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Formulation and evaluation of Rutin trihydrate loaded "Microsponges gel" for topical drug delivery

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Abstract

The aim of the present study was to formulate Rutin trihydrate loaded microsponges through quasi-emulsion solvent diffusion technique. Rutin trihydrate is a flavonoid glycoside that possesses anti-inflammatory and mild antibacterial property, however it belongs to BCS Class II. Rutin trihydrate microsponges were developed with various ratios of drug : polymer (Ethyl cellulose) to study the influence of composition on microsponge charecteristics. The prepared microsponges were evaluated for production yield, particle size, entrapment efficiency, drug content, and *in-vitro* drug release. FTIR study confirmed good compatibility between drug and excipients. Among all the formulations, F2 formulation showed better results compared to the other formulation. The percentage yield was found to be 90.2%, particle size was 10.62 µm, entrapment efficiency (%EE) was 93.6%, drug content was 88.9%, and drug release was 91.9% within 8 hours. The selected F2 formulation was incorporated into Carbopol gel and further evaluated for pH, viscosity, Spreadability, drug content, drug diffusion. The F2 microsponge-loaded gel exhibits suitable properties for topical application with drug diffusion of 82.04% over a period of 8 hours, indicating controlled drug release and potential for acne vulgaries treatment.

Keywords: Rutin Trihydrate; Microsponges; Quasi-Emulsion Solvent Diffusion Technique; Carbopol 934

1. Introduction

Acne vulgaris is a chronic inflammatory disease, characterized by the presence of comedones (blackheads and whiteheads), papules, nodules, and in severe cases, cysts and scars. It is one of the most common skin conditions worldwide, predominantly affecting adolescents but also persisting or even starting in adulthood. It is mainly caused due to hormonal changes, stress, diet, environmental factors, medications, genetic factors[1].

There are number of synthetic drugs are available to treat the acne such as Salicylic acid, benzyl peroxide, azelaic acid as topical dosage form but it causes skin irritation, resistance and skin sensitization[2]. Due to these limitation and side effects of synthetic drugs, natural compounds with anti-inflammatory and antibacterial properties have gained attention for the treatment of skin disorders such as acne.

Rutin trihydrate is a naturally occurring flavonoid glycoside widely distributed in many plants such as Citrus species. Chemically, it is known as rutinoside , Vitamin P, and it consisting of the flavanol aglycone quercetin bound to the disaccharide routinise. Rutin trihydrate exhibits multiple biological activities, including antioxidant, anti-inflammatory, mild Antibacterial, Antifungal, & cardioprotective, Neuroprotective effects. Rutin Trihydrate has classified BCS class II drug because it has low water solubility and high permeability. Rutin trihydrate has Anti-inflammatory and Antibacterial therapeutically useful in conditions such as Acne vulgaris[3,4].

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Microsponges are novel drug delivery systems that have emerged as a promising solution to address the challenges associated with poorly soluble drugs. This microsponge technology was developed by Won in 1987. The size of the microsponges generally ranges from 5 to 300nm.These are microscopic, spherical, porous structures composed of polymeric materials offer a unique platform for enhancing the therapeutic efficacy of various medications, particularly those classified as BCS Class II under the Bio pharmaceutics Classification System [5].

Microsponges are highly efficient drug delivery systems that prolong drug action for up to 12 hours while maintaining controlled release. Their large surface area enhances trapping capacity, and they are non-toxic, hypoallergenic, and stable against physical, chemical, and thermal factors. By increasing the solubility and bioavailability of drugs and decreasing toxicity, they improve therapeutic outcomes and prevent substance accumulation on the skin[6]. The present study was to develop rutin trihydrate loaded microsponges to enhance the solubility of rutin trihydrate and to achieve controlled drug delivery. The effects of variables including the drug: polymer ratio were evaluated.

