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IMIQUIMOD LOADED MICROSPONGE GEL FOR EFFECTIVE TREATMENT OF ACTINIC KERATOSIS: FORMULATION AND CHARACTERIZATION

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ABSTRACT

Dermatologists most frequently find actinic keratoses, which are pre-malignant lesions that can develop into squamous cell carcinomas.Microsponge delivery systems are used to improvethe safety, effectiveness and quality of topical prescription, over-the-counter and personalcareproducts.The microsponge was prepared by quasi emulsion method and was evaluated for its different parameters which revealed many interesting results for efficient preparation of the microsponges. The formulation F3 has better results than other 9 formulations. F3 have its particle size 31.3 µm, percentage yield 79.27, Entrapment efficiency 93.44%, Drug content 83.04%, Spreadability 14.4, pH 7.4, Viscosity 2564 cps, and Cumulative Release 49.89 % in 24 hour, all these parameters are in optimized range for preparing a controlled release dosage form so showing itself as an optimised formulation in this project work. FTIR spectroscopy analyses indicated the chemically stable, amorphous nature of the drug in these microsponges. SEM photographs revealed the spherical nature of the microsponges in all variations. However, at higher ratios, drug crystals were observed on the microsponge surface. With the revealed results by different evaluation parameters, it is concluded that microsponges drug delivery system has become highly competitive and rapidly evolving technology and more and more research are carrying out to optimize cost-effectiveness and efficacy of the therapy. It is a unique technology for the controlled release of topical agents and consists of microporous beads loaded with active agent and also use for oral as well as biopharmaceutical drug delivery.

KEY WORDS: *Imiquimod,Mocrisponge Gel, Actinic Keratosis, Zeta Potential, Spreadability, Viscosity, Drug content.*

INTRODUCTION

Actinic keratosis (AK), sometimes called solar keratosis or senile keratosis, is a pre-cancerous area of thick, scaly, or crusty skin. Actinic keratosis is a disorder of epidermalkeratinocytes that is induced by ultraviolet (UV) light exposure. These growths are more common in fair-skinned people and those who are frequently in the sun. They are believed to form when skin gets damaged by UV radiation from the sun or indoor tanning beds, usually over the course of decades. Given their pre-cancerous nature, if left untreated, they may turn into a type of skin cancer called squamous cell carcinoma. Notably, AKs are frequently felt before they are seen, and it is occasionally advised to see a dermatologist because of the feel. from 2 to 6 millimeters, yet they have the potential to develop to several centimeters document Treatment by an is necessary since untreated lesions carry a 20% chance of developing into squamous cell carcinoma. Actinic keratoses are characterized by thick, crusty, scaly patches that frequently have a harsh, dry feel to them. They can grow to be several centimeters in diameter, although their typical size is between two and six millimeters. Notably, AKs are frequently felt rather than seen, and their texture has occasionally been likened to sandpaper. They could be tan, pink, red, dark, light, or a considering that exposure to the sun causes AK development.

The possibility of in situ or invasive squamous cell carcinoma (SCC) cannot be ruled out based only on clinical examination, hence a biopsy or excision can be considered for a conclusive diagnosis by histologic study of the lesional tissue if the clinical examination results are not typical of AK. There are several AK therapy methods available. One therapeutic option for several AK lesions in a skin region known as "field cancerization" is photodynamic therapy (PDT). A photosensitizer is applied to the skin, and then a bright light source is used to illuminate the area. Applying topical creams like imiquimod or 5-fluorouracil Seniors with fair skin and sensitivity to the sun are the usual patients with actinic keratoses. [4] Dorsal forearms, hands, and the cheeks, ears, and, in men, the bald scalp are among the regions where the lesions first appear after prolonged sun exposure. A single anatomic region may see a patient acquire several lesions, to the point where the lesions collide and result in confluent actinic keratosis over a sizable area.

The following variations are possible. Actinic keratoses appear as hyperkeratotic plaques, papules, or macules on photo exposed areas, and they have an erythematous background. In the early stages, palpation may be a more reliable method of identification than visual inspection. They can also exhibit varying degrees of penetration and pigmentation; when present in multiples, they form the so-called field cancerization. Between 11% and 60% of Caucasian people over 40 have this condition. Although ultraviolet light is the primary pathogenic agent, other variables can also contribute to the development of lesions. Lesion diagnosis is based on clinical and dermoscopic examination; however, histological study may be required in certain circumstances. The main worry with actinic keratoses is the possibility of developing into squamous cell cancer. Actinic keratoses can be treated with topical drugs, ablative techniques,

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and surgery; the optimal course of action should always be determined by the specific needs of the patient.

