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FORMULATION OF DATURA POWDER LOADED NISOMES AND STUDY ITS PARTICLE SIZE AND PARTICLE SIZE DISTRIBUTION

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ABSTRACT

Background: Herbal medicines are gaining prominence for their therapeutic potential, but challenges such as poor bioavailability and stability often limit their clinical applications. Niosomes—vesicular systems composed of non-ionic surfactants and cholesterol—have emerged as promising nanocarriers for enhancing the delivery and efficacy of herbal bioactive. This study was undertaken to formulate Datura powder-loaded niosomes and to systematically evaluate their physicochemical characteristics, focusing on particle size and particle size distribution. Methodology: Datura powder, known for its traditional medicinal properties, was encapsulated into niosomal vesicles using the ether injection method. The formulation involved non-ionic surfactants (Span and Tween) and cholesterol to achieve stable vesicle formation. To assess the phytochemical integrity post encapsulation, qualitative tests were conducted, including Tannic Acid Test, Wagner's, Hager's, Mayer's, and Volatile tests. Particle size and distribution were analyzed using dynamic light scattering (DLS) techniques. Results: Phytochemical analysis confirmed the presence of tannins, alkaloids, and volatile constituents, suggesting the preservation of active components after niosomal encapsulation. DLS results showed a surface area moment diameter (D [3,2]) of 2.35 µm and a volume moment diameter (D [4,3]) of 12.2 µm. Distribution values-Dv (10), Dv (50), and Dv (90)-were 0.713 µm, 6.04 µm, and 30.7 µm respectively, indicating a moderately polydisperse particle size range suitable for sustained drug delivery.

KEYWORDS: Niosomes, Datura, Ether Injection Method, Particle Size Study.

1. INTRODUCTION

1.1 Introduction of Datura

1.1.1 Biological Source: Datura Consists of the Dried Leaves & Flowering Tops of Datura Metel & D. Metel Var Fastuosa Safford. It Should Contain Not Less Than 0.20% Of Total Alkaloids of Datura, Calculated as /-hyoscyamine.

1.1.2 Family: Solanaceae

1.1.3 Geographical Source: It Is Found in India, England & Other Tropical & Sub Tropical Regions.

1.1.4 Chemical Constituents: Datura Herb Contains Up to 0.5% Of Total, Among Which Hyoscine (Scopolamine) Is the Main Alkaloid, Which /-hyoscyamine (Scopoline) & Atropine Are Present in Very Less Quantities.

1.1.5 Use: Datura Herb & Its Main Alkaloids Hyoscine Are Parasympatholytic with Anticholinergic & Central Nervous System Depressant Effects. The Drug Is Used in Cerebral Excitement. Along With Morphine, It Is Used as Preoperative Medication. It Is Also Used in Treatment of Asthma & Cough. Hyoscine Hydrobromide Is Used in Motion Sickness, Gastric or Duodenal Ulcers. Datura metel L., a recognized poisonous plant in the Solanaceae family, is widely distributed in the world. Traditionally, D. metel is used in many diseases, including neurological and heart diseases; fever; catarrh; pain; diarrhea; skin diseases; chronic bronchitis; asthma; digestive disorders; and so on. It possesses many important phytochemicals that can be used to treat various types of diseases. This review aims at summarizing the traditional uses, phytochemical, biological, and toxicological profiles of D. metel based on the database reports. For this, an up-to-date search was made in the databases: PubMed, Google Scholar, Science Direct, Scopus, and Medline, with relevant keywords for the published evidence. Findings suggest that the plant has many traditional uses, such as a cure for madness, epilepsy, psoriasis, heart diseases, diarrhea, mad dog bites, indigestion, etc. It possesses various important phytochemicals, including with anolides, daturaolone, datumetine, Datu glycosides, ophiobolin A, baimantuoluoline A, and many others. D. metel has many important biological activities, including antioxidant, anti-inflammatory, anti-microbial, insecticidal, anti-cancer, anti-diabetic, analgesic, anti-pyretic, neurological,

contraceptive, and wound healing capacity. In conclusion, the toxic plant, D. metel, can be considered a potential source of phyto-therapeutic lead compounds.[1-7]

1.2 Introduction of Niosomes

1.2.1 Definition: Niosomes Are Synthetic Microscopic Vesicles Consisting of An Aqueous Core Enclosed in A Bilayer Consisting of Cholesterol & One or More Nonionic Surfactant. Vesicles Are Prepared from Self Assembly OF Hydrated Nonionic Surfactants Molecules.

