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PARKINSON'S SUPPORT SIMPLIFIED: DESIGN AND OPTIMIZATION OF ORAL THIN FILM WITH TURMERIC EXTRACT

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ABSTRACT

The current research targeted the development of oral thin film of curcumin. Parkinson's disease (PD) is the second-most prevalent neurodegenerative condition that affects 2-3% of individuals > 65 years. Oral thin film has been termed as an alternative route to traditional dosage form. They are a platform that offer rapid, local or systemic action. The key objective of this is to allow for rapid onset of action, enhanced bioavailability and to make administration more convenient to the patient. Curcumin is a polyphenolic extract from the rhizomes of *Curcuma longa* (turmeric). It has been shown to exhibit strong anti-inflammatory, antioxidant, mitochondrial protective effects and is thought to be a potential therapeutic and nutraceutical agent in treating PD. The dissolution rate can be enhanced by HPMC as a polymer and glycerine as a plasticizer through solvent casting technique. Ashwagandha is incorporated in formulation possess neuroprotective property and utilized in the treatment of PD. The film was tested for their physiochemical parameter such as disintegration time, surface pH, thickness, weight, percent moisture absorption, folding endurance, drug content and stability testing. Curcumin has low bioavailability but formulation with piperine (black pepper) is employed to facilitate absorption. Curcumin possesses neuroprotective property and has the ability to cross the blood brain barrier, hence it aids in the treatment of Parkinson disease.

Keywords: Curcumin, Parkinson's disease, Neuroprotection, Oral thin film

INTRODUCTION

Parkinson's disease (PD) is the second most prevalent neurodegenerative disorder, surpassed only by Alzheimer's, affecting approximately 1% of the population by age 65 and 4-5% by age 85. Oral thin film has been defined as a novel approach to traditional dosage form. They are a versatile platform that deliver rapid, local or systemic effect. The primary objective of this is to ensure rapid onset of action, enhanced bioavailability and to enhance the patient convenience of administration. Curcumin is a polyphenolic compound derived from the rhizomes of *Curcuma longa* (turmeric). It has been shown to possess strong anti-inflammatory, antioxidant, mitochondrial protective and is a potential therapeutic and nutraceutical agent for the management of PD. The dissolution rate can be enhanced by HPMC as a polymer and glycerine as a plasticizer by solvent casting technique. Ashwagandha is incorporated in formulation possess neuroprotective property and employed in the treatment of PD. The film was assessed for their physiochemical parameter such as disintegration time, surface pH, thickness, weight, percent moisture absorption, folding endurance, drug content and stability testing. Curcumin is poorly absorbed but formulation with piperine (black pepper extract) is utilized to increase absorption. Curcumin possesses the neuroprotective property and can traverse the blood brain barrier, thereby aiding in the treatment of Parkinson disease **[1, 3]**.

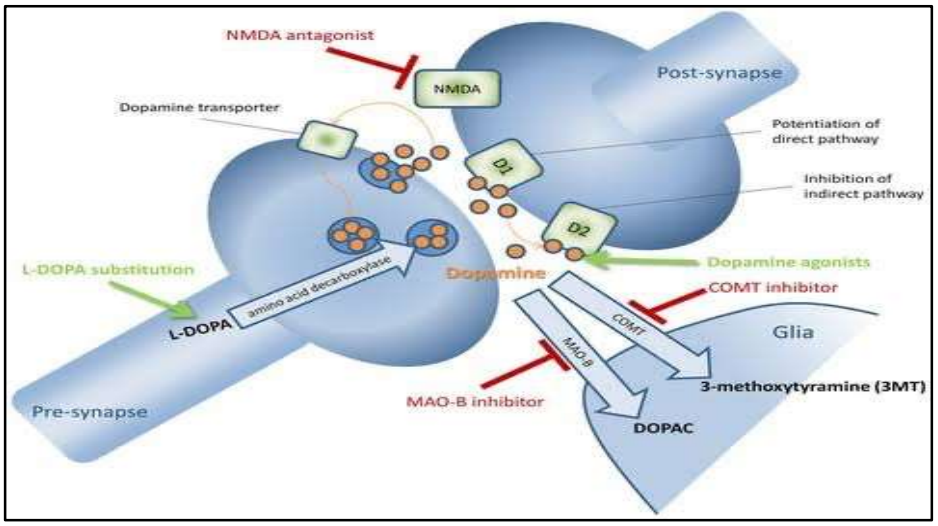

Figure 1: MOA of Parkinson's Disease

Parkinson's disease (PD) is a complex neurodegenerative disorder that is characterized by the progressive loss of dopamine-producing neurons in the