Material and Methods

1. **Preformulation Studies**
   Preformulation testing is the first step in the rational development of dosage forms of a drug substance. It can be defined as an investigation of physical and chemical properties of a drug substance alone and combination with excipients.

a. Organoleptic evaluation of drug: Organoleptic properties of the drug substance are very important for designing the dosage form. The colour, odour and tests of the drug are characterized.

b. Solubility studies of drug in various organic and inorganic solvent: A qualitative determination of the solubility was made by adding solvent in small incremental amount to a test tube containing fixed quantity of drug. After each addition, the system is vigorously shaken and observed visually.

c. Determination of partition coefficient: The partition coefficient determined by hand shaking method.The partition coefficient is defined as the ratio of unionized drug distributed between the organic and aqueous phase at equilibrium. For a drug delivery system, Lipophilic/Hydrophilic balance has been shown to be a contributing factor for rate and extent of drug absorption. Partition coefficient provides a mean of characterizing Lipophilic/Hydrophilic nature of drug.

d. Melting Point determination: Melting point of drug determined by melting point apparatus. It is performed by filling of drug in capillary tube and capillary tube and the thermometer were putin the apparatus. Now the point was noted at which the compounds starts melting.

e. Determination of ƛ max and preparation of standard curve: 100 mg of drug sample was weighed accurately and dissolved in 100 ml of methanol in 100 ml of volumetric flask and stock solution was prepared. Dilution was prepared and scanned from 200 – 400 nm by UV spectrophotometer.

f. Drug Excipient Compatibility study: Drug excipient interaction studies by FT-IR. It is Spectroscopy used to investigate and predict any physicochemical interactions between different components, in a formulation and therefore it applied to selection of suitable chemically compatible excipient. While selecting the ingredients, we would choose those which are stable, compatible and therapeutically acceptable. The aim of compatibility study was to test, whether there is any interaction between the excipients and the drug and compatibility between the drug and excipients.

g. Formulation and Development of Microsponges: Microsponges of imiquimod and Ethyl Cellulose was prepared by quasi-emulsion solvent diffusion method. The process involved formation of quasi-emulsion of two different phases i.e. internal phase and external phase similar to emulsions. The internal phase of drug-polymer solution (1: different ratio) made in a volatile solvent dichloromethane (10ml). And then it was added to external phase comprising the aqueous 5% (5mg/100mlwater) polyvinyl alcohol (PVA) solution with vigorous stirring. Glycerol (1-2ml), which was added at an adequate amount in order to facilitate plasticity. Stirring lead to the emulsion globules. The stirring was continued upto 6 hrs till the insoluble, rigid microparticles i.e. microsponges is formed. Then it was filtered to separate the microsponges. The microsponges were then dried in an air heated oven.

B. Characterization of Drug Loaded Microsponges

(i). **Production yield:**The production yield of the microsponge was determined by calculating accurately the initial weight of the raw materials and the last weight of the microsponges obtained:

$$\text{Production yield} = \frac{\text{Practical Mass of microsponges}}{\text{Theoretical Mass (Drug + Polymer)}} \times 100$$

(ii). **Entrapment Efficiency:** A sample of imiquimodmicrosponges (10 mg) was dissolved in 100 ml of phosphate buffer, freshly prepared (pH 5.5). The solutions were subsequently diluted suitably with the phosphate buffer pH 5.5and spectrophotometric absorbance was taken at the maximum wave length of imiquimod. The drug content was calculated from the calibration curve and expressed as the loading efficiency:

$$\text{Drug Loading} = \frac{\text{Mass of drug present in microsponges}}{\text{Theoretical Mass (Drug + Polymer)}} \times 100$$

(iii). Particle Size Determination: Particle size analysis of loaded and unloadedmicrosponges can be performed by laser light diffractometry or any other suitable method. The values can be expressed for all formulations as mean particle size range. Cumulative percentage drug release from microsponges of different particle size will be plotted against time to study effect of particle size on drug release. Particles larger than 35 µm can impart gritty feeling and hence particles of sizes between 10 and 35µm are preferred to use in final topical formulation.

(iv). Surface topography/ Particle morphology by SEM: For morphology and surface topography, the prepared microsponges can be coated with gold– palladium under an argon atmosphere at room temperature and then the surface morphology of the microsponges can be studied by scanning electron microscope (JEOL Instrument, JSM-6360, Japan).

