World Journal of Pharmaceutical Sciences
ISSN (Print): 2321-3310; ISSN (Online): 2321-3086
Available online at: https://wjpsonline.com/
Research Article

FORMULATION AND INVITRO EVALUATION OF LURASIDONE ORAL THIN FILMS

[1]S Mounika Reddy, [2]K Sathwik, [2]Aryaman Yadav, [2]B Pavan Kumar.

[1]Associate Professor, Department of Pharmaceutics, Malla Reddy Institute of Pharmaceutical Sciences, Hyderabad, Telangana, India, Mail Id: s.mounika02@gmail.com.
[2]Student, Department of Pharmaceutics, Malla Reddy Institute of Pharmaceutical Sciences, Hyderabad, Telangana, India.

Received: 01-07-2025 / Revised Accepted: 05-07-2025 / Published: 10-07-2025

ABSTRACT:
Fast dissolving drug delivery system offers a solution for those patients having difficulty in swallowing tablets/capsules. The present research work is to develop oral thin films of Lurasidone by using solvent casting method. Oral thin films were developed by using various super disintegrants like Lycoat and Ludiflash in different concentrations with Xanthan Gum, Poly vinyl alcohol as a film forming agents and Propylene Glycol as Plasticizer. The prepared formulations of films were evaluated for film thickness measurement, folding endurance study, in-vitro disintegration time, in-vitro drug release pattern (in pH 6.8 phosphate buffer). Drug content, and drug-polymers interaction study (IR spectroscopy). Among all formulations, the formulation (F12) prepared by 180 mg of Lycoat show good drug release (99.37±1.45%).

Keywords: Lurasidone, Poly vinyl alcohol, Lycoat, oral thin films and FTIR.

INTRODUCTION

Oral thin film is a dose form containing therapeutic compounds that disintegrates fast, generally within seconds, when put on the tongue.[1] Approximately 60% of all possible dose formulations are oral solids. Patients with limited bioavailability, a long onset time, and dysphagia prompt the manufacturer to use parenteral and liquid orals. However, liquid orals (syrup, suspension, emulsion, etc.) have a problem with correct dosage, while parenteral drug administration is unpleasant, resulting in high patient compliance. The pharmaceutical business seeks to create a unique oral dose form with the best bioavailability, quickest effect, and maximum patient compliance. As a result, they construct the rapid dissolving tablets with super disintegrants. Fast dissolving medication delivery systems were originally developed in the late 1970s as an alternative to conventional dosage forms for pediatric and geriatric patients who have difficulty swallowing typical oral solid dose forms[2-3] The primary method for medication absorption into the oral mucosa is passive diffusion into the lipoidal membrane[4]. Recently, fast dissolving technology has emerged as a novel drug delivery method, providing a more convenient manner of taking drugs and vitamins.[5] Fast-dissolving medication delivery systems were initially developed in the late 1970s to provide an alternative to standard dosage forms for juvenile and elderly patients who have difficulty swallowing typical oral solid-dosage forms. The buccal mucosa is an appealing route of administration for systemic medication delivery. Oral mucosa has a high vascularization and is more permeable to several medicines. It is widely known that following buccal and sublingual delivery, medication solutes are rapidly absorbed in the reticulated vein and then emptied into the systemic circulation[6]. The notion of a Fast Dissolving Drug Delivery System arose from the need to give patients with a traditional method of taking their medications. Difficulty swallowing (Dysphagia) is a prevalent condition of all age groups, notably the elderly and children, because of physiological changes linked with these groups of patients[7].

Address for Correspondence: S Mounika Reddy, Associate Professor, Department of Pharmaceutics, Malla Reddy Institute of Pharmaceutical Sciences, Hyderabad, Telangana, India Email ID: s.mounika02@gmail.com.

How to Cite this Article: S Mounika Reddy, FORMULATION AND INVITRO EVALUATION OF LURASIDONE ORAL THIN FILMS, World J Pharm Sci 2025; 13(03): 8-18; https://doi.org/10.54037/WJPS.2022.100905

