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Research Article

Formulation and Evaluation of Herbal Tablets Containing Ficus religiosa Leaf Extract for the Management of Polycystic Ovary Syndrome (PCOS)

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ABSTRACT

Polycystic Ovary Syndrome (PCOS) is a multifactorial endocrine disorder affecting women of reproductive age and is characterized by hormonal imbalance, insulin resistance, and the presence of multiple ovarian cysts. The present study was undertaken to formulate and evaluate herbal tablets containing Ficus religiosa leaf extract for the management of PCOS. Fresh leaves of Ficus religiosa were collected, authenticated, and extracted using a suitable extraction method. The obtained extract was subjected to preliminary phytochemical screening, which confirmed the presence of alkaloids, phenolic compounds, flavonoids, tannins, and steroids. The in-vitro anti-PCOS potential of the extract was evaluated using the KGN cell line, where it exhibited significant activity with an IC_{50} value of 59.53 µg/mL. Herbal tablets (F1–F4) were formulated using appropriate pharmaceutical excipients and evaluated for various physicochemical parameters, including hardness, friability, weight variation, thickness, and disintegration time. Among the formulated batches, formulation F3 demonstrated the most satisfactory performance, with a disintegration time of 10.2 minutes while meeting all prescribed quality evaluation criteria. The findings of this study suggest that Ficus religiosa leaf extract possesses promising therapeutic potential and can be developed into a standardized herbal tablet as a safe and effective alternative for the management of PCOS.

INTRODUCTION

Herbal Tablet

A herbal system is a holistic medical approach in which herbs are used in various forms such as powders, decoctions, tablets, and oils to maintain health and treat illnesses. Herbal tablets are pharmaceutical preparations made from natural plant materials or their extracts. They are commonly used in traditional healthcare systems

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like Ayurveda for maintaining health and treating various conditions. [1-3]

PCOS (Polycystic Ovary Syndrome)

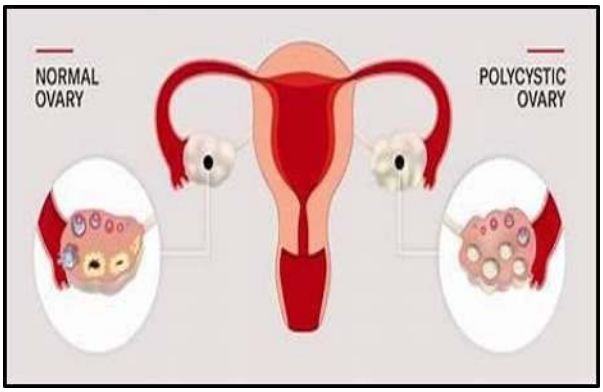
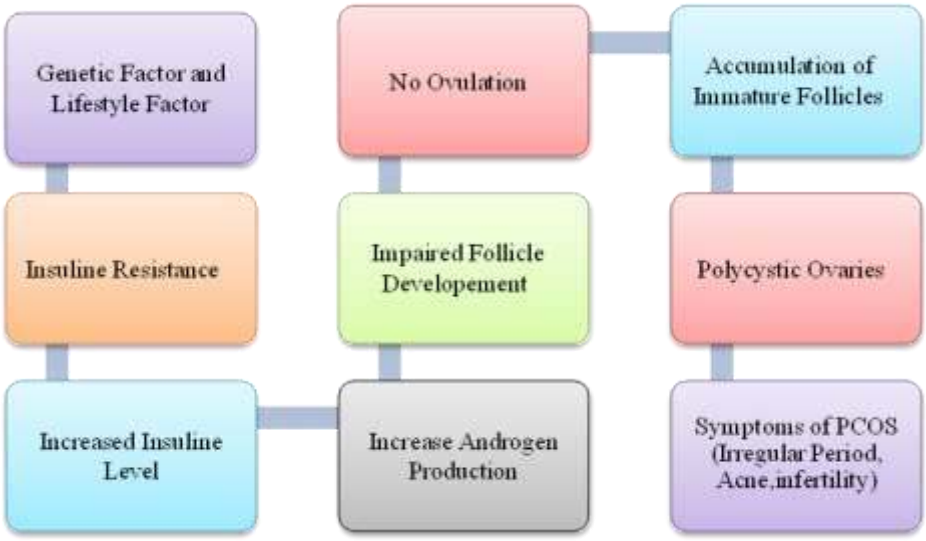


