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FORMULATION AND EVALUATION OF HERBAL EXTRACT LOADED NIOSOMAL GEL

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ABSTRACT

Because of their impact on pharmacokinetics, bioavailability, and toxicity, niosomes play an essential role in medication administration. Niosomes, when applied topically, reduce drug absorption and increase medicine retention in the epidermis and stratum corneum. Additionally, niosomes can store medications and modulate their release rate and binding affinity at the target region. The possible medicinal plant Colocasia esculenta Linn is well-known for the flavonoids, β-sitosterol, and steroids it contains. Vitamin C abounds in the plant's leaves, whereas carbohydrates and other nutrients are abundant in the root. Colocasia esculenta juice extract has central nervous system effects, is an expectorant, helps with hair loss, lowers blood pressure, and stimulates the central nervous system. It reduces inflammation, alleviates pain, prevents diabetes, protects the liver from damage, and kills microbes. Thin film hydration was used to prepare Herbal Extract loaded Niosomes (HEN) with varying ratios of non-ionic surfactants (Soya Lacithin) and cholesterol (CHO), with the goals of improving the low skin penetration and minimising the side effects associated with topical conventional drug administration. Size, shape, entrapment efficiency, stability, antibacterial study, and in vitro drug release were some of the criteria used to assess the formulations. This study found that the entrapment efficiency and drug release rate from niosomes were affected by the kind of surfactant and the amount of CHO. The drug release was greater in the formulation with a surfactant to CHO ratio of 1.55:0.75. Research suggests that a gel formulation using Niosomes loaded with Herbal Plant Extract might have potential benefits. Niosomes demonstrated a longer duration of action compared to formulations using non-niosomal Herbal Plant Extract Niosomes, and they have the potential to be effectively developed to enhance antimicrobial activity.

KEYWORDS: Niosomes; Colocasia esculenta; Herbal Plant Extract Niosomes; non-ionic surfactants; microbial activity.

1. INTRODUCTION

A growing number of medications are being delivered by means of niosomes because of their potential to modify pharmacokinetics and bioavailability while simultaneously decreasing pharmaceutical toxicity.[1] You can reduce the quantity of medicine taken into your system and increase the amount of time that pharmaceuticals remain in the stratum corneum and epidermis by applying niosomes to your skin.[2] They may store pharmaceuticals in their vesicles, and by modifying their compositions or surface characteristics, we may control how quickly the drug is released and how well it binds to the target site.[3] We know one medical plant, Colocasia esculenta Linn, (Family: Araceae), as a possible medicinal herb.[4] It is often called "Taro" in English, Arvi, Kachalu in Hindi, and Alupam, Alukam in Sanskrit. The tall herb Colocasia esculenta Linn. has a tuberous root system or a sturdy, short caudex, and it blooms and leaves at the same time. The most common components are the corms and leaves. Colocasia esculenta mostly contains flavonoids, β-sitosterol, and steroids.[5] Vitamin C is abundant in the plant's leaves as well as its roots, which are also a good source of starch and other essential nutrients like thiamine, riboflavin, niacin, and oxalic acid.[6] Colocasia esculenta juice extract has several medicinal uses, including treating baldness, stimulating the immune system, preventing blood clots, and alleviating aches and pains. According to reports, it possesses a wide range of pharmacological effects, such as those on the central nervous system, inflammation, pain, antidiabetic, antihepatotoxic, and microbiological processes.[7]

2. MATERIALS AND METHODS

2.1 Extraction and Phytochemical Evaluation of the Methanolic extract of Colocasia esculenta (L.) (MLCE)

Leaves were shade dried, grinded and a coarse powder was obtained which was extracted using methanol as solvent using Soxhlet apparatus. The percentage yield

was calculated and quantitative (8) and qualitative (9) phytochemical evaluation was done for the extract.

2.3 Formulation of the Herbal Extract loaded Niosomes (HEN)

A lipid combination including surfactant (Soya-Lacithin) and CHO, in various specified ratios as listed in Table 1, was used to create niosomes utilising a thin film hydration process. Ten millilitres of chloroform was used to dissolve the surfactant, CHO, and medication. After that, the lipid mixture was moved to a 100 ml round-bottom flask. A rotary flash evaporator was used to lower the pressure of the solvent while maintaining a temperature between 55 and 65°C. This process was continued until a thin lipid film had formed. Thirty millilitres of phosphate buffer saline (pH 7.4) were added to the created film to hydrate it. For 1 hour, the rotary evaporator was used to keep the flask rotating at 55-65°C while the hydration was continued. A niosomal dispersion comprising both free and entrapped medicines of various sizes was obtained by subjecting the hydrated niosomes to 20 minutes of sonication in a bath sonicator.[10]

Table 1: Formulation of Herbal Extract loaded Niosomes (HEN).