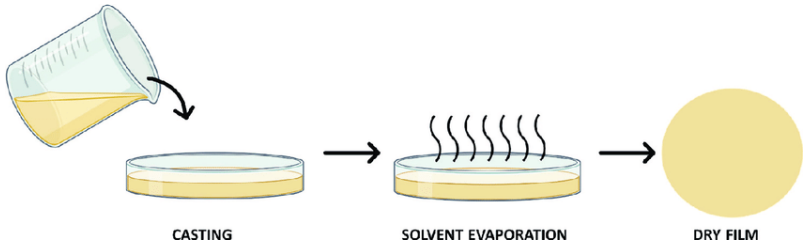

Figure.No.1 Solvent Casting Method

Schizophrenia and bipolar depression are severe mental diseases with far-reaching consequences for people, families, and society. Approximately one percent of the general population is diagnosed with schizophrenia[8], while 1.8% have bipolar disorder. Individuals with schizophrenia and bipolar depression have a significantly worse quality of life; hence, appropriate therapy is required to assist control these symptoms and enhance their overall well-being. Lurasidone[9], a second-generation atypical antipsychotic that metabolizes slowly, has been shown to be effective in treating both diseases. Recent research has revealed exceptional safety and good metabolic adverse effect profiles, making it a viable choice in treating schizophrenia and bipolar disorder[10]. Lurasidone therapy is associated with much less weight gain than olanzapine and quetiapine.[11,12]. Although there was no significant difference in adverse effects when compared to ziprasidone, lurasidone had a reduced rate of somnolence [13]. Lurasidone has a sedating effect similar to other antipsychotic drugs, albeit to a smaller extent than other agents. Lurasidone, like risperidone, causes a dose-dependent rise in prolactin levels, but to a smaller amount [14]. Lurasidone is rapidly absorbed and achieves peak plasma concentrations within 1.5 to three hours.[15] The pharmacokinetics of lurasidone is linear for the dose range of 20 mg to 160 mg. The body reaches a steady state with lurasidone within seven days. For a dose of 40 mg, the volume of distribution is estimated to be 6173 liters, and the clearance is reported to be 3902 mL/min. The elimination half-life in healthy subjects in single-dose pharmacokinetic studies (doses less than 100 mg/day) yielded a mean terminal half-life ranging from 12.2 to 18.3 hours but rose to between 28.8 and 37.4 hours at a steady state in individuals with schizophrenia. However, lurasidone plasma steady-state concentration levels were reached within seven days in individuals with schizophrenia.

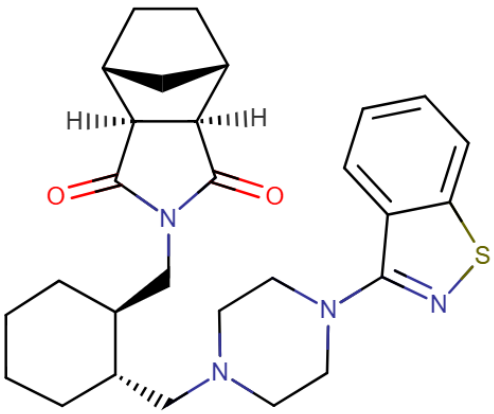

Figure.No.2 Structure of Lurasidone

MATERIALS & METHODS USED: Lurasidone API was procured from Dr. Reddy's Laboratories, Hyderabad and Gelatin, Propylene Glycol, Citric acid, Ludiflash, Aspertame were procured from S.D Fine Chemicals, P.V.A were procured from INR chem. Mumbai, Lycoat were procured from Signet Chemical Corp., Mumbai, Vanilla Flavor were procured from International flavours of fragnance India Ltd.

Solubility studies:

Solubility of Lurasidone was carried out in different buffers. Saturated solutions were prepared by adding an excess drug to the vehicles and shaking on the shaker for 24 hrs at 25°C under constant vibration. Filtered samples (1ml) were diluted appropriately with suitable buffer and solubility of Lurasidone was determined spectrophotometrically at suitable nm.

Flow properties of the pure drug:

Angle of repose

The angle of repose is determined by using funnel method. The accurately weighed blend is taken in a funnel. The height of the funnel is adjusted in such a way that the tip of the funnel just touches the apex of the heap of the blend. The drug-excipient blend is allowed to flow through the funnel freely onto the surface. The diameter of the powder cone is measured and angle of repose is calculated using the following equation. The Angle of Repose less than 30° shows the free flowing of the material.

$$\theta = \tan^{-1}(h / r)$$

Bulk density

Apparent bulk density is determined by pouring a weighed quantity of blend into graduated cylinder and measuring the volume and weight.

$$Db=M/Vo$$

Tapped density:

It is determined by placing a graduated cylinder, containing a known mass of drug-excipients blend. The cylinder is allowed to fall under its own weight onto a hard surface from the height of 10 cm at 2-second intervals. The tapping is continued until no further change in volume is noted.

$$DT=M/Vt$$

Compressibility index:

The simplest way for measurement of free flow of powder is compressibility, an indication of the ease with which a material can be induced to flow is given by compressibility index(I) which is calculated as follows,

Carr's Index (I) = (Tapped Density- Bulk Density)/(Tapped Density) x100

Hausner's Ratio:

Hausner's ratio is an indirect index of ease of powder flow. It is calculated by the following formula

$$\text{Hausner's Ratio} = \frac{\text{BulkDensity}}{\text{Tapped Density}}$$

Preparation of Standard Stock Solution:

10mg of Lurasidone was accurately weighed into 10 ml volumetric flask and dissolved in a small quantity of 6.8 pH Buffer solution. The volume was made up to 10 ml with the 6.8pH Buffer solution to get a concentration of (1000 µg/ml). From this, 1 ml was withdrawn and diluted to 10 ml with 6.8pH Buffer solution to get a concentration of (100 µg/ml) SS-II.

Determination of UV spectrum:-

From stock solution (SS-II), 1 ml was withdrawn and the volume was made up to 10 ml with 6.8 pH Buffer solution to get a concentration of 10 µg/ml. UV scan range was taken between the wavelengths 200-400 nm. It gave a peak at 230 nm and the same was selected as λmax for Lurasidone.

PREPARATION OF CALIBRATION CURVE OF LURASIDONE

Procedure for standard curve in pH 6.8:

10 mg of Lurasidone was dissolved in 10 ml of pH 6.8 by slight shaking (1000 µg/ml). 1 ml of this solution was taken and made up to 10 ml with pH 6.8, which gives 100 µg/ml concentration (stock solution). From the stock solution, concentrations of 5, 10, 15, 20, 25 and 30 µg/ml in pH 6.8 were prepared. The absorbance of diluted solutions was measured at 230 nm and a standard plot was drawn using the data obtained.

Drug-excipient compatibility study.

FTIR spectroscopy

The physical compatibility between the pure drug and polymers used in the research was tested by Infra Red (IR) spectroscopy. FTIR absorption spectra of pure drug and physical mixture were recorded in the range of 400-4000cm-1 by KBr disc method using FTIR spectrophotometer.