Fig No.01: PCOS Disorder

Polycystic Ovary Syndrome (PCOS) is a common endocrine disorder that affects women of reproductive age. It is characterized by hormonal imbalance, irregular menstrual cycles, and the presence of multiple small cysts in the ovaries. PCOS is one of the leading causes of infertility in women. In this condition, the normal functioning of the ovaries is disrupted due to increased levels of male hormones (androgens) and abnormal insulin activity. This leads to irregular or absent ovulation, resulting in menstrual irregularities and difficulty in conceiving. PCOS is a complex disorder influenced by genetic, hormonal, metabolic, and environmental factors. It is also associated with other health problems such as obesity, acne, excessive hair growth, insulin resistance, and increased risk of diabetes and cardiovascular diseases. Early diagnosis and proper management through lifestyle changes, diet control, and medication can help in controlling symptoms and improving quality of life. [4-5]

Mechanism of PCOS



Plant Profile

Fig No.02: Ficus Religiosa

Ficus religiosa or sacred fig is a species of fig native to the Indian Subcontinent and Indochina that belongs to Moraceae, the fig or mulberry family. It is also known as the bodhi tree, peepul tree, peepal tree, pipala tree or ashvattha tree (in India and Nepal) [6-7]. The sacred fig is considered to have a religious significance in four major religions that originated on the Indian subcontinent: Hinduism, Buddhism, Sikhism and

Jainism. Hindu and Jain ascetics consider the species to be sacred and often meditate under it. Gautama Buddha is believed to have attained enlightenment under a tree of this species. The sacred fig is the state tree of the Indian states of Odisha, Bihar and Haryana [8-10].

Traditional Uses and Ethno Medicinal Significance

In traditional systems of medicine such as Ayurveda, different parts of Ficus religiosa including leaves, bark, fruits, and roots are extensively used for the treatment of various ailments. It possesses several pharmacological properties such as antidiabetic, anti-inflammatory, antioxidant, antimicrobial, and wound healing activities. Apart from its medicinal importance, Ficus religiosa holds great cultural and spiritual value [11-12]. It is revered as the Bodhi tree under which Lord Buddha attained enlightenment, making it a symbol of knowledge and spirituality [13-14]. Due to its wide range of therapeutic uses and bioactive constituents, Ficus religiosa has attracted significant attention in modern research for the development of herbal formulations and pharmaceutical applications [11].

Table No.01: Drug Profile

Scientific name	Ficus religiosa
Synonyms	Sacred fig, Bodhi tree, Peepul tree, Pipal tree
Biological source	Ficus religiosa Linn. commonly known as Peepal or Sacred Fig, is a large perennial tree belonging to the family Moraceae (mulberry family).
Family	Moraceae
Taxonomical classification	Kingdom: Plantae Sub kingdom: Viridiplantae Division: Angiosperms Class: Magnoliopsida Order: Rosales Family: Moraceae Genus: Ficus (Fig genus) Species: Ficus religiosa L. (Sacred fig)
Phytochemical constituents	Ficus religiosa contains phenols, flavonoids (quercetin), Amino acids (Alanine), tannins and phenolic compound, alongside bioactive steroids like stigmasterol and triterpnoids like lupeol. Its fruits and bark are further enriched with serotonin, vitamin K, and essential minerals that support its various medicinal properties.