substantia nigra pars compacta. Major pathophysiologic characteristics are dopamine depletion, neuroinflammation, oxidative stress, protein misfolding, and mitochondrial dysfunction. At the molecular level, PD is characterized by impaired dopamine receptor function, decreased neurotrophic factors, and glial cell activation. Dopamine neuron apoptosis is responsible for disease progression, whereas neurotransmitter imbalance impacts motor control, cognitive function, and emotional regulation. Therapeutic approaches aim at dopamine replacement, inhibition of monoamine oxidase B, inhibition of catechol-O-methyltransferase, glutamate antagonism, and neuroprotection by antioxidants and anti-inflammatory drugs **[2, 6]**.

There is always a growing need for convenience to the patient. All the different routes, the oral route is the most common route for the delivery of therapeutic agents due to the low cost of treatment and ease of administration resulting in high rates of patient compliance. Mostly geriatric, paediatric and bedridden patient along with travelling patients who might not have immediate access to water face challenges in swallowing the standard oral dosage form. Solid preparations are unwilling to take among most paediatric and geriatric patients as they fear choking. With even fast dissolving tablets there is choking fear due to its tablet form appearance. To counter this issue a new formulation i.e. oral fast dissolving films which is extremely thin oral strip, which is merely placed on the patient's tongue or any oral mucosal tissue (buccal/sublingual), immediately wet by saliva, and then film quickly hydrates and sticks onto the application site. It then quickly disintegrates and dissolves to deliver the drug in mucosal cavity. This rapid dissolving behaviour is largely attributed to the extensive surface area of the film, which wets rapidly upon encountering the aqueous oral surroundings. Buccal films present an attractive mode for systemic delivery of drugs. The enhanced systemic bioavailability is due to circumventing the first pass effect and enhanced permeability from optimal vascular and lymphatic drainage. Also huge surface area of absorption, simple ingestion & pain prevention make oral mucosa an extremely promising and viable location for systemic drug delivery **[4, 7, 8]**.

Dissolving films are rapidly gaining popularity in the field of pharmacy due to their own characteristic properties and definite benefits such as no requirement of water for disintegration, precise dosing, quick action onset, convenient transportability, convenient handling, pleasant mouth feel and better patient compliance. They have the ability to administer the drug systemically by

intragastric, sublingual or buccal route of administration and have been employed for local action too **[9, 10]**.

Curcumin is a natural lipophilic polyphenolic compound extracted from *Curcuma longa* rhizomes. It is utilized as a spice for food preparation of India, Iran, Malesia, China, Polynesia, and Thailand. Curcumin is employed as a potent therapeutic reagent in Chinese and traditional Indian medicinal systems for the prevention and treatment of various diseases like rheumatoid arthritis, ocular disorders, osteoporosis, diabetes, hypertension, chronic kidney disorders, and chronic infections. It possesses a half-life value of approximately 8 hours in human plasma. Curcumin is able to cross blood-brain barrier and exerts neuroprotective actions due to its antioxidant, anti-inflammatory, and antiapoptotic effects in neurological disorders **[5]**. The aim of this is to summarize the therapeutic potential and molecular mechanism of action of curcumin and Parkinson's disease. Some studies also reveal that to enhance the bioavailability of curcumin must be paired with bioavailability enhancers like piperine **[11, 12]**.

Withania somnifera , otherwise referred to as "Indian Ginseng" or "Indian Winter cherry" (family Solanaceae), is a very sought-after native Ayurvedic medicinal plant. The therapeutic uses are varied, dealing with different types of health problems like stress, anxiety, arthritis, and CNS disorders, among them Parkinson's and Alzheimer's diseases. *Withania somnifera* herbal plant extracts have been used long ago by Ayurvedic medicine to cure Parkinson's disease, as reported by clinical models. Research has also examined the therapeutic uses of other parts of the plant, such as the entire plant, roots, stem, leaves, seeds, and fruits. Steroidal lactones, alkaloids, and other bioactive molecules are present in the roots of Ashwagandha. Its phytoconstituents have been studied, and a justification for drug formulation with improved pharmacological activities is suggested **[13, 14]**.

