World Journal of Biology Pharmacy and Health Sciences
eISSN: 2582-5542
Cross Ref DOI: 10.30574/wjbphs
Journal homepage: https://wjbphs.com/

(REVIEW ARTICLE)

Liposomal CoQ10: Turning Liquid Nanosystems into Stable Dosage Forms, an Approach of West Bengal Chemical Industries Limited.

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World Journal of Biology Pharmacy and Health Sciences, 2026, 25(03), 070-078

Publication history: Received on 07 December 2025; revised on 24 February 2026; accepted on 27 February 2026

Article DOI: https://doi.org/10.30574/wjbphs.2026.25.3.0030

Abstract

The design and development of Lipoedge liposomal CoQ10 primarily depends on the composition of liposomes, physicochemical characteristics, interaction of CoQ10 with the liposomal structure, and their ability to demonstrate anti-oxidant levels post encapsulation. This is determined by the rearrangement of the phospholipids to embed CoQ10 molecules in the bilayer. Phospholipids present in the liposomes are dominated by a class of phospholipids called Phosphatidylcholine (PC). Depending on the method of liposome preparation, PC rearrange into a bilayer formation to encapsulate CoQ10. However, the process of assembling PC molecules to encapsulate CoQ10 stably remain to be a challenge due to the fragile nature of CoQ10. This article tries to address this gap by bridging the current understanding of the manufacturing parameters critical to ensure liposomal systems to stably encapsulate CoQ10 molecules and at the same time maintain its biological efficacy.

Keywords: Liposomal CoQ10; Spray-drying; Biological Responses; Lipoedge Liposomal Technology

1. Introduction

Liposome remains to be a most widely used molecules to encapsulate Active Pharmaceutical Ingredients (APIs) and minerals for enhancing their absorption and physiological stability profiles [1,2]. However, in case of *2,3-dimethoxy-5-methyl-6-deca-prenyl-1,4-benzoquinone*, commonly known as CoQ10, liposomal encapsulation remains to be a topic of considerable focus. Given the multi-faceted application of this molecule in generating optimum cellular functionality in our body, the molecule faces significant challenge in keeping its molecular integrity optimum for desired application once encapsulated [3,4]. This is because in its encapsulated stage the molecule is prone to oxidation and degradation if not encapsulated in the right physio-chemical conditions.

Chemically the structure of CoQ10 contains a benzoquinone ring with 10 isoprene units contributing to long isoprenoid side chain. This enables the molecule to exhibit bifunctional moieties to carry tasks parallelly [5]. The benzoquinone head group performs all related chemistry for binding with enzyme sites by cycling between the three different redox states of CoQ10. The three different states are mentioned as follows: fully oxidized form known as ubiquinone (Q:), the partially reduced intermediate (Q.-) called the semiquinone radical and the fully reduced form known as ubiquinol (or dihydroxyquinone). The interconversion between each form is necessary for electron transport and generation of cellular energy [6]. Whereas the long decaprenyl tail ensures that the molecule remains embedded and mobile within the membrane [7]

Keeping the highly sensitive chemical nature of CoQ10 in mind, stable encapsulating systems must be designed that are able to maintain the chemical and functional property of this molecule. Liposomal encapsulation often allows considerable molecule stability while ensuring reduced oxidation and optimum activity. The phospholipid bilayer

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enables the molecules to exhibit significant molecular fluidity while keeping CoQ10 moieties active for its functions including transporting electrons for generating energy for the cells, shielding the body against oxidative stress, by re-generating vitamins E, C and supporting the mitochondrial membrane by enabling its biogenesis pathway [6].

Primarily, CoQ10 is responsible for shuttling electrons in the electron transport chain for generating power to the cells via mitochondria, the power house of the cell [6]. As the use of CoQ-10 as an electron transporter is seen in all the cells, its presence in our body is almost ubiquitous to each and every part of the human body. Since the molecules' primary role remains in the generation of energy via transporting electrons in the cells, the presence of this molecule often determines the efficacy of generating energy [6]. Cells utilize CoQ10 in the body to transport electrons in the inner mitochondrial membrane thereby generating energy required by the cells to go about their usual function in our body [6].

