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Novasome - An Important Discovery in Pharma Industry a Review Article



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ABSTRACT

The Pharma industry has introduced many types of novel drug delivery aspects. Tempering in the earlier subsist drug delivery technique has led to many fresh revolution technologies serving as a safe and effective means of ameliorating the existing ones. This technique is one of the new inventions of liposomes which find out the solution of various problems that belonged to the drug delivery system. It serves as the encapsulation process for effective delivery of a variety of things in the field of chemical, agrochemical food, cosmetics, personal care, and pharmaceuticals.



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INTRODUCTION:

Novasome technology is the revolutionary encapsulation method for the satisfactory delivery of a variety of drugs. First of all this technique was developed by Novavax. IGI Laboratories. The parent form of novasome is liposome¹. Novasomes are prepared from a mixture of monoester of cholesterol, free fatty acid, and polyoxyethylene fatty acid. It can be defined as the non-phospholipid paucilamellar vesicles. It is 0.1-1.0 micron in diameter. It contains bilayered shells which are two to seven in the quantity that covered the unstructured space inhabited by a large amorphous core of hydrophilic or hydrophobic material.

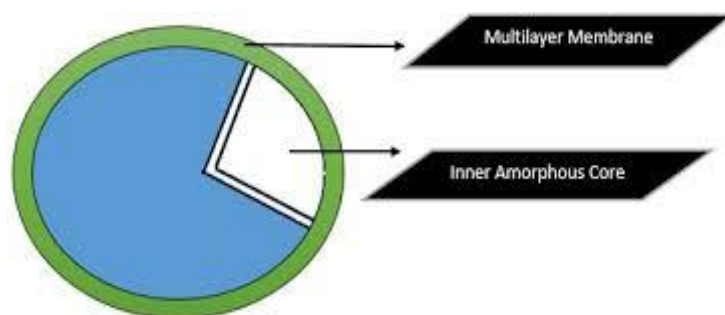


Figure No. 1: Novasome

This molecule includes the hydrophilic head group linked to a hydrophobic tail and is also joined with long-chain fatty alcohols, glycerolipids, long-chain acids, and long-chain amino. The membrane that is made up of many layers may be formed of various single-tailed amphiphiles as well as phospholipids selected for particular purpose².

Bilayer membranes consist of fatty acid tails designate into the membrane internal side and outer part pointed by the polar head group. The presence of a polar group at one surface of the membrane point toward the internal site of the vesicle while the polar group at another surface points towards their external environment.

The molecules that are dissolved in water have been mixed into the water during the formulation process of vesicle gets incorporated into the aqueous space in between the lipid bilayers membrane. Everything happens the same when it is done with the lipid-soluble molecule. The amorphous core account for much of the volume of vesicles. It incorporates water-miscible and water-insoluble and small solid particles. It is uniform in size. Its efficiency of encapsulation range varies from 100% for lipid moieties to 85% for aqueous materials.

The suitable pH range of the microvesicle is 2-13 and the temperature range of liquid nitrogen is more than the boiling point of water. The expenditure of producing these vesicles is equivalent to that used in making simple emulsion ranging from microliter to milliliter continuous flow batches.

Characteristics of Novasomes: A few characteristics of Novasomes are mentioned below(3):

- Novasome can be in a steady-state over a broad range of pH i.e from 2-13.
- It contains the agile elements in a tiny volume.
- The medicinal substance is filled in the internal shapeless core.
- It's plain contains a charge that may be a positive, negative, and neutral charge.
- Particular parameters are used to create a specific size range.
- It is capable to stick with the skin and hair shaft, it depends upon the charge contained by skin and blisters.
- It makes the exact release of agile element thus decreases the frequency of application.
- It can bring and release a huge amount of water-soluble ingredients.

Benefits:

- The same preparation used the incorporate the water-loving and water-hating drugs.
- Medicines subsume in the bilayers that showing interconnection to escape from incompatibility.
- It has a specific site because its plane contains a particular charge.
- It transfers a huge amount of agile elements because it operates a loading organization of 80 %, thus also decrease the frequency of administration.
- It is capable to stick with the hair shaft and skin, it depends upon the charge contained by skin and blister.
- It is also used in cosmetic formulation.

How it releases the drug

The novosome bilayer never shows ideal array ordering. It carries vaccines that are used as a track for flowing the encapsulated ingredients. Encapsulated components such as agile ingredients in the core flow within and between multilayered via a sequence of accidental leaps which cause sidewise movements of the vacancies in the bilayer.

It is a source of uninterrupted release of agile moieties from the bilayers through the liquid suspension divides the bilayers. The negative and positive charges contained by the plane of the microvesicle determine their activity.

For example, the negatively charged skin, mucous membrane, or hair combine with the positively charged microvesicle. Likewise, sustained-release mechanisms are given by the structure of the novosome vesicle so a controlled release of agile substance can be attained.

Because of secured entrapment of agile substance within the core before use, it enhances the steadiness of storage and agile substance. This causes the most effective delivery of agile substance³.

Preparation: Many appliances have been employed for the formulation of novosome manufacturing high shear enough for shear mixing. some of these devices available in the market.

For example Microfluidizer (it is a French-based press) and some other device that give us high enough shear force and is capable to hold heated and semiviscous lipids. A system introduces a device that is helpful to the formulation of paucilamellar lipid vesicles (Novasomes) named as Microvesicular system. This device contains a cylindrical mixing chamber with one inlet orifice. The presence of an orifice helps the reservoir to contain another type of phases like lipid loving phase, a mixture of an oil phase if lipid core paucilamellar lipid vesicles are to be synthesized, and liquid phase. These reservoirs are linked to the pumps which divide in a manner that forms a burble point inside the chamber.

