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Formulation and Evalution of Neem Microsponges Gel

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Abstract: ***The aim of the present study was to improve the release of neem by microsponges prepared through quasi-emulsion solvent diffusion technique using ethyl cellulose and PVA as carriers. Microsponges technology has become developed in novel drug delivery system are carrying out and improves the efficacy and safety of therapeutic substances for controlled release of topical agent. The prepared microsponges were further filled in hard gelatin capsule shell and loaded in carbopol gel to evaluate its potential in topical drug delivery. The main purpose of this project work was to formulated microsponges containing the neem oil and incorporate it into gel.***
Keywords: Microsponges, neem oil, antibacterial activity.

I. INTRODUCTION

A. Drug Delivery System

A drug delivery system enables the introduction of a therapeutic substance in the body and improves its efficacy and safety by controlling the rate, time and place of release of drug in the body. The preparation and evaluation of gel containing neem microsponges which is topical dosage form and it shows therapeutic activity as an anti-fungal, anti-bacterial activity.

B. Introduction to topical drug delivery system:

Topical drug delivery system is defined as the application of a drug containing formulation to the skin or mucous membrane, to treat specific cutaneous disorders (e.g. acne) or cutaneous manifestations of a generalized disease (e.g. psoriasis), with the intent of containing the pharmacological effect of the drug only to the surface or within the layers of skin or mucous membrane.

Types of Topical Drug Delivery System:

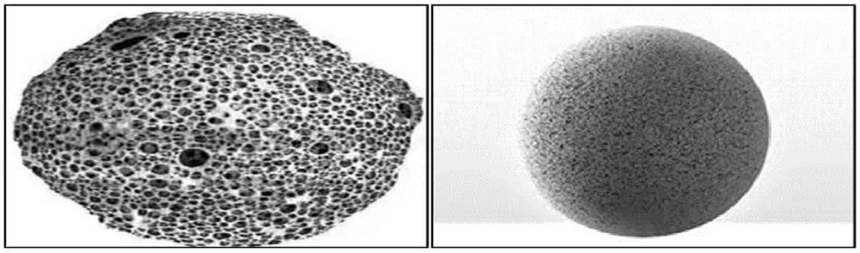
Includes two types of Topical Drug Delivery System:

1)External- that are spread or dispersed on the cutaneous surface covering the affected area.

2)Internal- that are applied to the mucous membrane of eye (conjunctiva), ear, oropharyngeal cavity, nasal cavity, vagina or anorectal region for local activity.

C. Microsponges

Microspongesis novel drug delivery system.It is a patented, highly cross linked, porous, polymeric microsponges that can entrap wide range of active ingredient and release them with desired rate. It having particlesize ranges from 5 to 300 micrometer that can entrapped wide range of active ingredient and release them over extended time. This system is applicable for the improvement of performance of topically applied drugs.When these microsponges used topically they prevent accumulation of the drug in both dermis and epidemis. Microsponges can has easily entrapped and formulated into pharmaceutical product such as gels, creams, powders, liquid, and suspensios. It is unique technology for contolled release of topical agents and consists of microsponges beads.



(A) (B)

Fig 1: (A) Highly Porous structure of microsponges (B) Microsponges

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D. Advantages of Microsponges

- No monomer entrapement.
- Low solvent traces.
- High drug loading.
- Size of microsponges is easily controlled by controlling stirring.
- Dose dumping effect can be reduced by microspheres.
- Improve formulation flexibility.
- Reduced irritation and improve patient compliance.
- Microsponges drug delivery can improve bioavailability of drug.

II. LITERATURE REVIEW

Table 1: Literature Review

Author's	Title of the article	Journal name	Guidelines
Mr.SantanuKaity, SabyasachiMaiti, AshokeKumar Ghosh	Microsponges: Anovel strategy for drug delivery system	Journal Of Advanced Pharmaceutical Technology & Research	Introduction
SunitaShinde, ShamikaShirke, Mrs.ManishaKarpe, Dr.VilasraoKada m	Formulation And Evaluation Of Topical Microsponges Based Gel Of Turmeric	Indo American Journal of Pharmaceutical Research	Methodology
Mohammad. A. Alzohairy	Therapeutics Role Azadirachtaindica (Neem) and Their Active Constituents in Diseases Prevention and Treatment	Articles from Evidence based Complementary and Alternative Medicine	Introduction: NEEM
Shan Monhanan, NabeelaRashe ed, Bimal Raj KS	Formulation And Evaluation Of Antimicrobial Gels For The Treatment Of Paronychia	International Journal Of Applied Pharmaceutics	Evaluation Parameters

Table no:-1 literature review

III. MATERIAL & METHODOLOGY

SR.NO.	INGREDIENTS	ROLE
1.	Eudragit 934	Polymer
2.	Polyvinyl alcohol	External Phase
3.	Dichloromethane	Solvent
4.	Glycerol	Plasticity, Stabilizer
5.	Carbopol	Gelling Agent
6.	Triethanolamine	Surfactant
7.	Glycerine	Lubricant

Table no 2: List of Ingredient along with their roles

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A. Methodology

Formulation development of Microsponges:

The drug was incorporated in a novel micro particulate microsponge system having a drug dispersed matrix. The selection of a particular encapsulation method is primarily determined by the solubility characteristics of the drug and polymer. The method should ideally produce,

(a) High yields of micro particles and free of extensive agglomeration.

