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Research Paper

Formulation And Evaluation of NSAID Loaded Invasomal Gel

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ABSTRACT

One way of delivering targeted therapies especially for diseases like arthritis is through the topically administration of drugs. This research was based on developing and testing the efficacy of the invasomal gel containing indomethacin for in vitro experiments. The invasomes were formulated using the ethanol injection technique. SEM results indicated that the vesicles were spherical and had smooth surfaces. DLS confirmed that the vesicles were less than 300nm. Six invasome formulations were made. From all the six formulations, formulation 4 (F4) exhibited good results for PDI, vesicle sizes, and high EE % (88.2%). after the development of invasomes 4 formulations of invasomal gels were also formulated. Among the four, formulation 4 also showed promising results for in vitro drug delivery.

INTRODUCTION

The administration of drugs transdermally is gaining popularity rapidly because new formulations are being discovered to improve the bioavailability of multiple drugs. The skin layer gets affected negatively through the application of medications transdermally. The vesicular carriers have gained popularity in drug delivery systems as a means of transdermal and dermal administration of drugs.[1][2]

Compared to the traditional dosage forms, the conventional liposomes have been shown to be effective in improving the amountof drugs that accumulate in the skin layer.Over the past two decades, there have been numerous developments in the field of vesicles in the form of the development of novel vesicle types. There is now much interest in a new group of vesicles referred to as invasomes. To begin with, invasomes are composed of ethanol and terpenes alongside phospholipids. Both ethanol and terpenes facilitate the penetration of drugs through skin and also deform vesicles. The result of all these is an increase in the penetration of drugs through the epidermis.[1][3]

Invasomes refer to the flexible lipid nanocarriers which are made up of phosphatidylcholine,

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ethanol, terpenes, or a combination of terpenes. Apart from partitioning of the stratum corneum, modification of lipid in the stratum corneum, and protein interaction within cells, terpenes are excellent permeation enhancers. Terpenes along with ethanol enable the vesicles to penetrate through the skin. Because of the nature of semi-solid nature of the drug in the form of a gel or cream, there are various advantages that invasomes have, such as non-invasive delivery of drugs, drug skin penetration, and distribution of lipophilic and hydrophilic drugs.[4]

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) is a group of drugs that have a common mode of action but vary widely in structure. They are the first choice in treating rheumatological conditions and other degenerative inflammatory diseases due to their pain-relieving, fever-reducing, and anti-inflammatory effects.[5]

MATERIAL AND METHOD

MATERIAL

Indomethacin,Carbopol934 and triethanolamine were obtained from Central drug house (CDH).Soylecthin was purchased from DhamtecPharma and Consultants, Mumbai.Ethanol and eugenol were obtained from college lab.

METHODOLOGY:

Table 1: Formulation details of Indomethacin loaded Invasomes:

Formulation Code	Phospholipid(%w/v)	Terpene (%w/v)	Ethanol (%w/v)
B1	1	0.2	10
B2	1	0.5	10
B3	2	0.2	10
B4	2	0.5	10
B5	3	0.2	10
B6	3	0.5	10

Indomethacin Loaded Invasomes Preparation

The method of ethanol injection is characterized by the quick distribution of lipids and drug molecules that exist in ethanol into the aqueous phase, resulting in the creation of vesicles due to the precipitation of the diffused components. This technique can be employed when preparing invasomes, which include ethanol and terpenoids like eugenol.[6]

Characteritation Of Indomethacin Loaded Invasomes

1.Morphological evaluation of invasome:

The electron microscopic technique (SEM)Scanning electron microscopy was employed for surface and shape characterization of the prepared invasomes.[7]

2.Determination of entrapment efficiency

The process of centrifugation was employed to calculate the entrapment efficiency of the invasomal formulation. The invasomal formulation was placed in the tube and then centrifuged using a refrigerated centrifuge at 20,000 rpm for 30 minutes. The resulting supernatant was then diluted using methanol. UV spectrophotometer (UV 1900i, Shimandzu, Japan) was employed to measure the absorbance at 318 nm. Using the regression formula from the calibration curve, the invasomal formulation's concentration was calculated. The entrapment efficiency was calculated as follows[8]