LITERATURE REVIEW

Murugesu et al. (2021) In 2021, Murugesu et al. reviewed phytochemistry and applications of Ficus religiosa and highlighted its suitability for modern dosage forms, including tablets. The study emphasized its antioxidant and metabolic regulatory properties, which are beneficial for formulation into standardized herbal products.

Maheshwari et al. (2023) In 2023, Maheshwari et al. conducted a systematic review focusing on phytochemistry and pharmacology of Ficus religiosa. The study highlighted the need for converting plant extracts into stable dosage forms like tablets for improved patient compliance and dose accuracy.

Rawat et al. (2024) A recent 2024 review by Rawat et al. provided updated insights into phytochemical constituents and pharmacological activities of Ficus religiosa. The authors stressed the importance of standardization and evaluation of herbal formulations, including tablets, to ensure consistent therapeutic efficacy.

Phytochemistry Letters Review (2026) A 2026 comprehensive review summarized recent advances in phytochemistry and therapeutic applications of Ficus religiosa. It emphasized that plant-based compounds can be developed into pharmaceutical formulations with proper extraction, granulation, and evaluation techniques.

General Herbal Tablet Formulation Studies (Various Authors, 2015–2022) Multiple pharmaceutical studies (2015–2022) on herbal tablet formulation techniques describe standard procedures such as wet granulation, direct compression, and evaluation parameters (hardness, friability, disintegration time). These methods are applicable to Ficus religiosa extracts for developing effective tablet formulations.

MATERIAL AND METHODOLOGY

Materials

Table No. 02: List of Chemicals used and their uses in formulation.

Sr. No.	Chemicals	Use in Formulation
1	Microcrystalline Cellulose	Diluent
2	PVP	Binder
3	Sodium Starch Glycolate	Disintegrating Agent
4	Magnesium Stearate	Lubricant
5	Talc	Glindant

Equipment: Soxhlet apparatus, Electronic balance, Heating mental, pH Meter, Hot Air Oven, Tablet Compression Machine, Hardness tester, Disintegration apparatus, Friability Tester, FT-IR

EXPERIMENTAL METHODS

Extraction and Drying of herb

Fig No. 03: Ficus Religiosa leaves powder.

Pre-formulation study of Hydro alcoholic Extract

Study of organoleptic characters

Color of extract were observed by naked eyes. Odor of extract were felled by smelling. Taste and texture were observed by touching and tasting. All tests were carried out visually.

Solubility of extract

To check out solubility Buchanania lanzen Spreng leaf extract in different solvents and find out

solubility range, here 10 mg of extract was added in 10ml variety of solvents such as Methanol, Ethanol, Acetone, Chloroform and Water and solubility was observed.

Phytochemical screening of extract

A scientific process known as phytochemical screening uses analysis, inspection, extraction, and experimentation to identify different kinds of phytoconstituents that are present in different portions. It helps in the discovery of novel drugs. By using phytochemical screening, the presence of phytoconstituents such as alkaloids, flavonoids, glycosides, phenols, saponins and tannins was verified.

Table No.03: Phytochemical screening

Sr. No.	Test	Observation	Inference
1	**Fehling's Test**	Brick Red	Carbohydrate Present
2	**Salkowshi Reaction**	Choloroform layer appears red and acid layer show greenish yellow fluorescence	Steroid Present
3	**Foam Test**	Formation of stable persistent foam (froth) for a few minutes	Saponins present
4	**Shinoda Test**	Formation of orange color	Flavonoids Present
5	**Dragendorff's Test**	Formation of reddish-brown precipitate	Alkaloids present

Experimental Design:

Tablet formulations were developed using a factorial design approach. The design matrix was generated and analyzed using Design Expert DX 13.0 (Stat-Ease Inc., MN, USA).

Two formulation variables were considered as independent factors: Polyvinylpyrrolidone (X_1) and Sodium Starch Glycolate (X_2). The prepared batches were evaluated for critical quality attributes, namely hardness and disintegration time, which were selected as dependent variables.

Table No .04: Design layout of 22 factorial design.

