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Preparation and Evaluation of niosomalgels containing mebendazole with Anti fungal activity

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ABSTRACT
Niosomes are non-ionic surfactant vesicles obtained on hydration of synthetic nonionic surfactants, with or without incorporation of cholesterol or other lipids. They are vesicular systems similar to liposomes that can be used as carriers of amphiphilic and lipophilic drugs. Niosomes are promising vehicle for drug delivery and being non-ionic, it is less toxic and improves the therapeutic index of drug by restricting its action to target cells. This review article focuses on the preparation methods, characterizations, factors affecting release kinetic, advantages, and applications of niosomes. Mebendazole is an anthelminticor anti-worm medication. It prevents newly hatched insect larvae (worms) from growing or multiplying in your body.
Mebendazole is used to treat infections caused by worms such as whipworm, pinworm, roundworm, and hookworm. It is also used to treat infections caused by more than one of these worms at the same time.

I. INTRODUCTION

Niosomes or non-ionic surfactant vesicles are microscopic lamellar structures formed on admixture of non-ionic surfactant of the alkyl or dialkylpolyglycerol ether class and cholesterol with subsequent hydration in aqueous media. They are vesicular systems similar to liposomes that can be used as carriers of amphiphilic and lipophilic drugs. The method of preparation of niosome is based on liposome technology. The basic process of preparation is the same i.e. hydration by aqueous phase of the lipid phase which may be either a pure surfactant or a mixture of surfactant with cholesterol. After preparing niosomal dispersion, unentrapped drug is separated by dialysis centrifugation or gel filtration. A method of in-vitro release rate study includes the use of dialysis tubing. Niosomes are promising vehicle for drug delivery and being non-ionic, it is less toxic and improves the therapeutic index of drug by restricting its action to target cells. Niosomes are unilamellar or multilamellar vesicles formed from synthetic non-ionic surfactants. They are very similar to the liposomes. Niosomal drug delivery is potentially applicable to many pharmacological agents for their action against various diseases. Niosomes have shown promise in the release studies and serve as a better option for drug delivery system. This class of vesicles was introduced by Handjani – Vila et al. They are vesicular systems similar to liposomes that can be used as carriers of amphiphilic and lipophilic drugs.(Thersa 1998) One of the reasons for preparing niosomes is the assumed higher chemical stability of the surfactants than that of phopholipids, which are used in the preparation of liposomes.

OBJECTIVES:

The objectives of formulating and evaluating mebendazole niosomes typically include enhancing drug solubility, stability, and targeting for improved delivery, while also minimizing side effects. Specifically, researchers aim to increase drug entrapment efficiency, optimize vesicle size and distribution, and assess the release profile of the drug from the niosomes.

Detailed Objectives:

- Enhancing Drug Solubility and Stability:

Niosomes, with their vesicular structure, can solubilize and protect drugs from degradation, improving their stability and bioavailability compared to conventional dosage forms.

- Optimizing Vesicle Size and Distribution:

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The size and size distribution of niosomes affect their penetration into the skin and other tissues, as well as their ability to be taken up by cells.

- Improving Drug Entrapment Efficiency:

Niosomes can encapsulate a high percentage of the drug, leading to a more efficient delivery system.

- Controlling Drug Release:

Niosomal formulations can be designed to release the drug at a controlled rate, ensuring sustained and prolonged therapeutic effects.

- Targeting Specific Tissues or Cells:

By modifying the niosomal surface, researchers can target specific tissues or cells, improving the efficacy of the drug and minimizing side effects.

- Assessing Safety and Efficacy:

The formulations are evaluated for safety and efficacy through in vitro studies and, if appropriate, animal models, to assess their potential as a drug delivery system**.**

ADVANTAGES:

Advantages of Mebendazole Niosomes:

- **Enhanced Bioavailability:**

Niosomes can improve the absorption of mebendazole by increasing its solubility and protecting it from degradation in the digestive tract.

- **Controlled Release:**

Niosomes can be designed to release the drug over a sustained period, reducing the frequency of administration and potentially improving therapeutic efficacy.

- **Targeted Drug Delivery:**

By modifying the niosome's surface or composition, it may be possible to target the niosomes to specific tissues or cells, potentially enhancing the drug's effectiveness and reducing side effects.

- **Improved Stability:**

Niosomes are generally more stable than other vesicular systems like liposomes.

- **Patient Compliance:**

Niosomes can be formulated in various forms, such as oral suspensions or topical gels, enhancing patient compliance.

In summary, formulating mebendazole into niosomes offers several advantages, including enhanced bioavailability, controlled release, and potential for targeted drug delivery, making them a promising drug delivery system for treating parasitic infections**.**

MECHANISM OF ACTION:

- **Mebendazole:**

Mebendazole acts by binding to β-tubulin, a protein essential for microtubule formation in parasitic cells. This binding disrupts the polymerization of tubulin dimers, preventing the formation of microtubules, which are vital for parasite structure and movement.

- **Niosomes:**

Niosomes are vesicular carriers composed of non-ionic surfactants and cholesterol, creating a lipid bilayer. They can be loaded with drugs like mebendazole.

