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Formulation and Evaluation of Hydrogel

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Abstract: *Novel drug delivery systems offer several advantages as compared To conventional systems. Drugs can be effectively delivered Topically by being incorporated into gel, which will prevent first pass metabolism and increase local action for skin conditions. Hydrogels are 3D polymeric system structures of hydrophilic Polymers. The main goals of hydrogels are to improve patient Compatibility and release medication at a controlled rate with Maximum therapeutic effects. Sucralfate synthetic drug obtained from chemical reactions. The research was conducted to investigate How to enhance anti-ulcer activity by using sucralfate in The form of hydrogel. Carbopol 940 (carbomer) polymer, Propylene glycol as a permeation enhancer, and triethanolamine for pH Adjustment were used to prepare hydrogel. The impact of Formulation variables, such as concentration of polymer and Permeation enhancer, on the formulation responses was assessed. Optimized formulation F8 demonstrated a maximum drug release Of 94.40 ± 0.33% in 1-hour. Viscosity and spreadability of Formulation F8 were found to be 82.40± 94.50 cps and 11.45 ± 6.45Gm.cm/sec, respectively. The findings suggested that a successful Hydrogel containing Sucralfate can be developed with Improved rheological properties and good permeation profile.*

Keywords: Sucralfate, Spreadability, Extrudability, Hydrogel.

I. INTRODUCTION

A hydrogel can be defined as a hydrophilic polymer which links with each other and not dissolve in water. They are mostly as a Polymer which are easily absorbed and form accurate shape in structures. The structure is such like that it hold a more amount of Water in their well maintained structure also more swollen in water. The hydrogel is such like that they swells up more in liquid Medium just like water, and links with each with one or another monomer(1). They mainly soaks a large amount of liquid from functional groups hydrophillic attached to the support of more polymers, while Their barrier are network to network chains. They are available in natural and synthetic. polymers can be easily modified to yield their degradability and functionality. They are stable in sharp and high degree Of temperature also. They found in a number of chemical ways which comprise of only single step procedures like polymerization And cross-linking of more functional monomers, along with multiple step procedures. They have reactive groups and cross-linking, React with polymers which suits to maze liked polymer.(2) Engineer can constructs its shape and make polymer through with molecular Based control over structure They also have properties, such as biodegradation, provide strengthen properties, chemical and Biological response(3). Sucralfate, a cytoprotective agent traditionally used for peptic ulcer disease, has gained attention for its off-label application in the management of oral ulcers. Sucralfate is a basic aluminum salt of sucrose octasulfate, that exerts its therapeutic effect through a localized mechanism of action. In an acidic environment it polymerizes to form a viscous, adhesive gel that binds selectively to ulcerated mucosa, creating a protective barrier over the lesion. This barrier shields the ulcer surface from mechanical irritation, microbial invasion, and salivary enzymes, thereby promoting faster epithelial regeneration.(4)

In addition to its physical protective action, sucralfate stimulates prostaglandin synthesis, enhances mucus secretion, and facilitates the binding of growth factors such as epidermal growth factor (EGF), all of which contribute to mucosal repair and tissue healing.(5)

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II. MATERIAL AND METHODS

Material

- Sucralfate
- Acetone
- Ethanol
- Methanol
- Distilled water

Preformulation study of Drug

Sample was subjected to the following preformulation Studies

Organoleptic properties

Sucralfate was manually analyzed for the organoleptic Properties including colour,odour and appearance(6)

Solubility profile

Solubility of Sucralfate was checked visually in methanol, Distilled water, petroleum ether, ethanol, acetone, DMSO, Chloroform (pH 5.4)(7) Accurately weighed, 1-mL of oil was transferred in a test tube. Above mentioned Solvents were individually added and shaken vigorously And the solubility of oil was estimated visually in each Solvent.(8)

UV visible spectrophotometer

Estimation of lambda max for sucralfate

A precisely measured 100 mg portion of sucralfate was Placed in a volumetric flask of capacity 100 mL and allowed To dissolve with a small amount of ethanol. The given solution was examined in a UV Spectrophotometer between 200 and 400 nm(9)

Calibration of sucralfate in Ethanol(pH 5.4)

Serial dilutions from stock solution having conc. Of(1000 µg/mL) with ethanol (pH 5.4) was prepared within A 2 to 10 µg/mL range. Absorption readings of above Solutions were measured at determined λmax (281nm) Taking Ethanol(pH 5.4) as blank and the calibration plot Was prepared.