Formulation Batches	X1	X2
F1	15	30
F2	15	10
F3	35	10
F4	35	30

Formulation of Tablet

Table No. 05: Composition of 22 factorial batches of Tablets.

Sr No.	Ingredients	F1	F2	F3	F4
1	Extract	200	200	200	200
2	Microcrystalline Cellulose	248	270	248	230
3	PVP	30	15	35	35
4	Sodium Starch Glycolate	30	10	10	30
5	Magnesium Stearate	4	3	3	2
6	Talc	3	2	4	3

Process of Formulation of Tablet

- Ingredients were accurately weighed and sieved through sieve no. 40 to ensure uniform particle size
- The sieved formulation ingredients were uniformly blended using a mortar and pestle
- The binder solution was prepared by dissolving Polyvinylpyrrolidon e (PVP) in a hydroalcoholic medium to obtain a 5% w/v solution, followed by gentle heating for 10–15 minutes to ensure complete dissolution.
- Granulation was carried out by gradual addition of binder solution to the powder

blend with continuous mixing until a uniform damp mass was formed.

- Screening of Damp mass was performed using sieve no. 22 to obtain wet granules of uniform size.
- Drying of the wet granules was carried out in a hot air oven at 40°C for 20 minutes to obtain dry granules with suitable moisture content.
- The dried granules were subjected to sizing through sieve no. 44 to obtain granules with uniform particle size.
- Compression of the lubricated granules was carried out using a tablet compression machine to obtain tablets with an average weight of 500 mg.

Evaluation of tablets

General appearance

The general appearance and color of tablets were found by visual determination.

Weight variation test

The weight variation test was carried out to assess the uniformity of tablet weights. A total of 20 tablets were randomly selected and individually weighed using a calibrated analytical balance, and their respective weights were recorded. The average tablet weight was calculated by summing the individual weights and dividing by the total number of tablets. Each tablet weight was then compared with the calculated mean to determine the percentage deviation. The results were evaluated in accordance with pharmacopoeial specifications, which state that not more than two tablets may deviate from the average weight by more than the prescribed percentage limit, and no individual tablet should deviate by more than twice that limit.

Hardness and Thickness

The mechanical strength and dimensional uniformity of the tablets were evaluated by determining hardness and thickness. For each formulation, 20 tablets were randomly selected. Tablet hardness was measured using a Monsanto hardness tester, while thickness was determined using a Vernier caliper.

Friability Test

Friability was assessed to evaluate the resistance of tablets to mechanical stress during handling and transportation. The test was performed using a Roche friabilator. A pre-weighed sample of tablets was placed in the friabilator, which was operated at 25 rpm for 100 revolutions, allowing the tablets to fall from a height of approximately 6 inches during each rotation. After completion of the test, the tablets were dedusted and reweighed. The percentage friability was calculated, and a weight loss of less than 1% was considered acceptable for compressed tablets.

Disintegration Time

The disintegration test was conducted to determine the time required for tablets to break down into smaller particles under specified experimental conditions. The test provides an indication of the rate at which the tablet disintegrates, which is a critical parameter influencing drug release. The study was performed using a standard disintegration test apparatus, and the time required for complete disintegration of the tablets was recorded.

In-Vitro Anti-PCOS Activity:

1. KGN Cells were incubated at a concentration of 1 × 104 cells/mL in culture medium for 24 h at 37°C and 5% CO2.

2. Cells were seeded at a concentration (100 µL) 104 cells/well) in 100 µL culture medium and 20, 40, 60, 80, 100 µg/mL of samples into micro plates respectively (tissue culture grade, and 96 wells).

3. Control wells were incubated with DMSO (0.2% in PBS) and cell line. All samples were incubated in triplicate. Controls were maintained to determine the control cell survival and the percentage of live cells after culture.

