may vary. Patients should always consult with their healthcare providers for the most appropriate and up-to-date treatment options for tuberculosis. Niosomes can encapsulate both hydrophilic and lipophilic drugs, offering advantages such as increased drug stability, prolonged circulation time, controlled release, and targeted delivery. They have applications in various fields including pharmaceuticals, cosmetics, and agriculture.

Keywords: Tuberculosis, Niosomes, Drug delivery system

INTRODUCTION

Tuberculosis: One of the biggest global health issues is tuberculosis (TB), which is second only to HIV as the leading cause of mortality globally. The recent data based on the data given by World Health Organisation (WHO)& that is 10 million new cases reported in 2016.It is estimated that one in three individuals globally may have Mycobacterium tuberculosis and be at risk of the illness reoccurring[1,2].TB is a serious illness caused by these bacteria. In order to stop the worldwide tuberculosis epidemic, the End TB Strategy will be put into action starting in 2016 established by the World Health Assembly in May 2014, the plan provides countries with a roadmap to cure tuberculosis fatalities by 87% by 2030 with targets connected to the recently established Sustainable Development Goals[3,4]. These days, a typical six-month course of short-term treatment involves taking various anti-tuberculosis (anti-TB) medications orally together, such as rifampicin, isoniazid, pyrazinamide, ethambutol, and streptomycin. We refer to these as first-line medications [5]. More than 60% of newly diagnosed cases of tuberculosis worldwide are attributed to six countries: South Africa, China, India, Indonesia, and Pakistan. Thus, the development of tuberculosis prevention and treatment in this nation is largely dependent upon worldwide success[6,7].

All things considered, nanotechnology has the capacity to deeply explore and take advantage of new aspects and features of particles in order for creating fresh approaches and deliver methods for illness treatment and diagnosis, to improve the qualities of process that have already been produced. Interestingly, nanotechnology may improve and encourage the use of novel drug/antigen delivery methods by fusing and blending the most updated data of nano-materials with the comprehension of various biological processes[8,9].