Drug-excipients Compatibility Studies

Fourier transfer infrared spectrophotometer spectroscopy

The functional groups present in sucralfate were Determined by FTIR-ATR (BRUCKER, TENSOR-27) Spectrophotometry; selected formulation was also Examined by FTIR-ATR spectrophotometry. The samples Were added on sample holder and scanned between IR Range of 1000-1200 cm−1

Formulation Studies Preliminary screening of penetration enhancer

The solubility of Sucralfate was investigated in permeation enhancers including tween 80, Carbopol 940 . The selection of penetration enhancers for further research was based on their ability to effectively solubilize drugs. Excess of oil was added in 1-mL of each penetration enhancer which was then vortexed for 30 seconds. After that, centrifugation of sample were carried out for 10 minutes at 1000 rpm to extract the clear supernatant liquid. Oil solubility was measured at 255 nm using UV spectroscopy.

Independent variable	Low level	High Level
A=Concentration of polymer (Carbopol 940 w/v)	0.5%	2%
B=Concentration of permeation enhancer (transcutol-P% w/v)	1%	5%
C=Stirring speed (RPM)	500	15000

Table No1:Independent variable and their level in the design of Box -Benken

Optimization Study

Experimental design and statistical analysis can assess and determine the most crucial parameters and their interactions by reducing the amount of experimention. The polymer concentration and the permeation enhancer concentration were found to be the most critical factors influencing the pH, viscosity, and drug diffusion of the hydrogel based on preliminary research and the literature that was available. [17,18] Design-Expert® version 13, a commercial software

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program, was used to apply Box-Behnken design to statistical evaluation the impact of formulation variables on the responses. Table 1 shows the independent variable and their level used in the investigation

Formulation of Hydrogel

Each component was gathered using the formula shown in Table 2. Dispersion of Carbopol 940 was carried out in distilled water until formation of homogenized solution. Then, Sucralfate was dissolved in glycerol and this solution was added to the Carbopol-940 mixture. Transcutol- P (selected enhancer) was added in different concentration to formulas. Finally, to achieve the necessary skin pH of 6.8 to 7.2, 0.3 mL of triethanolamine was added dropwise to the formulation. Composition of Sucralfate hydrogel is given in Table 2.

Evaluation test for Topical sucralfate Hydrogel

pH

pH meter was used for the determination of pH of hydrogel. For determination of pH, 1% solution of hydrogel formulation was prepared in distilled and pH was determined.

Viscosity

Viscosity is a crucial characteristic that determine the resistance of flow of hydrogel formulation so that it can easily spread on the skin after application. A Brookfield viscometer with Spindle 4 was used to measure the hydrogel preparations' viscosity at a speed of 50 revolutions per minute. For every preparation, the process was done 3 times, and the mean viscosity was measured in centipoise units.

Spreadability

Spreadability was measured with the help of apparatus containing a wooden block having lifter at one end (Fig. 1). This process measured spreadability based on the basis of drag and slipe characteristic of hydrogel. On the bottom slide, an excess of the hydrogel under investigation (roughly 20 gm) was placed. After that, the hydrogel was positioned with the hook in between glass slide and other one that had the same measurement as a fixed bottom slide. For 5 minutes, a 1000 g weight was kept on top of each of the 2 slides to eliminate air and produce a consistent layer of hydrogel between them. The extra hydrogel was removed by scraping off the edges. The upper plate was subsequently pulled with a 5 g weight. The entire time and distance travelled by upper slide were examined. A shorter time for spreading showed well spreadability. Spreadability was determined by formula given below: $S = (M \times L)/T$ Where, S; Spreadability M; Weight placed the pan L; Length travelled by upper glass slide T; Time (in sec.) taken to travel upper slide

Fig No:1-Spreadability of Hydrogel

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Extrudability

The quantity of hydrogel that squeeze out from the tube after application of pressure was used to determine the extrudability of hydrogels. The prepared hydrogel was poured into a spotless, collapsible aluminum tube with a 5 g capacity and a 5 mm orifice. A 500 g weight was added to the end that had been crimped.The quantity Hydrogel that as squeeze out (in Percentage)through the orifice following the application of pressure was used to determine the extrudability.