4. Cell cultures were incubated for 24 h at 37°C and 5% CO2 in CO2 incubator.

5. After incubation, the medium was completely removed and added 20 µL of MTT reagent (5 mg/mL PBS).

6. After addition of MTT, cells incubated for 4 h. at 37oC in CO2 incubator.

7. Observed the wells for formazan crystal formation under microscope. The yellowish MTT was reduced to dark colored formazan by viable cells only.

8. After removing the medium completely. Added 200 µL of DMSO (kept for 10 min) and incubate at 370C (wrapped with aluminum foil).

9. Triplicate samples were analyzed by measuring the absorbance of each sample by a micro plate reader at a wavelength of 550 nm.

RESULT AND DISCUSSION

Pre formulation study:

Plant Authentication:

Authentication of herb was done from Shivraj College of Science, Gadhinglaj Affiliated to Shivaji University, Kolhapur by Dr. Vinayak A. Sardesai.

Organoleptic Characters:

Table No. 06: Physical properties of extract

Sr. No	Physical properties and tests	Methods	Description of drug extract
1	Physical state	Visual observation	solid
2	Colour	Visual observation	dark green
3	Odour	By smelling	characteristic

Solubility:

Table. No. 07: Solubility of extract in different solvent

Sr. No.	Solvents	Solubility of extract
1	Water	Slightly soluble
2	Ethanol	Highly soluble
3	Methanol	Highly soluble
4	Chloroform	Slightly soluble
5	Petroleum ether	Insoluble
6	Acetone	Moderately soluble

Phytochemical Screening

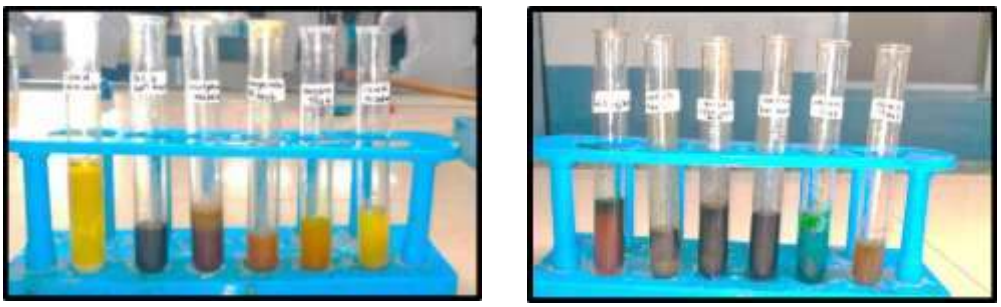


Fig.no.04: Phytochemical screening

Table No.08: Phytochemical screening results

Sr. No.	Test	Observation	Inference
1	Fehling's Test	Brick Red	Carbohydrate Present
2	Salkowshi Reaction	Choloroform layer appears red and acid layer show greenish yellow fluorescence	Steroid Present
3	Foam Test	Formation of stable persistent foam (froth) for a few minutes	Saponins present
4	Shinoda Test	Formation of orange color	Flavonoids Present
5	Dragendorff's Test	Formation of reddish-brown precipitate	Alkaloids present
6	Ferric chloride Test	Deep Blue Colour Produce	Phenolic Compound Present

Evaluation Test **Physical appearance**

Fig. No.5: Physical appearance of Tablet

Table No.09: Physical Appearance of Tablet

Formulation	Colour	Shape	Appearance
F1	Greenish	Biconvex Circular (round)	Opaque
F2	Greenish	Biconvex Circular (round)	Opaque
F3	Greenish	Biconvex Circular (round)	Opaque
F4	Greenish	Biconvex Circular (round)	Opaque

Pre Compression evaluation of granules

Table No.10: Pre-Compression Evaluation of Granules

Batches	Bulk Density	Tapped Density	Hausners Ratio	Cars Index	Angle of Repose
F1	0.47	0.56	1.19	16.07	29.8
F2	0.49	0.55	1.12	10.91	27.4
F3	0.46	0.55	1.20	16.36	30.6
F4	0.48	0.58	1.21	17.24	31.8