Preparation Method:

Formulation of Oral Thin Films of Lurasidone:

The oral thin films of Lurasidone was prepared by solvent casting technique. The Oral Thin Films were prepared using polymers like Xanthan Gum, PVA. Propylene glycol is used as a plasticizer and super disintegrants like Ludiflash and Lycoat. The calculated amount of polymer was dispersed in the three-fourth volume of with continuous stirring using magnetic stirrer and the final volume was adjusted with distilled water. The calculated amount of Lurasidone was incorporated in the polymeric solutions after levitation with required volume of Propylene Glycol and Aspartame and Vanilla Flavor. The solution was cast onto Glass Plate then kept in hot air oven at 400c. The films were punched into size of 4cm2 containing 50mg of Lurasidone. By carrying out the trial and error method different concentrations for a film forming polymers were used like Xanthan Gum, PVA. It has been found that 360mg of Xanthan Gum, 360 mg of PVA shows better films. Which these concentrations of films were prepared by dissolving different quantities of film forming polymers in required amount of water.

Table.No:1 Formulation details of Lurasidone Oral thin films

Formulation Code / Ingredients(mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
Lurasidone	180	180	180	180	180	180	180	180	180	180	180	180
Xanthan Gum	360	360	360	360	360	360	-	-	-	-	-	-
PVA	-	-	-	-	-	-	360	360	360	360	360	360
Ludiflash	30	60	90	120	150	180	-	-	-	-	-	-
Lycoat	-	-	-	-	-	-	30	60	90	120	150	180
Aspartame	10	10	10	10	10	10	10	10	10	10	10	10
Vanilla Flavor (mg)	10	10	10	10	10	10	10	10	10	10	10	10
Propylene Glycol(ml)	20	20	20	20	20	20	20	20	20	20	20	20
Distilled Water	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S

Calculation of dose for Lurasidone:

The dose of Lurasidone is 180 mg. Therefore, amount of Lurasidone required in 4 cm2 film is 50 mg.

- Length of glass plate =6 cm.
- Width of glass plate =6 cm.
- Area of the plate =36 cm2.
- No. of 4 cm2 films present whole plate =36/4 =9 films.
- Therefore, Each films contains 20 mg of drug
- 9 films contain 180 mg drug (9*20).
- So, the Labelled claim of drug = 20 mg

Evaluation of Oral Thin Films:

Post formulation studies:

The Lurasidone Oral Thin Films were evaluated for the following properties

a) Physical appearance and surface texture
b) Weight uniformity
c) Thickness uniformity
d) Folding endurance
e) Surface pH
f) In vitro disintegration time
g) Drug content uniformity
h) In vitro drug release

a) Physical appearance and surface texture of film:

This parameter was checked simply with visual inspection of films and evaluation of texture by feel or touch.

b) Weight uniformity of films

Three films of the size 4cm square were weighed individually using digital balance and the average weights were calculated.

c) The thickness of films

The thickness of the films was measured using screw gauge with a least count of 0.01mm at different spots of the films. The thickness was measured at three different spots of the films and average was taken.

d) Folding endurance of films

The flexibility of films can be measured quantitatively in terms of folding endurance. Folding endurance of the films was determined by repeatedly folding a small strip of the films (approximately 4 cm2) at the same place till it broke. The number of times films could be folded at the same place, without breaking gives the value of folding endurance.

e) Surface pH of films

Surface pH was determined by the films were allowed in contact with 1ml of distilled water. The surface pH was noted by bringing a combined glass electrode or pH paper near the surface of films and allowing equilibrate for 1 min.

f) In vitro disintegration time of films

Disintegration test was performed in the USP disintegration time testing apparatus. 0.1N HCl solution used as a medium. The films were placed in the tubes of the container and disintegration time was recorded.

g) Drug content uniformity study of films

The films were tested for drug content uniformity by a UV-Spectrophotometric method. Films of 2 cm diameter were cut from three different places from the casted films. Each film was placed in 100 ml volumetric flask and dissolved in 6.8 pH Buffer solution and 0.2 ml is taken and diluted with Buffer up to 10 ml. The absorbance of the solution was measured at 218 nm using UV/visible spectrophotometer (Shimadzu UV-1700). The percentage drug content was determined using the standard graph and the same procedure was repeated for three films.

h) In-vitro Dissolution Study

In vitro dissolution of Lurasidone Oral thin films was studied in Type II dissolution test apparatus 900ml 6.8 pH Buffer solution was used as dissolution medium. The stirrer was adjusted to rotate at 50rpm.The temperature of dissolution medium was maintained at 37±0.5ºC throughout the experiment. One film was used in each test. Samples of dissolution medium (5ml) were withdrawn by means of a syringe fitted with pre-filter at known intervals of time and analyzed for drug release by measuring the absorbance at 230 nm. The volume withdrawn at each time interval was replaced with the fresh quantity of dissolution medium. Cumulative percent Lurasidone released was calculated and plotted against time.

i) Drug Release Kinetics

To analyze the mechanism of the drug release rate kinetics of the dosage form, the data obtained were plotted as:

1) **Cumulative percentage drug released Vs time (In-Vitro drug release plots)**
2) **Log cumulative percentage drug remaining Vs Time (First order plots)**

- **Zero order release rate kinetics:**

To study the zero–order release kinetics the release rate data are fitted to the following equation.

$$F = K.t$$

Where,

'F' is the fraction of drug release,
'K' is the release rate constant and
't' is the release time.

