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FORMULATION AND EVALUATION CURCUMIN LONGA EMULGEL AND ITS ACTIVITY ON VITILIGO TREATMENT

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ABSTRACT : Turmeric is a perennial herbaceous plant that reaches up to 1m tall. It has highly branched, yellow to orange, cylindrical, aromatic rhizomes. The condition occurs when your body's immune system destroys melanocytes. Melanocytes are skin cells that produce melanin, the chemical that gives skin its colour, or pigmentation. Emul gel is known as an Emulsion that has been gelled by using a gelling agent. They can be made either o/w or w/o type. Emul gel is a stable and superior system that incorporates poor water soluble drugs. In brief, emul gel is a combination of emulsion and gel.Despite the numerous advantages of gels one significant disadvantages is the delivery of hydrophobic medication. As a result, an emulsion-based solution is being used to overcome this limitation, allowing even hydrophobic therapeutic moieties to benefit from the unique properties of gel.Emul gel can deliver both hydrophilic and lipophilic drugs due to the presence of both aqueous and non aqueous phases. In recent years, they have been used as a controlled released formulation. These are biphasic systems that have better drug loading capacity and better stability. Emul gel has several good properties, such as good spreadability, greaseless, thixotropic, good shelf life, odourless, and a pleasant appearance over the conventional topical formulation. Emul gel has both gel and emulsion properties and functions has a dual control release system.

KEYWORDS:

Turmeric, Emulgel, Rhizomes, Melanocytes, Spreadability..

➢ 1.INTRODUCTION

Vitiligo is a depigmenting skin condition characterized by a specific melanocyte depletion, resulting in melanin attenuation inside the skin's damaged regions. A distinguishing feature is a completely amelanotic, non-scaly, chalky-white macule with clear borders. The understanding of the etiology of vitiligo has advanced significantly in recent years. It is now categorically recognized as an autoimmune disorder associated with metabolism and oxidative stress, including cellular detaching diseases, as well as hereditary and environmental factors. The consequences of vitiligo can be mentally distressing and frequently have a significant impact on daily life thus, this should never be dismissed as an esthetic minor illness. The two main types of the condition recognized by a global consensus in 2011 were nonsegmental vitiligo (NSV) and segmental vitiligo (SV**).**

Turmeric is the rhizome or underground stem of ginger like plant. plant is an herbaceous perrineal, 60-90 cm high with a short stem tufted leaf. Its flowers are yellow, between 10-15 cm in length and they group together in dense spikes, which appear from the end of spring untill the middle session. No fruits are known for this plant. The whole turmeric rhizome, with a rough, segmented skin. The rhizome is yellowish-brown with a dull orange interior that looks bright yellow when powedered. Rhizome measures 2.5-
7.0 cm (in length), and 2.5 cm (in diameter) with small tuber branching off. Turmeric held with a some place of honour in an indian traditional ayurvedic medicine. In ayurvedic it was prescribed for the treatment of many medicinal problems ranging from constipation to skin diseases.

Anti-inflammatory : Oral administration of curcumin in instances of acute inflammation was found to be as effective as cortisone or phenylbutazone. Oral administration of curcuma longa significantly reduced inflammatory swelling. Curcuma longa's anti-inflammatory properties may be attributed to its ability to inhibit both biosynthesis of inflammatory prostaglandins from arachidonic acid, and neutrophil function during inflammatory states. Curcuminoids also inhibit LOX, COX phospholipases, leukotrienes, prostaglandins, thromboxane, nitric oxide elastase, hyaluronidase, collagenase, monocyt chemoattractant protein-1, interferon include protein TNF and interleukin-12. They also decrease prostaglandin formation and inhibit leukotriene biosynthesis via the lipoxygenase pathway. An RCT investigated the effect of a combination of 480mg curcumin and 20mg quercetin on delayed graft rejection in 43 kidney transplant patients of 39 participants who completed the study, to of 14 in the control group 71% of those in the low dose treatment group. Since the amount of quercetin in the compound was minimal, the majority of benefit is tought to be due to curcumin's

anti-inflammatory and antioxidant activity. Likely mechanisms for improved early function of transplanted kidneys include induction of the hemeoxygena enzyme, and proinflammatory cytokines, and scavenging of free radicals associated with tissue damage [7,8].