Evaluation of Tablet formulation

Weight variation test

Table No.11: Weight variation test of Tablet

Batches	Mean Weight	Sandard Deviation (mg)	Acceptable range (mg)	Result
F1	500.8	3.6	475 - 525	Pass
F2	499.6	2.9	475 – 525	Pass
F3	501.4	4.1	475 – 525	Pass
F4	500.2	3.8	475 – 525	Pass

Hardness:

Table No.12: Hardness test of Tablet

Batches	Hardness (kg/cm²)	Result
F1	2.5	Poor
F2	2.7	Poor
F3	6.0	good
F4	5.4	fair

Friability:

Table No.13: Friability of Tablet

Batches	Initial Weight	Final Weight	Friability (%)	Result
F1	12 gm	11.90	0.83%	Good
F2	12 gm	11.92	0.67%	Good
F3	12 gm	11.91	0.75%	Good
F4	12 gm	11.88	1.00%	Borderline/ Acceptable

Disintegration time:

Table No.14: Disintegration Time of Tablet

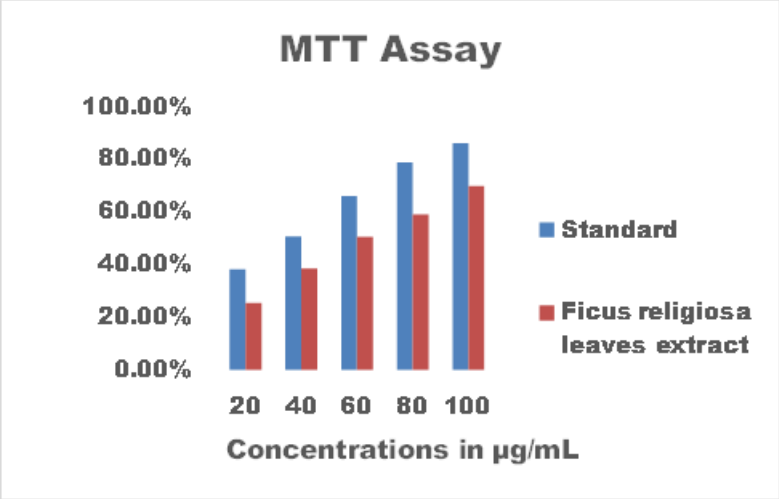
Batches	Disintegration Time (min)	Result
F1	9.8 min	Good
F2	7.5 min	Very good
F3	10.2 min	Good
F4	15min	Acceptable

In-Vitro Anti-PCOS Activity

Table No.15: Disintegration Time of Tablet

Sr No	Sample Code	Concentrations (µg/mL)	OD at 550 nm	Mean	% of Inhibition	% of Viability	IC50 (µg/mL)
1	Control		1.482	-	-	-	-

2	Standard (5,Flurouracil)	20	0.916	0.915	0.916	0.915	38.25%	61.75%	39.33
		40	0.732	0.729	0.734	0.731	50.67%	49.33%	
		60	0.507	0.504	0.502	0.504	65.99%	34.01%	
		80	0.315	0.312	0.314	0.313	78.87%	21.13%	
		100	0.208	0.205	0.207	0.206	86.09%	13.91%	
3	*Ficus religiosa* leaves extract	20	1.106	1.108	1.109	1.107	25.30%	74.7%	59.53
		40	0.912	0.915	0.914	0.913	38.39%	61.61%	
		60	0.732	0.734	0.736	0.734	50.47%	49.53%	
		80	0.608	0.609	0.605	0.607	59.04%	40.96%	
		100	0.446	0.448	0.449	0.447	69.83%	30.17%	