Additionally, CoQ10 molecules in its reduced form ubiquinol are utilized in the body to act as an anti-oxidant by protecting cell membranes from lipid peroxidation [7]. This helps in the prevention of aging by promoting neutralization of free radicals in the body. This is carried out by donating Hydrogen atom to free radicals via a process called hydrogen abstraction [7]. Also, CoQ10 indirectly upregulates anti-oxidant synthesizing enzymes that promotes antioxidation by neutralization of radicals attacking the cells like super oxide dismutase and catalase [7]. Other indirect implications of CoQ10 presence in anti-oxidation functionalities include improvement of Nitric Oxide (NO) bioavailability for improving blood vessel functionality [7]. Thus, the presence of CoQ10 plays an important role in promoting anti-oxidant functionalities of the body.

Encapsulation of CoQ10 remains to be a go-to strategy to improve anti-oxidant performances of CoQ10 in the human body to address aging effects, detrimental effects of statin-associated-myopathy, mitochondrial defects and high oxidative stress [7]. Due to the chemical nature of CoQ10, the phospholipid head group remain embedded within the lipid structure of the membrane. This ensures that the molecule is able to exhibit its molecular functionality by remaining mobile within the phospholipid bilayer. This nature of CoQ10 is widely utilized in liposomal systems that allows CoQ10 to maintain its molecular integrity in encapsulated systems.

In this article, current industry practices to manufacture liposomal CoQ10 will be discussed. Starting with the sourcing of raw materials, to the biological characterization of Liposomal CoQ10. Since, liposomal CoQ10 quality is determined by the utilization of right materials including (tight-packing, sensible drug load, embedded antioxidants, low residual moisture), along with spray drying processes tuned to ensure that product meets defined specifications [8]. Critical process parameters (CPPs) include inlet/outlet temperature, atomization gas flow, feed solids %, pump rate, and nozzle type, with other carrier specifications [9]. Once the process parameters are discussed, specific studies on in-vitro and in-vivo results will be presented that will characterize the biological efficacy of Liposomal CoQ10 to provide an informative narrative to the readers who wishes to identify the advantages of liposomal CoQ10 to improve cellular functionalities.

Figure 1 A microscopic image of Liposomal CoQ10 from the Formulation & Development Laboratory of West Bengal Chemical Industries Limited

2. Methods of Literature Review

Literature search from scientific article indexing search engines and databases including but not limited to google scholar, pubmed, web of science and science direct were performed that covered related literature spanning mostly between 2000 and 2025. However, literatures with authoritative and ground-breaking research extending beyond the timeline mentioned may have been included in the article. Studies were included that described and detailed the composition, source and impact of phospholipids for liposome stability and integration of CoQ10 within liposomes. Biological studies were included where cell-line and in-vivo data related to finished formulation of liposomal CoQ10 were reported. Extracted findings were documented using a narrative that were most suitable to address the gaps on scalable manufacturing capabilities for meeting the industrial demand of Liposomal CoQ10 to meet expected requirements of the consumers.

2.1. Liposomal CoQ10 Design

Liposomes are manufactured from lecithin. Usually, lecithin is sourced either from soybeans or sunflower. Soy based lecithin are most abundant because of its ease of availability. Whereas sunflower based lecithin is typically preferred as an allergen-free ingredient for preparation of active pharmaceutical ingredients for pharmaceuticals and nutraceuticals. Typical composition of phospholipids includes phosphatidylserine (PS), phosphatidylcholine (PC), phosphatidylethanolamine (PE), Phosphatidic Acid (PA) and Phosphatidylinositol (PI) [2]. Their contents vary across factors due to processes like extraction, purification, and most importantly, the source of phospholipids. A summary of how each components influence liposomal structure and integrity is mentioned as follows:

Table 1 Comparison of Phospholipid Components for Liposomal Encapsulation

Phospholipid Component	Typical Content in Soy Lecithin	Typical Content in Sunflower Lecithin	Structural / Functional Role in Liposome	Ref
Phosphatidylcholine (PC)	~20–25% (can reach 30–35% in high-purity grades)	~25–30% (naturally higher PC proportion)	Primary bilayer which is cylindrical in shape forming components that ensures liposomes are smoother and uniform and primary contributors of lamellar types of liposomes - Contributes to membrane fluidity, encapsulation efficiency, and liposome stability.	[10]
Phosphatidylethanolamine (PE)	~15–25%	~10–15%	- PE has a cone shaped geometry with a negative surface curvature are more prone to contribute to non-lamellar types of liposomes - Increases membrane fusion ability and can reduce permeability when balanced with PC. - Excess PE may destabilize vesicles, so sunflower lecithin's lower PE yields more stable bilayers.	[11]
Phosphatidylinositol (PI)	~10–20%	~10–15%	- Contributes negative surface charge, improving colloidal stability via electrostatic repulsion between vesicles. - Enhances interaction with cationic drugs or polymers. - Higher PI levels in soy lecithin can reduce aggregation, but may also slightly increase permeability.	[12]
Phosphatidic Acid (PA)	~5–10%	~3–8%	- Acts as an anionic surfactant and precursor for other phospholipids. - Provides negative charge and enhances	[13]