Formulation Code	Carbomer 940 (%w/v)	Sucralfate	Transcutol-P(%v/v)	Glycerol	Triethanolamine (mL)	Distilled water(mL)
F1	0.5 (-1)	5 %	1 (-1)	5 %	q.s	q.s to100ml
F2	2.0 (+1)	5 %	1 (-1)	5 %	q.s	q.s to100ml
F3	0.5 (+1)	5 %	5 (+1)	5 %	q.s	q.s to100ml
F4	2.0 (+1)	5 %	5 (+1)	5 %	q.s	q.s to100ml
F5	0.5 (-1)	5 %	3	5 %	q.s	q.s to100ml
F6	2.0 (+1)	5 %	3	5 %	q.s	q.s to100ml
F7	1.25	5 %	1 (-1)	5 %	q.s	q.s to100ml
F8	1.25	5 %	5 (+1)	5 %	q.s	q.s to100ml
F9	1.25	5 %	3	5 %	q.s	q.s to100ml
F10	1.25	5 %	3	5 %	q.s	q.s to100ml

Table No 2-Composition of Hydrogel

In-vitro drug diffusion

In-vitro drug diffusion assay was conducted with the Franz diffusion compartment. Dialysis membranes were made of cellophane. As a donor compartment, 1 g of gel was applied to a cellophane membrane. The dissolution medium in the receiver compartment was methanol (pH 5.4). The whole diffusion cell system was positioned on a magnetic stirrer that had a thermostat set at 37℃. At regular intervals, samples were gathered.[24] Sink conditions were preserved by substituting a fresh buffer solution. The samples were collected and subjected to UV spectrophotometer analysis at 255 nm.

In-vitro anti-inflammatory activity

When an external stressor or complex, such as organic solvent, strong base or strong acid or heat is applied to proteins, they lose their secondary and tertiary structures. This process is known as denaturation, and most biological proteins become functionally denatured as a result. Inflammation is known to be caused by protein denaturation. The ability of the extract to prevent denaturation of protein was studied as part of the anti inflammatory action. Well-known cause of inflammation is albumin denaturation. Diclofenac sodium, in the concentration series of 200 to 1000 µg per mL, was used as a reference drug.

Inhibition of albumin denaturation

The % of protein denaturation inhibition was assessed by using the below procedure.

• Control solution

Methanol (pH 5.4) (14 mL), egg albumin (2 mL), and 20 mL distilled water.

Reference drug

28 mL of (pH 5.4) phosphate buffer, egg albumin (2 mL), and 10 mL different concentration of reference drug (Diclofenac sodium) conc. range of 200, 400, 600, 800 and 1000 µg/mL.

Test solution

Methanol (pH 5.4) (28 mL), 2 mL of egg albumin, and 10 mL various concentration of gel solution [1000, 800, 600, 400, and 200 µg/mL]. The samples were heated to 70℃ for five minutes after being incubated at 37℃ for 15 minutes. Following cooling, the turbidity absorbance was measured in a UV-vis spectrophotometry at 660 nm. Using the formula below, the % of inhibition of denaturation of protein in the above solutions was determined.