C. Formulation development of Fusidic acid microsponges loaded topical gel:

Microsponge loaded topical gel of imiquimod (100mg) was prepared step by step a clear dispersion of Carbopol was prepared in water using moderate agitation. A clear dispersion

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of carbopol (35 mg) is prepared in water (q.s) using moderate agitation. Triethanolamine (1-2 drops) is used to neutralise the formulation and subsequently preservatives Methyl paraben (3 mg) and Propyl paraben (1 mg) was added to resist the microbial growth. And then volume was maintained with water. Gel prepared were degassed with ultrasonication.

D. Characterization of imiquimodmicrospongesloaded topical gel

- **The visual examination:** The examination considered a series of visual characteristics (consistency, colour, and homogeneity).
- **pH determination:** The pH of the prepared gel was measured using pH meter by putting the tip of the electrode into the gel and after 2 minutes the result was recorded.
- **Spreadability:** A sample of 0.1g of gel was pressed between 2 slides with 500g weights and left for about 5 min where no more spreading was expected. Diameters of spread circles were measured in cm and were taken as comparative values for spreadability (diameter of the spread circle –initial diameter.
- **Viscosity:** The viscosity of imiquimodloaded microspongecarbopol gel was measured in Brookfield viscometer, model-VL2 (Lemis Baltic) with spindle No 4.
- **Drug Content:** Imiquimodcontent in the gel was determined by taking required quantity of the gel which is equivalent to 10 mg of imiquimod transferred to 100 ml volumetric flask containing phosphate buffer (pH 5.5) and it allowed to sonicate and filtered. Then, suitably diluted and analyzed at λ max 205.
- **In vitro diffusion studies using KC cell:** In vitro release studies was performed using KC cell diffusion apparatus at 37 °C. The release medium is selected, while considering solubility of active ingredients to ensure sink conditions. Sample aliquots were withdrawn from the medium and analyzed by the suitable analytical method at regular intervals of time. Egg membrane was fitted at the donor side of the cell and predetermined amount of formulation was mounted on the membrane. The receptor medium is continuously stirred at and thermostated with a circulating jacket. Samples are withdrawn at different time intervals and analyzed using suitable method of assay.
- **Zeta Potential:** The zeta potential of imiquimodmicrosponge formulations were measured using Zetasizer (Malvern instruments, Worcestershire, UK). The measurement was performed at 250C. A sample of 1 ml was diluted using double distilled water).

E. Stability Studies: Stability of a drug has been defined as the ability of a particular formulation in a specific condition, to remain within its physical, chemical, therapeutical and toxicological specifications. The reason of stability testing is to provide evidence on how the quality of drug formulation varies with time under the influence of various environmental conditions such as temperature, humidity, light. From this study we know about recommended storage condition, re-test periods and shelf-life of the drug can be established.

1. **Stability studies are important for the following reasons:**This is an assurance given by the manufacturer that the patient would receive a uniform dose throughout the shelf life.The drug control administration insists on manufacturers on conducting the stability studies, identity, strength, purity and quality of the drug for an extended period of time in the conditions of normal storage. Stability testing prevents the possibility of marketing an unstable product. Both physical and chemical degradation of drug can result in unstable product.
2. **Purpose of stability studies:** Stability studies are done to understand how to design a product and its packaging, such that product has appropriate physical, chemical and microbiological properties during a defined shelf life when stored and used.
3. **Storage conditions:** The selected formulations were subjected for three month stability study as per ICH guidelines. The selected formulations were placed in a wide mouth glass bottles, mouth of the bottle was tightly closed and packed in aluminum foils. In the present study, stability studies were carried out at 25ºC/60% and 40ºC/75% RH for a specific period of 3 months for the selected formulations.

RESULT AND DISCUSSION

Preformulation Study

Physical Characteristics

Table 5: Organoleptic and physical properties of drug

Test	Observations
Colour	White
Taste	Bitter
Odour	Odourless
Form	Crystalline

Solubility

Table 6: Solubility profile of drug

S. No.	Solvents	Solubility
1.	Water	Insoluble
2.	Methanol	Freely Soluble
3.	Ethanol (95%)	Freely Soluble
4.	Dimethyl formamide	Freely soluble
5.	Dimethyl sulfoxide	Freely soluble

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Partition Coefficient

Table No. 7: Partition Coefficient

Material	Observation
Imiquimod Sovent system: Octanol: water	2.7

Melting Point Determination

Table No. 8. Melting point of drug

Material	Observation
Imiquimod	292°C-294^{O}C

Determination of ƛ max and preparation of standard curve: The calibration curve of imiquimod was prepared in phosphate buffer pH 1.2 in table 5 shows the absorbance at λmax 226 nm for different concentration of imiquimod and figure 2 shows calibration curve.