Graph No..1: MTT Assay % of Inhibition

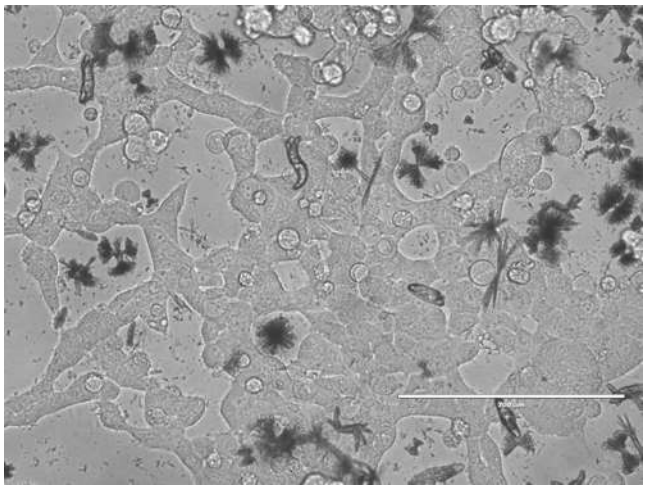


Fig. No.06: Control Group of MTT Assay

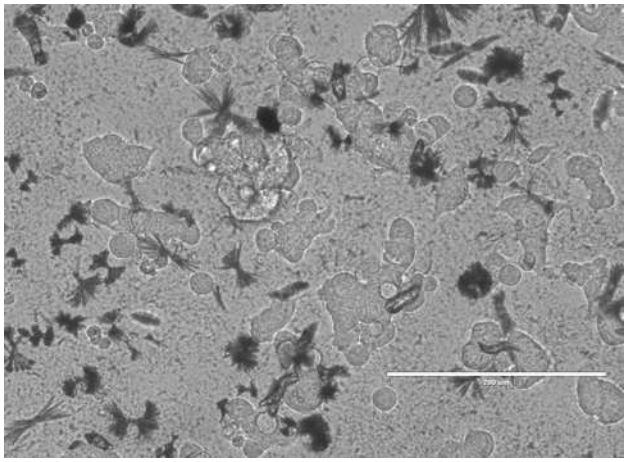


Fig. No. 07: Extract of MTT Assay

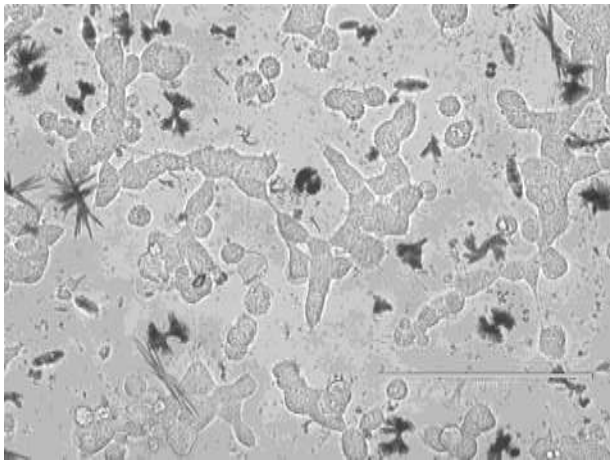


Fig No. 08: Standard of MTT Assay

CONCLUSION

The present study successfully formulated and evaluated herbal tablets of Ficus religiosa leaves for PCOS management. Phytochemical screening confirmed presence of phenolics, flavonoids, alkaloids, and steroids which contribute to antioxidant and hormone-regulating activity. The MTT assay on KGN cell line showed that Ficus religiosa leaf extract possesses significant anti-PCOS activity with IC50 of 59.53 µg/mL compared to standard 5-Fluorouracil. Among the four formulations, batch F3 exhibited very good disintegration time of 10.2 min and acceptable physical parameters and also pass the Pre formulation studies as well as all post compression evaluation tests . The tablets were greenish, biconvex, circular, and opaque in appearance. Hence, Ficus religiosa leaf extract can be effectively formulated into a stable, patient-compliant herbal tablet dosage form. Further in-vivo and clinical studies are warranted to establish its therapeutic efficacy in PCOS. The study supports traditional use of Ficus religiosa in reproductive disorders and provides scientific basis for herbal formulation development.

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