1.2.2 Advantages:

- Niosomes dispersion in an aqueous phase can be emulsified in non-aqueous phase to regulate the drug delivery rate and administered normal vesicle in external non aqueous phase.
- The vesicle liquid/suspension is water-based vesicle. This gives high patient conformity with viscus dosage forms.
- Niosomes can access the stability of entrapped drug, osmotically active in nature as well as stable.
- Handling of surface-active agent does not need any special conditions.
- Storage of surface-active agent does not require any other specific conditions for the same pharmacological effect.
- Skin penetration of drugs and increase oral bioavailability of poorly absorbed drugs.
- They can be formulated in such a way that to reach the site of action by topical routes, oral routes and parenteral routes.
- The surface-active agents, which used for the niosomes are biocompatible, biodegradable and non-immunogenic.
- They enhance the therapeutic effects of the drug by covering the drug from biological environment, delayed clearance from the circulation and controlling effects to target cells.
- Niosomes are consist of lipophilic, hydrophilic and amphiphilic moieties because of that; they can help drug molecules with a broad spectrum of solubility.
- The characteristics of the vesicle's development are fluctuating and handle able. Altering lamellarity, tapped volume, vesicle composition, size, surface charge and concentration can control the vesicle characteristics.
- The vesicle also acts as a releasing the drug in a controlled manner.

- They amend the therapeutic effect of the drug molecules by delayed clearance from the systemic circulation, restricting effect of target cells and protecting the drug from biological surrounded.
- They can also work as reservoir to release drug in granule form in controlled manner with proper suitable dosage form.
- Osmotically active and stability is acquired by niosomes in this state.[8-14]

2. MATERIAL AND METHODOLOGY

MATERIAL

Methanol, Span 60, Cholesterol, Diethyl-Ether, Tween-80 purchased from Madhav Lab Chem., Vallabh Vidyanagar, Anand, Gujarat.

METHODOLOGY

The required amount of cholesterol and surfactant (span 60, tween-80) were first dissolved in diethyl ether and 10mg datura powder is dissolved in of methanol. After dissolving mix the both the solution to get clear solution. The resulting clear solution is slowly injected into the preheated aqueous solution (Phosphate buffer pH 7.4) maintained at 60 °C through the 26-gauze needle. The vaporization of ether leads to the formation of unilamellar vesicles of the surfactants containing Datura powder.[15]

3. Preparation of Primarily Batches of Niosome:

Batch No.	Cholesterol (mg)	Span 60 (mg)	Tween 80 (mg)	Description
D1	100	100	-	Size- Coarse Stability- Agglomeration found
D2	100	200	-	Size- Coarse Stability- Agglomeration found
D3	100	250	-	Size- Coarse Stability- Agglomeration found
D4	100	300	-	Size- Coarse Stability- Agglomeration found
D5	100	400	-	Size- Coarse Stability- Agglomeration found
D6	100	500	-	Size- Coarse Stability- Agglomeration found
D7	100	-	100	Yield are less Size- Coarse Stability- Agglomeration found
D8	40	40	-	Size- Coarse Stability- Agglomeration found
D9	40	120	-	Size- Coarse