2. Materials and Methods

Rutin trihydrate was purchased from Yarrow chem. Ltd., Mumbai, Poly vinyl alcohol from Yarrow chem. Ltd., Mumbai, E t h y l cellulose from Yarrow chem. Ltd., Mumbai, Dichloromethane from S.d.fine chem. Ltd., Mumbai, Carbopol 934 yarrow chem Ltd, Mumbai, Glycerine from MOLYCHEM -Mumbai, India, Propylene Glycol from Thermo fisher scientific, India, Pvt Ltd, Triethanolamine from S.d.fine chem. Ltd., Mumbai, Methyl paraben from yarrow chem Ltd, Mumbai, Propyl paraben from MOLYCHEM -Mumbai, India.

2.1. Preparation of Rutin trihydrate loaded microsponges

Six batches of microsponges F1-F6, were formulated using varying ratios of drug: polymer, as detailed in table 1. The quasi-emulsions solvent diffusion method was employed for the preparation Rutin trihydrate of microsponges. Rutin trihydrate and ethyl cellulose (EC) were dissolved in dichloromethane and ethanol to form the organic phase. Separately, polyvinyl alcohol was dissolved in distilled water to prepare the aqueous phase. The organic phase was added drop wise into the aqueous phase under mechanical stirrer and the speed was maintained at 1500 rpms for 3 hrs at room temperature to facilitate solvent evaporation and microsponge formation. The dispersion was filtered using 0.45 µm Whatman filter paper, washed with distilled water, and dried at room temperature for 24 hours. The microsponges were then stored in desiccator to preserve dryness and prevent moisture absorption [7].

Table 1 Formulation Table of Rutin Trihydrate loaded Microsponges

Formulation Code	Ingredients					
	Internal Phase				External Phase	
	Rutin trihydrate	Ethyl cellulose	DCM	Ethanol	PVA	Distilled Water
F-1	0.5	0.5	5	5	1	200
F-2	0.5	1	5	5	1	200
F-3	0.5	1.5	5	5	1	200
F-4	0.5	2	5	5	1	200
F-5	0.5	2.5	5	5	1	200
F-6	0.5	3	5	5	1	200

2.2. Evaluation parameters of microsponges [8-10]:

2.2.1. Drug Excipient compatibility studies:

Fourier Transform Infrared Spectroscopic Analysis (FTIR) Studies:

FTIR spectroscopy was done to identify the functional groups present and interaction between drug and excipients. FTIR spectra were developed for pure drug and formulation by potassium bromide, the disk was prepared by

compression of 10 tons pressure for mins. Finally, disk was placed in a holder of FTIR machine and a spectrum was recorded from 4000cm $^{-1}$ to 5000cm^{-1} band width.

2.2.2. Production/Percentage yield:

The production yield of the microsponges can be obtained by calculating accurately the initial weight of the raw materials and the last weight of the micro sponge. The dried micro sponges of each batch are weighed separately and percentage yield is calculated by using following equation.

$$\text{percentage yield} = \frac{\text{Practical mass of microsponges}}{\text{Theoritical mass (drug+polymer)}} \text{x}100$$

2.2.3. Particle Size:

The particle size distribution is evaluated with the help of optical or electron microscope. The size of the particles affects the consistency of the formulation and its stability. Particles larger than 30µm can impart grittiness and hence particles of sizes between 10 and 25µm are preferred in topical preparations. Particle size was determined using optical microscopy at 10x . The microsponges were placed on glass slide and observed under optical microscope. The size of 50-100 micro sponges was measured.