			membrane cohesion via hydrogen bonding. - Small amounts improve structural integrity, but excessive PA (>10%) increases liposome rigidity and leakage.	
Neutral Lipids & Triglycerides (non-polar fraction)	5–15%	3–10%	- Reside within bilayer defects or interfacial regions. - Influence viscosity and permeability. - Sunflower lecithin generally has lower neutral lipid content, giving cleaner bilayer packing and less leakage.	[1,14]

Excipients such as cholesterol, chitosan, sucrose, etc., can be utilized for stabilizing liposomes. Each excipients have individual roles in contributing to the structure and functionality of the liposomes in question. The presence of cholesterol is known to stabilize the liposomal structure so that leakages of drugs may be prevented from the liposomes and extend the shelf life of drugs, minerals and nutraceuticals in question [15,16]. However, liposomal product manufacturing facilities like West Bengal Chemical Industries Limited ensures cholesterol-free liposomal encapsulation of CoQ10.

The presence of oxidizing radicals in storage, transport and physiological conditions promote lipid degradation of liposomes. This is turn reduces the quality of product formulated hence has a detrimental effect in the quality of liposomal drugs created [4,13]. Along with excipients promoting liposomal rigidity, some anti-oxidants may be added to the liposomal formulation prepared like Vitamin E and C. These excipients are added to prevent lipid peroxidation and enhance the liposomal life and stability [17–19]. In-vitro studies like TBARS and FRAP may be conducted to assess the extent of lipid peroxidation that may occur in liposomes [20].

2.2. Process Routes

Historically, thin film hydration has been used to prepare and produce liposomes. However, owing to its low yield and scale up issues, industrial adaption of this technique remains to be a challenge [21–23]. Spray drying on the other hand can improve the scale of producing liposomes encapsulating APIs [19]. Spray drying process first includes the preparation of colloidal solution that contains either soy or sunflower lecithin. Based on the lipid profile of the target liposomal product containing CoQ10, phospholipids from either soy or sunflower lecithin may be considered [24]. As discussed, in previous sections sunflower-based lecithin promotes the stability of liposomes and reduces allergen content in the product [25].

Purification of lecithin may be considered depending on the percentages of phospholipids present. This step ensures that phospholipids are present in the desired quantity so that liposomes composed of PC, PE, PA and PI may be obtained [26]. Once purified lecithin is obtained, a colloidal mix of lecithin is produced by dispersing it in custom designed bioreactors preferably in aqueous solution using an emulsification process at 60° C under high speed [1]. The process utilized in the emulsification process including the bioreactor dimension, stirring conditions and airflow utilized is critical to determine liposomes PDI, Zeta potential and particle size [1]. The process of emulsification is continued until the suspension reaches and achieves homogenous level of sample uniformity which is achieved using step-wise QC checks [1].

Once the empty liposomal suspension has achieved a desired level of consistency, analyzed using Dynamic Light Scattering (DLS), Fourier-Transform Infrared Spectroscopy (FTIR), Scanning Electron Microscopy (SEM), Transmission Electron Microscopy (TEM), Differential Scanning Calorimetry (DSC), Thermogravimetric Analysis (TGA) and other analytical quality parameters [27], CoQ10 may be added to the liposomal suspension for entrapment [28]. The process of hydration after the addition of CoQ10 ensures that the liposomes are entrapped within the liposomes [9]. Due to the amphipathic nature of the liposomes, the phospholipids enable the sequestration of the CoQ10 molecules within the fatty acid layer of the liposomes during this stage [15]. Sequestration of the CoQ10 molecules into the non-polar fatty acid bilayer is mostly enabled by the fluidity of the phospholipid bilayer that draws the CoQ10 molecules within the bilayer [21]. This results in liposomal vesicle formation as CoQ10 molecule moves inside the bilayer of liposomes away from the aqueous core of the liposomes [29].

