

Formulation, Development and Evaluation of Microsponge Based Gel of Crisaborole

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ABSTRACT:-The objective of present research work was to formulate microsponge gel of crisaborole drug for the treatment of atopic dermatitis. By using 3^2 full factorial design optimization of crisaborole microsponge gel was done and optimized microsponge was incorporated into gel and micro sponge gel of crisaborole was formulated.

Spectrometric analysis of Crisaborole was done by using UV- Visible spectrophotometer and Drug-Excipients compatibility study was conducted by Fourier transform infrared spectroscopy. The preliminary trial batches were formulated using the two different polymers like ethyl cellulose and Eudragit S 100. From it the micro sponge batch was selected. The 3^2 full factorial design was applied using Design Expert 13 software. Concentration of Ethyl cellulose (X1) and Concentration of PVA (X2) were chosen as independent variables, while % Entrapment efficiency (Y1), Particle size (nm) (Y2) was selected as dependent variables. Check point batch was prepared and evaluated for the validations of model. From this the optimized batch was selected and evaluated further for different parameters such as pH, consistency, homogeneity, % drug diffusion and % drug content. The SEM study and the particle size of the optimized batch were evaluated. Optimized microsponge was converted into microsponge gel by utilizing carbopol 934 as gelling agent and evaluated for different parameters such as colour, homogeneity, consistency, pH, viscosity, spreadability, extrudability, % drug release and % drug content. Microsponge gel was subjected to stability study under accelerated condition for one month.

Key words: Atopic dermatitis, Crisaborole, Microsponge, 3^2 full factorial design, Microsponge gel.

I. INTRODUCTION TO DISEASE

- Eczema is a condition that causes your skin to become dry, itchy and bumpy. This condition weakens your skin's barrier function, which is responsible for helping your skin retain moisture and protecting your body from outside elements.
- It mainly causes in childhood, young people any age group, male or female. It mainly occurs due to genetic or environment factor.
- It is present on knees, scalps, hands, wrists, ankles, legs, face etc.
- It affects patients physically and emotionally.
- There are different types of eczema
 1. Atopic dermatitis
 2. Contact dermatitis
 3. Nummlar dermatitis
 4. Neuro dermatitis
 5. Seborrheic dermatitis

Treatment of eczema [3]

- The main management and treatment protocols for eczema include hydration and topical anti-inflammatory medications for flare-ups.
- The priority in treatment is focusing on a daily skin moisturizing regimen with a fragrance-free ointment with limited preservatives.
- An ointment is preferred over a cream due to the high proportion of oil to water in lotions. Patients and caregivers should also identify and address any triggers.
- They should be instructed to avoid any environmental allergens, harsh soaps, detergents, fragrances as well as rough or non breathable fabrics.
- Skin flare-ups can be treated with topical anti-inflammatory medications, such as topical steroids or steroid free products like pimecrolimus, tacrolimus, or Eucirsa. In children, itching tends to be worse at night

time.

- Oral antihistamines can be used intermittently at bedtime for disturbed sleep due to itch; however, antihistamines are no longer recommended for daytime use for itching in eczema.
- Patients with poorly controlled eczema have a higher risk of cutaneous infections.

Introduction of Microsponge [6][7][8]

- Micro particular drug delivery system has shown a great interest in the pharmaceutical area to improve novel microspongel based drug delivery systems, in order to adapt release behaviour of the drugs by incorporation into a carrier system.
- The therapeutic index, duration of the activity of drugs, and its therapeutic efficacy, with reduction of side effects. Carrier technology in the microparticulate system adopted to solve the problems related to above challenges to achieve targeted and sustained release of drugs.
- Each microsponge comprises of interconnecting voids spaces, inside a non-collapsible structure, with large porous surface area.
- Microsponges belongs to polymeric delivery systems consisting of porous nature surrounded to microspheres, that can protect by entrapping wide range of active ingredients such as, anti- infective, anti-fungal, and anti-inflammatory agents.