2.2.4. Entrapment efficiency:

Entrapment efficiency is the content of core material effectively entrapped in a formulation. It can be measured by an indirect method in which microsponge suspension can be centrifuged at 2000 rpm for 10 min. The supernatant obtained can be suitably diluted with suitable solvent and the amount of free drug present in supernatant can be quantified using UV– Visible spectroscopy or HPLC. The drug entrapment efficiency can be calculated using the following formula.

$$\text{Entrapment Efficiency} = \frac{\text{Actual drug content in microsponges}}{\text{Theoritical drug content}} \text{X}100$$

2.2.5. Drug Content:

For determination of drug content, 50 mg of drug-loaded microsponges are dissolved in 50 mL of pH 6.8 phosphate buffer to obtain a concentration of 1000 µg/mL. From this solution, 10 mL is pipetted out and the volume is made up to 100 mL with pH 6.8 phosphate buffer to obtain 100 µg/m. The solution is shaken thoroughly and filtered. From the above solution 2.5 mL is pipetted out and diluted to 10 mL with pH 6.8 phosphate buffer to obtain a final concentration of 25 µg/ml. The absorbance of the resulting solution is then measured using a UV–Visible spectrophotometer at the appropriate wavelength to calculate the drug content.

$$\textbf{Drug Content} = \frac{\text{Practical drug content}}{\text{Theoritical drug content}} X100$$

2.2.6. In-vitro Drug Release:

In-vitro release studies have been carried out using dissolution apparatus USP Type-I equipped with a basket consisted of 10µm stainless steel mesh. 900ml of phosphate buffer pH 6.8 was used as the dissolution medium, temperature was maintained at 37$\pm$ 0.5°C and the rotation speed was set at 75rpm. Sample aliquot was withdrawn from the dissolution medium and analysed by suitable analytical method (UV spectra- photometer) at regular intervals of time. The best formulation was found basing on Evaluation Results and incorporated into gel.

2.3. Preparation of Microsponge Gel

Carbopol 934P (1% w/v) was Prepared by soaking initially soaked in water for 2 hours and then homogenously dispersed by agitation at 600 rpm using a magnetic stirrer. Rutin trihydrate loaded F2 microsponges were subsequently incorporated into the dispersion and mixed uniformly. Glycerine was added as a humectant. Methyl paraben and propyl paraben were dissolved separately in Water and added to the gel as preservatives. The pH of the formulation was adjusted to neutral using triethanolamine (1% w/v). Finally, propylene glycol was incorporated as a permeation enhancer to obtain a smooth and homogeneous gel formulation[11].

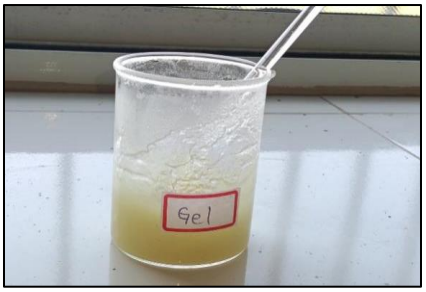

Figure 1 Prepared microsponge gel

2.4. Evaluation Parameters of Microsponges Gel [12-14]:

2.4.1. pH determination

The pH of the prepared gel was measured using pH meter (standardized using buffer, pH 6.8 before use) by putting the tip of the electrode into the gel and after 2 min the result was recorded. The measurement of pH of formulation was done in triplicate and the mean value was calculated.

2.4.2. Spreadability

Spreadability of the gel was determined after placing a weighed amount of sample between 2 glass slides and a weight of 500 g was kept over the slides for about 5 min after which no more spreading was expected. Diameters of spread circles (initial and final) were measured in cm and were taken as comparative values for Spreadability.

$$S=M*L/T$$

Where,
S = Spreadability
M = Weight put on the upper glass
L = Length of glass slide
T = Time of spreading gel in seconds.

2.4.3. Viscosity

The viscosity of the prepared gel was determined using a Brookfield viscometer. An adequate quantity of gel was placed in a clean beaker and kept at room temperature suitable spindle (e.g., spindle No. 64) was immersed in the gel sample and the instrument was operated at a fixed speed of 3 rpm. After allowing the spindle to rotate for a few seconds, the viscosity reading was recorded in centipoise (CP). The measurement was performed in triplicate and the average value was calculated.