Antioxidant properties :water and fat-soluble extracts of turmeric and its curcumin component exhibit strong antioxidant activity, comparable to vitaminc C and

E. A study of ischemia demonstrated that curcumin pretreatment decreased ischemia induced changes in the heart. An in vitro study measuring the effect of curcumin on endothelial heme oxygenase-1, an inducible stress protein, was conducted medicinal and pharmacological properties of turmeric [9,10].The curcumin treated animals showed a decrease in microvessel density and cell proliferation and ana increase in apoptosis compared to controls. Incubation of endothelial cells from bovine aorta with curcumin showed induction of heme oxygenase expression. Heme oxygenase is an enzyme that reacts to oxidative stress, by producing the antioxidant biliverdin, and it enhances resistance to oxidative damage to cells [11,12]. Clinical research on curcumin's therapeutic benefit for pancreatitis is limited and has primarily focussed on its antioxidant properties. However, research indicates the inflammatory response plays a critical role in development of pancreatitis and subsequent tissue damage. For this reason, it seems likely an anti-inflammatory agent like curcumin, effective against a variety of inflammatory molecular targets and shown to decrease inflammatory markers in an animal model of pancreatitis. One plot study examine the effect of curcumin for tropical pancreatitis in patients. Treatment effect on pain patterns as well as erythrocyte malonylaldehyde and glutathione were assessed at base line and after six weeks. In the curcumin group there was a significantly reduction in MDA levels. Further research is neede to determine the role of lipid peroxidation in pain and other symptomology associated with pancreatitis.

Anticarcinogenic properties : Animal research demonstrates at all three stages of carcinogenesis-initation, promotion and progression .during initation and promotion,curcumin modulates transcription factors controlling phase one and two detoxification if carcinogens, down-regulates proinflammatory cytokines, free radical-activated transcription factors, and arachidonic acid metabolism vicyclooxygenase and lipoxygenease pathways, and scavenges free radicals. Studies involving rats and mice, as well as in vitro studies utilizing human cell lines, have demonstrated curcumin's medicinal and pharmacological The ability to inhibit carcinogenesis at three stages : tumor promotion, angiogenesis, and tumor growth. Turmeric and curcumin are also capable of suppressing the activity of several common mutagens and carcinogens in a variety of cell types in both in vitro and in vivo studies. The anticarcinogenic properties of turmeric and curcumin are due to direct antioxidant and free-radical scavenging properties, as well as their ability to indirectly increase glutathione levels, thereby aiding in hepatic detoxification of mutagens and carcinogens, and inhibiting nitrosamine and curcumin also induces apoptosis of cancer cells and it inhibits angiogenesis. The efficacy of curcumin or turmeric extracts in reducing chemically-induced tumours was studied. Application of both curcumin and turmeric extract during carcinogenesis and promotion resulted in less papilloma production, compared to controls. This indicates that both curcumin and turmeric extract produce their best properties during tumour production. The effect of dietary curcumin (0.2% and 1,0%) on, 7,12-dimethylbenz (a) anthracene (DMBA) and 12,0-tetradecanoylphorbol-13-acetate (TPA0)-promoted skin tumour formation was investigated by intrakule et al. They found a significant lower number of papillomas in the curcumin treated group compared to the control group. The enhanced expression of ras-p21 and fos-p62 oncogenes were decreased dose dependently in the curcumin treated group [14,15].

Antidiabetic properties : A hexane extract (containing ar-turmerone), ethanolic extract (containing ar-turmerone, curcumin, demethoxycurcumin and bisdemethoxycurcumin) and ethanolic extract from the residue of the hexane extraction were found to be dose-dependently stimulate adipocyte differentiation. The result indicate that turmeric ethanolic extract containing both curcuminoids and sesquiterpenoids is more strongly hypoglycemic than either curcuminoids or sesquiterpenoids. Wickenberg et al. 2010 studied the effects of turmeric on postprandial plasma glucose and insulin in healthy subjects, they found out that the ingestion of 6g curcuma longa had no significant effect on the glucose response. The change in insulin was significantly higher 30min and 60min after the OGTT including curcuma longa. The insulin AUCs were also significantly higher after the ingestion of curcuma longa after the OGG [16].