STRUCTURE OF MICROSPONGES

- The microsponges size can be varied from 5-300 μm in diameter, although the microsponge sphere can have upto 2,50,000 pores, this results in a larger surface area to diffuse the drug from each microsponge. The microsponge particles are relatively larger than skin pores as they can't go into the skin, rather they are entrapped in tiny hooks and stay in the layers of the skin. There slow release of entrapped drug takes place, this adds a point of safety to these microsponge by preventing

bacterial contamination and bacterial cannot enter into the pores of the microsponges.

Advantages of Microsponge gel

- It improves penetration of drugs across skin.
- Good loading capacity. It is easy to manufacture.
- Low production cost.
- It is less oily and easy to remove. Non invasive and improve patient compliance.
- As it is applied topically it avoids GIT irritation and first pass metabolism.
- Non invasive and improve patient compliance

EXPERIMENTAL WORK

MATERIAL AND METHOD

- Microsponge of Crisaborole was prepared by Quasi emulsion solvent diffusion technique.
- **Preparation of internal phase:** the phase was consisted of drug (Crisaborole), polymer (Ethylcellulose and Eudragit S100) and solvent (ethanol and dichloromethane in ratio 1:1). To prepare this phase, Ethylcellulose and Eudragit S100 were dissolved in the mixture of solvents (ethanol and dichloromethane in ratio 1:1) and then drug was further added to it and dissolved under sonication.
- **Preparation of external phase (aqueous phase):** for the preparation of aqueous phase, weighed quantity of polyvinyl alcohol was taken and dissolved in 100 ml of water in beaker.
- **Mixing:** The internal organic phase was poured into the external aqueous phase by drop wise.
- **Stirring:** The stirring was continued up to 6 hrs till the insoluble, rigid microparticles i.e. microsponges is formed.
- **Filtration:** The mixture was allowed to stir until the foam settled down and after the complete evaporation of dichloromethane the mixture was filtered with whatmann filter paper.
- **Drying:** The microsponges were then dried in an air heated oven

Table-1. PRELIMINARY DATA

| Batch no | Polymer name | Polymer EC (mg) | Polyvinyl alcohol(mg) | %EE |
|----------|-----------------|-----------------|-----------------------|-------|
| C1 | ETHYL CELLULOSE | 100 | 100 | 92.47 |
| C2 | | 100 | 150 | 88.69 |
| C3 | | 100 | 200 | 82.85 |
| C4 | | 200 | 100 | 93.43 |
| C5 | | 200 | 150 | 87.02 |
| C6 | | 200 | 200 | 83.23 |
| C7 | | 300 | 100 | 91.19 |
| C8 | | 300 | 150 | 84.52 |
| C9 | | 300 | 200 | 77.85 |
| C10 | EUDRAGIT S-100 | 100 | 100 | 71.5 |
| C11 | | 100 | 150 | 58.5 |
| C12 | | 100 | 200 | 56.5 |
| C13 | | 200 | 100 | 68.57 |
| C14 | | 200 | 150 | 58.34 |
| C15 | | 200 | 200 | 49.43 |
| C16 | | 300 | 100 | 67.03 |
| C17 | | 300 | 150 | 56.05 |
| C18 | | 300 | 200 | 43.72 |

PREPARATION OF MICROSPONGE GEL:

➤ Carbopol is a commonly utilized gelling agent. Typically, Carbopol is employed as a gelling agent. In this research work, Carbopol 934 was utilized for the preparation of microsponge. For the preparation of gel, 1% of Carbopol 934 was incorporated into distilled water with constant stirring. After that triethanolamine (TEA) was added to neutralize and arrange the pH in range of 6 to 6.5 for compatibility to

skin. The optimized Crisaborole loaded microsponges formulation was added to hydrate Carbopol solution with continuous stirring.