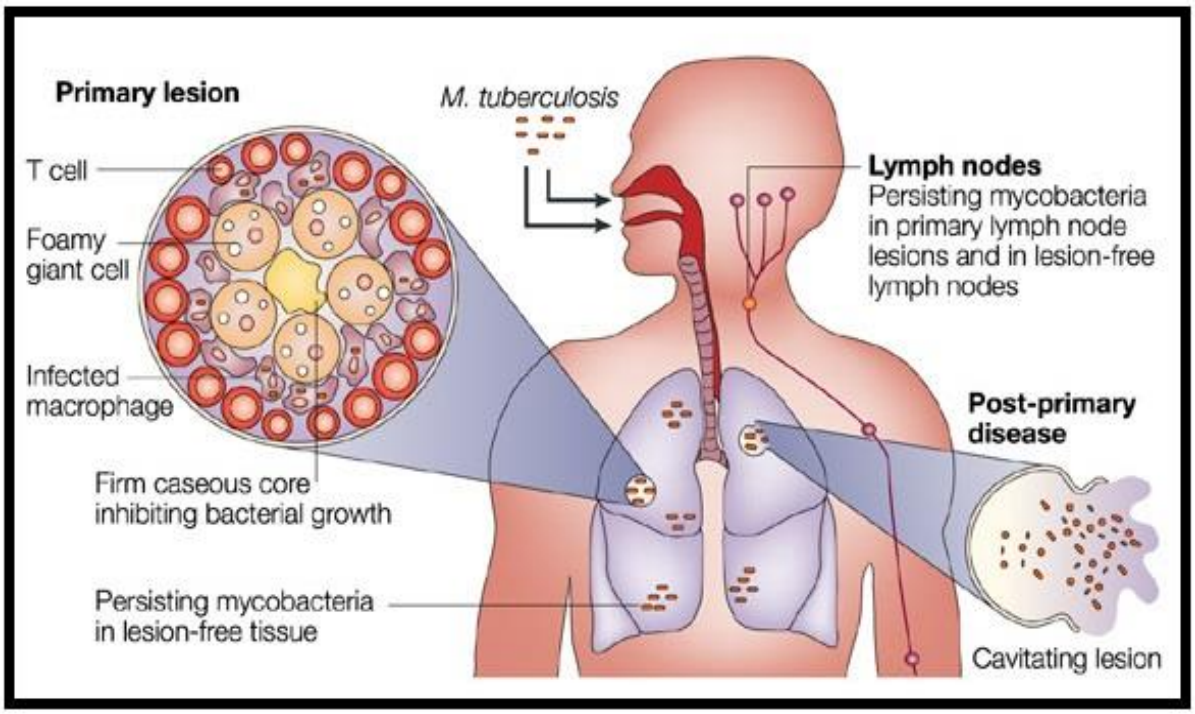
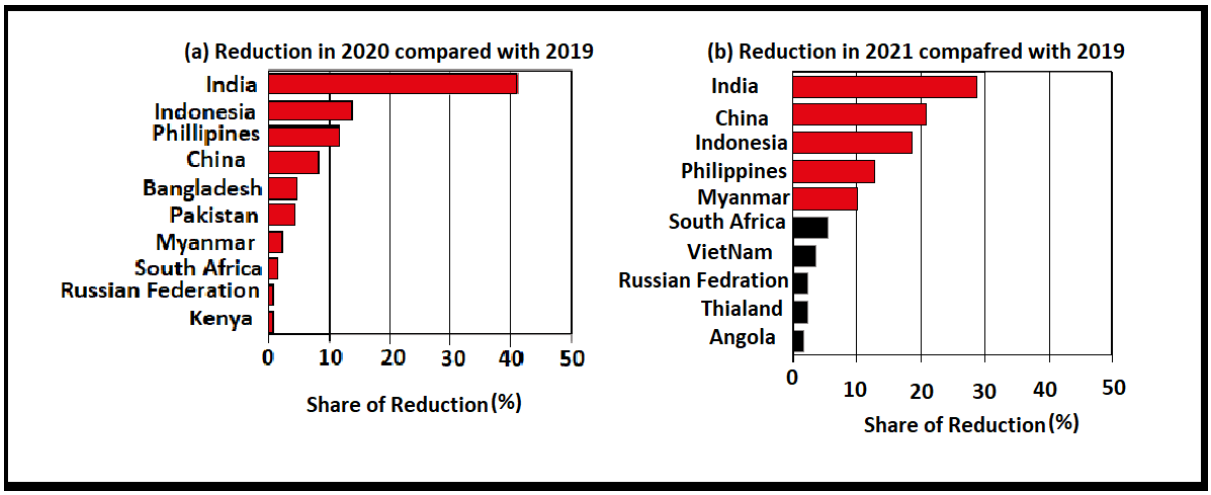


Figure 1: Structure of tuberculosis infected lungs[2]

Table 1: Goal for ending TB

VISION A WORLD FREE OF TB zero deaths, disease and suffering due to TB				
GOAL	END THE GLOBAL TB EPIDEMIC			
INDICATORS	MILESTONES		TARGETS	
	2020	2025	2030	2035
Drop in percentage of total tuberculosis fatalities (comparing with 2015)	35%	75%	90%	95%
proportional decrease in the incidence rate of tuberculosis (comparing with 2015)	20%	50%	80%	90%
percentage of families infected by tuberculosis (TB) that are experiencing catastrophic costs as a result of TB (level in 2015 unknown)	0%	0%	0%	0%

Chart 1: The top 10 countries (those with a red tint indicate those that accounted for 90% of the reduction in case notifications of newly diagnosed TB patients worldwide in 2020 and 2021)[8]



Deaths caused by TB

A decline in newly reported cases of tuberculosis in 2020 and 2021 points to a rise in undiagnosed and untreated tuberculosis cases, which has preceded, albeit slightly, an increase in tuberculosis cases developing. This increase in tuberculosis deaths and community infection transmission has resulted from these cases[10]. Since most less or medium income nations faces problem in their national disease surveillance system , registration system &population based services to quantify the counting of TB deaths and cases in the country throughout the 2020–2021 period, new techniques for estimating Incidence and death from tuberculosis in these years. These approaches have undergone a thorough evaluation and mostly depend on dynamic models unique to each nation and region[11]. Essential presumptions include a 50% decrease in TB when strict restrictions are follows by the health care system and real decreases in TB case detection. Although the expected yearly death toll from TB cases decreases between 2005 and 2019, but the data comes in 2020 & 2021 which indicate that this trend is reversed[12].