(b) Appropriate encapsulation of the core material.

Methodology for formulating Neem Microsponges:

Quasi Emulsion Solvent Diffusion consist of the emulsification of organic solution of drug which is miscible with water and it also contains stabilizers.

Microsponges were prepared by Quasi Emulsion Solvent Diffusion Technique which requires two immiscible phases internal and external phase with a surfactant which aids formation of an emulsion by reducing the interfacial tension. The method consists of two steps. In the first step internal phase was prepared and in second step external phase was prepared.

B. Quasi-Emulsion Solvent Diffusion Technique

Formulation Table: Microsponges

SR.NO	INGREDIENTS	QUANTITY TAKEN
1	Neem Oil	1ml
2	Eudragit 934	0.5gm
3	Polyvinyl alcohol	20ml
4	Dichloromethane	10ml
5	Glycerol	1ml
6	Water	100ml

Table no 3: Formulation of Microsponges

C. Procedure

Step 1:Preparation of internal phase

- Eudragit 934 (0.5gm) is use as polymer in this formulation.
- The polymer is allowed to soaked in the solvent is dichloromethane (10 ml).
- Neem oil (1 ml) is added to this solution leading to the formation of internal phase.

Step 2: Preparation of external phase

- The external phase was prepared by adding 5% polyvinylalcohol in water to produced 100ml.

Step 3: Mixing of internal and external phase

- The inner phase was poured drop wise by the help of the syringe into external phase at room temperature.
- Glycerol (1-2ml) was added at an adequate amount in order to facilitate plasticity.
- After emulsification the mixture was continuously stirred for 3hrs.at 1000rpm.
- After the formation of microsponges the mixture was filter to separate to microsponges.
- The product was dried by using Hot Air Oven

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Formulation Table: Gel

SR.NO	INGREDIENT	QUANTITY TAKEN
1.	Carbopol	1to2%
2.	Water	100 times that microsponges
3.	Triethanolamine	Quantity sufficient
4.	Glycerine	Quantity sufficient

Table no 4: Formulation of gels

Step 4: Prepartion of gel

- The amount of microsponge obtained was weighted.
- Ammount of Carbopol taken quantity equal to that of microsponge. Carbopol was suspended in water.
- Microsponge were soaked in glycerine.
- After the suspension of Carbopol in water the microsponge were added to it .
- Sufficient amount of triethanolamine was added.

IV. EVALUTION PARAMETER

A. pH METER

It measures the voltage between the electrode .Two electrodes arethere, one is the glass and another is reference. The voltage between that is corresponding pH value. Both the bulb are the hollow bulb containing potassium chloride with the silver chloride wire suspending into it glass electrode has bulb and reference electrode bulb containing non -conducting glass or plastic

Fig :- pH meter

B. Franze Diffusion Cell Apparatus

Diffusion is the net movement of molecules or atoms from a region of high concentration with high chemical potential to a region of low concentration with low chemical potential. This is also referred to as the movement of a substance down a concentration gradient. Diffusion is the movement of a component through space under the influence of a physical stimulus. The most common cause of diffusion is a concentration gradient, which tends to adjust the component concentration until it reaches equilibrium. In short, diffusion is the physical flow of material.

Fig.no- Franze Diffusion Cell Apparatus

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Procedure:

1. Ensure the working area is neat and clean.
2. Place the Diffusion cell Apparatus on the level surface.
3. Connect the required power supply to the instrument.
4. Switch on the main power switch on the instrument.
5. Switch on the heater switch.

.6. LED displays the temperature of the water jacket. Let the temperature rise to the required temperature e.g., body temperature.

C. Particle Size And Zeta Potential Analyser

It measures particle size from 0.3 nm to 8 µm zeta potential. Particle size can be determined by measuring the random changes in the intensity of light scattered from a suspension or solution. Small particle insuspension undergo random thermal motion known as Brownian motion. This random motion is measured to calculate particle size using the process described below. A top view of the optical setup for particle size.

EVALUTION TESTS FOR FORMULATION OF GEL:

Physical Appearnce Test –

- Colour-Colourless
- Odour-Pleasant
- Consistency-Semisolid

pH Test-

TEST	RESULT
The pH of the prepared gel was measured using pH meter (standardized using buffer,pH7 before use) by putting the tip of electrode into the gel and after 2 min result was recorded. The measurement oh pH was done in triplicate and the mean was calculated.	pH= 7.3

Table no 5 : pH Determination

Spreadability Test

TEST	RESULT
Spreadability of the gel was determine after placing a weighed amount of sample between two glass sildes and weight of 500 gm was kept over the silde for about 5 min after which no more spreading is expected.Initial and final diameter were measured in cm and were taken as comparative values of it.	Slide diameter: (7.5cm × 2.5cm) Result diameter: (6.5cm × 2.5cm)

Table no 6 :Spreadability Test

V. OBSERVATION AND RESULTS

In these antimicrobial and antifungal testing it complies the test and gives the satisfactory results. In antifungal testing, the inhibition of growth of the

Streptococcus Aureus microorganisms by the neemmicrosponges gel with standard Flucanazole marketed preparation as compared to the blank sample testing.