METHODS OF PREPARATIONS:

- **Niosomal Gel:**

The incorporation of niosomes into a gel base provides a sustained release and targeted drug delivery to the affected tissues, potentially improving the effectiveness of mebendazole.

Mebendazole niosomal gels can be prepared using the thin-film hydration method. This involves dissolving the drug, a non-ionic surfactant (like Span 60), and cholesterol in a solvent mixture (e.g., chloroform:methanol), followed by evaporating the solvent to form a thin, dry film. This film is then hydrated with an aqueous solution to form niosomes, which are then incorporated into a carbopol-based gel

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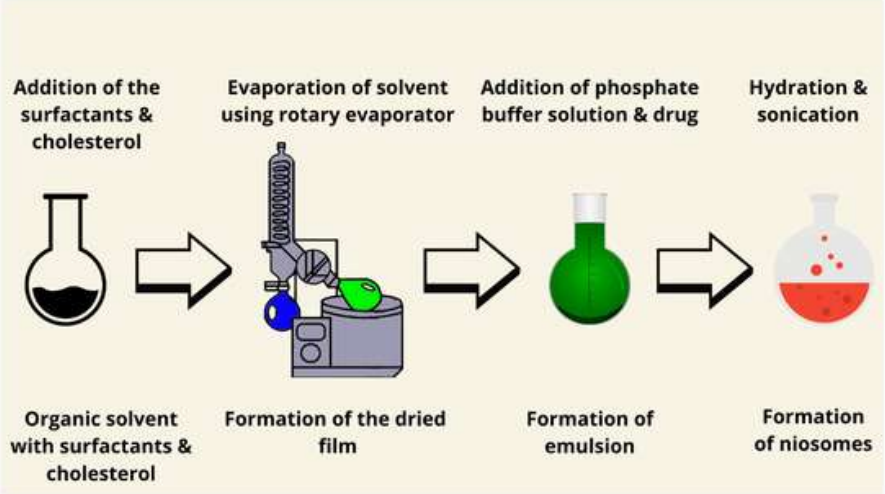

Detailed Method:

1. **Prepare the lipid film:**

- Dissolve mebendazole, Span 60, and cholesterol in a solvent mixture (e.g., chloroform:methanol).
- Evaporate the solvent under reduced pressure in a rotary evaporator, creating a thin, dry film of lipids on the flask walls.

2. **Hydrate the lipid film:**

- Add an aqueous solution (e.g., phosphate-buffered saline) to the dry lipid film.
- Hydrate the film by stirring or shaking to form niosomes.

3. **Form the gel**:

- Prepare a gel base using carbopol and a suitable gelling agent (e.g., triethanolamine).
- Incorporating the prepared niosomal dispersion into the gel base.

S.no	Ingredients	Category
1.	Mebendazole	Anti-viraldrug
2.	Span60	Non-ionicsurfactant
3.	Cholesterol	Sterols
4.	Diethylether	Hydratingsolvent
5.	Phosphatebuffer solution	Physiologicalbuffer

S.no	Ingredients	Quantity
1.	Mebendazole	100mg
2.	Span60	500mg
3.	Cholesterol	100mg
4.	Diethylether	25ml
5.	Phosphatebuffersaline	50ml

EVALUATION PARAMETERS

1. Spreadability of Niosomal Gels:

Spreadability simply means how easily a gel spreads over the skin. For **niosomal gels**, this property is really important because it affects how well the drug is applied, how much gets absorbed, and how comfortable it feels for the user.

Niosomal gels are soft, jelly-like formulations that contain tiny carriers called **niosomes**. These are made from non-ionic surfactants and help deliver the drug through the skin more effectively.

Here's why spreadability matters in niosomal gels:

- The gel's **thickness (viscosity)** needs to be just right—not too thick (which makes it hard to spread) and not too runny (which won't stay in place).
- **Good spreadability** means the drug spreads evenly on the skin, which helps improve how well it works.

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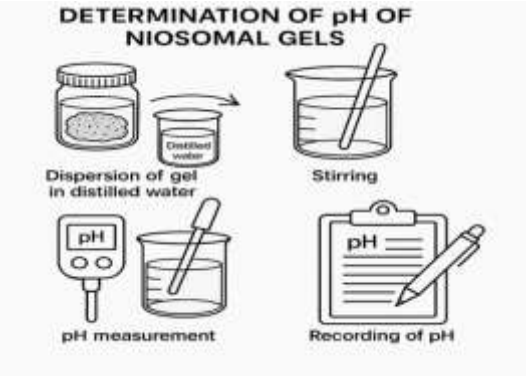
- Scientists test spreadability using simple tools, like measuring how far a gel spreads between two plates (like in the **slip and drag** or **parallel plate method**).
- Things like the type of gel base (polymers), the amount of surfactant, and how much water is in the gel all play a role in how easily it spreads.

2. Determining the pH of niosomal gels:

Determining the pH is an important step in ensuring the product is skin-friendly and stable. Since these gels are often used in topical or transdermal drug delivery, their pH should be close to the natural pH of the skin (around 5.5) to avoid irritation.