Phyto-pharmacological evaluations have established the potential of Ashwagandha as Anti-inflammatory, Anti-oxidant, Anti-cancer- Anti-microbial, Anti-malarial, Diuretic, Sedative, Immunomodulatory, Cardioprotective This article seeks to uncover the potential role of Ashwagandha in neurological conditions, summarizing data on its extracts, purified compounds. Medicinal herbs are increasingly being studied for their utilization in treating human diseases, as they hold promises of efficacy along with fewer side effects. Therapeutic potentials of Ashwagandha in Parkinson's disease treatment **[15, 16]**.

Table 1: Drug profile of *curcuma longa*

NAME	DESCRIPTION
Physical Description	Bright yellow-orange powder (turmeric root)
Molecular formula	C21H20O16
Molecular weight	368.38 g/mol
Category	Natural product / Spice / Dietary supplement
Density	0.65 g/cm^3
Solubility	Dimethyl sulfoxide (DMSO), ethanol and oils; very poorly soluble in water
Melting point	183-186 ºC
R_f value	0.9
Odour	Earthy, slightly peppery aroma
Half life	Minutes to hours
BCS class	Class II (low solubility, high permeability)
Log P	3.0 to 3.5 (indicative of its lipophilicity)

Table 2: Drug profile of *Withania somnifera* (L.)

NAME	DESCRIPTION
Physical Description	Brown to dark brown powder
Molecular formula	C28H38O6
Molecular weight	470.60 g/mol
Category	Steroidal lactones
Density	0.30 to 0.70 g/cm^3
Solubility	Soluble in organic solvents like ethanol & methanol, poorly soluble in water.
Melting point	283-285ºC
Solubility	0.0014 mg/ml
R_f value	0.3 to 0.5
Odour	Strong disagreeable
Half life	4-14 hr.
BCS class	Class III
Log P	3.36

MATERIAL AND METHOD

Ashwagandha was collected as gift sample from Anand Agriculture university, Anand. Turmeric and black paper was collected from local market of Anand. The Department of Pharmacognosy at Anand Pharmacy college confirmed the authenticity, assigning it the identification number APC/2024/10.

A. Drug-excipient compatibility study by FT-IR spectroscopy:

FT-IR Spectroscopy of the pure drug (Curcumin) and their formulations were done to check whether there is any interaction between drug and the used polymers (HPMC K100) or not. Compatibility of drug in the formulation was ensured by FT-IR comparison of pure drug with FTIR of its formulation **[17, 18]**.

B. Construction of calibration:

⇒ **Preparation of phosphate buffer of pH 6.8 solution:** To make 6.8 pH phosphate buffer, Dissolve 6.8 gram of potassium dihydrogen phosphate and 0.9 gram of sodium hydroxide pallet in distil water. Complete the volume up to 1000 ml by distil water.

Curcumin

1. Preparation of standard stock solution of curcumin

10 mg of curcumin is precisely weighed and dissolve in 10 ml volumetric flask of

methanol and sonicated. The volume is completed with up to 10 ml of methanol to prepare a concentration of 1000 µg/ml which is our stock solution.

2. Determination of λ_{max} of curcumin

Above solution was UV-Visible spectrophotometer scanned between the wavelength of 200-800 nm. From the scan it was deduced that the λ_{max} of curcumin was 421 nm.

3. Calibration curve of curcumin in phosphate buffer of pH 6.8

0.2 ml, 0.4ml, 0.6ml, 0.8ml, 1.0ml, 1.2ml were pipetted out from standard stock solution aliquots into 10 ml volumetric flask. Phosphate buffer of 6.8 was added to make the volume and get a final concentration of 20, 40, 60, 80, 100 and 120 µg/ml respectively. Absorbance of each concentration was determined at λ_{max} 421 nm against blank (phosphate buffer 6.8).

Withania somnifera

1. Preparation of standard stock solution *Withania somnifera*

10 mg of *Withania somnifera* was weighed accurately and dissolve in 10 ml of volumetric flask containing methanol and sonicate. The volume is made up to 10 ml with methanol to get a concentration of 1000 µg/ml which is our stock solution.

2. Determination of λ_{max} of *Withania somnifera*

Above solution was UV-Visible spectrophotometer scanned between the range of 200-400 nm. From the scan it was inferred that *Withania somnifera* λ_{max} was 208 nm.