Antimicrobial properties : Turmeric extract and the essential oil of curcuma longa inhibit the growth of a variety of bacteria, parasites, and pathogenic fungi. A study of chicks infected with the caecal parasite Eimera maxima demonstrated that diets
supplemented with turmeric resulted in a reduction in small intestinal lesion scores and improved weight gain/ Another study, in which guinea pigs were infected with either dermatophytes, pathogenic molds, or yeast, found that topically applied turmeric oil inhibited dermatophytes and pathogenic fungi. Improvents in lesions were observed in the dermatophyte and fungi-infected guinea pigs, and at seven days post-turmeric applications the lesions disappeared. Curcumin has also been found to have moderate activity against Plasmodium falciparum and Leishmania major organisms. Khattak et al. studied the antifungal, antibacterial, phytotoxic, cytotoxic and insecticidal activity of an ethanolic extract of turmeric

Antidepressant properties : The effect of curcumin was investigated in chronic mild stress (CMS) model. In comparison with normal rats, rats suffering the CMS procedure have a significant lower intake of sucrose, increase IL-6, TNF-α levels, CRF- and cortisol levels. Treatment with ethanolic extract increased the sucrose intake to normal control levels, reduced the CMS-induced increase in serum IL-6 and TNF-α levels and reduce the CRF levels in serum and medulla oblongata to lower than normal. It is also lowered the cortisol levels in serum to normal levels. Turmeric has antidepressant properties mediated through inhibition of monoamine oxidize. Curcuma longa reserved the decrease in serotonin, noradrenalin and dopamine concentrations as well as the increase in serotonin turnover, cortisol level and in serum corticotrophin- releasing factor. **2.NEED OF THE STUDY.**

Turmeric is used alone (or)in combination with mustard oil to treat the vitiligo. It works by penetrating into the skin barrier and provides soothening action by formulating into emulgel. Turmeric contains curcumin as a major component (5-6.6%) and volatile oils less than 3.5%. in this present investigation it was proposed To formulate curcumin longa emulgel (oil/water) by using Carbopol & sodium alginate.

- To evaluate the binding characteristics of the formulation.
- To study the oil phase &water phase of emulgel.
- To study the gelling properties of curcumin longa emulgel.
- To evaluate the physico - chemical characteristics like drug interaction using FTIR.
- To evaluate the drug release studies.

3.RESEARCH METHODOLOGY

3.1 Extraction of Pectin:

Conventional methods for extraction of curcumin Solvent extraction of solid samples, which is commonly known as "solid-liquid extraction", (also referred to as "maceration" or "soaking"), is a well-understood and widely-used method. An extensive range of solvents including non-polar organic solvents and a combination of organic solvents and water has been used to extract curcumin from plants. Popuri & Pagala (2013) carried out a comparison of extraction solvents (acetone, ethyl acetone, ethanol, methanol, and isopropanol) for isolation of curcumin from Curcuma Longa L. It was found that extraction with ethanol gave the highest yield (0.26 mg/10 g) when the extraction was performed at 30°C for 1 h with a solid to solvent ratio of 1:8. Consistent with this, ethanol was the most preferred solvent for extraction of curcumin among all organic solvents employed.

3.2 Organoleptic Properties:

Turmeric has yellow colour with bitter taste and astringent smell with good solubility in water and mustard oil has good spreadibility with yellow color and strong pungent smell.

3.4 FTIR Analysis:

In Ftir the turmeric shows different wavelengths in Ftir a graph is obtained.In 3016 wavelength FTIR in turmeric phenyl groups are present. It has antioxidant, anti- inflammatory, anti-oxidant anti-bacterial, anti-fungal is present.In 2958 the turmeric alkyl groups are present. It shows hydrophobicity, influence on volatility, stabilization of compound is present.In 2925 wavelength alkyl groups are present. In this essential oils and turmerones. It has aromatic compounds interaction .In 1681 alkenes groups are present.it has anti-inflammatory, volatility, anti-oxidant and potential bioactivity.In 2000 alkenes groups are present. In this curcumin and essential oils is present. It shows anti- inflammatory, volatility, anti-oxidant, potential bioactivity is present.In 2500 hydroxy and methoxy groups are present. It contains essential oils and tumerones. It shows anti- oxidant, acid base behaviour, reactivity in ester formation, hydrophobicity is present[46].