Based on the type of finished product required, the emulsion may be subjected to either spray drying or spray freezing. Where samples were first introduced to biopolymer coat to protect the samples from degradation from high

temperature and pressure during spray drying or freezing[1]. In a study by Hoven et. al. hydroxypropyl-β-cyclodextrin (HPβCD) commonly referred to as cyclodextrin was used as a membrane protectant in place of trehalose or sucrose [30]. Where it was found that the liposomal membranes were more stabilized due to the protection from ice-crystal formation during the freezing phases of the lyophilization cycle and prevention of loss of water during spray drying [30].

Spray drying of the samples are performed to reduce the water content of Liposomal CoQ10 [28]. Spray-dryers with two fluid nozzles are typical. Feeds may be pumped at low rate (≈2.5–6 mL/min) with a throughput of drying-air. Usually inlet temperatures are kept at (150 – 160 °C) and outlet temperatures at (80 -90 °C) [31].

2.3. Post-processing after spray drying

After spray-drying, CoQ10 powders should be collected under low light and inert handling conditions to protect it from oxidation [8]. Gentle de-agglomeration steps are carried out in a paddle blender to restore powder-flow [28]. Depending on the requirements of loss-on-drying and water contents, shorter drying secondary drying steps may be considered at ≤40–45 °C with nitrogen purge—to stabilize lipids and minimize Q/QH_2 drift, if a higher water content is observed [31].

Quality control measure before releasing Liposomal CoQ10 must be determined to verify product performance [1]. Assays on redox speciation (Q/QH_2), moisture and water activity may be conducted to ensure product conformity [4]. Solution phase studies to confirm particle size, poly-dispersity and zeta potential need to be conducted to ensure product stability in solution [2]. To finalize product quality before subjecting to in-vitro/in-vivo analysis, stability studies according to ICH guidelines need to be considered [1]. This may include long-term and accelerated studies with light/oxygen as additional study parameters to determine product stability in real world conditions [32]. Especially in solvent free liposomal preparation utilized by West Bengal Chemical Industries, stabilities of liposomal products are often found to be meeting the criteria beyond the market expectations as demonstrated by some products like Liposomal Iron [33].

2.4. Dosage Forms of Liposomal CoQ10

Stability of liposomal CoQ10 dosage form is important to ensure that the molecules are able to elicit biological responses in cells and tissues. Since stable encapsulation of CoQ10 in liposomes ensure that liposomes are able to effectively carry and deliver their payload to the target cells with losing their inherent efficacy. As discussed before, CoQ10 provides key resources to cells to mitigate oxidative challenges encountered by the body. Steps ensuring encapsulation efficiency, particle characteristics and measurement of lipid peroxidation is necessary to ensure that liposomal CoQ10 produced meets the expectations in terms to exhibiting their anti-oxidant properties. Once the characterization of Liposomal CoQ10 is carried out confirming their specifications, dosage forms may be designed to ensure that the molecule is able to demonstrate their expected levels anti-oxidant behavior post formulation [34].

Table 2 Parameters for Determining Stable Dosage Forms of Liposomal CoQ10

Dosage Form	Stability Advantage	Typical EE%	Shelf-Life	Best Use Case
Liquid dispersion	Fast absorption	50–70%	3–6 months	Oral liquids, serums
Lyophilized powder	Highest long-term stability	80–95%	24–36 months	Injectable or high-end nutraceuticals
Spray-dried powder	Industrial scalability and long term stability	75–90%	18–36 months	Capsules, sachets, dry blends
Softgel/Capsule	Oxidation protection	60–85%	18–24 months	Consumer nutraceuticals
Topical gel/cream	Enhanced penetration	—	12–18 months	Cosmetic/dermatology
Granules/Tablets	Easy handling; solid form	—	12–24 months	OTC supplements

Liposomal CoQ10 may be developed in different dosage forms like spray-dried powers, liquid dispersions, free-dried powders, softgel and hard capsule, transdermal liposomal gels, creams and serums, and direct compressed granules

and tablets [34]. Table 2, demonstrates the dosage forms of liposomal CoQ10 that are available based on patient outcomes and need [35]. Determination of dosage forms are mainly dependent on the utilization of the administration of the molecule in our body. They require careful balancing of liposomal components with the CoQ10 added. Additionally, excipients to improve shelf life and stability in solution may be added to the product [36].