3. Calibration curve of *Withania somnifera* in phosphate buffer of pH 6.8

From the standard stock solution aliquots 0.3 ml, 0.6 ml, 0.9 ml, 1.2 ml, 1.5 ml, 1.8 ml were pipetted out into 10 ml volumetric flask. The volume was made up with phosphate buffer of 6.8 to get a final concentration of 30, 60, 90, 120, 150 and 180 µg/ml respectively. The absorbance of each concentration was measured at λ_{max} 208 nm using against blank (phosphate buffer 6.8) **[19]**.

C. Thin layer chromatography (TLC) of Extract

Turmeric and ashwagandha methanolic extracts were analysed by thin-layer chromatography.

- **Sample preparation:** Turmeric and ashwagandha extracts were taken in small quantities and dissolved in the respective solvents.
- **For Turmeric:** A 500 ml beaker of toluene and methanol (9:1) was saturated. With the help of a capillary tube, the sample is deposited in the

stationary phase (Silica gel G) and is transferred to the mobile phase in a beaker for development. Once the chromatogram has developed by ¾, the plate will be removed, dried and detected by the UV fluorescence chamber. Calculation was done for the retention factor for eluted active compounds.

- **For Ashwagandha:** 500 ml beaker was saturated with chloroform and methanol (9:1). Under the help of a capillary tube, the sample is placed in the stationary phase (Silica gel G) and taken to the mobile phase in a beaker for development. The plate will be removed after the chromatogram develops by ¾. The plate is dried and analysed using the UV fluorescence chamber.

Calculation were performed for the retention factor of eluted active compounds **[20]**.

D. Preparation of oral thin film:

- Total area of Petry dish = 50.24 cm^2
- Each film area = 2 x 2 = 4 cm^2
- Number of film in batch = 50.24/4 = 12.5 (Approximately 12 films)

Oral thin film was prepared using solvent casting method. Aqueous solution I was formulated by dissolving film forming polymer, in appropriate proportion of distilled water and left to stir for 3 h and stored for 1 h to drive out all the air bubbles present. Aqueous solution II was formulated by dissolving the pure drug, sweetener, and plasticizer in appropriate proportion of the solvent. The aqueous solution I and II were combined and stirred for 1 h.

The solutions were poured on to 64 cm^2 glass plate and dried in oven at 45 ºC for 12 h. The film was gently peeled off from glass plate surface and cut as per required size for testing (2 cm length, 2 cm width). The samples were kept in glass container at a temperature of 30ºC and relative humidity 60% ± 5% until further analysis **[21, 22]**.

Figure 2: Oral thin film

Table 3: Formulation of oral thin film

Ingredients (mg)	F1	F2	F3
Curcumin	25	25	25
Withania somnifera	1	1	1
piperine	9	9	9
HPMC K 100	24	35	24
Poloxamer	3	3	3
Glycerine	0.15	0.15	0.3
Citric acid	6	6	6
Sorbitol	6	6	6
Sodium starch glycolate	3	3	3
Sucrose	3	3	3
Potassium sorbate	q.s	q.s	q.s
Water	q.s	q.s	q.s

EVALUATION OF ORAL THIN FILM

[1] Visual inspection:

Property such as Homogeneity, colour, transparency and surface of oral thin film were tested for all the prepared films **[23]**.

[2] Weight variation:

The variation in weight of the film was achieved by weighing 20 films separately and calculating the average weight. In order for the film to be accepted, not more than 2 films differed from the average weight by not more than 7.5 % and no film differed by not more than 15 % **[24]**.

[3] Thickness:

The thickness of the film is accurately measured with a micrometre screw gauge or a calibrated digital vernier calliper. The ideal film thickness should be 5 to 200 micrometres. For uniformity, five separate points on the film are evaluated: the corners and the middle part. Uniform film thickness is important since it affects the dose distribution accuracy directly **[25]**.

[4] Folding endurance:

The folding resistance of a film is tested by cutting a strip and folding it repeatedly at the same location until it fails. This test establishes the folding resistance value of the film, as the number of folds resisted before breakage. Typically, films have a folding resistance between 100 and 150 folds **[26]**.

[5] Surface pH:

Surface pH of film was calculated in order to discover any potential side effect. For this, commercially available pH strip was used. The film under test was taken in Petry dish and was wetted little with water. pH was assessed by pH strip in touch with the oral thin film surface. Average of three determination of every formulation was calculated **[27]**.