Formulation	N1	N2	N3	N4	N5	N6	N7	N8	N9
Herbal extract (mg)	100	100	100	100	100	100	100	100	100
Soya-Lacithin (mg)	100	150	200	100	150	200	100	150	200
Cholesterol (mg)	20	20	20	30	30	30	40	40	40
Chloroform (ml)	15	15	15	15	15	15	15	15	15
PBS (pH 7.4)	25	25	25	25	25	25	25	25	25

2.4 Evaluation of the Herbal Extract loaded Niosomes (HEN)

The formulated Herbal Extract loaded Niosomes (HEN) were evaluated for Particle Size[11], Content uniformity[12], Entrapment efficiency[13], In vitro drug release assay[14] and Stability study[15] using appropriate methods.

3. RESULTS AND DISCUSSION

3.1 Percentage Yield and Phytochemical Evaluation

The percentage yield of the Methanolic extract of Colocasia esculenta (L.) (MLCE) was found to be 43.69 % ^{w}/w with a sticky greenish blue texture. Qualitative evaluation reveals the presence of carbohydrate, saponins glycosides, flavonoids, tannins and phenolics while proteins, amino acids, alkaloids, cardiac glycosides and sterols were absent. Quantitative estimation reveals the total phenolic content was found to be 47.91 mg TAE/g of extract of Colocasia esculenta while total flavonoid content was found to be 20.15 mg quercetin equivalents/g of extract.

3.2 Evaluation of the Herbal Extract loaded Niosomes (HEN)

3.2.1 Particle Size

To maintain a steady ratio of hydrophilic to hydrophobic groups in non-ionic surfactants, niosomal vesicles must be formed (Table 2). Niosomes are vesicles that are both round and smooth on the outside; the presence of CHO affects their size. Niosome size is inversely proportional to CHO concentration because hydrophobicity reduces surface energy and niosomal matrix and extract interact favourably. The absorption rate of lipophilic medicines via niosomes is higher than that of hydrophilic medications.

3.2.2 Entrapment Efficiency

Careful consideration of process factors including vacuum, hydration medium, hydration period, and flask rotation speed is necessary for niosome preparation. Niosome fragility and medication leakage might result from poor selection (Table 2). The lipid film's thickness and homogeneity are influenced by the flask's spinning speed. In order to maximise entrapment efficiency, hydrating temperatures should be higher than the gel liquid phase transition temperature. The amphipathic compound CHO affects several membrane characteristics, including size, shape, elasticity, ion permeability, aggregation, and the fusion process. Since CHO reinforces drug levels in niosomes by sealing the leaky gap in bilayer membranes, a rise in CHO concentration leads to an increase in Herbal extract entrapment levels. Both the surfactant concentration and the time required for optimal drug release contribute to the entrapment efficiency.

Table 2: Evaluation of Herbal Plant Extract Niosomes.

Formulation	Particle Size	Entrapment Efficiency
N 1	6.12 ± 0.23	59.47 ± 0.61
N 2	6.14 ± 0.83	61.18 ± 0.27
N 3	5.96 ± 0.06	63.08 ± 0.54
N 4	6.04 ± 0.01	69.08 ± 0.41
N 5	7.04 ± 2.93	66.36 ± 2.27
N 6	6.44 ± 1.04	69.08 ± 0.44
N 7	6.26 ± 0.54	70.95 ± 0.33

N 8	6.94 ± 0.44	69.99 ± 0.89
N 9	7.01 ± 0.47	70.07 ± 0.91

3.2.3 In vitro Drug Release Study

Initially, a PBS pH 7.4 was selected, which has shown a better stability of Extract. A medium with 10% methanol was considered to be sufficient for the diffusion study. The volume of the receptor medium used was 100 ml. The increase of CHO content resulted in a reduction of membrane permeability, which leads to lower drug elution from the vesicles (Figure 1; Table 3).

Table 3: In vitro Drug Release Study.