Table 9: Absorbance of different aliquots of Imiquimodat 226 nm

Concentration(µg/ml)	Absorbance
5	0.0802
10	0.1727
15	0.2908
20	0.4030
25	0.5077

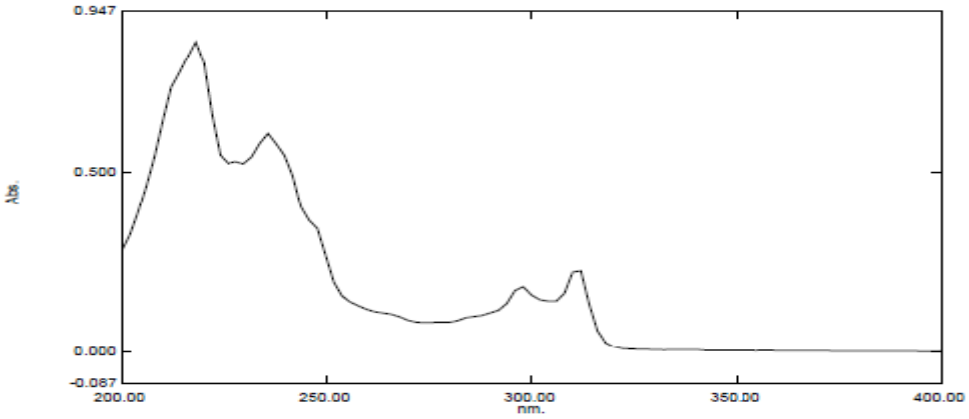


Fig. 1: UV Spectrum of Imiquimod in 0.1N HCl

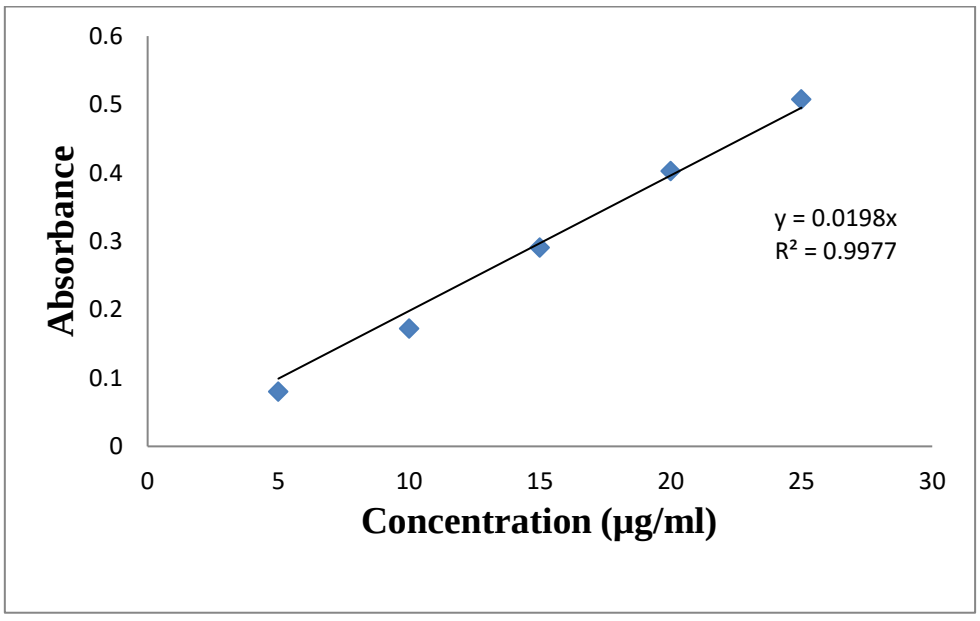


Fig. 2: Calibration curve of Imiquimod in 0.1N HCl buffer

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Drug–Excipient Compatibility study: Drug excipient interaction studies by FT-IR. It is Spectroscopy used to investigate and predict any physicochemical interactions between different components, in a formulation and therefore it applied to selection of suitable chemically compatible excipient. While selecting the ingredients, we would choose those which are stable, compatible and therapeutically acceptable.