The paucilamellar novosome synthesized within one second is expelled from the chamber through the ejecting orifice axially find out on the chamber. These oil cavities contain the non-phospholipid surfactant, targeting molecule and agent which generate the charge.

Novasome made up of:

- Polyoxyethylene cetyl ether
- Polyoxyethylene lauryl ether
- Glyceryl monostearate
- Polyoxyethylene glyceryl stearate
- Antioxidant

It is also used in the synthesis of an oil-loving phase, it includes the combination of many oil-loving components also contain the surfactant material. After that provide sufficient heat to the material and then blend it. This resultant material again going to the process of blending under the shear mixing condition with a liquid phase.

It includes:

- Aqueous buffer
- Aqueous soluble collagen
- This formulation is used to synthesis of Novasomes ⁴.

Wallach et al.⁵ discovered a new way for the formulation of Novasomes with the help of N-acyl sarcosinates This method also used to controlled drug delivery method and sustained drug delivery of cargo group, such as:

- Fragrant
- Emollient oil

These are affected by varying pH.

Applications of Novasomes:

- Novasome is utilized in cosmetics because of its penetration depth.
- Novasomes vehicles can be used for many functions in foods and beverages because of their ability to protect, transport, and deliver flavor oils, nutrients, or other acts.

- It is used in chemicals because it provides high stability to chemical ingredients.
- It is used in the pharmaceutical product because it increases the absorption rate.
- It is having the capacity to transport and deliver flavor oil.
- It enhances the delivery to the site of action.
- It provides sustained release of drug.
- FDA –regulated product such as vaccine and related to pharmaceuticals can be developed.



Figure No. 2: Application of Novasome

Recent advancement in novasome technology

1. It is also known as non phospholipid vesicles. It is made up of glyceryl dilaurate, cholesterol, and polyoxyethylene -10-stearyl.
2. We can use glyceryl distearate instead of glyceryl dilaurate.

3. It supplies a huge amount of cyclosporine in the hairless mouse skin than phosphatidylcholine or ceramide-based vesicles.
4. It is more successful when it moves under the non-occluded condition from a finite dose.
5. Most vaccines that are formed from the novasomes have been permitted for the immunization of poultry against Newcastle disease virus and avian reovirus.
6. Some vaccine that is based upon the Novasomes it works against bacterial and viral infections have been improved such as smallpox vaccine.
7. These novasomes disable viruses such as:
 - Orthomyxoviruses
 - Paramyxoviruses
 - Coronaviruses
 - Retroviruses etc.
8. By combining with enveloped virus and that the nucleic acid of the virus transforms shortly after the blend.
9. It also provides that additive that enhances the medical treatment for the delivery of the vaccine.

Composition of Novasomes evaluated by Gupta et al.

- Dioxyethylene cetyl ether
- Cholesterol
- Oleic acid
- Human vaccine antigen
- Tetanus toxoid
- Diphtheria toxoid, in mice and rabbit

10. Novasomes also show their behavior as a potent medical treatment enhancer to the currently employed adjuvant for the human vaccine that is aluminum phosphate. Chambers et al. discovered that a unit dose of formalin-inactivated BCG combined with Novasomes™ when it delivered in the body of guinea pigs as a unit subcutaneous inoculation protects them from lethal tuberculosis.

11. Pushko et al. find out the secure vaccine through novasome medicine enhancer for avian influenza H9N2 virus with pandemic potential.

12. Nortan et al. checked the agglutinating activity of the S19mAb in the production structure for vaginal use. It also includes the study of combining of S19-Novasome, a multilamellar liposomes delivery vehicle.

13. The conclusion appears that the S19-Novasome formulation agglutinated human spermatozoa and was as effective as unbound S19 mAb. It shows the feasibility of spermatic contraceptives targeted to the male reproductive tract-specific carbohydrate epitope.

Studies declared that this advancement has improved the localized delivery of H₂ antagonists for the treatment or prevention of periodontal disease due to enhance local absorption of the H₂ antagonist and improve the drug action.

In the practical study done on the rabbit periodontitis model, the inventor also revealed the topical application of the Novasomal preparation H₂ antagonist (cimetidine), which reduces the gingival allergy and bone destruction in the model. It also discovers some properties against skin infection and other disorders. It also makes possible the delivery of protein and peptide therapeutics. The first victorious preparation of topical peptide (PTH) i.e parathyroid hormone analog encapsulated in Novasome cream was introduced by Holick et al. This topical preparation proved to be a novel, safe and effective therapy for the treatment of psoriasis, this technique also improves the absorption of PTH into human skin. Due to all these advancements, Novasome technology is used in the cureness of many skin problems. To use the Novasome in the cureness of psoriasis by delivering the extract of *Mahonia aquifolium* is patented by Mills et al. *Mahonia aquifolium* extract combined with other excipients utilized as cream and lotion in the topical preparation to the affected area.

One more patented formulation of Novasomes is available that containing a surfactant known as NONOXYNOL-9. It is designed to inactivate enveloped viruses and spermatozoa on contact.

Marketed formulation of non phospholipid:

- Novasome^{RA}
- NovasomeRD
- Novasome^R Day cream

It contains skin protective agents, oil, moisturizers, and a skin cleanser.⁶⁻¹⁸

CONCLUSION

This study concludes that Novasome technology has more encapsulation efficiency and proved better targeting and sustained release of active ingredients. Its patented information tells us that Novasomes used in various fields for example in the field of pharmaceutical, food agrochemicals, also used in dermatological preparations.

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