Nanotechnology:

The uses of nanotechnology form the targeted drug delivery system, reduce the side effects &improve treatment methods .These also developing the long acting drug formulations that need less common dosing, which can improve treatment outcomes[13].

Digital Health and Telemedicine:

Telemedicine and remote monitoring: Using digital platforms to provide virtual consultations, monitor treatment adherence, and offer support to patients, especially in areas with limited access to healthcare facilities.

Public Health Interventions:

Contact Tracing and Surveillance: Innovations in contact tracing and surveillance systems using technology and data analytics to identify and treat TB cases earlier [14,15].

Behavioural Interventions:

Patient education and support: Developing innovative methods to educate and support TB patients, including digital health tools, peer support networks, and community engagement.

Social factors of Health:

Addressing underlying social factors of health, like poverty, housing, and access to education, this can contribute to TB transmission and treatment outcomes [16].

Research and Data Analytics:

Using advanced analytics, modelling, and big data approaches to better understand TB epidemiology, drug resistance patterns, and treatment outcomes [17].

Global Collaboration and Partnerships:

Encouraging collaboration between governments, NGOs, academia, and industry to pool resources, share knowledge, and accelerate the development and implementation of innovative TB solutions.

Remember that the success of any innovation in TB prevention and treatment will depend on factors like accessibility, affordability, cultural considerations, and healthcare infrastructure in affected regions [18,19]. Collaborative efforts involving healthcare professionals, researchers, policymakers, and communities are crucial for the effective implementation of these innovations. The aim of novel treatment techniques is to prevent drug-resistant strains from arising, to guarantee cure without recurrence, and to prevent fatalities and infections. It is now critically necessary to find shorter and unique techniques in order to achieve these aims. Basically, there are two primary approaches to fighting this enormous illness. The first strategy is drug discovery, which involves either finding a new chemical entity or repurposing an existing medicine[20,21].

Drug discovery

The creation of safe and efficient medications for the treatment of tuberculosis is fraught with difficulties. The primary factor is the pharmaceutical industry's limited investment in finding of the new anti-TB medications due to the poor profit margin of this sector. The cost of a conventional TB regimen is only approximately $11 per patient, compared to the estimated $250 million cost of discovering and developing a novel chemical entity [22]. Many nations have thrown in the towel and begun funding the development of anti-TB drugs in an effort to address this issue. There are few committees which provide the funding to TB research are Centres of Disease Control, Medical Research Council, National Institutes of Health, European & Developing Countries Clinical Trial Partnership, Global Alliance for TB drug Development. The second major factor contributing the therapeutic treatment failure is the MTb's quick development of resistance to new chemical substances [23,24].

New drugs

With the current arsenal of anti-tubercular medications, treating MTB has become increasingly challenging due to the disease's daily rise in antibiotic resistance. To prevent bacterial resistance or cross resistance, it is imperative from a clinical standpoint to design a novel, safe, and effects new chemical product with a bactericidal action & innovative mechanism[25]. Following the 'World Health Organization's' declaration of a global emergency of Tuberculosis, numerous nations have increased their funding for the development of new anti-TB medications, working with both public and commercial funding organisations worldwide. Some of the new compounds are passing through various clinical phases as a result of the combined efforts of all these agencies. These compounds will soon join the TB arsenal and aid in achieving WHO's "END TB STRATEGY" aim if they meet all safety, efficacy, and regulatory standards [26,27].