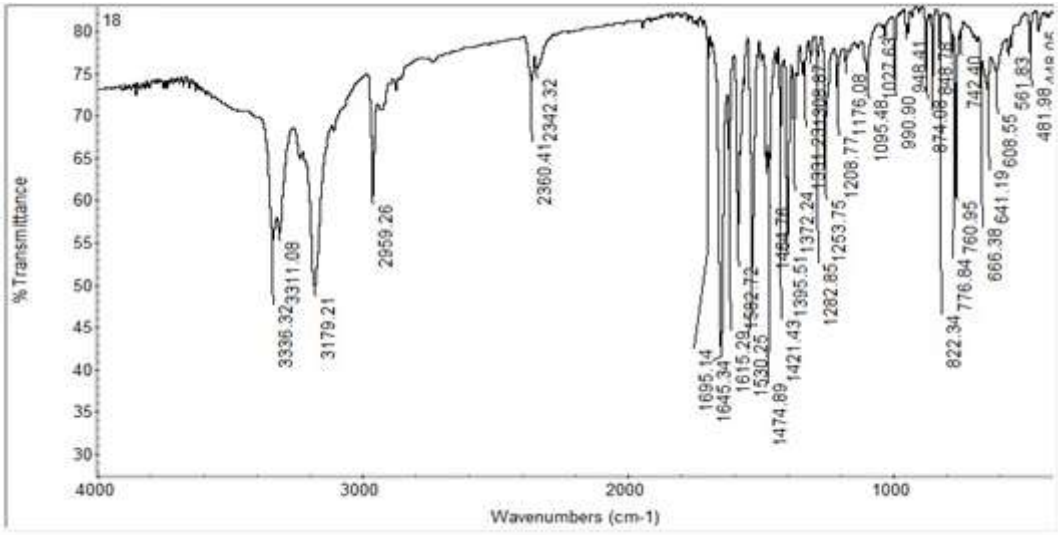


Figure 3: FTIR Spectrum of imiquimod

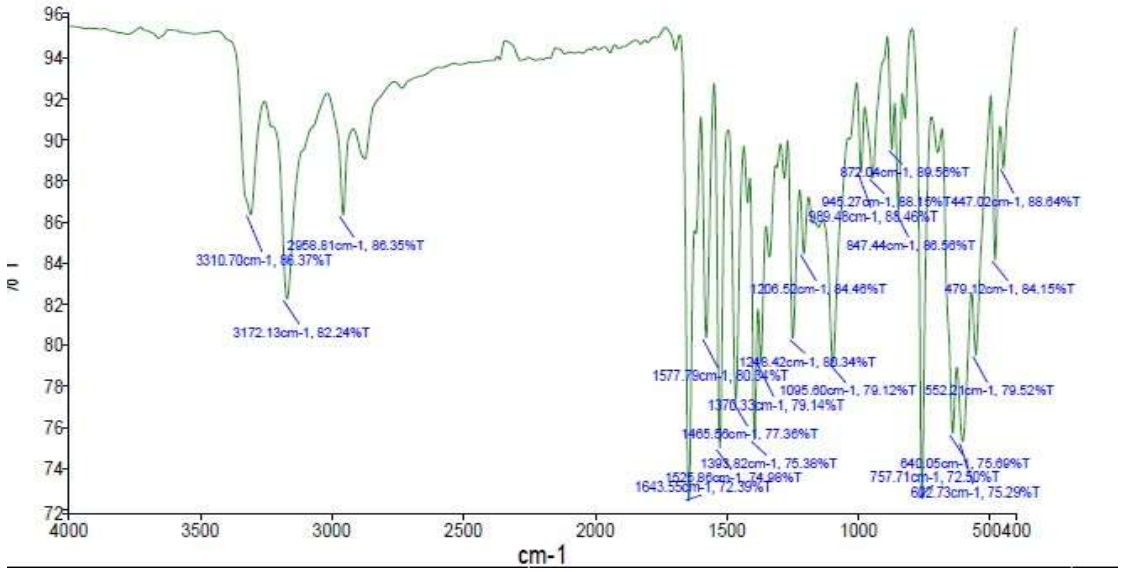


Figure 4: FTIR Spectrum of imiquimod+ Excipients

Formulation and Development of Microsponges:
Microsponges of imiquimod and Ethyl Cellulose was prepared by quasi-emulsion solvent diffusion method. The process involved formation of quasi-emulsion of two different phases i.e. internal phase and external phase similar to emulsions.