In antimicrobial testing, the inhibition of growth of the Proteus Vulgaris microorganisms by the neemmicrosponges gel with standard Amoxycillin marketed preparation as compared to the blank sample testing.

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VI. CONCLUSION

The purpose of present research work was to develop a topical neem loaded microsponge based anti inflammatory, anti fungal and anti microbial gel formulation. It has improved the efficacy and safety of neem that may be better administered through skin. A controlled release drug delivery system aims for a prolonged period so that can satisfy the goals of the reduction in inflammation. The need of the hour is design a topical drug delivery system of neem that could not only increase the presence of the drug locally and for a prolonged period, but also reduce the risk of toxicity.

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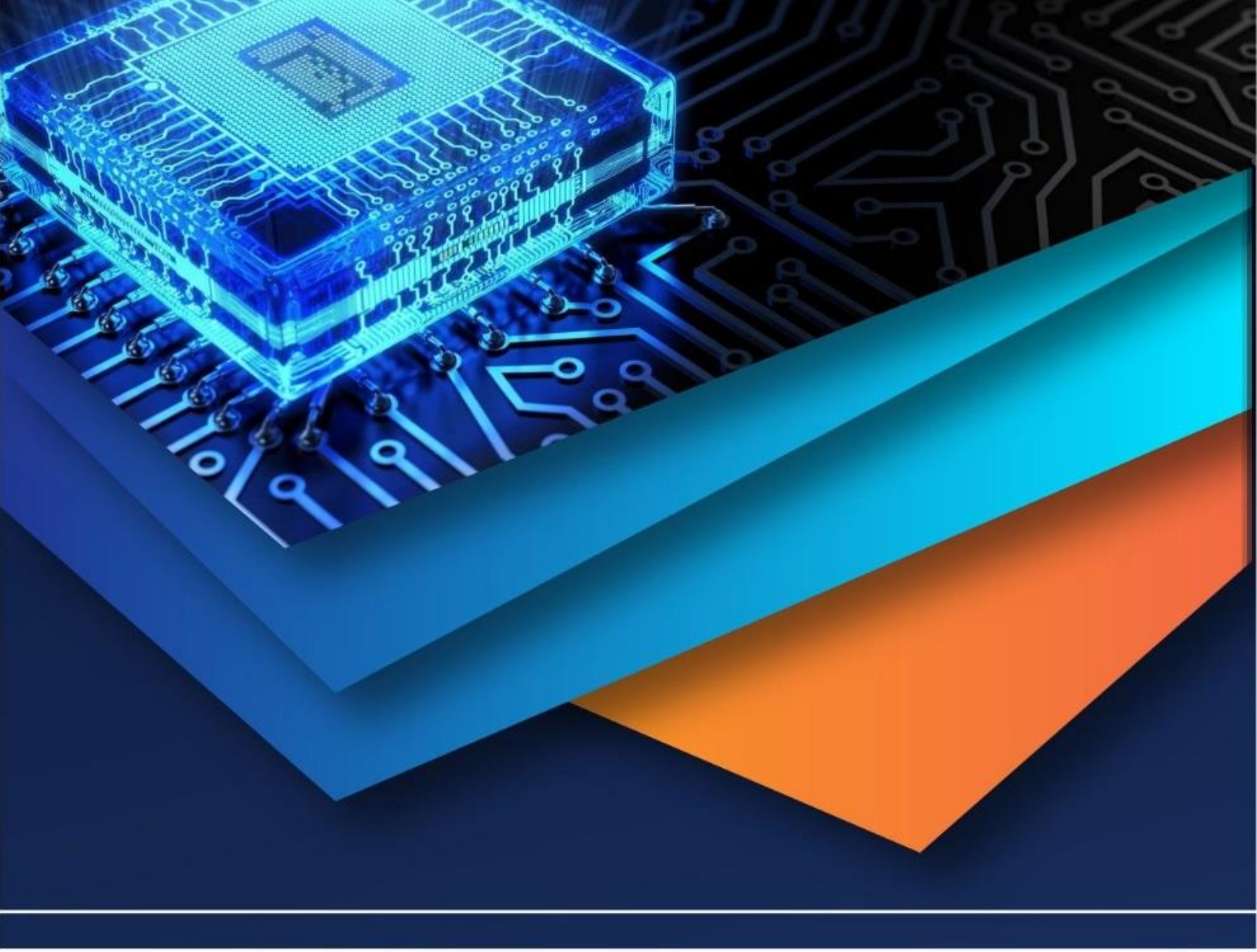

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