Repurposed drug

The striking rise in MTB drug resistance has made it problematic to cure the illness with the current anti-tubercular medication portfolio. To combat drug-resistant tuberculosis, it is crucial to identify new chemical entities with unique mechanisms of action[28]. Nevertheless, because it takes more than ten to fifteen years of study and significant funding, the process of finding and developing new drugs is extremely expensive and time-consuming. Repurposing out-dated medications is an appealing alternative approach to address this issue. Numerous medications with established safety profiles and decades of use have demonstrated efficacy against MTB[29].

Niosomal Drug Delivery System

Niosomes which are vesicles made of cholesterol and non-ionic surfactants are used in Niosomal Drug Delivery System. These structures provide benefits such enhanced medication, solubility, stability and targeted delivery by encapsulated both hydrophobic and hydrophilic medicines.Studies on Niosomal Drug Delivery Systems are being conducted to treat infectious diseases, and other ailments. Because of their potential to improve treatment outcomes and patient compliance, niosomes present a viable drug delivery platform[30].

Key features of niosomal drug delivery system

1. Biocompatibility
2. Stability
3. Targeted delivery
4. Controlled release
5. Reduced toxicity
6. Drug encapsulation

Niosomes

Their structure is similar to that of liposomes. The arrangement of the self-combined niosomes is such that the hydrophilic heads form the core and exterior of the vesicle, and the tails which are form the bilayer facing each other are hydrophobic.The system shows strong Thermodynamic stability, Biocompatibility, Minimal Toxicity, Non Immunogenicity & Biodegrability. It can also regulate drug release for an extended duration [31,32].

The main constituents of Niosomes include lipids like cholesterol, hydration medium, and non-ionic surfactants.The hydrophilic and steric repulsion bet the top groups of non-ionic surfactants makes sure that the hydrophilic termini point outward and come into touch with water. Generally speaking, energy input such as mechanical or thermal energy is needed for assembly into closed bilayers. Niosomes are also categorised into three groups that are consistent with their sizes and bilayer structures [33].

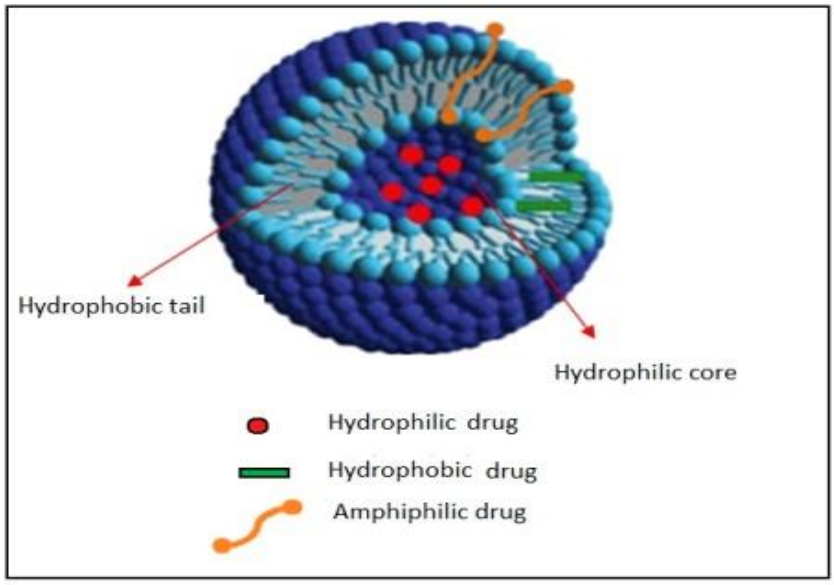


Figure 2: Structure of Niosome[33]

Surfactants

Surfactants that do not have any charged groups in their hydrophilic heads are classified as non-ionic surfactants. In addition, compared to their cationic, amplified, or anionic counterparts, they are more biocompatible, stable and less toxic [34].For applications involving the production of stable niosomes both in vitro and in vivo, this makes them the preferred option. The two distinct areas of amphiphilic nonionic surfactants are hydrophilic and hydrophobic.In the niosome processing process, the primary non-ionic surfactant groups that are used include fatty acids, alkyl ethers, alkyl esters, and alkyl amides. Important factors to take into account while choosing particles of surfactant for synthesis for niosome are the HLB and substantial packing parameter values[35].