2.4.4. Irritability

Mark a 1 square cm region on the left hand of human being. The gel was applied to the designated region and the duration was recorded. The presence of irritancy, erythema, and edema was monitored for up to 24 hours at regular intervals.

2.4.5. Drug Content

Taking a clean volumetric flask and adding 25 mL of Phosphate Buffer (pH 6.8). Accurately weigh 1 gm of the gel and add it directly into this solution. To ensure the drug is fully released from the gel matrix into the buffer, the mixture must be sonicated (subjected to ultrasonic waves), which helps in uniform dispersion and dissolution Once sonication is complete, the solution is filtered through Whatman filter paper to remove any insoluble polymers or particulates that could interfere with optical readings. Finally, the clear filtrate is collected, and its absorbance is measured using a UV-Visible Spectrophotometer at the drug's specific maximum wavelength.

2.4.6. In-vitro Diffusion study:

Modified franz diffusion cell apparatus was used to study the *in-vitro* drug diffusion of prepared formulation. A 4 × 4 cm cellophane membrane was taken and soaked for 24 hours in phosphate buffer solution (pH 6.8). The receptor compartment was filled with suitable diffusion medium. 1g of the prepared gel was accurately weighed and placed on

the membrane, which was then mounted between the donor and acceptor compartments of the diffusion apparatus. The gel was kept in the donor compartment, while 100 ml of phosphate buffer (pH 6.8) was added to the acceptor compartment. The system was maintained under continuous stirring by setting the rpm. At predetermined time intervals of 1, 2, 3, 4, 5, and 6, 7, 8 hours, 5 ml samples were withdrawn from the acceptor compartment and replaced with an equal volume of fresh buffer to maintain sink conditions. The collected samples were analysed for absorbance using a UV–visible spectrophotometer to determine the drug diffusion profile.

Figure 2 Modified Franz Diffusion Cell

3. Results

3.1. Drug excipient compatability studies

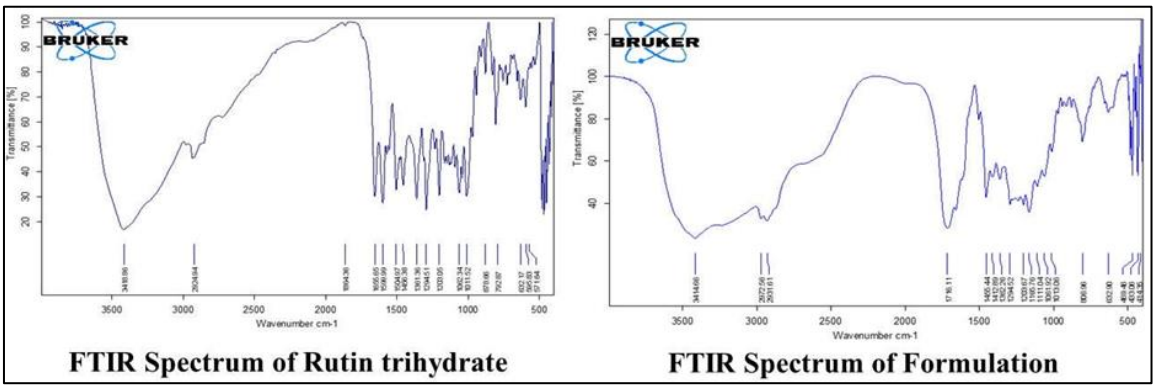

Figure 3 FTIR studies

Table 2 FTIR Spectrum of Rutin trihydrate

Type of bond	Actual frequency range (cm^{-1})	Observed frequency in pure drug spectra (cm^{-1})	Observed frequency in Formulation spectra (cm^{-1})	Functional group Conformation
O-H Streaching	3200 – 3600	3418.86	3414.66	Phenol
C-H Streaching	2900 – 3100	2924.94	2931.61	Alkane
C=O Streaching	1650 -1665	1655.65	1655.44	Ketone
C=C Streaching	1500 – 1600	1599.99	1599.99	Carbonyl
C - O – C Streaching	1000 – 1300	1294.51	1294.52	Ether
O-H Bending	1300 – 1500	1361.36	1362.26	Phenol