EVALUATION OF MICROSPONGE

1. Entrapment efficiency

The weighed samples of Crisaborole microsponges were dissolved in 10 ml methanol under ultra sonication for 30 min at 30°C, The

samples were filtered using filter. After the resulting solution take up to 1 ml and make up to 10 ml with methanol into volumetric flask. Absorbances were read at 250 nm using an UV double-beam Spectrophotometer after suitable dilutions with Methanol were obtained. The drug content and entrapment efficiency were calculated using Equations.

$$EE\% = \frac{\text{Actual drug content in microsponges}}{\text{Theoretical drug content}} \times 100\%$$

2. Particle size

All formulations of the microsponges were analyzed for particle size analyzer. Microsponges Small globule size is preferred for microsp sponge. As it increases penetration across the skin. Polydispersity index ranges from 0 to 1.

EVALUATION PARAMETERS OF MICROSPONGE GEL

(1) Physical appearance

➤ Microsp sponge gel was visually examined for colour, homogeneity and consistency.

(2) pH

➤ pH meter was utilized for measurement of pH. 1 gm of microsp sponge gel was diluted with 9 ml of water. pH meter electrode was dipped into microsp sponge gel. Values were observed at room temperature.

(3) Viscosity

➤ Viscosity is a key assessment factor for the topical dosage form.

➤ Viscosity was measured by Brookfield viscometer using spindle no 64. Microsp sponge was placed within the beaker and spindle was dipped into it and viscosity was measured.

(4) Spreadability

➤ One of the essential requirements for dermatological preparations is to exhibit optimal qualities, particularly in terms of possessing excellent spreadability. Spreadability refers to the capacity of the gel to easily cover a significant area when applied to the skin and affected regions.

➤ The spreadability of the microsp sponge gel was assessed by putting 0.5 gm of the gel in the center of a watch glass, and then another watch glass was gently placed over the first one and left for 5 min to make sure that there was no expectation of further spreading. Diameters of the spread circles were assessed and

considered as comparative values for spreadability.

(5) Extrudability

➤ The microsp sponge was loaded into the collapsible tube. The amount of weight in grams, required to extrude a 0.5 cm ribbon of microsp sponge gel from the collapsible tube within a 10-second period was utilized to assess the formulation's extrudability. Extrudability was measured using a specific formula:

$$\text{Extrudability} = \frac{\text{Applied weight to extrude the microsp sponge gel from tube (gm)}}{\text{Area (cm}^2\text{)}}$$

(5) Drug content

➤ 1 gm of microsp sponge gel was taken and dissolved into 10 ml methanol by sonication.

➤ From above solution 1 ml was taken and diluted with methanol. Then, absorbance was taken at 250 nm using a UV spectrophotometer against methanol as blank.

(6) In-Vitro drug diffusion study

➤ In-vitro drug diffusion study of microsp sponge gel was done by Franz-diffusion cell. Franz-diffusion cell contains donor compartment and receptor compartment. Receptor compartment was filled with pH 6.8 phosphate buffer and it was under continuous stirring and 37°C temperature was maintained. Membrane was clamped between donor and receptor compartment of Franz-diffusion cell. 1 gm of microsp sponge gel was administered onto the membrane. 0.5 ml of sample was taken from receptor compartment at regular interval and volume was made up with the equal volume of pH 6.8 phosphate buffer for maintenance of sink condition. Then concentrations of Crisaborole in each sample were determined by using UV-Visible spectrophotometer at 249 nm.

(7) Stability study

➤ Stability study was conducted according to ICH guideline under accelerated condition (40±2°C & 75±5% relative humidity) for 1 month and microsp sponge gel was tested for physical and chemical stability.

OPTIMIZATION OF MICROEMULSION BY USING 3² FACTORIAL DESIGN

➤ Following the measurement of responses, various models such as simple linear,

interactive, or quadratic can be developed through conducting multiple regression analysis on the data. This process involves utilizing F statistics to pinpoint statistically significant terms within the models.