Cholesterol

The hydrophilic head of a surfactant and cholesterol establish hydrogen bonds in the bilayer structure of niosomes. Thus, the structure of niosomes is affected or depends on the amount of cholesterol present in it and there will also change in physical characteristics, bio stability etc. Cholesterol decreases vesicle permeability for entrapped molecules, preventing leakage, and increases vesicle rigidity and stabilises niosomes against destabilising effects caused by plasma and serum components[36].

Formulation Method of Niosomes

The Proniosomes Method:

Pro-niosomesnow frequently utilised in niosome formulations because of their high stability. Better chemical & physical stability for long period storage, ease of transportation from one place to another &simplicity in scaling up are only a few benefits of this technology [37]. Additionally, this approach may provide additional possibilities for the formulation of niosomes in other forms, such as tablets and gel. Many studies have also shown that Proniosomes can be applied to drug delivery in an effective manner via a variety of routes including ocular, parenteral, transdermal. To enhance the stability of niosomes, it is recommended to reduce their water content as much as possible. This approach could potentially address the issue of long-term storage[38].

Sonication:

An old-fashioned technique for making niosomes is sonication. Using this approach is simple. To get the required niosomes, the drug mixture must only be introduced to the right non-ionic surfactant combination at an optimised ratio[40].Sonication should then occur at the chosen duration, temperature & frequency. Additionally, this is a good method of managing the niosomes particle sizes. Two-stage methods (mechanical sonication & agitation) were used to create resveratrol niosomes with an encapsulation rate of 42%, according to D.Pandoet al. For niosomes with a restricted size range, sonication can reduce their sizes. Probe sonication, however,

uses a lot of energy and can result in a temperature spike and titanium shedding [41].

Thin-film Hydration method

Thin-film hydration, or TFH, is a popular technique for making liposomes. Niosomes could instead be made using this technique. In a flask, dissolve the components that make the membrane in an organic solvent using this easy procedure. Initially, the medication is dissolved in an aqueous solution, like buffer or water, to moisten the parched layer [42]. Niosomes are produced by culturing it in a water bath that is heated above the surfactant's transition temperature. Multilamellar vesicles, or niosomes, are produced by the TFH technique (MLV). Sometimes, sonication is combined with this method to create niosomes with a certain size distribution[43].

Preparation of Niosomes Containing Anti-Tubercular Drugs

With Isoniazid:

Solubitan monostearate and Span 60 and Span 20; Cholesterol, dicetyl phosphate,diethyl ether, chloroform &isoniazid .The additional reagents that were utilised were all analytical grade.the drug which contain niosomes are prepared by the Reverse face Evaporation. The hydrophilic drugs are entrapped by this method very commonly. The non-ionic surfactant Span 20 or 60 (SP), cholesterol to enhance niosomal membrane rigidity &di-cetylphosphate (DCP) to induce -ve charge were used in the experiment. Different ratios of these components were used to create niosomes[44]. The organic phase was formed by dissolving them (10 mg/ml) in a 1:1 combination of diethyl ether and chloroform (10 ml) in a 100 ml round-bottom flask. The ratio of the aqueous phase to the organic phase was fixed at 5:1, and an aqueous phase containing isoniazid (10 mg/ml) was added. After covering the flask with Para film to stop the organic phase from evaporating, the flask was sonicated for five minutes at 50 0C using an ultrasonic bath sonicator. After the formation of a stable white emulsion, the organic solvents were progressively evaporated using a rotary vacuum evaporator at 50 0C until a thin coating developed on the flask walls[45,46].The drug-niosome was first obtained by keeping this suspension at 50 0C in a thermostatted water bath for one hour, and then letting it sit at room temperature for the entire night. The medication that was not entrapped was extracted from the niosomes using centrifugation of the dispersion in a chilled centrifuge for 60 minutes at 4 0C and 14,000 rpm. The residue was suspended in PBS after the supernatant was discarded. To make sure that all free drugs was eliminated, this procedure was done again[47].