[6] *In-vitro* Disintegration time:

The in vitro disintegration time is visually evaluated in a glass dish with 10 mL of distilled water. The dish is slowly swirled every 10 seconds to notice the disintegration of the film. The disintegration time is noted as the time when the film starts breaking off or disintegrating **[28]**.

[7] Sweeling index:

The oral thin films (OTFs) water absorption ability and resistance are tested using swelling studies. Weighed OTF samples are placed individually in simulated physiological fluid in a petri dish for a defined period of time. Each film is re-weighed and measured at regular intervals of time until equilibrium swelling is reached, as evidenced by constant weight. The degree of swelling is determined by the following formula **[29]**.

Swelling Degree (%) = [(Final Weight - Initial Weight) / Initial Weight] × 100

[8] Drug content:

Drug content of every film was quantified by UV-Spectrophotometric technique. For the purpose 2 x 2 cm2 film was dissolved in 100ml phosphate buffer solution pH 6.8 and the solution was agitated on a magnetic stirrer for 1 hour. Solution was filtered and absorbance was measured at 421 nm and 208 nm for curcumin and *Withania somnifera* respectively. Drug content was obtained from standard curve of drug **[30]**.

[9] Tensile strength:

Tensile strength is the maximum stress that the material can absorb at the moment of breakage. It is found by dividing the rupture load by the cross-sectional area of the film according to the following formula **[31]**.

Tensile Strength (TS) = (Load at Failure × 100) / (Film Thickness × Film Width)

RESULT AND DISCUSSION

[1] Drug-excipient compatibility study by FT-IR spectroscopy:

The FT-IR spectra of oral thin film and APIs are shown in **Figure 3**. The FTIR spectrum of curcumin depicts a characteristics absorption band at 3277.70 cm^{-1} representing the presence of OH group. The CH_2 vibration show a characteristic absorption band in the region of 2929 cm^{-1}, C=C, CHO vibration shows a characteristic absorption band in the region of 1633 cm^{-1} and 995 cm^{-1}. The spectrum of *Withania somnifera* depicts a characteristics absorption band at 3292 cm^{-1} representing the presence of OH group. The CH_2 vibration show a characteristic absorption band in the region of 2931 cm^{-1} and C=C absorption band in the region of 1621 and 1020 cm^{-1}. The spectrum of APIs – polymer mixtures shown absorption band at 3305, 2932, 1633 and 1032 cm^{-1} OH, CH_2, CHO and C=C. It indicates drug and drug containing physical mixture absorption bands were near that there were no chemical and physical changes in the functional groups present in curcumin and *Withania somnifera*.