- **First Order Kinetics:**

A first order release would be predicted by the following equation

$$\text{Log } C = \log Co \; Kt \; 2.303$$

Where,

C = Amount of drug remained at time't'
Co = Initial amount of drug
K = First order rate constant (hr-1), When the data is plotted as cumulative percent drug remaining versus time yields a straight line, indicating that the release follows First-order kinetics. The constant 'k' can be obtained by multiplying 2.303 with slope values.

RESULTS AND DISCUSSION

Solubility

The solubility of Lurasidone was carried out at 250C using 0.1 N HCl, 6.8 pH phosphate buffer, and purified water.

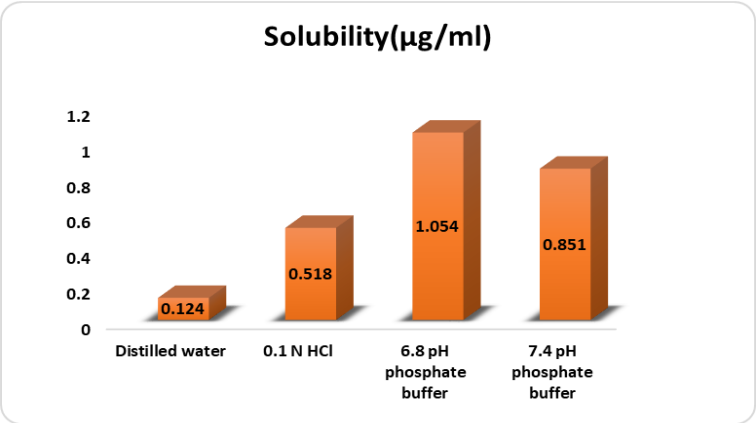

Figure.No.3 Graphs representing solubility studies

Discussion:

From the conducted solubility studies in various solutions, we can say that 6.8 pH phopshate Buffer solutions have more solubility when compared to other buffer solutions.

Flow properties of the pure drug:

Table.No:2 Flow properties of the pure drug

Angle of repose	**24.18±1.02**
Bulk density	0.318±0.02
Tapped density	0.385±0.01
Carr's index	13.28±1.45
Hausner's ratio	1.12±0.02

Discussion: From the above flow properties of the pure drug, it was concluded that the all the parameters are within the limits indicating the free flow of drug. Total 10 formulations were prepared and three different film forming polymers without disintegrants and complete composition of all batches. The films were then characterized by various physicochemical parameters.

UV spectrum of Lurasidone:

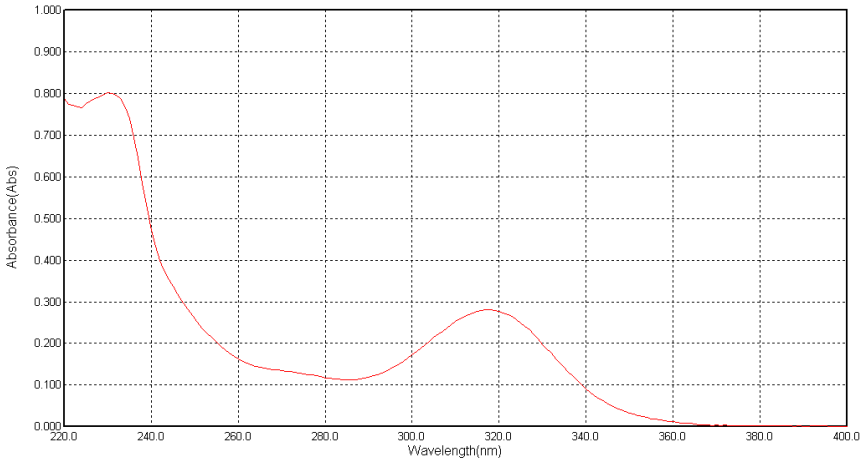

Figure.No.4 Absorption maxima of Lurasidone in 6.8 pH phosphate buffer

Discussion: The maximum absorbance of the Lurasidone in 6.8 pH phosphate buffer was found to be 230 nm as shown in Fig. Hence, the wavelength of 230 nm was selected for analysis of drug in dissolution media.

Standard Calibration Curve of Lurasidone in 6.8 pH Phosphate Buffer:

Standard calibration curve of Lurasidone was drawn by plotting absorbance vs concentration. The λmax of Lurasidone in 6.8 pH phosphate buffer was determined to be 230 nm as shown in Fig. The absorbance values are tabulated in Table. Standard calibration curve of Lurasidone in the Beer's range between 0-30 µg/ml is shown in Fig.

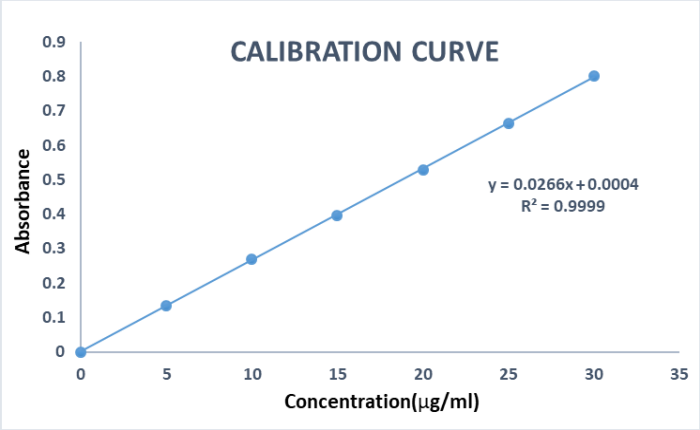

Figure.No.5 Standard calibration curve for Lurasidone 6.8 pH Phosphate Buffer at λmax 218 nm.