With Pyrazinamide:

Pyarizinamide, Span 60 and 85, Cholesterol, dihexadecyl phosphate and octadecylamine,All other chemicals were of analytical grade.

Span 60 and Span 85, the two principal non-ionic surfactants, were used in the preparation process. PZA niosomes were prepared utilising Span in conjunction with CH at two distinct molar ratios: Span: CH (1:1) and Span: CH (4:2). In order to impart a positive surface charge, charge inducing agents SA and DCP were used. They did this by using the molar ratios Span: Charge inducing agent (4:2:1) and Charge inducing agent (1:1:0.1). Included is a list of all the prepared niosomal formulations and their component [48].

With Rifampicin:

Different ratios of surfactants, cholesterol, and dicetyl phosphate were used to create the niosomes[49]. For additional research, the formulation that produced the best physicochemical properties, maximal entrapment, and longest-lasting drug release was chosen. Diethyl ether (10–15 ml) was used to dissolve these components [50,51]. Using a rotary flash evaporator, the solvent was evaporated at a temperature of roughly 60°C under reduced pressure. A thin coating of solid mixture was left on the circular bottom flask wall after the flask was rotated, under reduced pressure, to reach this temperature, which was approximately 1.5 cm above a boiling water bath. After heating the flask to roughly 50°C on the water in a vortex,10 millilitres of the 1 mg/ml solution was added and stirred until the mixture was well dispersed [52,53]. To create unilamellar niosomes, the suspension was sonicated for 15 minutes. Using spectrophotometric tests, the drug content of each niosome formulation was examined. A Coulter LS Particle Size Analyser was used to ascertain the size distribution of each lot of niosomes loaded with rifampicin. Using a Millipore filter, a filtration process was used to sterilise niosome batches. After sterilisation, niosome formulations were kept at 20°C in desiccators until they were needed [54,55].

Approaches of Niosomes

There have been reports of niosome administration by a variety of routes, and it is evident that the route is essential for creating a vesicular formulation[56].Oral Delivery Method It is frequently suggested that niosomes could be used as an oral drug delivery mechanism[57].Some of the obstacles that prevent biopharmaceuticals from being delivered to the circulation through oral administration are limited epithelial permeability, proteolytic enzymes, and pH gradients [58]. An investigation utilising niosomal formulations based on poly-oxy ethylene alkyl ethers revealed the oral administration of recombinant human insulin. In vitro proteolytic activity of pepsin, trypsin & chymotrypsin was threatened within insulin entrapment in the bilayer structure of niosomes [59]. Ganciclovir encapsulation in a lipophilic vesicular structure may even improve oral absorption and prolong the drug's presence in the circulation. Niosomes were created by reversing the evaporation of Span40, Span60, and Cholesterol[60].

Applications of Niosomes

To enhance the drugs physical characteristics and stability

To Increase Oral Bioavailability: Comparing the niosome formulation to the medication alone, it was revealed that the oral bioavailability of griseofulvin and acyclovir was strengthened. Poorly absorbed peptide and ergot alkaloid absorptivity have been demonstrated to be enhanced by the injection of micelle solution in conjunction with POE-24-cholesteryl ester into the rat common bile duct[61,62].

For Peptide Drug Stability: The utilisation of niosomes, such as 9-glycinamide , 8-arginin vasopressin etc., can greatly enhance the stability of peptide medications.44 Additionally, niosomes created by span[40] and span[60] released less insulin in vitro when placed in simulated intestinal fluid as compared to niosomes created by span[20] and span[80]. When exposed to high storage temperatures and sodium deoxycholate, niosomes made using the span[60] method demonstrate strong resistance against proteolytic enzymes and good stability [63,64].