Linear equation: $Y = b_0 + b_1X_1 + b_2X_2$

Quadratic equation:

$$Y = b_0 + b_1X_1 + b_2X_2 + b_{12}X_1X_2 + b_{11}X_1^2 + b_{22}X_2^2$$

➤ In this context, Y represents the dependent variable, b_0 signifies the mean response across the nine runs, and b_i denotes the estimated coefficient for the factor X_i . Main effects (X_1 & X_2) indicate the average outcome when altering one factor independently from its low to high level. Interaction terms (X_1X_2) demonstrate how the response alters when two factors are altered concurrently. Polynomial terms (X_1^2 & X_2^2) are introduced to detect nonlinearity within the model.

- In the present research work, a 3^2 factorial design was used for optimization of microsponge.
- Compared to the conventional approach, which demands significant time and effort, factorial design stands out as an efficient method for swiftly developing intricate formulations with minimal batch requirements. Additionally, it provides insights into the relative importance of chosen variables and their interactions.
- In this design, 2 each factor was evaluated at 3 levels and experimental trials were conducted using all possible 9 combinations.
- Factors and levels for batches were determined based on Preliminary batches, which were constructed using different ratios of Concentration of ethylcellulose and concentration of PVA.
- In the present study, Concentration of ethylcellulose and concentration of PVA were selected as independent variables. The % Entrapment efficiency (Y_1), Particle size (Y_2) and were selected as dependent variables.

Table 2. 3^2 factorial design batches of Crisaborole microsponge

| Formulation code | Concentration of Ethylcellulose (mg) (X1) | | Concentration of Polyvinyl alcohol (mg) (X2) | |
|------------------|---|--------------|--|--------------|
| | Coded value | Actual value | Coded value | Actual value |
| A1 | -1 | 150 | -1 | 100 |
| A2 | -1 | 150 | 0 | 150 |
| A3 | -1 | 150 | +1 | 200 |
| A4 | 0 | 200 | -1 | 100 |
| A5 | 0 | 200 | 0 | 150 |
| A6 | 0 | 200 | +1 | 200 |
| A7 | +1 | 250 | -1 | 100 |
| A8 | +1 | 250 | 0 | 150 |
| A9 | +1 | 250 | +1 | 200 |

II. RESULT AND DISCUSSION

Table 3 – Evaluation parameter of factorial batches of microsponge

| Formulation code | Concentration of Ethylcellulose (mg) (X1) | Concentration of Polyvinyl alcohol (mg) (X2) | Y1 (%EE) | Y2 (PARTICLE SIZE) |
|------------------|---|--|----------|--------------------|
| A1 | 150 | 100 | 93.54 | 487.2 |
| A2 | 150 | 150 | 89.29 | 542.4 |
| A3 | 150 | 200 | 84.35 | 721.4 |
| A4 | 200 | 100 | 93.49 | 458.3 |
| A5 | 200 | 150 | 87.56 | 728.3 |
| A6 | 200 | 200 | 82.32 | 1625 |
| A7 | 250 | 100 | 91.38 | 995.0 |
| A8 | 250 | 150 | 85.32 | 1243 |
| A9 | 250 | 200 | 76.52 | 1654 |

Table-4 Evaluation data of microsponge gel with stability study

| Sr.No. | Evaluation Parameter | Initial | After one month |
|--------|-------------------------|-------------------------|--------------------------|
| 1 | Colour | White | White |
| 2 | Homogeneity | Excellent | Excellent |
| 3 | Consistency | Good | Good |
| 4 | pH | 6.42 | 6.48 |
| 5 | Viscosity | 8314cps | 8320 cps |
| 6 | Spreadability | 5.2 cm | 5.3 cm |
| 7 | Extrudability | 16.23gm/cm ² | 16.20 gm/cm ² |
| 8 | % Drug content | 97.84% | 97.79% |
| 9 | % Drug diffusionat 7 hr | 94.47% | 93.11% |

➤ **Effect of independent variable on entrapment efficiency (Y1)**

- The analysis of multiple regression for response Y1 (Entrapment efficiency) was done by the quadratic model using Design Expert 13 and the data was interpreted as follows: The negative sign in X1 suggests that the amount of polymer ethyl cellulose has inversely

relation with EE. With the increase in the concentration of polymer EC, the EE of microsponge will decreasing. The negative sign in X2 suggests that the amount of polymer PVA has inversely relation with EE. With the increase in the concentration of polymer, the EE of microsponge will decreasing. Model p-value is 0.0012 which was less than 0.05 which indicates the model is significant.