3.5 Formulation of Emulgel:

Ingredients % W/W	F1	F2	F3	F4	F5
Drug	1g	1g	1g	1g	1g
Carbopol	2g	2g	-	-	-
Clove oil (or) mustard oil	5 ml	5 ml	-	5 ml	-
Tween 80	2 ml	2 ml	2 ml	2 ml	2 ml
Mentha oil	-	-	5 ml	-	5 ml
Sodium alginate	-	-	2g	2g	2g
Propylene glycol	1 ml	1 ml	1ml	1 ml	1ml
Benzoic acid	0.5 ml	0.5 ml	0.5 ml	0.5 ml	0.5 ml
H2o	Q.s	Q.s	Q.s	Q.s	Q.s

Table 1: Formula of Preparation of Emulgel using curcumin longa using Carbopol and mustard oil

3.6 PREPARATION OF EMULSION:

1)Preparation of aqueous phase

The aqueous phase of the emulsion was prepared by dissolving the tween 80 in the 10 ml purified water.

2)Preparation of oil phase

Take 1gm of turmeric powder and then add 5 ml of ethanol in a beaker. Now we take benzoic acid o.5g and then add 1 ml of propylene glycol in a beaker.

3)Preparation of gel

Take water bath and both the oil phase & aqueous phase are kept at water bath and heated at 75℃ and adding the oil phase to the aqueous phase.

4)Preparation of emulgel

Take Carbopol 2g and add 10 ml of water to form a gelling agent. Now take the aqueous phase in to china dish and Carbopol is added and cool the emulsion [42] .

3.7 Evaluation parameters of turmeric emulgel Physical appearance

The prepared emulgel is checked visually for their colour, homogeneity, consistency and the phase variation.

3.7.1PH Evaluation

PH evaluation is the important criteria especially for the topical formulation. The pH of emulgel should be between5.8-6 to mimic the skin condition. If the pH of the prepared emulgel is acidic or basic, it may cause irritation to the patient. pH of the prepared emulgel was measured using digital pH meter by dipping the glass electrode into an emulgel. The measurement of PH of each formulation was done in triplicate and average values were calculated **[42].**

3.7.2Spreadability Spreadability of emulgel is measured in terms of diameter of emulgel circle produced when emulgel is placed between two glass plates of definite weight. A weighed quantity of emulgel is taken on one glass plate and another glass plate is dropped from a distance of 5 cm. the diameter of the circle of spread emulgel is measured **[43] .**

It is calculated by using the formula: S=M.L/T

Where, S=spreadability

M=weight tied to upper slide. L=length of glass slide.

T=time taken to separate the slides completely.

3.7.3Rheological studies

Viscosity of emulgel is determined at 25℃ using a cone and plate viscometer with spindle 52 and connected to a thermostatically controlled circulating water bath **[44] .**

3.7.4Swelling index

It is determined by taking 1 g of emulgel in a porous aluminum foil and mixed with 0,1 N NaOH kept in a 50 ml beaker. Then sampels are withdrawn at different time intervals and kept for drying and it is reweighed. Swelling index is calculated as follows;

Swelling index = (Wt – Wo/Wo) Where,

(SW) % = Equilibrium percent swellingss

Wt = Weight of swollen emulgel after time 't' Wo = Weight of emulgel at zero time.

3.7.5Drug Content Determination

Emulgel is mixed in a suitable solvent. Filter it to obtain clear solution. Determine its absorbance using UV spectrophotometer. From the standard equation by putting the ansorbance value concentration and drug content can be obtained. Drug content = (concentration × Dilution factor × volume taken) × conversion factor[45].

3.7.6Bioadhesive strength measurement;

The modified was used for the measurement of bioadhesive strength. The apparatus consist of two arm balance, both the ends are tied to glass plkates using strings. One side contains single glass plate for keeping weight. The right and left oans were balanced by adding extra weight on the lef hand pan. The balance was kept in this position for 5 mints.

Accurately weighed 1 g of emulgel was placed between these two slides containing hair less fresh rat skin pieces, extra weight from the left pan was removed to sandwich the two pieces of glass and some pressure was applied to remove the presence of air. The balance was kept in the position for 5 min. Weight was added slowly at 200mg/min to the left hand pan until the two glass slides got detached from each others.