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Table 10: Formula for Microsponge Formulation

S. No.	Ingredient(mg /ml)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
1	Imiquimod	100	100	100	100	100	100	100	100	100	100
2	Ethylcellulose (polymer)	1	2	3	4	5	6	7	8	9	10
3	Polyvinylalcohol	500	500	500	500	500	500	500	500	500	500
4	Dichloromethane	10	10	10	10	10	10	10	10	10	10
5	Glycerol	1	1	1	1	1	1	1	1	1	1
6	Water	100	100	100	100	100	100	100	100	100	100

Characterization of Drug Loaded Microsponges

Practical yield and Entrapment efficiency: The production yield of the microsponge was determined by calculating accurately the initial weight of the raw materials and the last weight of the microsponges. The drug content was calculated from the calibration curve and expressed as the loading efficiency.

Table 11: Results of practical yield and Entrapment efficiency

S. No	Formulation code	Production yield (%)	Entrapment Efficiency (%)
1	F1	20.60	85.12
2	F2	37.41	87.08
3	F3	79.27	93.44
4	F4	63.00	81.28
5	F5	70.13	76.11
6	F6	50.40	70.13
7	F7	25.17	60.24
8	F8	37.12	68.41
9	F9	20.13	72.21
10	F10	19.11	76.11

Particle Size Analysis of Microsponge: Particle size analysis of loaded and unloaded microsponges can be performed by laser light diffractometry or any other suitable method. The values can be expressed for all formulations as mean particle size range.

Table 12: Results of Particle size analysis of microsponge

S. No.	Formulation code	Particle size (µm)
1	F1	28.7
2	F2	29.8
3	F3	31.3
4	F4	33.7
5	F5	37.2
6	F6	31.8
7	F7	31.9
8	F8	29.4
9	F9	27.5
10	F10	23.9

Surface Topography/ Particle Morphology by SEM

Scanning electron microscopy (SEM) was used to determine the Morphology of the prepared microsponges. SEM is useful for characterizing the morphology and size of microscopic specimens with particle size as low as 10^{-10} to 10^{-12} grams. The sample was placed in an evacuated chamber and scanned in a controlled pattern by an electron beam. Interaction of the electron beam with the specimen produces a variety of physical phenomena that, when detected, are used to form images and provide elemental information about the specimens.

It was observed that the microsponges were spherical, and uniform with no drug crystals on the surface. The shape of the microsponges affects the surface area and surface area per unit weight of spherical microsponges. The irregular shape of the particles may affect dissolution rate present in dissolution environment.

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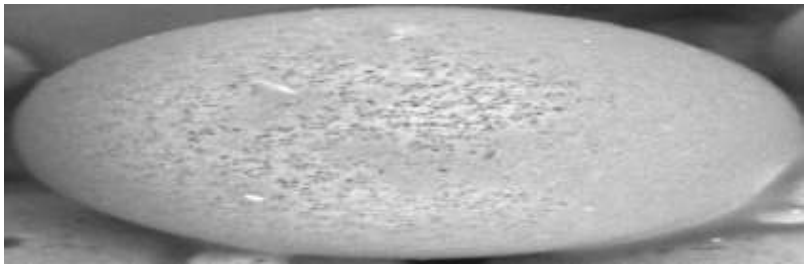


Figure 6: Microsponge

Formulation Development Of Imiquimodmicrosponges Loaded Topical Gel: Gel Of Imiquimod Was Prepared By Using Following Formula Given In Table. A Clear Dispersion Of Carbopol Was Prepared In Water Using Moderate Agitation. A Clear Dispersion Of Carbopol (50 Mg) Is Prepared In Water (Q.S) Using Moderate Agitation. Triethanolamine (1-2drops) Is Used To Neutralize The Formulation And Subsequently Preservatives Methyl Paraben (5 Mg) And Propyl Paraben (2 Mg) Was Added To Resist The Microbial Growth. And Then Volume Was Maintained With Water. Gel Prepared Was Degassed With Ultrasonication.

Table 13: Formula for gel formulation

S. No.	Ingredient	Quantity(mg/ml)
1	Carbopol934P	50
2	Triethanolamine	2
3	Methylparaben	5
4	Propylparaben	2
5	Distilledwater	q.s

Characterization of Imiquimodmicrospongesloaded Topical Gel

- **pH determination:** The pH of the prepared gel was measured using pH meter by putting the tip of the electrode into the gel and after 2 minutes the result was recorded.

Table 14: Results of pH of formulation

S. No.	Formulation code	pH
1	F1	6.9
2	F2	6.5
3	F3	7.4
4	F4	7.0
5	F5	7.4
6	F6	7.1
7	F7	7.2
8	F8	6.9
9	F9	7.4
10	F10	7.3

- **Viscosity Measurement:**

The viscosity of imiquimodloaded microspongecarbopol gel was measured in Brookfield viscometer, model-VL2 (Lemis Baltic) with spindle No 4.