				Stability- Agglomeration found
D10	40	-	120	Yield are less Size- Coarse Stability- Agglomeration found
D11	60	120	-	Size – Coarse Stability- Agglomeration found
D12	60	180	-	Size – Coarse Stability- Agglomeration found
D13	60	-	120	Yield are less Size- Coarse Stability- Agglomeration found
D14	30	140	-	Size – Coarse Stability- Agglomeration found
D15	30	120	-	Size – Appropriate Stability - Agglomeration was not found
D16	30	100	-	Size – Coarse Stability- Agglomeration found
D17	30	80	-	Size – Fine Stability- Agglomeration found
D18	30	-	120	Yield are less Size- Coarse Stability- Agglomeration found
D19	30	-	100	Yield are less Size – Coarse Stability- Agglomeration found
D20	30	-	80	Yield are less Size – Coarse Stability- Agglomeration found
D21	20	140	-	Yield are less Size – Coarse Stability- Agglomeration found
D22	20	120	-	Yield are less Size – Coarse
D23	20	-	-	Size – Coarse Stability- Agglomeration found
D24	20	140	140	Yield are less Size – Coarse Stability- Agglomeration found
D25	20	120	120	Yield are less Size – Coarse Stability- Agglomeration found
D26	20	100	100	Yield are less Size – Coarse Stability- Agglomeration found

4. Method of Preparation Datura Powder Loaded Niosomes

The required amount of cholesterol(40mg) and span 60(130mg) were first dissolved in 6 ml diethyl ether and 10mg datura powder is dissolved in 4 ml of methanol. After dissolving mix the both the solution to get clear solution. The resulting clear solution is slowly injected into the preheated aqueous solution (Phosphate buffer pH 7.4) maintained at 60 °C through the 26-gauze needle. The vaporization of ether leads to the formation of unilamellar vesicles of the surfactants containing Datura powder.

5. RESULT AND DISCUSSION

Result

- D [3,2] was found to be-2.35 µm. In simple term, D (3,2) represent the Sauter Mean Diameter (SMD). It is a weighted average diameter which takes into account the surface area of the particles.
- D [4,3] was found to be- 12.2 µm. In simple term, D (4,3) represents the De Broecker Mean Diameter (DMD). It is a weighted average diameter, which takes into account the volume of the particles.
- Dv (10) was found to be- 0.713 µm. It is the diameter below which 10% of particles in sample fall, based on their volume. It provides information on the finer particles in the sample, which can be important in understanding the behavior and properties of the materials.
- Dv (50) was found to be - 6.04 µm. It is often considered a representative diameter for the sample as it divides the distribution into two equal parts. It provides information on the middle size of the particles in the sample, which can be important in understanding the behavior and properties of the material
- Dv (90) was found to be -30.7 µm. It often used to characterize the upper end of the particle size distribution, identifying the presence of larger particles, monitoring changes in the particles size distribution during processing or storage. It provides the information on the coarser particles in the sample, which can be important in understanding the behavior and properties of the material.