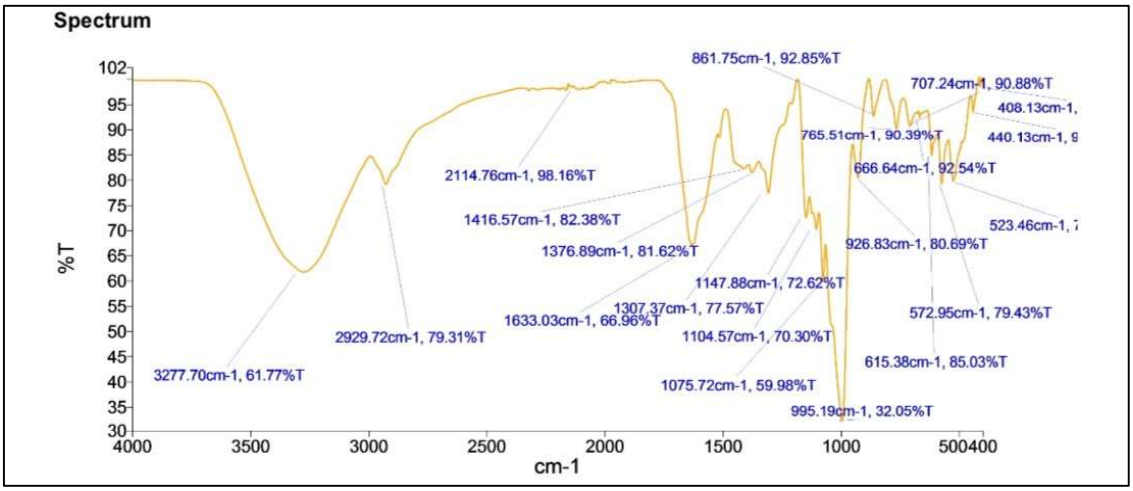

Figure 3: FTIR Spectra of Turmeric extract

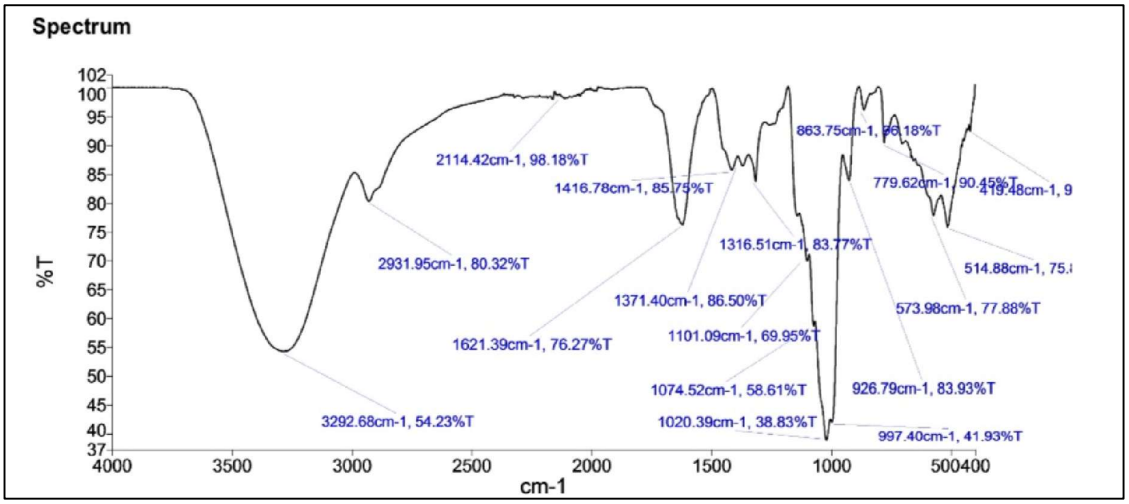

Figure 4: FTIR Spectra of *Withania somnifera* extract

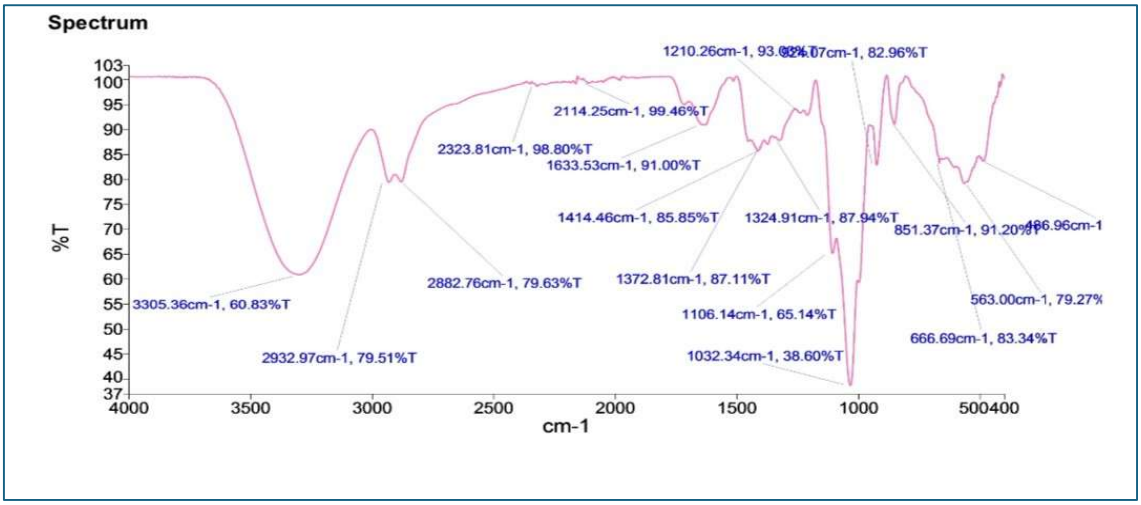

Figure 5: FTIR Spectra of oral thin film

[2] Calibration curve:

Curcumin

Table 4: Calibration curve

Conc. (µg/ml)	Absorbance (nm)
20	**0.149**
40	**0.356**
60	**0.524**
80	**0.708**
100	**0.854**
120	**0.938**