Table 15: Results of viscosity measurement

S. No.	Formulation code	Viscosity(cps)
1	F1	2874
2	F2	2745
3	F3	2564
4	F4	2731
5	F5	2345
6	F6	2814
7	F7	2781
8	F8	2498
9	F9	2791
10	F10	2747

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a. Spreadability Test

Table 16: Results of Spreadability of Microsponges

S. No.	Formulation code	Spreadability
1	F1	13.6
2	F2	13.8
3	F3	14.24
4	F4	14.3
5	F5	13.9
6	F6	14.2
7	F7	14.1
8	F8	13.5
9	F9	13.8
10	F10	13.6

b. Drug Content Determination

Table 17: Results of drug content studies

S. No.	Formulation Code	Drug Content (%)
1	F1	19.07
2	F2	27.82
3	F3	84.03
4	F4	74.03
5	F5	69.85
6	F6	63.02
7	F7	58.01
8	F8	51.06
9	F9	3705
10	F10	33.09

In-vitro diffusion studies using K Ccell

Table 18: Results of diffusion study of different formulation

S. N.	T. (hr.)	Cumulative Release (%)									
		F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
1	**1**	2.89	3.39	3.74	2.41	2.29	1.93	1.71	1.36	1.04	0.81
2	**2**	6.08	7.78	8.03	4.83	3.91	3.63	3.03	2.56	2.11	1.38
3	**3**	8.27	9.17	10.22	6.21	5.33	4.29	4.03	3.8	3.37	2.61
4	**4**	12.01	13.56	15.27	10.59	9.07	7.86	7.35	6.04	5.09	3.77
5	**5**	19.81	20.02	22.01	17.25	15.32	14.03	11.97	10.05	8.12	6.85
6	**24**	67.27	76.09	89.83	61.24	53.01	49.89	33.53	26.91	19.25	17.23

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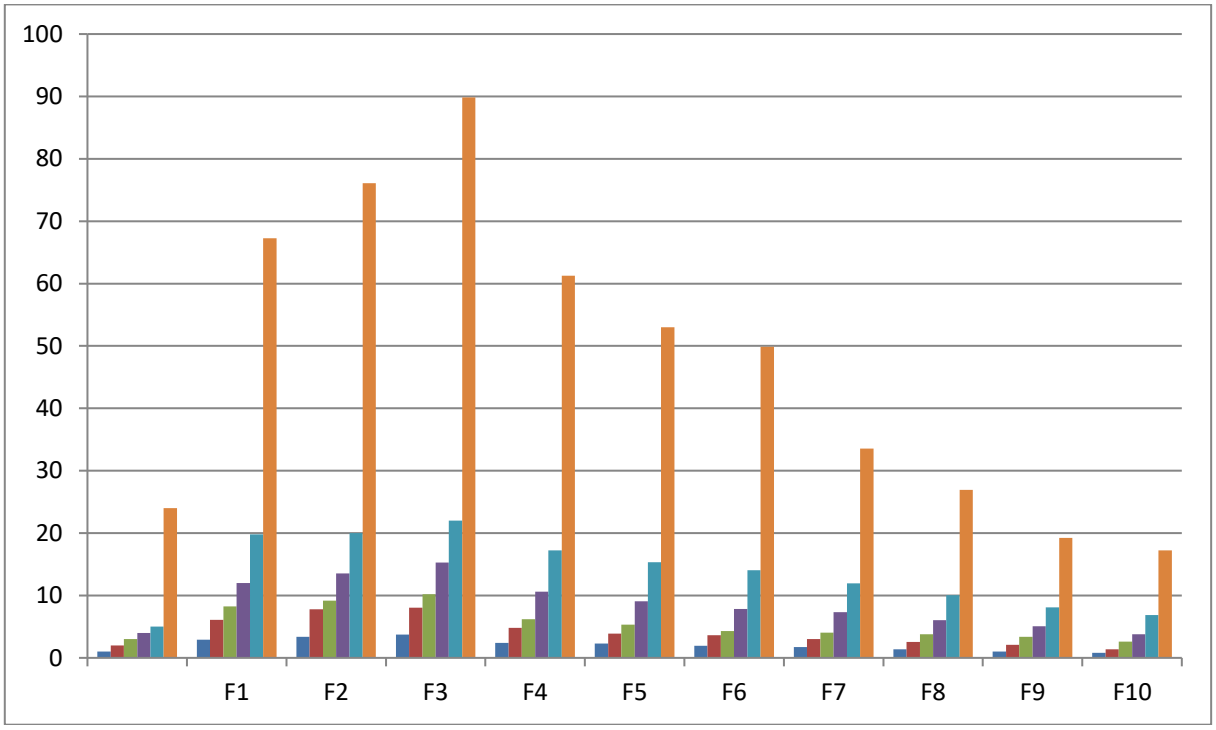