EE=total drug -free drug /total drug *100

3.Size distribution and zeta potential

The zeta potential and particle size distribution analysis were carried out in triplicates using the Zetasizer-3000 (Malvern, UK) instrument through

the DLS technique. The polydispersity index (PDI) and mean hydrodynamic diameter (Z-average) were the two variables that described the size distribution.[8]

Table 2: Frmulation details of Indomethacin Loaded Invasomal Gel:

Ingredients (%)	IG1	IG2	IG3	IG4
Carbopol 934	1	1.5	2	2.5
Invasomeeq to (%)	1	1	1	1
Triethanolamine (%)	0.5	0.5	0.5	0.5
Distilled Water (qs) mL	100	100	100	100

Perparation Of Indomethacin Loaded Invasomal Gel

A beaker was taken and a blend was made by adding Polymer Carbopol 934 to distilled water, which was kept soaking overnight. After dispersing the optimum formulation invasomes containing Indomethacin in water, Carbopol 934 was neutralized by adding an appropriate quantity of triethanolamine. Methylparaben and propylparaben (preservatives) along with glycerine (moisturizer) were subsequently added gradually under gentle stirring until a uniform gel formation was achieved. Carbopol 934 was used in varying quantities to form gels of indomethacin.[10]

Characteritation Of Invasomal Gel

1.DETERMINATION OF PH:

pH of selected optimized formulations was measured using digital pH meter. Prior to measuring the pH of the solution, the pH meter must be calibrated by using a buffer solution with pH values 4, 7 and 9.2. Afterwards, the electrode of the pH meter was immersed in the vesicle suspension until it was fully covered by the vesicles. The pH reading was taken thereafter.[10]

2.DETERMINATION OF VISCOSITY:

The viscosity of the invasomal gel formulated was measured by the Brookfield viscometer with the use of spindle no. 63 and ideal rotation at 10 rpm; results have been presented in the table below.[10]

3. SPREADABILITY:

In order to obtain a therapeutic response and to provide a proper dose that can be absorbed through the skin the formulation should have good spreadability . It comprises of a device in which a slide is fixed on a wooden block, the upper slide is capable of moving, and the end part of the upper slide is attached with a weight pan. The spreadability of the gel was determined using the method in which two to five grams of gel was put between two slides, the load was applied gradually in the weight pan, and the time taken for the top plate to move up ten centimeters was recorded.[10]

4.IN-VITRO RELEASE STUDY:

The Franz diffusion cell was employed in this study to conduct the in vitro drug release study. The volume of the receiver cell and the area of effective permeation were 15 ml and 0.196 cm, respectively. The receptor cell was filled with phosphate buffer saline solution (pH 7.4), while the donor cell containing the optimized invasomal formulation was mounted on top of the receptor cell. The test was conducted at 37 ± 1◦C with constant stirring at 600 rpm for 12 hours. At specific time points, like 1, 2, 3, 4, 5, 6, 8, and 12 hours, samples were withdrawn from the receptor cell, and their indomethacin concentrations were quantified using a UV spectrophotometer at 318 nm wavelength.[4]

RESULT AND DICUSSION:

SEM:

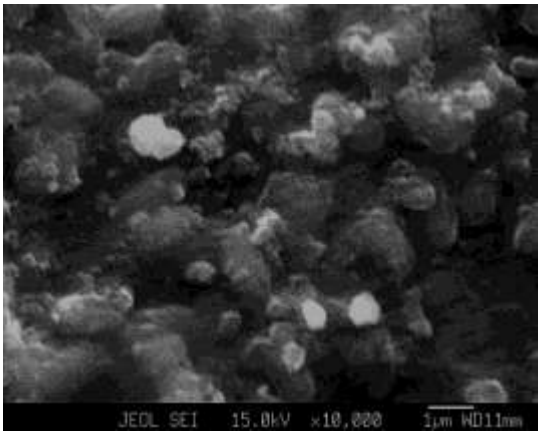


Fig no.00 SEM Image of formulation F4

Entrapment efficiency:

F. No.	% EE
F1	68.8 +1.4
F2	72.5 +3.1
F3	76.3+1.1
F4	88.1+2.2
F5	80.7+1.3
F6	83.4+1.4

Table-000 : %EEof Invasome

Particle Size Determination of Formulation F4:

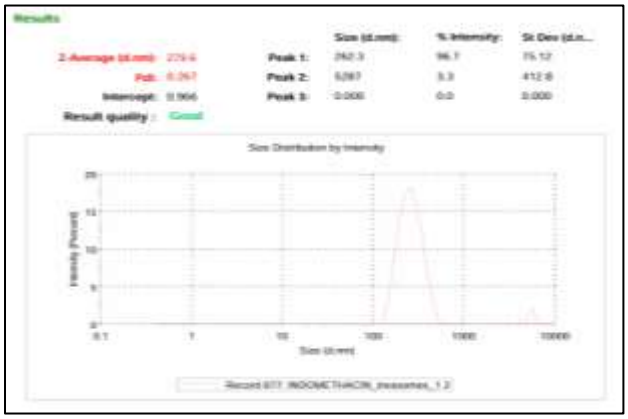


Fig. no. 000 Particle size of determination of formulation F

pH:

For the determination of pH value for topical invasomal gel, digital pH meter was employed. The pH range for all tested topical invasomal gels was observed between 6.3 to 7.1.

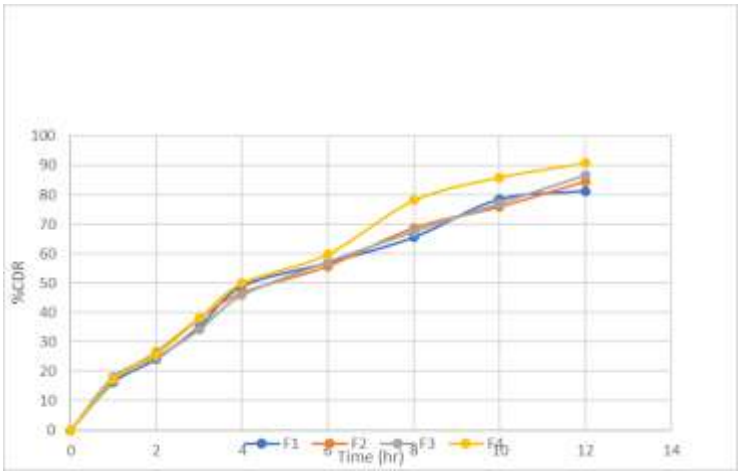
F. No.	pH
F1	6.3
F2	6.5
F3	6.9
F4	7.1

Table-000 :pH value of topical Invssomal gel

Viscosity:

In Vitro

Time	F1	F2	F3	F4
0	0	0	0	0
1	16.21	17.20	18.14	17.12
2	24.19	26.47	24.83	25.91
3	35.15	37.90	34.17	37.92
4	48.88	46.62	45.85	49.93
6	56.87	55.75	57.19	59.85
8	65.50	68.62	67.45	78.10
10	78.47	75.85	77.12	85.96
12	81.27	84.48	86.65	90.82



Drug Release Kinetics:

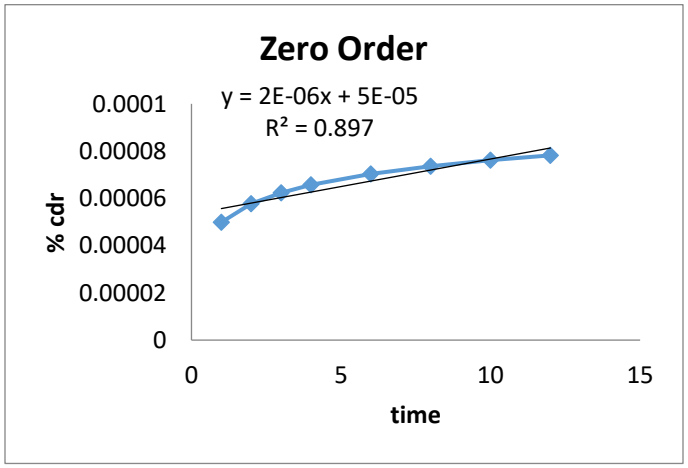


Fig- Zero Order Kinetics

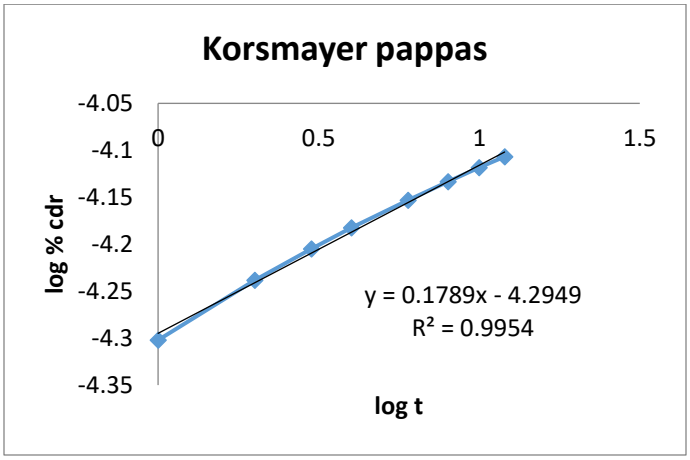


Fig- Korsmayer pappas

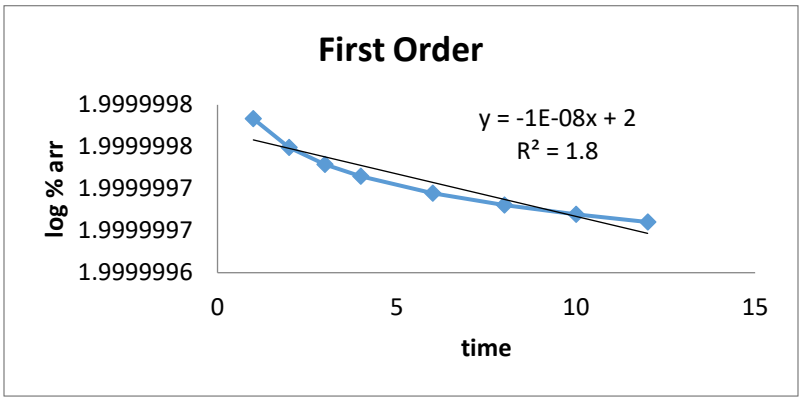


Fig- First Order Kinetics

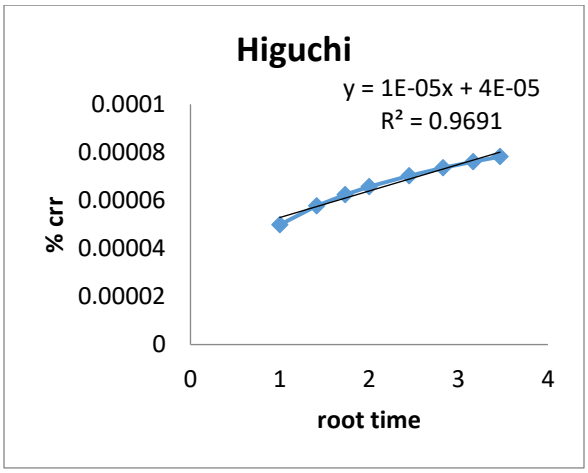


Fig- Higuchi Model

Spreadability & Viscosity:

Specifications	IG1	IG2	IG3	IG4
Spreadability	15.82 ± 4.15	12.87 ± 3.74	16.58 ±3.62	20.51 ±4.32
Viscosity	1765 ±1.21	1648 ±1.75	1812 ±1.52	1894 ±1.25

CONCLUSION

The study successfully developed an indomethacin-loaded invasomal gel for topical delivery. The optimized formulation (F4) showed nanosized vesicles, uniform distribution, and high entrapment efficiency, along with enhanced in

vitro drug release. These findings indicate that invasomal gel is a promising approach for improving the topical delivery of NSAIDs and may enhance therapeutic efficacy with reduced systemic side effects.

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