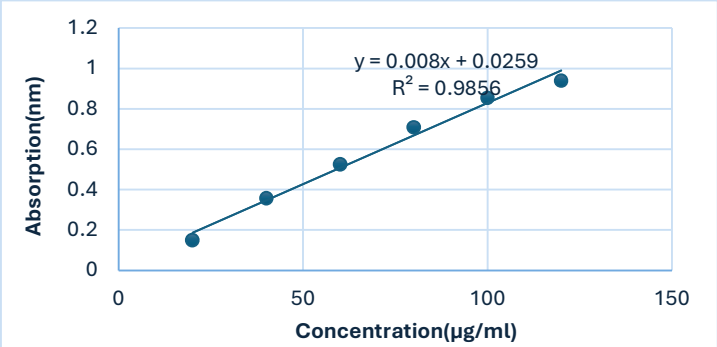

Figure 6: Plot of Curcumin in Phosphate buffer of pH 6.8

Withania somnifera

Table 5: Calibration curve

Conc. µg/ml	Absorbance (nm)
30	**0.236**
60	**0.357**
90	**0.462**
120	**0.638**
150	**0.714**
180	**0.852**

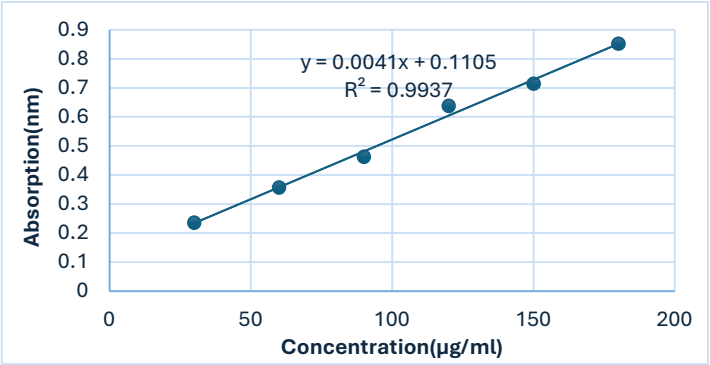

Figure 7: Plot of *Withania somnifera* in Phosphate buffer of pH 6.8

[3] Thin layer chromatography (TLC):

The extracts of turmeric and ashwagandha were spotted in the stationary phase, the developed chromatogram is shown in **Figure 8**. For turmeric extract spot were observed at R_f value 0.48 and for ashwagandha extract spot were observed at R_f value 0.58.