| | |
|----------------------|--|
| Full model | $88.0944 + (-2.32667) X1 + (-5.87) X2 + (-1.4175) (X1) (X2) + (-1.05667) X1^2 + 0.456667 X2^2$ |
| Reduced model | $88.0944 + (-2.32667) X1 + (-5.87) X2 + (-1.4175) (X1)(X2)$ |

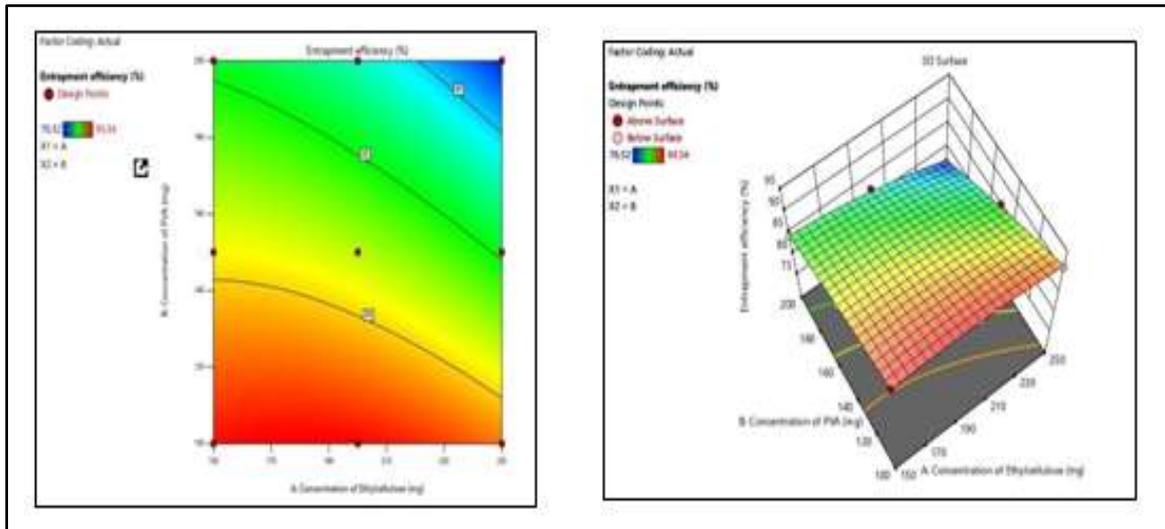


Figure-1 Counter plot and response plot for entrapment efficiency

➤ **Effect of independent variable on Particlesize (Y2)**

The analysis of multiple regression for response Y2 (Particle size) was done by the linear model using Design Expert 13 and the data was interpreted as follows: The positive sign in X1 suggests that the amount of polymer ethylcellulose has directly relation with particle size. With the

increase in the concentration of polymer EC, the particle size of microsponge will increase. The positive sign in X2 suggests that the concentration of PVA has a directly relation with particle size. With the increase in the concentration of polymer, the particle size of microsponge will increase. Model p-value is 0.0045 which was less than 0.05 which indicates the model is significant.

| | |
|----------------------|---------------------------------|
| Full model | $939.4 + 356.833X1 + 343.317X2$ |
| Reduced model | $939.4 + 356.833X1 + 343.317X2$ |