The characteristic peacks obtaind from FTIR spectrum of pure drug and formulation are depicted in figure no 3. The pure drug was analysed using FTIR, the peaks were observed at 3418.86, 2924.94, 1655.65, 1599.99, 1361.36, 1294.51 cm^{-1} frequencies which were indicating that presence of O - H str, C - H str, C = O str, C = C, O - H ben, C - O - C confirming the drug is pure rutin trihydrate. FTIR

studies shows that drug and polymer were compatible with each other and there was no interaction found between them.

3.2. Evaluation Results of Rutin trihydrate loaded micro sponges

Rutin trihydrate of microsponges were successfully prepared by quasi-emulsions solvent diffusion method. The prepared micro sponges were evaluated for the parameters like production yield, particle size, Entrapment Efficiency and drug content. The results of evaluations are shown in table no.3

Table 3 Evaluation Results of Rutin trihydrate micro sponges

Formulation code	Production yield%	Particle size (µm)	%E.E*	% Drug Content*
F1	59.3	9.82	84.1± 0.02	62.1± 0.06
F2	90.2	10. 62	93.6± 0.06	88.9± 0.03
F3	65.5	14.7	91.2± 0.03	69.4± 0.02
F4	54.8	15.3	80.2± 0.05	63.2± 0.07
F5	63.1	16.38	91.1± 0.01	74.5± 0.09
F6	70.4	16.52	90.2± 0.04	82.1± 0.02

*n=3, All the values are calculated as mean ± SD

4. Discussion

The Prepared microsponges were evaluated for the parameters - production yield, particle size, Entrapment Efficiency, drug content. Here the ratios of 1:05 to 1:3 for all the formulations the production yield increases as the Particle size increases and Entrapment Efficiency increase, drug content also increase. But all the formulations the production yield results will be 59% - 70%, particle size results will be in 9.82 - 16.52, Entrapment Efficiency results will be 84%- 90% Drug content results will be 62.1% - 82.1%.

In - Vitro Drug Release Study:

The *In - Vitro* drug release pattern of Rutin trihydrate from formulated microsponges as shown Fig 3 and table no 4.

Table 4 *Invitro* drug release of Rutin trihydrate microsponges (F1 - F6)

Time (hrs)	% Drug Release					
	F1	F2	F3	F4	F5	F6
0	0	0	0	0	0	0
1	21.71± 0.04	53.83± 0.05	28.36± 0.06	27.02± 0.09	29.52± 0.04	11.21± 0.03
2	23.80± 0.05	63.00± 0.03	30.91± 0.07	32.63± 0.05	40.32± 0.05	22.32± 0.05
3	24.06± 0.03	75.85± 0.03	42.84± 0.07	33.72± 0.02	43.74± 0.01	31.64± 0.02
4	31.30± 0.07	78.10± 0.02	50.67± 0.05	42.34± 0.05	50.4± 0.06	43.08± 0.07
5	33.65± 0.02	87.26± 0.02	54.19± 0.08	57.12± 0.06	53.64± 0.07	53.73± 0.02
6	44.60± 0.05	91.12± 0.01	56.34± 0.09	60.65± 0,03	5708± 0.02	60.31± 0.05
7	61.43± 0.06	91.60± 0.06	63.78± 0.07	76.28± 0.06	62.42± 0.04	72.08± 0.06
8	70.63± 0.09	91.91± 0.08	77.67± 0.08	90.01± 0.01	72.04± 0.07	83.01± 0.03