.7.7Microbiology assay

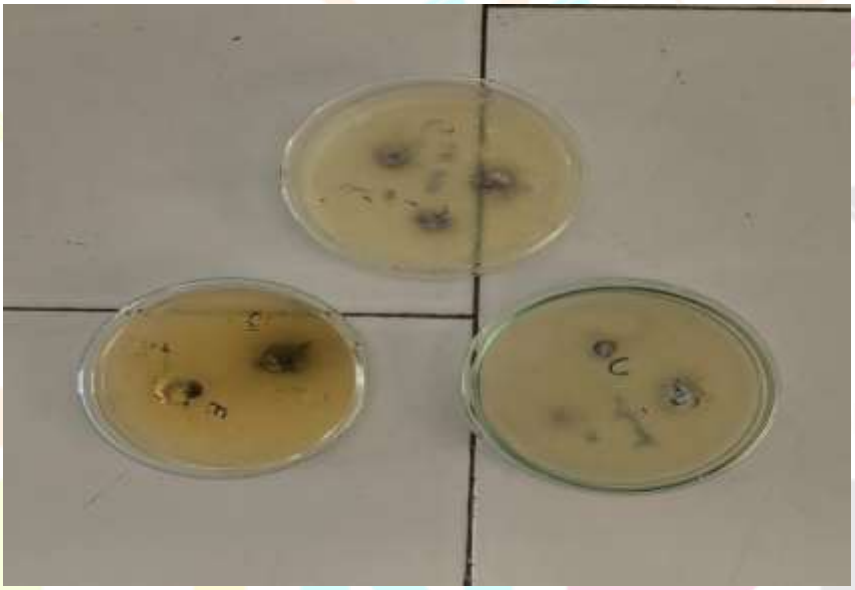


Fig.1.1 microbiology assay

Microbiological assay was performed by using ditch plate technique. Previously prepared Sabouraud's agar dried plates were used. 3 grams of the gelified emulsion are placed in a ditch cut in plate. After incubation for 18-24hrs at 25°C, the fungal growth was observed and the percentage inhibition was measures as follows % inhibition= L2/L1×100.

3.7.8In-vitro release studies:

The in vitro drug release studies were carried out by using a modified franz diffusion (FD) cell the formulation was applied on dialysis membrane which was placed between donor and receptor compartment of the FD cell. Phosphate buffer PH 7.4 was used as a donor and receptor compartment of the cell was maintained at 37°C by circulating water jacket. This whole assembly was kept on a magnetic stirrer and the solution was stirred continuously using a magnetic bead. A similar bank set was run simultaneously as a control. Sample (5ml) was withdrawn at suitable time intervals and replaced with equal amount of fresh dissolution media. Sampels were analysed spectrophotometrically at 318 nm and cumulative % drug release was calculated

4. RESULTS AND DISCUSSION

4.1 Standard graph of turmeric

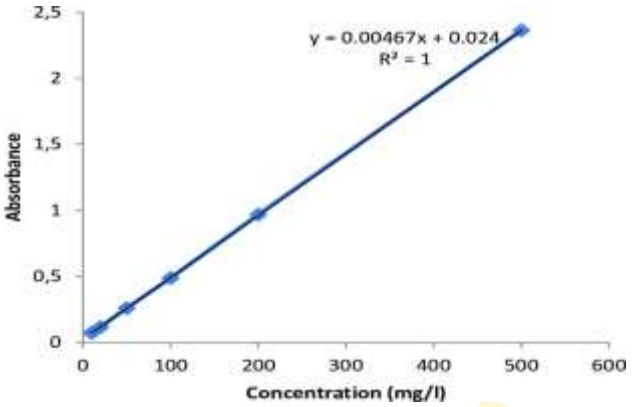


Fig.1.2 Standard graph of turmeric

4.2Physical Examination : The prepared turmeric emulgel formulations when subjected for colour appearance were transparent in carbapol 934, white viscous in HPMC K 100 and brownish gummy in sodium albinate, creamy preparation with a smooth homogenous texture and glossy appearance. Results have been discussed in table**.**

s.no	Formulation	Colour	Phase separation	Grittiness	Homogenicity	Consistency
1	F1	white	None	-	+++	+++
2	F2	white	None	-	+++	+++
3	F3	white	None	-	+++	+++
4	F4	Brownish white	None	-	+++	+++
5	F5	Brownish white	None	-	+++	+++
6	F6	Brownish white	None	-	+++	+++
7	F7	Creamy gummy	None	-	+++	+++
8	F8	Creamy gummy	None	-	+++	+++
9	F9	Creamy gummy	None	-	+++	+++