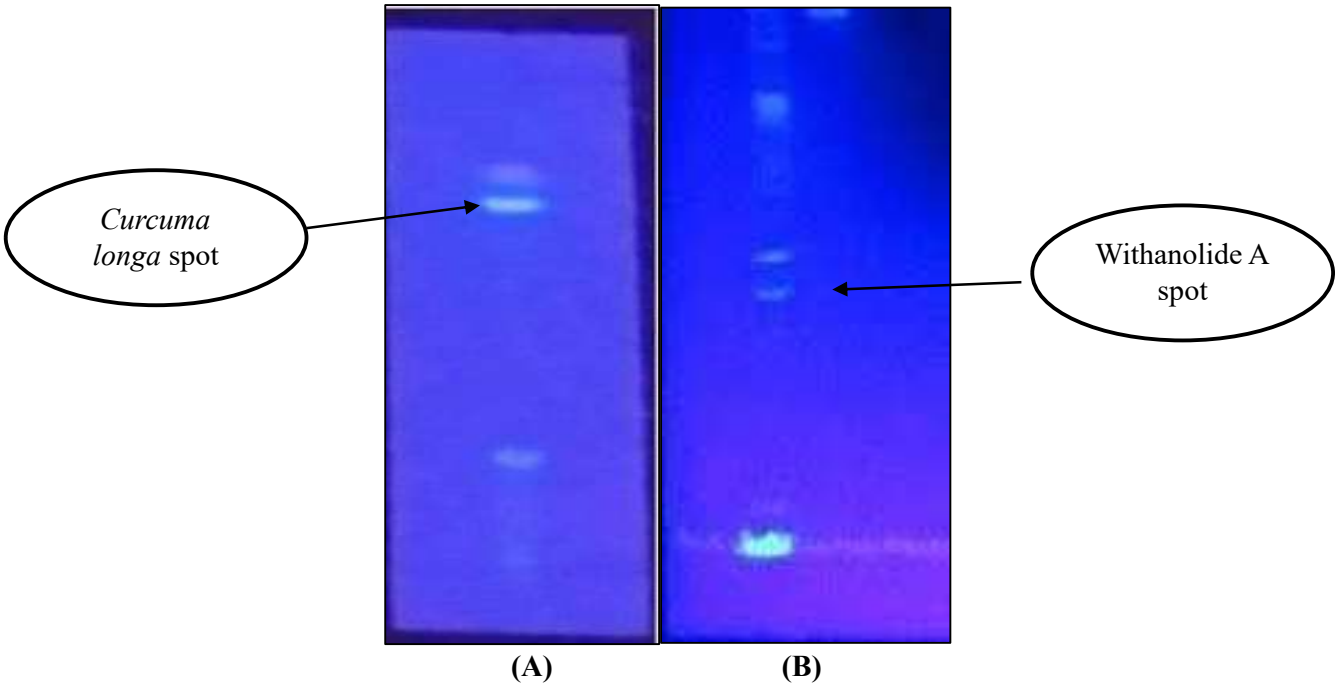

Figure 8: TLC of Turmeric extract (A) and *Withania somnifera* extract (B)

EVALUATION OF ORAL THIN FILM

[1] Visual inspection:

All the films prepared were found to be flexible, smooth, non-sticky, homogenous, yellow coloured and transparent with no visible particulate matter.

[2] Weight variation:

The observed result of weight variation test is shown the **Table 6**. The result reveal that the weight of the oral film varied with polymer concentration. Increase in polymer concentration resulted in increase in weight of the film, but the increase was marginal.

[3] Thickness:

Thickness of oral thin film depends on the concentration of polymer. Thickness of all the film was measured with micro meter screw gauge. The thickness was found to vary between 0.9 to o.15 mm with very low standard deviation **(Table 6)**.

[4] Folding endurance:

The folding endurance was found very near to 300 in case of all the formulations. This makes the system acceptable for movement of mouth indicating good strength and elasticity. Folding endurance test results indicated that the film would maintain the integrity with buccal mucosa when applied and has good plasticity.

[5] Surface pH:

The surface pH of all the film was found to be 6.4 to 6.6. The surface pH of all the formulation was close to the neutral pH, which indicated that film may have less potential to irritate the buccal mucosa, and hence more acceptable by the patients.

[6] *In-vitro* Disintegration time:

The disintegration time for prepared formulation batches was found to be within the limits. As expected, increase in the polymer concentration increase disintegration time while for a fixed polymer quantity and higher plasticizer content resulted in faster the disintegration of the film.

[7] Swelling index:

The swelling percentage of the formulated film was observed in phosphate buffer of pH 6.8. The result was in **Table 6**. From the results it was concluded that as concentration of polymer increases, swelling index of film increases.

[8] Drug content:

Drug content in the films was evaluated and the value were found to be between 94.4 to 98.8%. All the films were found to contain an almost uniform quantity of drug, as per the content uniformity studies indicating reproducibility of the technique. As per the USP requirements, the films found to meet the criteria for content uniformity (85-115%) of the label claim.

[9] Tensile strength:

The tensile strength was found to be 4.15±0.17 N/mm^2 and increase with increase in the concentration of polymer and plasticizer. The tensile strength gives an indication of the film strength which is important to resist the mechanical movements that may occur during the packing, storage and shipping of the film.

Table 6: Physicochemical parameters of oral thin film

	Weight (mg)	Thickness (mm)	Surface pH	Swelling index (%)	Disintegration In time	Drug Content (%)
F1	65.2 ±1.94	0.11±0.03	6.6 ±0.03	44.2±0.12	6 min 22 sec	98.8(T)&95.3(A)
F2	69.8 ±2.08	0.15±0.05	6.5 ±0.05	39.3±0.7	6 min 57 sec	94.4(T)&90.7(A)
F3	67.3 ±2.10	0.14±0.03	6.4± 0.05	41.6±0.15	6 min 34 sec	95.9(T)&88.9(A)

Values represent Mean ± SD (n=3) (T) indicating Curcumin and (A) indicating withaferin-A.

CONCLUSION

Based on performed test results are within the acceptable range but drug release of F1 formula with 6 min 22 sec which was desirable for fast absorption. Hence, oral thin film of curcumin was the most suitable dosage form for the Parkinson's disease, were a quicker onset of action for a dosage form is desirable along with the improved bioavailability and convenience of administration. Thus, the curcumin film can be easily administered by the patient.

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