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III. RESULTS AND DISCUSSION

Organoleptic Properties of Sucralfate

Organoleptic properties of Sucralfate are shown in Table 3

Solubility Profile of Sucralfate

Solubility profile of Sucralfate in various solvent is given in Table 4

Phytochemical Analysis of sucralfate

Phytochemical analysis of Sucralfate is shown in Table 5. UV-visible Spectrophotometry Estimation of λmax for sucralfate in Colour methanol (pH 5.4) λmax of sucralfate in methanol (pH 5.4) was found to be 255nm

Colour	White
Odour	Odourless

Table no 3- Organoleptic Properties of Sucralfate

Sr.No	Solvent	Solubility
1	Methanol	Insoluble
2	Ethanol	Insoluble
3	Chloroform	Insoluble
4	Acetone	Insoluble
5	DMSO	Insoluble
6	Distilled water	insoluble
7	Petroleum ether	Soluble

Table no 4-Solubility profile of Sucralfate

Calibration of Sucralfate in Methanol (pH 5.4)

With methanol pH 5.4, the Sucralfate standard calibration plot was created. It was discovered that the correlation coefficient was 0.998. Beer-Lambert's law is followed by Sucralfate in the conc. series of 2 to 10 µg/mL. Table 6 displays the calibration plot of Sucralfate in methanol at pH 5.4. Calibration curve of Sucralfate is given in Fig. 2.

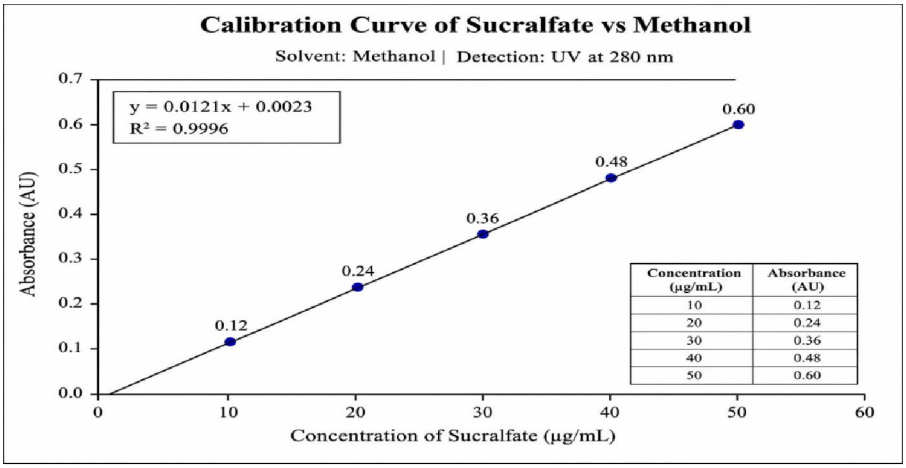

Fig No:2-Calibration curve of Sucralfate in methanol

Drug-excipients Compatibility Studies Fourier transfer infrared spectrophotometer (FTIR) spectroscopy

A OSO_3,OH ,aluminium hydroxide complex are some characteristic peaks from psoralen. The main functional group responsible action is sulfate group .This characteristic functional groups are also present in IR spectra of Sucralfate and hydrogel. Wide absorption band in Sucralfate at 1200 cm-1 and 1250 cm-1 describes (S=O) stretching vibration. After incorporation of Sucralfate in hydrogel, intensity of absorption band at 600 and 800 cm-1 reported from IR spectra of