To measure pH, a small amount of the gel is usually dispersed in distilled water and stirred gently. Then, using a calibrated digital pH meter, the pH is recorded. The process should be done at room temperature and in a clean environment to avoid contamination.

Maintaining an appropriate pH not only ensures user comfort but also helps in preserving the drug's effectiveness and the gel's physical stability.



3. Homogeneity of Niosomal Gels:

Homogeneity refers to how uniform or consistent a product is throughout—meaning every part looks, feels, and performs the same. In the case of pharmaceutical or cosmetic gels, like niosomal gels, homogeneity ensures that the active ingredients are evenly distributed so that each dose delivers the right effect.

To test for it, the gel is usually observed for any lumps, phase separation, or color differences. A well-mixed, smooth, and uniform gel indicates good homogeneity, which is important for both effectiveness and patient safety.

4. Smoothness of Niosomal Gels:

Smoothness refers to the texture of a gel or cream—how it feels when applied to the skin. A smooth gel spreads easily, feels pleasant, and leaves no gritty or rough sensation. In pharmaceutical formulations like niosomal gels, smoothness is a sign of good quality and proper mixing.

To check for smoothness, a small amount is rubbed gently between the fingers or on the skin. A smooth, lump-free texture means the formulation is likely well-prepared and user-friendly.

5. Viscosity of Niosomal Gels:

Viscosity is a measure of how thick or flowy a gel or liquid is. In simple terms, it tells us how easily a gel spreads or pours. For niosomal gels, the right viscosity is important—it should be thick enough to stay on the skin, but not so thick that it's hard to apply.

To check viscosity, we usually use a viscometer, but even simple observation can give an idea. A gel with proper viscosity ensures comfort, better absorption, and ease of use for the patient.

6. Absorbency of Niosomal gels:

Absorbency refers to how well and how quickly a gel is taken up by the skin. For niosomal gels, good absorbency means the product delivers its active ingredients effectively without leaving a greasy or sticky residue behind.

To assess it, a small amount is applied to the skin and gently rubbed in. If it disappears smoothly and quickly without needing much effort, the absorbency is considered good. This quality is especially important for user comfort and treatment efficiency.

7. Consistency and Greasiness:

Consistency refers to the overall feel and thickness of a gel—whether it's too runny, too stiff, or just right. A good niosomal gel should have a consistent texture that's easy to apply and doesn't separate over time. This helps ensure every application delivers a uniform dose.

Greasiness is how oily or sticky the gel feels after application. Ideally, a well-formulated gel should feel light and non-greasy, so it absorbs well and leaves the skin comfortable—not shiny or sticky.

These qualities are usually checked by touch and feel, ensuring the product is pleasant for regular use.

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8. **Appearance of niosomal gels:**

Appearance refers to how the gel looks—its color, clarity, and overall visual appeal. For niosomal gels, a clean, uniform appearance without any lumps, bubbles, or discoloration is a sign of good quality and proper formulation.

A good-looking gel not only builds trust with the user but also reflects the product's stability and consistency. If a gel looks cloudy or separates over time, it might need to be reformulated.

9. **Washability of niosomal gels:**

Washability describes how easily a gel can be removed from the skin with water. For niosomal gels, good washability means the product doesn't leave behind a sticky or oily residue and can be rinsed off effortlessly.

This is especially important for user comfort—if a gel feels heavy or difficult to clean, people may be less likely to use it regularly. A well-formulated gel should be effective when applied and easy to remove when needed.

10. Skin Irritancy Test of niosomal gels:

A skin irritancy test is used to check whether a product—like a niosomal gel—causes any negative reaction on the skin, such as redness, swelling, or itching. It's a safety step to make sure the product is gentle and suitable for human use.

Usually, a small amount of the gel is applied to a small patch of skin, often on the forearm or behind the ear. The area is then observed over 1 to 3 days for any signs of irritation. A good formulation should not cause discomfort or visible reaction.

This test helps build confidence that the product is safe for regular use.

S.no	EVALUATION PARAMETERS	RESULTS
1.	Spreadability	Easily spreadable
2.	Determination of PH	5.5 pH
3.	Homogeneity	Good
4.	Smoothness	Good
5.	Viscosity	5981+0.51 cPs
6.	Absorbency	Very well absorbed
7.	Consistency and Greasiness	Less greasiness
8.	Appearance	White colour
9.	Washability	Good (Easily washable)
10.	**Skin irritancy test**	**No irritation**

II. CONCLUSION:

The preformulation studies involving description such as melting point, colour ,appearance of the formulation were found to be comparable with that of standard formulation .Considering all the parameters of evalution f5 formulation is having greater acceptance criteria. Formulation f5 showing all the criteria required for lotion formulation. F5 formulation satisfied the following criteria like spreadability, Determination of ph, homogeneity, smoothness, viscosity, absorbency, consistency and greasiness, appearance, was hability and skin irritancy test. The stability studies were carried out on the most satisfactory formulation f5 for 2 months to assess their long term stability as per ICH guidelines.

Stability studies were carried out for 30 days and 60days the formulation was evaluated for physicochemical properties.

From the above studies and evaluation test,it is clearly indicated that formulation f5 given the best result.

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