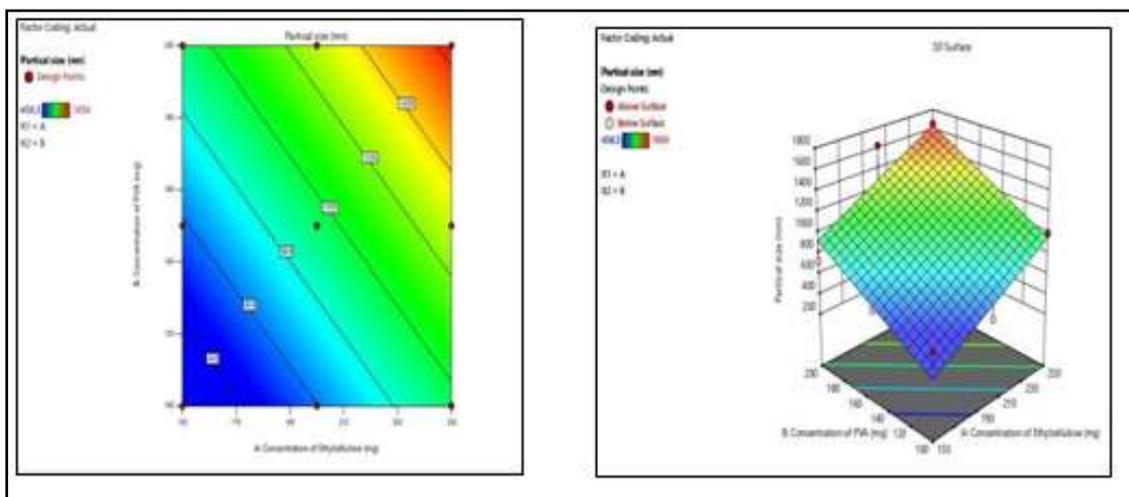


Figure-2 Counter plot and response plot Particlesize

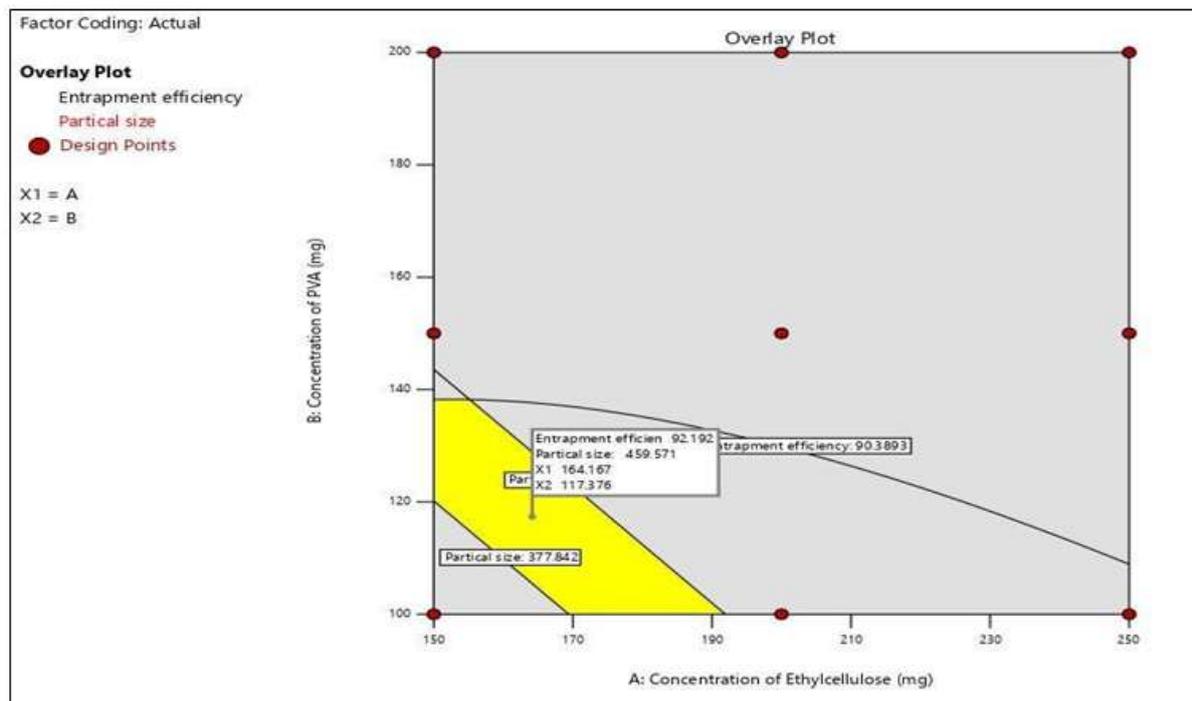


Figure-3 Overlay plot

Optimization of formulation:

- A-4 was selected as an optimized batch, as it shows good Entrapment efficiency and good

particle size. Thus it is further utilized for formulation of Microsponge Gel

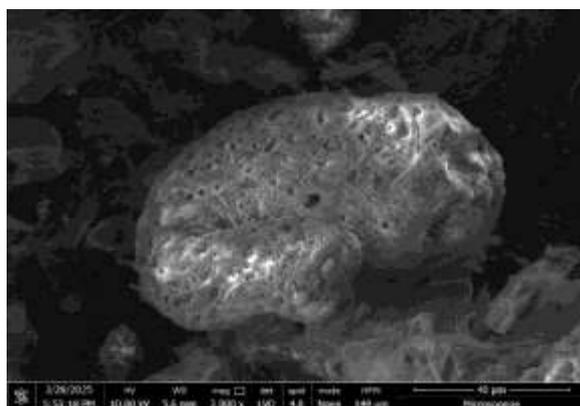


Figure-4 SCM of A4 Batch

Comparison with Conventional gel Invitro Diffusion Study

- The Comparison for in vitro diffusion study of Crisaborole microsponge gel and control gel

was carried out. Comparison of % drug diffusion data and Graph of formulations are given in table.

Table-5 Invitro drug diffusion of stability study batch and conventional drug diffusion

| Sr.No | Time (min) | %Drug diffusion (Initial) | %Drug diffusion (After one month) | Conventional gel % drug diffusion |
|-------|------------|---------------------------|-----------------------------------|-----------------------------------|
| 1 | 0 | 0 | 0 | 0 |
| 2 | 30 | 13.6 | 12.39 | 39.44 |
| 3 | 60 | 27.88 | 26.54 | 55.41 |
| 4 | 120 | 43.27 | 42.43 | 69.48 |
| 5 | 180 | 54.12 | 53.02 | 78.51 |
| 6 | 240 | 65.74 | 63.42 | 85.14 |
| 7 | 300 | 78.27 | 76.05 | - |
| 8 | 360 | 86.42 | 85.03 | - |
| 9 | 420 | 94.47 | 93.11 | - |