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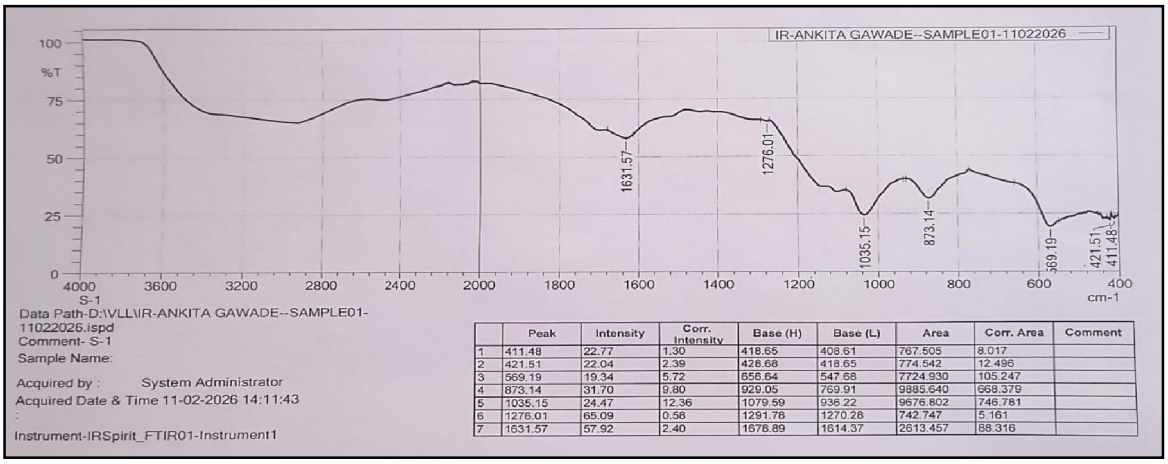
Sucralfate was found to be decreased in the spectra of Sucralfate loaded hydrogel due to some steric impediments and hydrogen bonding. Other peaks at 1000 and1100 cm-1 (C-O) reported from IR spectra of Sucralfate were signified at slight lesser frequency of 1200and 700cm-1 in sucralfate loaded hydrogel(10)

Formulation code	pH	Viscosity(CPS)	Spreadability	Extrudability(%)
F1	6.2±0.1	4210± 0.45	9.82± 0.54	92.4
F2	6.4 ±0.2	4560±0.62	10.12± 0.32	94.1
F3	6.5± 0.1	4890± 0.55	10.85 ± 0.41	95.8
F4	6.7 ±0.1	5120± 0.82	11.20 ± 0.25	96.5
F5	6.3 ± 0.2	4430± 0.38	10.05 ± 0.18	93.7
F6	6.6 ±0.1	4950± 0.47	11.10 ± 0.63	96.2
F7	6.5 ± 0.2	4780 ±0.47	10.95 ± 0.44	95.5
F8	6.8 ±0.1	5089± 0.70	11.45 ± 1.47	98.2
F9	6.4 +_ 0.1	4620± 0.33	10.45 ± 0.52	94.8
F10	6.5 ±0.1	4810± 0.29	10.78 ± 0.37	95.9
F11	6.7 ± 0.1	5010± 0.44	11.38 ± 0.48	97.5

Table no 7- Evaluation parameters for formulation batches

Fig. 3 shows that the solubilty of Sucralfate was significantly higher in Transcutol -P (49.74 mg/mL) as compared to other penetration enhancer. Transcutol® P's ability to solubilize hydrophilic and lipophilic APIs is one of its primary characteristics. Increasing the vehicle's drug solubility and, consequently, its thermodynamic driving force Transcutol-P gives higher drug release and better permeation of skin.(11)Thus, Transcutol-P was selected as a permeation enhancer for further formulation studies. Fig. 4 shows preliminary screening of penetration enhancer.



	Peak	Intensity	Corr. Intensity	Base (H)	Base (L)	Area	Corr. Area	Comment
1	411.48	22.77	1.30	418.65	408.61	767.505	8.017	
2	421.51	22.04	2.39	428.68	418.65	774.542	12.496	
3	569.19	19.34	5.72	656.64	547.68	7724.930	105.247	
4	873.14	31.70	9.80	929.05	769.91	9885.640	668.379	
5	1035.15	24.47	12.36	1079.59	936.22	9676.802	746.781	
6	1276.01	65.09	0.58	1291.78	1270.28	742.747	5.161	
7	1631.57	57.92	2.40	1678.89	1614.37	2613.457	88.316	

Fig No:3-FTIR Spectroscopy of Sucralfate

Evaluation Parameters of Hydrogel

Prepared hydrogel was examined for pH value, viscosity, spreadability and extrudability at room temperature. The pH value of the hydrogel which is convenient when used is 5.2 to 7.2 and will not irritate the skin when used(12,13). The pH of all hydrogel batches was found to be in range of 6 to 7 and which was near to the physiological pH of the skin. Viscosity is a property of preparations that affects the hydrogel preparation's spreadability, consistency, and drug release at the time of application. The hydrogels had viscosities ranging from 5000 to 11000 cPs. (14)For gel preparations, a viscosity of 5000 to 150,000 cPs is the ideal range. The gel preparations' capacity to disperse and spread when applied to skin was assessed by the spreadability test. The measurements of viscosity and the spreadability test