*n=3, All the values are calculated as mean ± SD

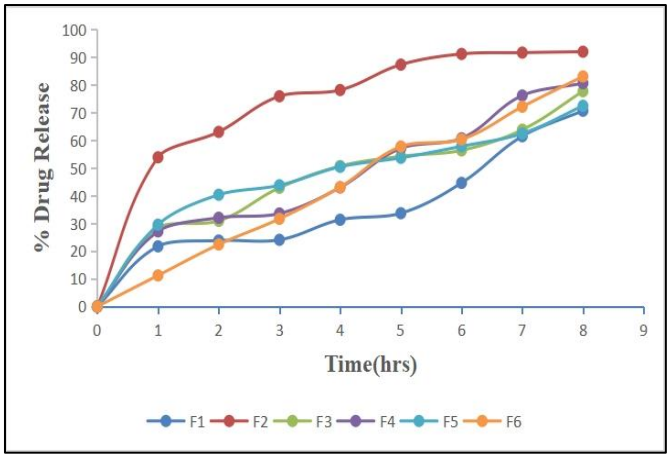

Figure 4 *In-vitro* drug release study

The *in-vitro* drug release profile of all rutin trihydrate micro sponges showed controlled and sustained release of the drug for 8 hrs as illustrated in fig no. 3. The cumulative drug release varied with the drug-to-polymer ratio, indicating the significant influence of polymer concentration on release behavior. Formulation F1 (1:0.5) showed 70.63% release, while F2 (1:1) exhibited the highest release of 91.92% due to an optimal balance between drug loading and polymer content. Formulations F3, F4, F5, and F6 demonstrated releases of 77.67%, 80%, 72.4%, and 83.01%, respectively, reflecting increased matrix density and diffusion path length with higher polymer concentrations. Overall, increasing polymer content generally reduced drug release by forming a denser polymeric network. Among all formulations, F2 was identified as the optimized batch and was further incorporated into a Carbopol gel for topical application.

4.1. Evaluation results of microsponges gel

The Rutin trihydrate gel formulated using Carbopol as the gelling agent and incorporating the optimized F2 formulation was evaluated for various physicochemical parameters, including pH, spreadability, viscosity, irritability, and drug content, in order to assess its suitability for topical application.

Table 5 Evaluation results of F2 loaded microsponge gel

Formulation	pH	Spreadability (g.cm/s)	Irritability	Viscosity (cps)	% Drug content
F2 formulation Carbopol gel	6.5	16.6	Non irritability	8000	95.03

4.1.1. pH

The pH of the prepared gel was found to be 6.5, which falls within the acceptable range for topical formulations (pH 5.0–7.0). This indicates that the formulation is compatible with the physiological pH of the skin and is unlikely to cause irritation or discomfort upon application. Maintaining an appropriate pH is essential to ensure skin safety and patient compliance.

4.1.2. Spreadability

The Spreadability value of 16.6 g.cm/s indicates good spreading characteristics of the gel. Adequate spreadability facilitates easy application and ensures uniform distribution of the formulation over the skin surface, which is critical for effective topical drug delivery. The favourable spreadability may be attributed to the optimized concentration of Carbopol and the presence of suitable formulation excipients.

4.1.3. Viscosity:

The viscosity of the gel was found to be 8000 cps, suggesting that the formulation possesses suitable consistency for topical use. Appropriate viscosity helps in maintaining prolonged contact of the formulation with the skin, thereby enhancing drug residence time without causing difficulty in application. The viscosity profile can be mainly attributed to the polymeric nature of Carbopol, which forms a stable and uniform gel matrix upon hydration and neutralization.

4.1.4. Irritability

The formulation exhibited non irritability, confirming that the gel is safe for topical application. The absence of skin irritation may be due to the skin-compatible pH and the non-irritant nature of the excipients used in the formulation.

4.1.5. Drug content

The drug content of the formulation was found to be 95%, which lies within the acceptable pharmacopoeia limit (90–110%). This indicates uniform distribution of Rutin trihydrate within the gel matrix and efficient drug incorporation during the formulation process. The high drug content reflects good solubilization and proper mixing of the drug with the polymeric gel base, ensuring dose uniformity and reproducible therapeutic performance.