Discussion: The standard calibration curve shown 0.999, through that the drug obeys Beers and Lamberts law in the concentration range of 5 to 30 µg/mL. A standard graph was plotted by keeping the known concentration on X – axis and obtained absorbance on Y – axis.

Compatibility Study:

FTIR

Compatibility studies were performed using FT-IR spectrophotometer. The IR spectrum of pure drug and physical mixture of drug and polymer were studied by making a KBr disc. The characteristic absorption peaks of Lurasidone were obtained at different wave numbers in different samples.

The peaks obtained in the spectra of each formulation correlates with the peaks of drug spectrum. This indicates that the drug is compatible with the formulation components. The spectra for pure drug and optimized formulation are shown below.

Pure Drug

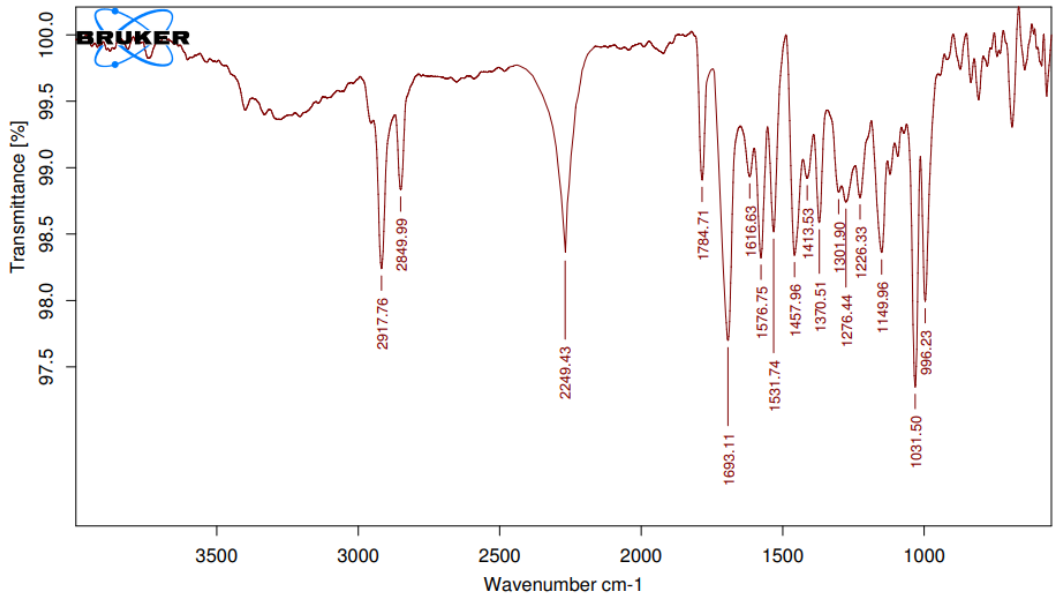

Figure.No.5 I.R. Spectra of pure drug

Optimized Formulation

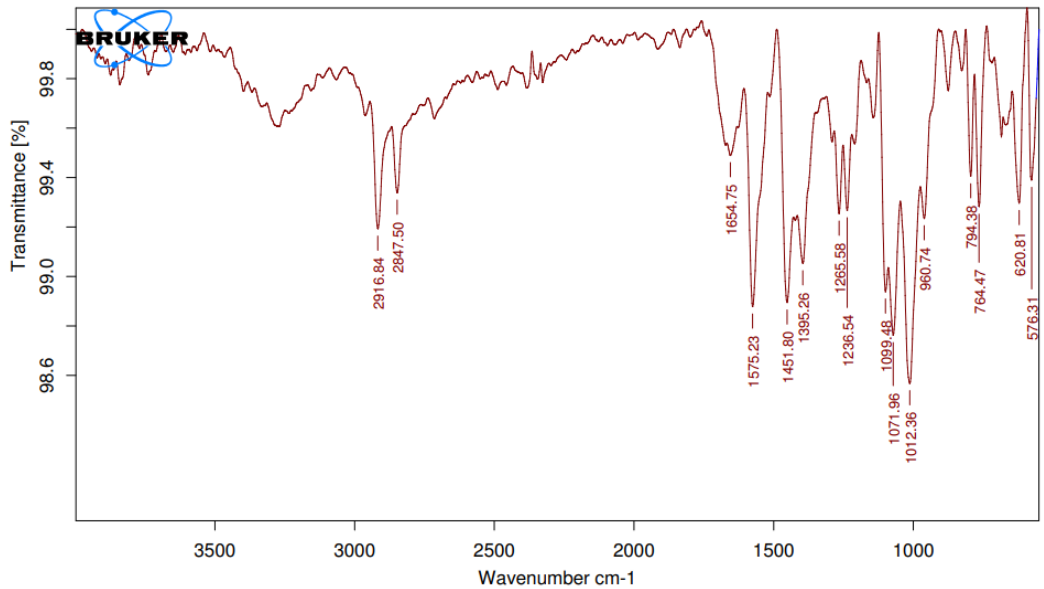

Figure.No.6 I.R. Spectra of optimized formulation

Discussion: From the drug excipients compatibility studies we observe that there are no interactions between the pure drug and (drug+ excipients) which indicates there are no physical changes.

Evaluation of Oral Thin Films Formulations:

Physical appearance and surface texture of films: These parameters were checked simply with visual inspection of films and by feel or touch. The observation suggests that the films are having the smooth surface and they are elegant enough to see.