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results were inversely correlated. (15,16) Every formulation had spreadability between 3-12 gm.cm/second. An essential factor in the hydrogel's application on skin and

Formulation code	%Drug release after 1 hour
F1	42.15
F2	48.30
F3	55.02
F4	61.10
F5	68.45
F6	74.20
F7	82.18
F8	94.50
F9	88.35
F10	81.12
F11	75.40

Table no 8- In-vitro drug diffusion of Formulation batches

Formulation code	Sucralfate (%v/v)	Carbopol(%w/v)	Transluctol-P(%v/v)	Glycerol (mL)	Triethanolamine (ml)	Distilled Water
F8	5.0	1.0	5.0	2.0	q.s	q.s

Table no-9 Formulation of optimized batch ,F8 of Hydrogel F

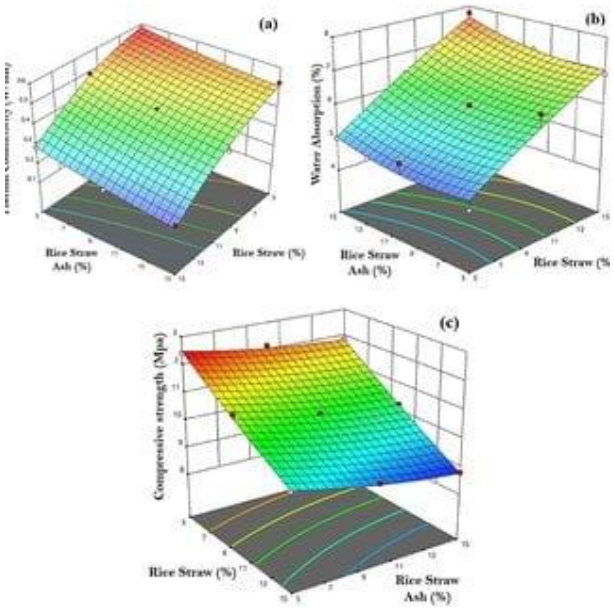

Fig 5 a-3dimensional response surface lot showing influence of formulation variable on pH
b-3 dimensional response surface plot showing effect of formulation variable on viscosity
c-3 dimensional response surface plot showing effect of formulation variable on %drug release

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parameter	result
pH	5.29
Viscosity	8240 pcs
Spreadability	6.45 gm cm \sec
Extrudability	Excellent
Drug release	94.50 %

Table No 10-Evaluation parameter for optimized batch for Hydrogel

patient acceptance is how well it extrudes from the tube. All of the formulations showed good extrudability between 60 and 90%. Table 7 shows evaluation parameters for formulation Fig. 6: 3-Dimensional response surface plot showing effect of formulation variable on viscosity Fig. 7: 3-Dimensional response surface plot showing effect of formulation variable on %drug release batches.(17)

In-vitro Drug Diffusion Profile

In-vitro drug release was studied by use of Franz diffusion setup for 1-hour. Formulation F8 was chosen as the optimized batch because it demonstrated good drug release when compared to the other formulation batches(18) Maximum release of Sucralfate from hydrogel was obtained with 0.5% Carbopol 940 and 4% Transcutol-P. Drug release of all formulation is given in Table 8.(19)

Optimization of Batch

After examination of all hydrogel batches for their evaluations including viscosity, spreadability, pH, and extrudability, it was found that formulation F8 has good results and suitable for topical use. Formulation F8 showed highest drug release as compared to other formulation(20). Based on physicochemical property and in-vitro drug diffusion profile formulation F8 was selected as optimized batch which was further used for in-vitro anti-ulcer study. Table 9 shows formulation of optimized batch, F8 of hydrogel. Table 10 shows evaluation parameters for optimized batch for hydrogel. (21)