2.5. Biological Responses of Liposomal CoQ10

In a study by Wang et al, CoQ10 nanoliposomes with either cholesterol or β-sitosterol was utilized to prepare liposomes. Demonstrating encapsulation efficiency of 73-75 % with particle size criteria between 108 – 110 nm and zeta potential (ζ) ≈ −36 mV [4]. The usual trend of this study indicated that cholesterol increased Liposomal CoQ10 particle size but reduced EE as concentration was increased during its formulation [4]. Lipid peroxidation assay indicated that β-sitosterol reduced the extent of lipid peroxidation when compared to cholesterol containing liposomal CoQ10 by 15% [4]. Cellular adhesion on CaCo-2 monolayers showed that encapsulated CoQ10 were able to adhere to cells by ≈2.1× with cholesterol and ≈2.3× with β-sitosterol [4]. Additionally, the level of cellular antioxidant activity (CAA) was found to have markedly increased in encapsulated COQ10. In case of free CoQ10 CAA was found to be 16%. Whereas, CoQ10-cholesterol liposome was found to demonstrate 70% and CoQ10-β-sitosterol liposomes demonstrate 79% [4]. The rationale of marked increase in CAA and reduced lipid peroxidation levels using CoQ10-β-sitosterol liposomes are due to the higher solubility of β-sitosterol in the phospholipid bilayers. The higher solubility in the phospholipid bilayers enables ordered bilayers which preserve membrane integrity and reduce leakage/oxidation [4].

Another study utilized CoQ10 loaded to liposomes with size less than 40 nm to human fibroblasts to measure how much anti-aging effects of the skin cells are observed in photo-aged cells [37]. The study found that CoQ10 Liposomes were able to restore redox balance of the skin by reducing intercellular ROS, reduced NMP-1 and increasing collagen-I [37]. Un-encapsulated CoQ10 was used as a control to measure the efficacy of the liposomal CoQ10 in-vivo and was found that topical application of Liposomal COQ10 improves skin appearance and normalizes epidermal thickness and collagen architecture [15].

To evaluate the effects of liposomal encapsulation on the digestion of CoQ10, Bhagavan et al. studied CoQ10 uptake on Caco-2 cell lines after subjecting them to in-vitro digestion [38]. The study found that liposomal CoQ10 were able to micellarize and deliver more CoQ10 to enterocytes than un-encapsulated forms [38].

Bio-accessibility remains to be a challenge for CoQ10 uptake from dietary sources for it to become available for absorption by the human body as it is susceptible to degradation when subjected to digestive acid and enzymes [6]. Therefore, the presence of the liposomal coating ensures that the molecule reaches the target without reducing much of its antioxidant activity [7]. Bio-accessibility of liposomal CoQ10 was found to be more than normal CoQ10 in a study by Lee et al [39]. The study found that encapsulated CoQ10 was 1.4x more bio accessible and remained fully suspended during digestion. Resulting in 98-106% recovery of CoQ10 in chyme versus 64% for control. The study further proved that liposomal fraction contained ubiquinone exclusively. Implying that the redox conditions in the gastric environment could not influence the encapsulated CoQ10 [39].

3. Conclusion

Liposomal CoQ10 have been utilized in industries spanning from nutraceutical, pharmaceutical and cosmeceutical for improving their current molecular stability and product characteristics [8,40–42]. This is because liposome encapsulation ensures that the fragile nature of CoQ10 is well protected before they are able to reach to their target cells and tissues [15]. However, challenges remain when industries try to address the evolving requirements of maintaining stabilities of Liposomal CoQ10 in various formulations forms of CoQ10. As different formulations of CoQ10 may not behave in the same way when incorporated in separate dosage forms for diversified applications which can disrupt the molecular stability overall. Hence utilization of liposomal encapsulation can be employed that promote their stability. But, process parameters of liposomal encapsulation of CoQ10 may be different for each dosage forms. Hence, a greater understanding of Liposomal process needs to be considered when manufacturing Liposomal CoQ10 in up-scaled environments. Currently, West Bengal Chemical Industries Limited (WBCIL) have utilized their Lipoedge technology to develop liposomal CoQ10 at a level that meets industry standards to cater market requirements. Thus, this work highlights a pathway and provides recommendations towards a GMP-compliant manufacturing of Liposomal CoQ10 products capable of meeting global regulatory expectations and consumer requirements for high-performance anti-oxidants for pharmaceutical and nutraceutical applications.

Compliance with ethical standards

Acknowledgments

The authors acknowledge West Bengal Chemical Industries Limited for their support in providing constructive discussions to finalize this manuscript.

Disclosure of conflict of interest

The authors confirm that there is no conflict of interest related to this manuscript.

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