Table.No:3 Evaluation of Oral Thin Films of Lurasidone

Formulation Code	Avg. Weight of Film(mg)	Avg. Thickness(mm)	Avg. Folding Endurance
F1	67.17±1.17	0.17±0.01	204±1
F2	72.42±1.42	0.16±0.02	219±2
F3	75.51±1.37	0.18±0.01	229±2
F4	78.49±1.19	0.16±0.02	235±1
F5	82.27±1.52	0.19±0.01	246±2
F6	85.18±1.74	0.17±0.02	259±2
F7	66.39±1.31	0.16±0.01	209±1
F8	71.28±1.45	0.18±0.01	228±1
F9	74.42±1.86	0.17±0.01	239±2
F10	77.37±1.20	0.18±0.01	247±1
F11	81.45±1.46	0.18±0.01	259±2
F12	84.18±1.89	0.15±0.02	270±1

Discussion: The average weight the film was found in between 67.17±1.17-84.18±1.89. The average thickness of the films was found in between the range of 0.15±0.02-0.19±0.01. The average folding endurance of the films was been found in between the ranges of 204±1-270±1.

Table.No:4 Evaluation of Oral films of Lurasidone

Formulation Code	Avg. Drug Content Uniformity (%)	Avg. In Vitro Disintegration (sec)	Avg. Surface pH
F1	93.64±1.75	30±2	6.7±0.1
F2	94.59±1.12	28±1	6.6±0.2
F3	95.38±1.34	26±1	6.8±0.1
F4	97.26±1.75	25±2	6.6±0.1
F5	97.11±1.51	26±2	6.5±0.2
F6	98.76±1.20	24±1	6.5±0.1
F7	94.28±1.95	27±1	6.6±0.1
F8	96.45±1.45	24±1	6.7±0.2
F9	97.62±1.30	21±2	6.8±0.2
F10	98.39±1.10	18±1	6.7±0.1
F11	98.46±1.42	15±1	6.6±0.2
F12	99.22±1.95	13±1	6.8±0.2

Discussion: The average content uniformity of the formulations from F1 to F12 was found in between 93.64±1.75%-99.22±1.95%. The Disintegration time of the films from F1 to F12 was in between the range of 30±2- 13±1. The average surface pH of the films was in the range of pH 6.5±0.1-6.8±0.2.

In-Vitro Dissolution Study:

The in-vitro drug release study of oral thin films from each batch (F1 to F12) was carried out in 6.8 pH phosphate buffer solution for 30 mins and the values are shown in Table. The plot of % Cumulative drug release V/s time (mins) were plotted and depicted as shown in Fig & Table.

Table.No:5 In vitro dissolution studies

Time(min)	F1	F2	F3	F4	F5	F6
0	0	0	0	0	0	0
5	33.46 ±1.10%	46.20 ±1.43%	45.52 ±1.10%	52.26 ±1.48%	57.12 ±1.45%	65.55 ±1.54%
10	55.37 ±1.51%	59.25 ±1.10%	59.45 ±1.20%	60.45 ±1.14%	65.37 ±1.45%	73.43 ±1.28%
15	64.27 ±1.42%	67.45 ±1.37%	70.46 ±1.75%	74.26 ±1.48%	79.69 ±1.52%	80.45 ±1.42%
20	79.36 ±1.18%	75.15 ±1.02%	79.69 ±1.15%	82.20 ±1.15%	85.43 ±1.27%	92.37 ±1.45%
25	86.20 ±1.46%	83.49 ±1.37%	86.24 ±1.45%	89.24 ±1.17%	93.45 ±1.32%	98.16 ±1.27%
30	91.84 ±1.25%	92.12 ±1.54%	93.57 ±1.45%	98.49 ±1.10%	99.42 ±1.87%	
35	98.37 ±1.42%	98.57 ±1.10%	99.57 ±1.59%			

Table.No:6 In vitro dissolution studies

Time(min)	F7	F8	F9	F10	F11	F12
0	0	0	0	0	0	0
5	34.15 ±1.45%	42.17 ±1.47%	47.37 ±1.25%	55.45 ±1.28%	62.45 ±1.22%	73.14 ±1.52%
10	51.35 ±1.45%	57.65 ±1.45%	64.15 ±1.45%	69.45 ±1.35%	75.15 ±1.26%	85.35 ±1.45%
15	58.15 ±1.42%	69.38 ±1.47%	76.37 ±1.45%	76.67 ±1.27%	87.45 ±1.18%	90.19 ±1.69%
20	65.25 ±1.45%	75.45 ±1.28%	82.48 ±1.57%	89.45 ±1.18%	94.45 ±1.97%	95.56 ±1.51%
25	77.67 ±1.45%	83.34 ±1.45%	89.48 ±1.34%	93.42 ±1.35%	98.75 ±1.52%	99.37 ±1.45%
30	88.48 ±1.51%	92.67 ±1.12%	98.45 ±1.28%	99.45 ±1.12%		
35	98.13 ±1.46%	99.14 ±1.45%				

Discussion:

From the In vitro dissolution studies it was identified that the Formulations containing Ludiflash in the concentration of 30-180mg and Xanthan Gum in concentration of 360mg i.e.,(F1-F3) shows 98.18±1.16%, 98.67±1.59%, 99.57±1.59% at the end of 35mins. Formulation F4 an F5 results 98.49±1.10%, 99.42±1.87%. While Formulation F6 contain 180mg of Ludiflash Shows 98.16±1.27% release at the end of 25 mins.