Effect of Formulation Variable on pH, Viscosity and Drug Release

Fig. 5 exhibits the 3D response surface plot, which shows influence of formulation variable on pH. pH of all hydrogel batches ranged between 6 to 7. From pH values of all hydrogel batches, it was found that high level of concentration of polymer showed decrease in pH of formulation. The conc. of Carbopol-940 has -ve effect on

Concentration (Ug/ml)	Absorbance at 660 nm	Percent inhibition (%)
Control	0.850	6.00
200	0.612	28.0
400	0.442	48.0
600	0.306	64
800	0.187	78
1000	0.110	87.06

Table no 11-In-Vitro anti ulcer activity of formulation

Concentration (ug/mL)	Absorbance at 660 nm	Percent inhibition (%)
control	0.850	0.00
200	0.582	31.52
400	0.408	52.00
600	0.255	70.00
800	0.144	83.05
1000	0.076	91.05

Table no 12-In vitro anti ulcer activity, Sucralfate

pH readings.(22) As concentration of penetration enhancer increases there is decrease in pH of formulation. (23,24)Fig. 6 exhibits the response surface plot, which shows influence of formulation variable on viscosity. Increase in

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concentration of polymer results into increase in viscosity of formulation. The viscosity of hydrogel is found to be positively impacted by polymer concentration because of a larger grade of interspecific cross-linking between the drug & polymer.(25) Concentration of Carbopol shows direct relationship with a viscosity. High viscosity was observed when Carbomer concentration was improved up to 1% perhaps due to swelling behaviour of Carbomer. (26) Hydrogel batch with (0.5% w/v) Carbopol 940 resulted in lower viscosity. Decrease in concentration of Transcutol-P resulted into increase in viscosity. Viscosity of hydrogel was hardly influenced by stirring condition. Increase in preparative stirring speed resulted into decrease in viscosity of hydrogel Fig. 7 exhibits the response surface plot, indicating effect of formulation variable on drug diffusion. Rise in amount of polymer decreases permeation of drug due to swelling.A decrease in the drug release rate was correlated with an increase in the content of carbopol 940. This might be the result of the polymer swelling extensively(27)Minimum levels of polymer concentration (0.5) resulted into increase in %DR of the formulation to the maximum 85.36%. Concentration of penetration enhancer (Transcutol-P) has slight significant effect on drug release. Transcutol-P is colorless liquid soluble in 692 both oil and water. Higher the % of Transcutol, higher the flux and gathering of drug into skin. Transcutol -P can grip water from skin, and improves skin penetration by increasing thermodynamic action because of variation in solubility.(28)

In-vitro Anti-inflammatory Assay with the Help of Albumin Denaturation Test

In-vitro anti-inflammatory action of optimized formulation was analysed by use of diclofenac sodium as a standard. These experimental results explained a concentration dependent, significant inhibition of egg albumin denaturation. Table 11 shows in- vitro anti-inflammatory activity of formulation. Table 12 shows In-vitro anti-inflammatory activity of diclofenac sodium.

IV. CONCLUSION

For skin disorders, the topical drug transport system is regarded as a crucial therapeutic approach. Comparatively speaking to oral therapy, it has a quicker onset of action and reduces the possibility of systemic toxicity. Systemic research was conducted to develop topical hydrogel for effective delivery of sucralfate . Hydrogel preparations containing sucralfate were developed to increase the penetration of drugs into skin and operative way to increase the effectiveness of topical formulations for psoriasis treatment. Appropriate selection of polymer is prerequisite for design and development of topical drug delivery system. Hydrogel batches [F1- F11] containing Sucralfate were developed with variation in amount of Carbopol 940 and Transcutol- P. The concentration of Carbopol-940 was found to have a crucial influence on drug release and rheological properties of hydrogel. The physicochemical properties of formulation F8, which contains 4% Transcutol-P and 0.5% carbopol 940, were found to be superior to those of the other formulations. As a result, it was determined that prepared formulation might offer psoriasis patients a promising topical substitute. By using topical hydrogels, one can prevent the side effects linked to conventional therapy.

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