To Promote Transdermal Delivery of Drugs: Numerous medications, including lidocaine, estradiol, cyclosporine, and others, are formulated as niosomes and employed as topical and transdermal drug delivery systems. An effective strategy for new medication delivery is the use of niosome in drug delivery systems [65]. Niosomes are useful in the pharmaceutical industry and have several benefits in other drug delivery system. The preparation of niosomes can be done using a number of established, thoroughly researched techniques. Future researchers must successfully utilise niosomes' potential in a variety of benefits for humanity, as they are

incredibly powerful tool of drug delivery for incorporating a wide range of pharmaceutically active moieties[66].

Challenges

Scale-Up and Manufacturing Challenges: It can be difficult to scale up the production of niosomal drugs for therapeutic application. Achieving uniformity and excellence in large-scale production is essential to bringing niosomal drug delivery technologies to the clinical setting [67].

Biodegradability and Clearance: Niosome biodegradability and bodily removal may provide difficulties. For these systems to be used safely and to avoid any build up in tissues, these problems must be resolved [68,69].

Optimization of Formulation:For niosomes to function as effective drug delivery vehicles, their size, surface charge, and stability must all be optimised. Every medicine and application requires a careful optimisation of the formulation parameters [70,71].

Limited Drug Loading Capacity: When it comes to the ability of niosomes to load drugs, they might not be as effective as other drug delivery methods. This might affect how some medications are administered at high dosages [72-74].

Complexity of Design:It can be difficult to design niosomes with the appropriate properties for some uses, like as the treatment of tuberculosis. Careful thought must be given to selecting the right surfactants, ratios, and other formulation characteristics [75,76].

Future Perspectives

Integration of Immunomodulatory Agents: Subsequent investigations could investigate the integration of immunomodulatory drugs in niosomal formulations. This strategy seeks to improve the overall effectiveness of tuberculosis treatment by both delivering anti-tuberculosis medications and modifying the host immunological response [77-80].

Personalized Medicine Approaches: Progress in customised healthcare could result in the creation of niosomal drug delivery regimens based on the unique characteristics of each patient. To improve treatment outcomes and reduce side effects, this may entail optimising formulations based on patient-specific characteristics, such as genetic differences [81-83].

Smart Drug Delivery Systems: Future work may focus on creating "smart" niosomal drug delivery systems that react to particular environmental stimuli. These devices could provide targeted and on-demand drug delivery by releasing pharmaceuticals in response to the microenvironment of the tuberculosis infection site[84-85].

Bio responsive Niosomes: The goal of research may be to create niosomes that react to bodily biological cues. This could incorporate niosomes that react to pH, enzymes, or temperature to release medications in a controlled way according to the particulars of the infection site[86,87].

Improved Biocompatibility and Biodegradability: Subsequent endeavours might focus on augmenting the biocompatibility and biodegradability of niosomes in order to reduce possible toxicity and enhance their elimination from the organism[88].

Conclusion

Future developments in the field of tuberculosis have better potential for investigation of niosomal drug delivery methods. With its many benefits such as improved drug stability, biocompatibility, and targeted delivery niosomes are a useful tool in the search for more efficient and patient-friendly tuberculosis treatment approaches.

Improved niosomal formulations for combination therapy and personalised medicine will probably become more and more popular as research continues. The development of theranostic niosomes and the possible incorporation of immunomodulatory drugs highlight how these delivery systems are changing and point to a path towards more complex and comprehensive healthcare strategies.

Thorough preclinical research and carefully planned clinical trials are essential as these systems approach clinical translation. If these initiatives are successful, it will not only prove that niosomal formulations are safe and effective, but it will also open the door for regulatory approval and broad clinical use.

In conclusion, niosomal drug delivery systems have a bright future ahead of them in the fight against tuberculosis. The dynamic interaction between cutting-edge scientific research and real-world issues highlights the continuous dedication to enhancing tuberculosis treatment outcomes, which will ultimately help patients everywhere. To bring in a new era of patient-centered, efficacious, and targeted tuberculosis therapies, researchers, physicians, and regulatory authorities must continue to work together.

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