Formulations containing Lycoat in the concentration of 30-180mg and PVA in concentration of 360mg i.e, (F7, F8) shows 98.13±1.46%, 99.14±1.45% at the end of 35mins, F9, F10 results 98.45±1.28%, 99.45±1.12%, at the end of 30mins.While Formulation F11, F12 contain 180mg of Lycoat Shows 98.75±1.52%, 99.37±1.45% release at the end of 25 mins

This shows that effectiveness of super disintegrants is in the order of Lycoat>Ludiflash. The concentration of super disintegrant's in the formulations also increased the dissolution rates. In all the formulations up to 360 mg concentration of PVA and 180 mg of Lycoat, there was linearly increase in dissolution rate. At higher concentration, all the formulations showed increase in dissolution rate.

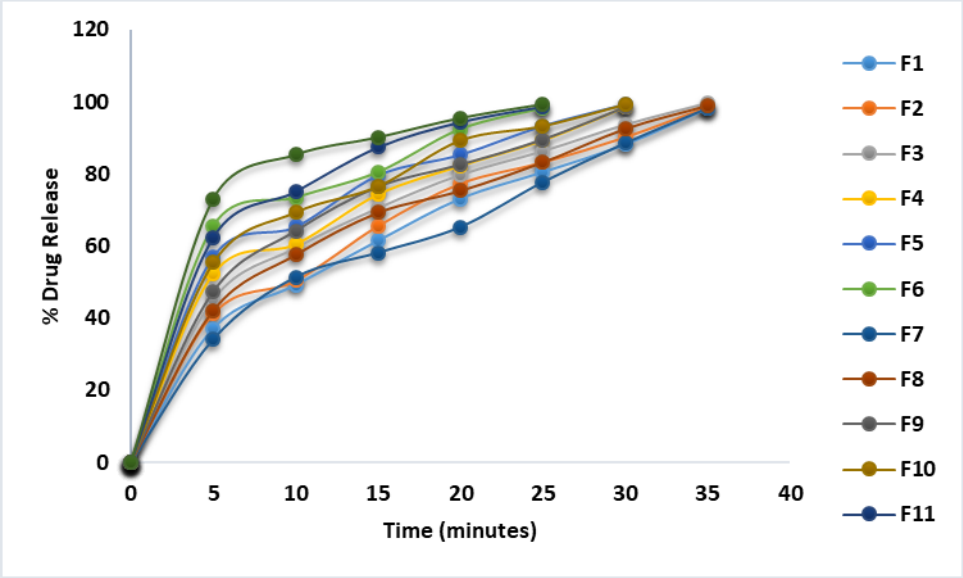

Figure.No.7 *In-vitro* drug release of formulations (F1-F12)

Drug Release Kinetics of Lurasidone
Zero Order Release Kinetics

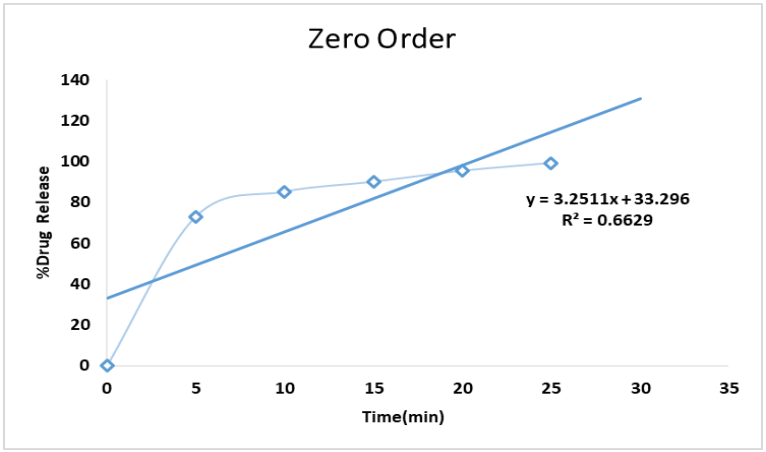

Figure.No.8 Zero order release profile of Lurasidone Best formulation (F12)

First Order Release Kinetics Data

Figure.No.9 First order release profile of Lurasidone Best formulation (F12)

Discussion: The in vitro dissolution data for best formulation F12 were fitted in different kinetic models i.e., zero order and first order. Optimized formulation F12 follows first order.

CONCLUSION:

In the present study Oral drug delivery system of Lurasidone were successfully developed in the form of oral thin films which offers a suitable and practical approach in serving the desired objective of faster disintegration and dissolution characteristics with increase bioavailability. Oral thin films of Lurasidone were prepared by using Ludiflash and Lycoat as super disintegrants. Under the pre-formulation studies, API characterization and drug-excipient compatibility studies were carried out. The API characterization showed compliance with the drug characteristics. The disintegrants and other excipients were selected based on the satisfying results produced during drug- excipient compatibility studies to develop the final formulation. The final suitable formulation (F12) was achieved fruitfully by the solvent casting method using poly vinyl alcohol and Lycoat as super disintegrant which exhibited a rapid disintegration time (13±1 sec) and in vitro drug release (99.37±1.45%) ate the end of 25minutes. Considering the results of batches containing lycoat and ludiflash as disintegrant it can be concluded that the formulation F12 was meeting the higher in-vitro correlation limits and in less instance of time when subjected to the comparison with other formulation with lycoat as the disintegrating agent. It was also observed that solvent casting method was the best suitable method used for immediate drug release.