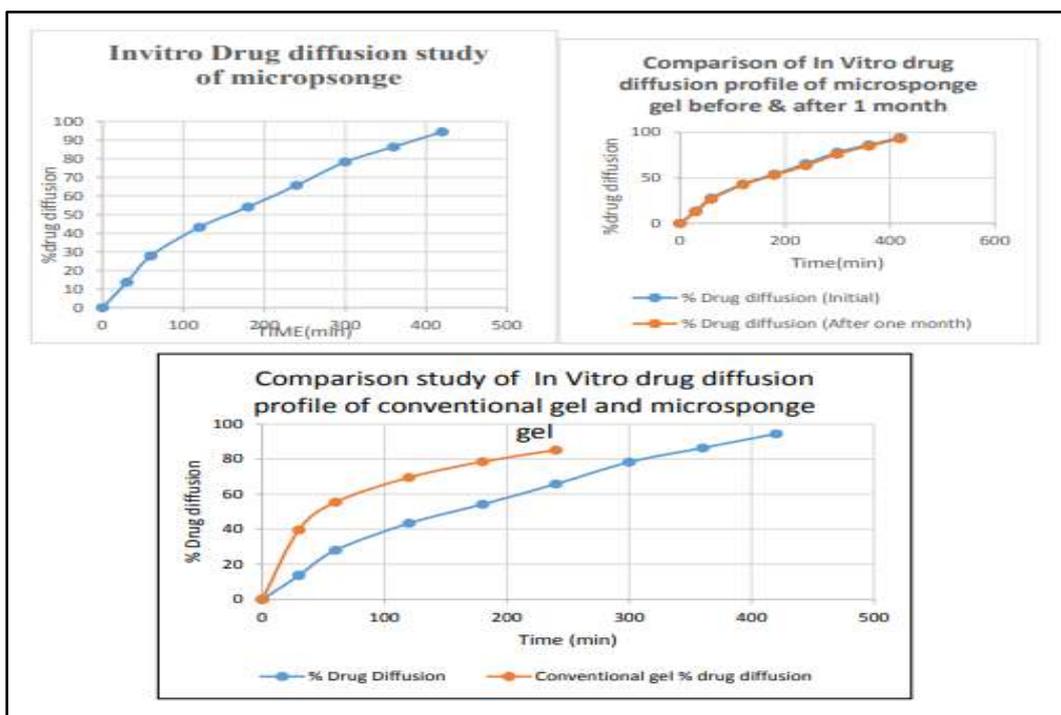


Figure-5: (A) In vitro drug diffusion (B) comparison of in vitro diffusion profile of microsponge gel before and after 1 month (C) Comparison with conventional gel with microsponge gel

III. CONCLUSION:

➤ The present research work aimed to formulate topical microsponge gel of Crisaborole for the treatment of atopic dermatitis. It has a board-spectrum anti-inflammatory activity by mainly

targeting phosphodiesterase 4 (PDE4) enzyme that is a key regulator of inflammatory cytokine production.

➤ As this enzyme is expressed in keratinocytes and immunecells, Crisaborole medicates an

anti-inflammatory effect on almost all inflammatory cells.

- Microsponge gel is a combination of microsponge and gel. It gives the advantages of both dosage form. Microsponge gel is less sticky, easily spreadable and exhibits superior stability compared to cream, lotion and ointment.
- Incorporating drug into microsponge gel enhances drug localization on the skin surface and within the epidermis without entering into the systemic circulations to a large extent.
- Microsponge systems are non-irritating, non-mutagenic, non-allergenic and non-toxic. So it ensures patient compliance
- Spectrometric analysis of Crisaborole in methanol and phosphate buffer pH 6.8 was done by using UV-Visible spectrophotometer and λ_{max} was obtained at 250 and 249 nm respectively. Identification of drug was done by Fourier transform infrared spectroscopy.
- Drug-Excipients compatibility study was conducted by Fourier transform infrared spectroscopy. In which there was no interaction of any kind.
- Microsponges were prepared with Quasi emulsion solvent diffusion technique. From the result of preliminary trial as ethylcellulose, Eudragit S100 was selected as polymer, polyvinyl alcohol, Water and Dichloromethane: Ethanol (1:1) mixture was used as organic solvent.
- The Crisaborole microsponges were optimized on the basis of 2 independent variables-concentration of Ethycellulose (X1) and Polyvinyl alcohol (X2) with 3 levels- low, medium and high for taking 2 responses of % Entrapment Efficiency (Y1) and Particle size (Y2) using 3^2 full factorial design. The optimization was done using Design Expert 13.
- Check point batch (A10) was formulated and evaluated. All experimental responses were near to predicted responses. Entrapment efficiency was found to be 93.49%, the particle size was founded to be 455.7.
- Optimized Crisaborole A4 was incorporated into 1% Carbopol 934 gel base and microsponge gel of Crisaborole was formulated.
- Prepared microsponge gel has excellent homogeneity, good consistency, skin compatible 6.42 pH, 8314 cps viscosity, 5.2 cm spreadability, 16.23 gm/cm² extrudability. In vitro drug diffusion study was carried out by

using Franz diffusion cell and it demonstrated 94.47% drug diffusion at 7 hr.

- Stability study of microsponge gel was conducted for one month. All the parameters of microsponge gel were evaluated before and after the one month. They were almost similar. So prepared microsponge gel was stable in stability study.
- The comparison study with the conventional gel was taken with the microsponge gel.
- It is concluded that topical microsponge gel can be effectively used for treatment of atopic dermatitis.

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