Table.2 physical examination

4.3Measurement of pH

The pH values of all the prepared formulation was ranging from 5.8-6.0, which is considered acceptable to avoid the risk of irritation upon application to the skin.

S.no	Formulation	PH
1	F1	5.1
2	F2	5.3
3	F3	5.5
4	F4	5.6
5	F5	5.7
6	F6	5.8
7	F7	5.9
8	F8	6.0
9	F9	6.0

Table 3 measurement of pH

4.4 Spreadability of pH

The values of spreadibility indicate that the emulgel is easily spreadable by small amount of shear. Spreadability of F3 was 6cm/sec, indicating spreadibility of emulgel containing turmeric was good as compound to marketed gel.

S.no	Formulation	Diameter
1	F1	4.2
2	F2	4.8
3	F3	5.7
4	F4	4.1
5	F5	4.0
6	F6	4.9
7	F7	4.4
8	F8	4.1
9	F9	4.7

Table.4 Spreadability coefficient

4.5Rheological studies

The viscosity of different emulgel formulations was determined at 250 using a brook field viscometer. The emulgels were rotated at 10[min] and 100 [max] rotations per minute with spindle.

4.6 Swelling index

Time (min)	F1	F2	F3	F4	F5	F6	F7	F8	F9

0	1	1	1	1	1	1	1	1	1
15	1.15	1.12	1.22	1.13	1.15	1.08	1.10	1.2	1.09
30	1.10	1.14	1.30	1.19	1.17	1.21	1.11	1.10	1.22
45	1.20	1.10	1.16	1.1	1.15	1.04	1.12	1.12	1.25
60	1.4	1.22	1.29	1.25	1.20	1.3	1.07	1.45	1.5
120	1.2	1.8	1.98	1.26	1.23	1.29	1.42	1.58	1.60

Table :5 Swelling index of emulgel

4.6 Skin irritation test:

(Before) **(After)**

Fig.1.3 skin irritation test

No allergic symptoms like inflammation, redness, irritation appeared on Skin after application**.**

4.7 Microbilogical Assay;

The antiprotozoal activity of turmeric in different emulgels formulations was passed in which the percentage inhibition was taken as a measure of drug anti protozoal. Thus the highest activity was observed with F3 where percentage inhibition found to be 48.48 when compared to other formulations**.**

4.8 In Vitro Drug Release

The cumulative % drug release profile of the formulation batches. The release profile increases with increase in the concentration of emulsifier. From the emulgel formulations Carbopol 934 showed high amount of drug release i.e (92%) in 6 hrs. In vitro cumulative % drug release data of formulations**.**