BIBLIOGRAPHY:

1. Nehal Siddiqui MD, Garima G, Pramod KS. A Short Review on "A Novel Approach in Oral Fast Dissolving Drug Delivery System and Their Patents". Adv BiolRes.2011; 5(6): 291-303.
2. Deepak H, Geeta A. Recent trends of fast dissolving drug delivery system - An Overview of formulation technology. Pharmacophore. 2013; 4(1): 1-9.

3. Nishi T, Mayank B, Neha S, Ghanshyam Y, Pragati K. Overview "A Novel Approach of Fast Dissolving Films and Their Patients". AdvBiol Res.2013; 7(2): 50-58.
4. Ashutosh M, Rajesh KP, Mukesh CG. Formulation, development and evaluation of patient friendly dosage forms of metformin, Part-II: Oral soft gel. 2008; 2(3): 172-176.
1) Biradar SS. Bhagvati ST, kuppasad IJ. Fast dissolving drug delivery systems; a brief review. Internet J Pharmcol. 2006; 4(2) available online on Error! Hyperlink reference not valid.
2) J.D. Smart, Buccal drug delivery, Expert Opin. Drug Deliv. 2 (2005) 507–517.
3) Lindgren S, Janzon L. Prevalence of swallowing complaints and clinical findings among 50-79 year old men and women in an urban population. Dysphagia. 1991; 6: 187-192.
4) Critical appraisal of lurasidone in the management of schizophrenia. Caccia S, Pasina L, Nobili A. Neuropsychiatr Dis Treat. 2012;8:155–168. doi: 10.2147/NDT.S18059. [DOI] [PMC free article] [PubMed] [Google Scholar]
5) Efficacy and safety of lurasidone in children and adolescents with bipolar I depression: a double-blind, placebo-controlled study. DelBello MP, Goldman R, Phillips D, Deng L, Cucchiaro J, Loebel A. J Am Acad Child Adolesc Psychiatry. 2017;56:1015–1025. doi: 10.1016/j.jaac.2017.10.006. [DOI] [PubMed] [Google Scholar]
6) Lurasidone in the treatment of schizophrenia: a critical evaluation. Bruijnzeel D, Yazdanpanah M, Suryadevara U, Tandon R. Expert Opin Pharmacother. 2015;16:1559–1565. doi: 10.1517/14656566.2015.1058780. [DOI] [PubMed] [Google Scholar]
7) Lurasidone for the treatment of acutely psychotic patients with schizophrenia: a 6-week, randomized, placebo-controlled study. Nasrallah HA, Silva R, Phillips D, Cucchiaro J, Hsu J, Xu J, Loebel A. J Psychiatr Res. 2013;47:670–677. doi: 10.1016/j.jpsychires.2013.01.020. [DOI] [PubMed] [Google Scholar]
8) Double-blind comparison of the safety and efficacy of lurasidone and ziprasidone in clinically stable outpatients with schizophrenia or schizoaffective disorder. Potkin SG, Ogasa M, Cucchiaro J, Loebel A. Schizophr Res. 2011;132:101–107. doi: 10.1016/j.schres.2011.04.008. [DOI] [PubMed] [Google Scholar]
9) Performance and interview-based assessments of cognitive change in a randomized, double-blind comparison of lurasidone vs. ziprasidone. Harvey PD, Ogasa M, Cucchiaro J, Loebel A, Keefe RS. Schizophr Res. 2011;127:188–194. doi: 10.1016/j.schres.2011.01.004. [DOI] [PubMed] [Google Scholar]
10) Effect of neuroleptic treatment on polysomnographic measures in schizophrenia. Taylor SF, Tandon R, Shipley JE, Eiser A. Biol Psychiatry. 1991;30:904–912. doi: 10.1016/0006-3223(91)90004-6. [DOI] [PubMed] [Google Scholar]
11) Effects of antipsychotic treatment on polysomnographic measures in schizophrenia: a replication and extension. Maixner S, Tandon R, Eiser A, Taylor S, DeQuardo JR, Shipley J. Am J Psychiatry. 1998;155:1600–1602. doi: 10.1176/ajp.155.11.1600. [DOI] [PubMed] [Google Scholar]
12) The effects of novel and newly approved antipsychotics on serum prolactin levels: a comprehensive review. Peuskens J, Pani L, Detraux J, De Hert M. CNS Drugs. 2014;28:421–453. doi: 10.1007/s40263-014-0157-3. [DOI] [PMC free article] [PubMed] [Google Scholar]
13) Long-term safety and tolerability of lurasidone in schizophrenia: a 12-month, double-blind, active-controlled study. Citrome L, Cucchiaro J, Sarma K, Phillips D, Silva R, Tsuchiya S, Loebel A. Int Clin Psychopharmacol. 2012;27:165–176. doi: 10.1097/YIC.0b013e32835281ef. [DOI] [PubMed] [Google Scholar]
14) Lurasidone: The 2016 update on the pharmacology, efficacy and safety profile. Jaeschke RR, Sowa-Kućma M, Pańczyszyn-Trzewik P, Misztak P, Styczeń K, Datka W. Pharmacol Rep. 2016;68:748–755. doi: 10.1016/j.pharep.2016.04.002. [DOI] [PubMed] [Google Scholar]
15) Lurasidone as adjunctive therapy with lithium or valproate for the treatment of bipolar I depression: a randomized, double-blind, placebo-controlled study. Loebel A, Cucchiaro J, Silva R, Kroger H, Sarma K, Xu J, Calabrese JR. Am J Psychiatry. 2014;171:169–177. doi: 10.1176/appi.ajp.2013.13070985. [DOI] [PubMed] [Google Scholar].