Time (Hrs)	N 1	N 2	N 3	N 4	N 5	N 6	N 7	N 8	N 9
2	30.05 ± 0.151	29.25 ± 0.136	27.55 ± 0.145	26.04 ± 0.133	25.49 ± 0.085	23.04 ± 0.147	21.04 ± 0.004	19.44 ± 0.484	18.99 ± 0.591
4	40.35 ± 0.364	39.88 ± 0.478	37.54 ± 0.144	34.04 ± 0.155	32.14 ± 0.984	30.05 ± 0.148	29.38 ± 0.048	27.38 ± 0.998	26.56 ± 0.347
6	47.04 ± 0.333	46.54 ± 0.614	44.54 ± 0.954	42.3 ± 0.143	41.39 ± 0.189	39.35 ± 0.247	35.38 ± 0.117	31.84 ± 0.481	29.54 ± 0.667
8	60.05 ± 0.500	58.54 ± 0.141	56.48 ± 0.174	49.91 ± 0.151	46.05 ± 0.151	41.35 ± 0.151	39.44 ± 0.001	36.05 ± 0.048	34.56 ± 0.187
10	66.53 ± 0.794	64.56 ± 0.157	62.77 ± 0.161	57.74 ± 0.163	54.44 ± 0.145	48.59 ± 0.188	43.54 ± 0.199	40.89 ± 0.087	38.45 ± 0.101
12	80.27 ± 0.984	78.54 ± 0.101	76.36 ± 0.151	62.35 ± 0.147	59.35 ± 0.745	54.38 ± 0.169	50.35 ± 0.177	47.59 ± 0.109	45.99 ± 0.177

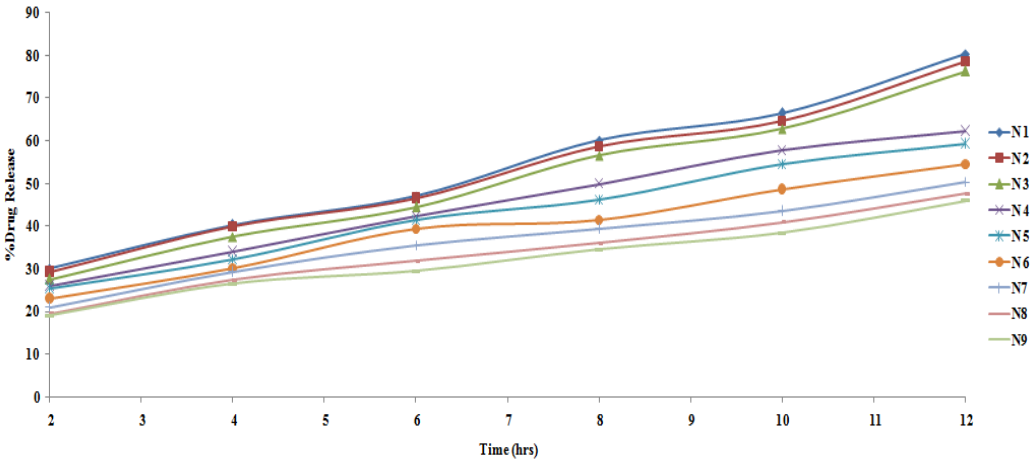

Figure 1: In vitro Drug Release Study.

3.2.4 Stability Studies

Stability Study of Optimized Batch (N1) is shown in Table 4. As per the data, it was concluded that formulated niosomal form was stable enough till 6 months under the accelerated conditions as per the ICH.

Table 4: Stability Study of formulated niosomal form (N1) under accelerated Conditions as per ICH guideline.

Test parameters	Specifications	Initials	1st Month	3rd Month	6th Month
Moisture content	NMT 2.5	1.31	1.32	1.33	1.31
Assay (Drug Content)	NLT 90% and NMT 110% of label claim	93.93 ±1.23	93.56 ±1.73	93.56 ±0.73	93.06 ±1.33
Microbial limit test	Total count < 102 CFU (As per USP)	Complies	Complies	Complies	Complies

4. CONCLUSIONS

This study found that the entrapment efficiency and drug release rate from niosomes were affected by the kind of surfactant and the amount of CHO. The drug release was greater in the formulation with a surfactant to CHO ratio of 1.55:0.75. All of these studies point to the same conclusion: niosome-loaded herbal plant extract niosome gel formulations outperformed non-niosomal Herbal Plant Extract niosome formulations in terms of duration of action, and this gel formulation has the potential to be developed into an effective antimicrobial agent.

5. Conflict of Interest

None.

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