Fig. 7: % drug release of different formulation

Zeta Potential:

The zeta potential value of imiquimodmicrosponge gel was found and which lies in ideal limit of ±10 to ± 30 mV. Imiquimodmicrospongic gel showed the zeta potential of–24.6 mV Figure 47. It indicates that systems may remain stable for longer period.

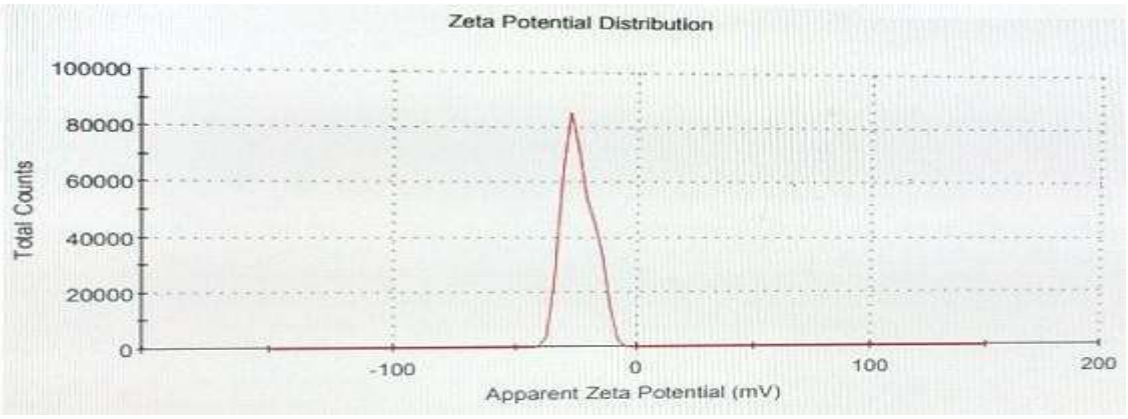


Fig. 8: Zeta potential of microsponge gel

Stability Studies on developed delivery system was performed to study the effect of storage temperature on surface morphology and residual drug content:

Table 19: Results stability study of best {F3} formulation

PARAMETERS	Loaded Microsponges			
	Room temperature			
	10Day	30 Day	45 Day	90 Day
Colour	White	White	White	White
Odour	Odourless	Odourless	Odourless	Odourless
pH	7.4	7.3	7.2	7.2
Spreadability	14.4	14.3	14.2	14.2
Viscosity (CPS)	2564	2563	2562	2562
% Drug content	84.03	84.02	84.01	84.01

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CONCLUSION

The microsponge was prepared by quasi emulsion method and was evaluated for its different parameters which revealed many interesting results for efficient preparation of the microsponges. The formulation F3 has better results than other 9 formulations. F3 have its particle size 31.3 µm, percentage yield 79.27, Entrapment efficiency 93.44%, Drug content 83.04%, Spreadability 14.4, pH 7.4, Viscosity 2564 cps, Cumulative Release 49.89 % in 24 hour, all these parameters are in optimized range for preparing a controlled release dosage form so showing itself as an optimised formulation in this project work. FTIR spectroscopy analyses indicated the chemically stable, amorphous nature of the drug in these microsponges. SEM photographs revealed the spherical nature of the microsponges in all variations. However, at higher ratios, drug crystals were observed on the microsponge surface. With the revealed results by different evaluation parameters, it is concluded that microsponges drug delivery system has become highly competitive and rapidly evolving technology and more and more research are carrying out to optimize cost-effectiveness and efficacy of the therapy. It is a unique technology for the controlled release of topical agents and consists of microporous beads loaded with active agent and also use for oral as well as biopharmaceutical drug delivery. Microsponge delivery systems can precisely control the release rates or target drugs to a specific body site have a vast impact on the health care system. A microsponge delivery system can release its active ingredient on a timer mode and also in response to other stimuli. Therefore, microsponge has got a lot of potential and is a very emerging field which is needed to be explored. Microsponges constitute a significant part by virtue of their small size and efficient carrier characteristics.

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