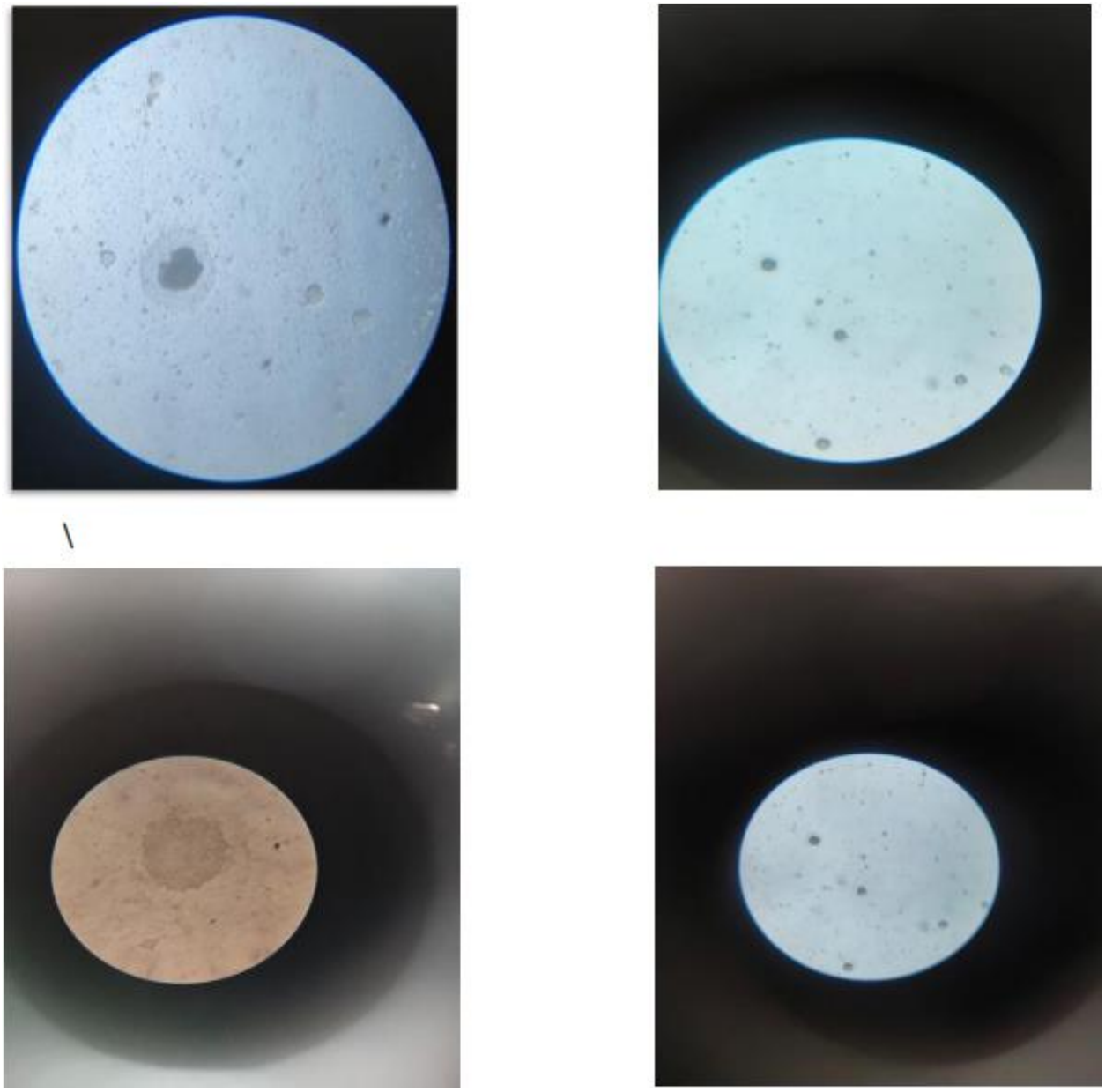

Figure 1: Microscopic Images of Datura powder loaded Niosomes.

Summary

Systemic evaluation of physical chemical characteristics particle size, particle size distribution. The present research work was undertaken with the objective of formulating Datura powder-loaded niosomes. Niosomes, which are vesicular systems composed of non-ionic surfactants and cholesterol, have emerged as promising carriers for enhancing the bioavailability, stability, and therapeutic efficacy of herbal bioactive. In this study, Datura powder, known for its traditional medicinal applications, was encapsulated within niosomal vesicles prepared by the the ether injection method. The method employed non-ionic surfactants such as Span and Tween, combined with cholesterol, to achieve stable and

efficient vesicle formation. Further, particle size and particle size distribution analyses were carried out utilizing dynamic light scattering (DLS) techniques to assess the physicochemical attributes of the niosomal formulation. The analysis provided precise particle size values, where the D[3,2] (surface area moment diameter) was observed at 2.35 µm, and the D[4,3] (volume moment diameter) was measured at 12.2 µm. The distribution profile indicated Dv(10) at 0.713 µm, Dv(50) at 6.04 µm, and Dv(90) at 30.7 µm, reflecting a moderately polydisperse system with particle sizes primarily within the micrometric range. These findings suggest that the formulated niosomes possess a particle size distribution suitable for controlled and sustained drug delivery applications. In conclusion, the study successfully established the feasibility of incorporating Datura powder into niosomal carriers, preserving its phytochemical composition while achieving favorable particle size characteristics. The combination of phytochemical screening and particle size analysis provides valuable insights into the formulation potential of niosomal systems for herbal bioactives, offering a promising platform for the development of herbalbased nanocarrier formulations with enhanced therapeutic performance and stability.

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