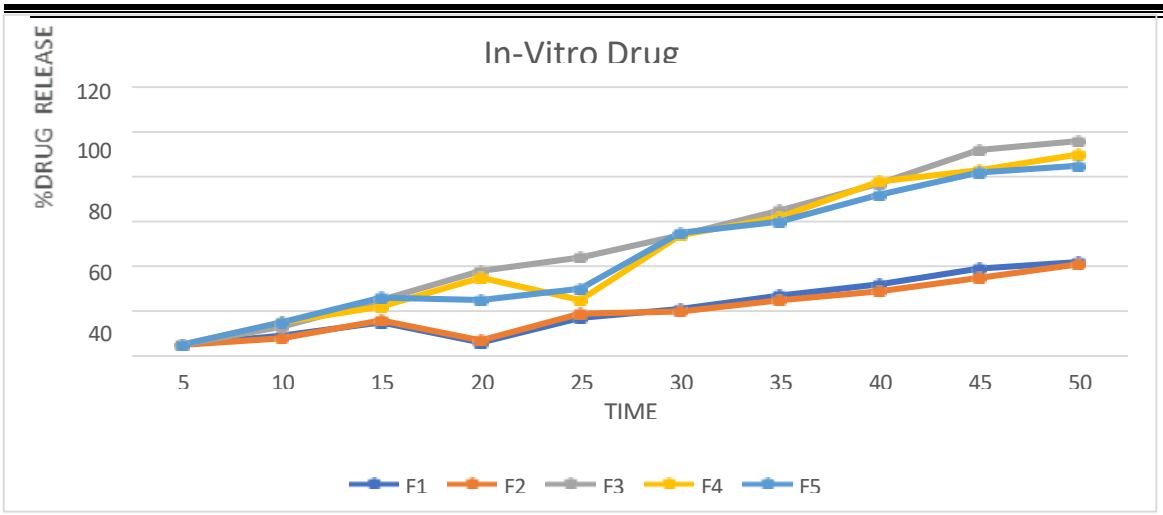
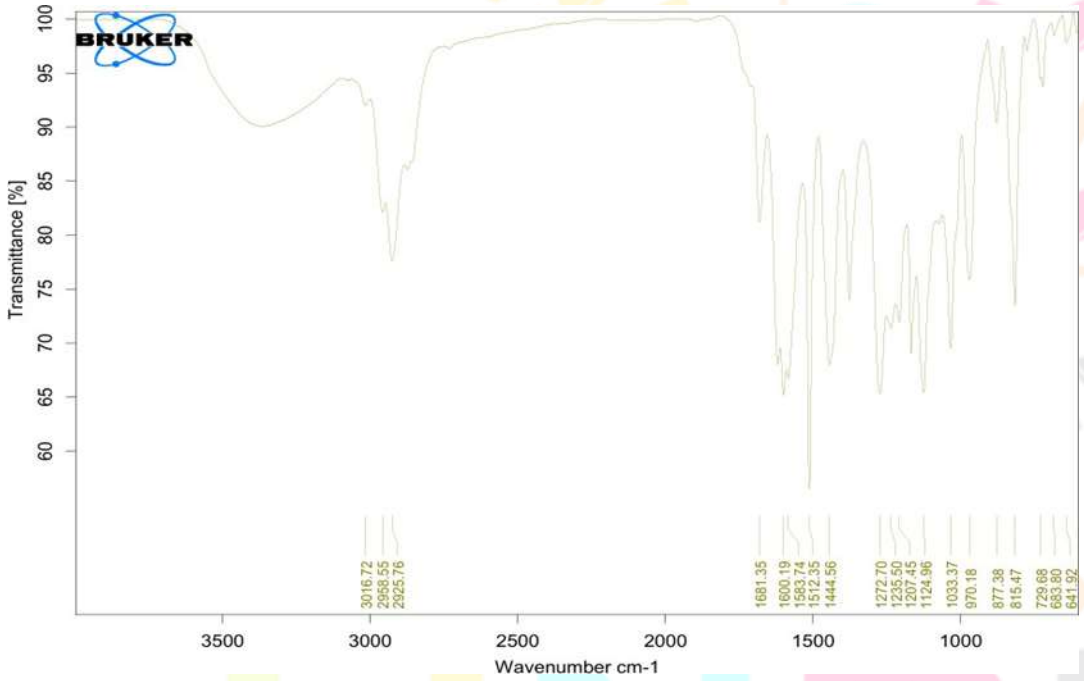


Fig.1.4 In-Vitro Drug Release

4.9 FTIR ANALYSIS:



Conclusion:

The evaluation and formulation of Curcuma longa (curcumin) emulgel for vitiligo treatment demonstrated promising potential as a novel topical therapy. The formulation successfully combined the advantage of both emulsions and gels, providing enhanced skin penetration, prolonged drug retention, and improved stability.Physicochemical evaluations, including pH, viscosity, spreadability, and drug content, confirmed the formulation's suitability for topical application. In vitro studies suggested that curcumin, with it's antioxidant, anti-inflammatory properties could contribute to repigmentation in vitiligo-affected areas. The emulgel formulation enhanced the bioavailability and permeability of curcumin, making it a more effective and therapeutic.

Curcuma emulgel as a promising alternative treatment for vitiligo.

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