Overall, the evaluation results demonstrate that the F2 formulation incorporated into Carbopol gel exhibits satisfactory physicochemical properties, excellent drug content uniformity, and good safety profile, making it a suitable and promising formulation for the topical delivery of rutin trihydrate.

4.1.6. Drug Diffusion from microsponge gel:

Table 6 Diffusion study of F2 loaded Microsponges Gel

Time (hrs)	% Drug Diffusion
0	0
1	33.06 ± 0.02
2	57.56± 0.04
3	66.03±0.01
4	71.12± 0.03
5	74.02± 0.02
6	79.14± 0.05
7	80.01± 0.03
8	82.04± 0.01

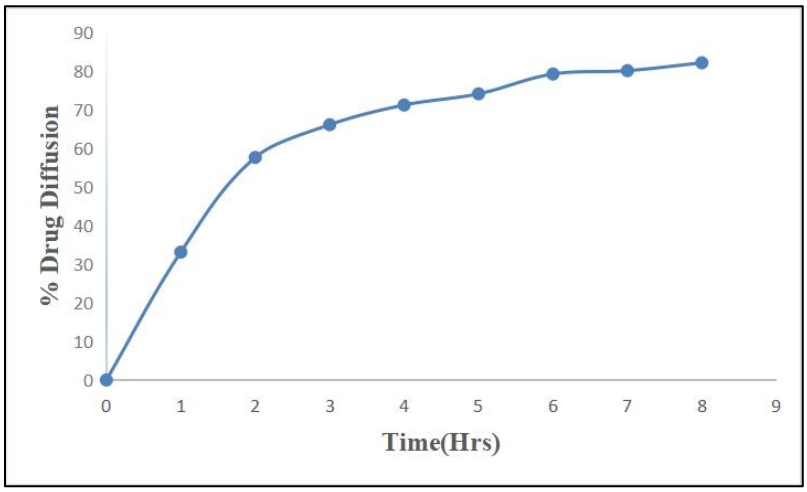

Figure 5 Diffusion study of microsponges Gel

4.2. Discussion

The *in-vitro* drug diffusion study of the F2 microsponge-loaded gel demonstrated a controlled and sustained release profile over 8 hours, with progressive drug diffusion from the gel matrix. An initial burst release during the first 2 hours was followed by a gradual and nearly linear diffusion phase, governed by the porous structure of microsponges and the

viscosity of the Carbopol gel. The optimized drug-to-polymer ratio (1:1) enhanced drug entrapment and prolonged diffusion by increasing the path length. Among all formulations prepared using the quasi-emulsion solvent diffusion method with ethyl cellulose, F2 exhibited superior production yield, particle size, entrapment efficiency, and drug content. The incorporated gel showed acceptable physicochemical properties and achieved 82.04% drug release within 8 hours. Therefore, the rutin trihydrate-loaded F2 microsponge gel represents a promising controlled topical drug delivery system for the treatment of acne vulgaris.

5. Conclusion

The study successfully formulated and evaluated rutin trihydrate-loaded microsponge gel for topical drug delivery. Microsponges were prepared using the quasi-emulsion solvent diffusion method with different ratios of drug and polymer (ethyl cellulose). Among the formulations, F2 showed the best performance, demonstrating good production yield, particle size, entrapment efficiency, drug content, and drug release.The selected F2 microsponges were incorporated into Carbopol gel, and the formulation was further evaluated for pH, spreadability, viscosity, and *in-vitro* drug release. The results showed satisfactory *in-vitro* drug release of 82.04% within 8 hours.Therefore, the developed rutin trihydrate-loaded microsponge gel can be considered a promising system for controlled topical drug delivery in the treatment of acne vulgaris.

Compliance with ethical standards

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Disclosure of conflict of interest

Authors declare no conflict of interest.

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