WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
Coden USA: WJPRAP Impact Factor 8.453
Volume 15, Issue 1, 694-711. Research Article ISSN 2277–7105

FORMULATION AND IN VITRO EVALUATION OF ARIPIPRAZOLE NANOPARTICLES ORAL DISPERSIBLE FILMS

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Article Received on 28 Nov. 2025,
Article Revised on 18 Dec. 2025,
Article Published on 01 Jan. 2026,

https://doi.org/10.5281/zenodo.18094421

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How to cite this Article: Ayesha Osman*1, Abdul Mannan2. (2026). Formulation And In Vitro Evaluation Of Aripiprazole Nanoparticles Oral Dispersible Films. World Journal of Pharmaceutical Research, 15(1), 694–711.
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ABSTRACT

The present research was aimed at the formulation and in vitro evaluation of Aripiprazole nanoparticles incorporated into oro-dispersible films (ODFs) to enhance the solubility, dissolution rate, and bioavailability of the poorly water-soluble antipsychotic drug, Aripiprazole. Nanoparticles were prepared using the emulsion solvent evaporation method, employing PLGA and Chitosan as polymers and Polyvinyl alcohol (PVA) as a stabilizer. A series of formulations (F1–F8) were developed and optimized based on particle size, zeta potential, and surface morphology. The mean particle size of the optimized formulation (F7) was 261 nm, and the zeta potential was –22 mV, indicating good stability. Scanning Electron Microscopy (SEM) revealed that the nanoparticles were spherical, smooth, and free from aggregation. The optimized nanoparticles were incorporated into ODFs using HPMC and sodium alginate as film-forming polymers and PEG 400 as plasticizer. The prepared films were evaluated for thickness, folding endurance, drug content, moisture absorption and loss, tensile strength, disintegration time, and in vitro drug release. The results indicated uniformity and satisfactory mechanical properties across all formulations. The optimized film (F7) showed a disintegration time of 12 seconds and a drug release of 98.85% within 30 minutes, following zero-order kinetics (R^2 = 0.972). Stability studies conducted as per ICH guidelines (40 ± 2°C / 75 ± 5% RH) for three months

confirmed the physical and chemical stability of the optimized formulation. In conclusion, the study successfully demonstrated that Aripiprazole nanoparticles loaded oro-dispersible films can serve as an effective, patient-friendly dosage form with enhanced solubility, faster onset of action, and improved bioavailability, providing a promising alternative to conventional oral tablets for psychiatric patients.

KEYWORDS: Aripiprazole, PLGA, Chitosan, Emulsion solvent evaporation method, FTIR, In vitro drug release studies.

INTRODUCTION

Nanotechnology-based strategies, particularly polymeric nanoparticles, offer a promising approach to overcome solubility limitations through particle size reduction, increased surface area, and improved wettability.[1] Nanoparticles can enhance dissolution velocity, absorption, and overall bioavailability of weakly soluble drugs. When embedded into an ODF matrix, nanoparticles can provide rapid drug release, improved stability, and uniform dispersion resulting in a fast-acting and patient-friendly delivery system suitable for psychiatric emergencies or routine therapy.[2] Oral dispersible films (ODFs) have emerged as a novel drug delivery system offering rapid disintegration without water, improved dosing accuracy, ease of administration, and better patient compliance, especially in pediatrics, geriatrics, and psychiatric population. However, incorporating poorly water-soluble drugs like aripiprazole into ODFs is challenging because it requires enhancement of solubility, dissolution rate, and uniform drug distribution within the film matrix.[3] Therefore, developing Aripiprazole Nanoparticles-loaded Oral Dispersible Films may significantly improve drug solubility, enhance dissolution characteristics, and potentially increase therapeutic effectiveness. Aripiprazole an atypical antipsychotic, is widely used in the management of schizophrenia, bipolar disorders, and adjunctive treatment of major depressive disorder. Despite its therapeutic significance, aripiprazole exhibits poor aqueous solubility (BCS Class II) and variable oral bioavailability, which often leads to delayed onset of action and dose-dependent side effects.[4] Moreover, conventional oral tablets may pose challenges for patients with dysphagia, psychiatric instability, poor compliance, or difficulty swallowing, making alternative patient-friendly dosage forms clinically valuable.[5] The present study is designed to formulate aripiprazole nanoparticles using suitable polymeric carriers, incorporate them into ODFs, and evaluate physicochemical properties, drug release behaviour, and film performance parameters.[6]

MATERIALS

Aripiprazole was procured from Hetero Labs, Hyderabad. PLGA and Chitosan were obtained from Synpharma Research Labs, Hyderabad. Other chemicals and the reagents used were of analytical grade.

METHODOLOGY

Fourier Transforms Infra-Red (FTIR) Spectroscopy: FT-IR spectra (Shimaduzu, Germany) was obtained to discover possible interactions between the drug and polymers. The ingredients were compressed with a hydraulic press to form a pellet (less than 5 k pas). The disc was put in the centre of the sample holding device and spectrum was recorded using an FT-IR spectrophotometer.[7]

Formulation Development

Table 1: Composition of Aripiprazole Nanoparticles (F1 to F8).

S. No.	Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8
1	Aripiprazole	50	50	50	50	50	50	50	50
2	PLGA	100	200	300	400	-	-	-	-
3	Chitosan	-	-	-	-	100	200	300	400
4	Dichloromethane	10	10	10	10	10	10	10	10
5	PVA	1%	1%	1%	1%	1%	1%	1%	1%

PLGA-Aripiprazole (PLGA-CIL) nanoparticles were prepared by an emulsification solvent evaporation/diffusion method. The method is ideal for encapsulation of hydrophobic compounds like Aripiprazole.[7]

Briefly, the polymer PLGA was dissolved in ethyl acetate as per table 1. 10 mg of Aripiprazole was dissolved in 1 ml of methanol and then added to polymeric phase with intermittent vortexing using vortex mixer.

The organic phase was then added to an aqueous phase of PVA to form solid in oil in water (S-O/W) emulsion. Once all the drug/polymer mixture was added to the PVA solution, the content was vortexed for 10 sec at high speed. The resulting suspension was sonicated for 60 sec at 45% amplitude with a sonic disrupter. Immediately after sonication, the emulsion was poured into an excess of aqueous phase (0.1% PVA in water; 40 ml) for diffusion under rapid stirring on a magnetic stirrer. This colloidal suspension was kept on a magnetic stirrer for complete solvent evaporation for 5–6 h. The nanoparticles were then collected by centrifugation, washed 3 times with distilled Milli-Q treated water. Finally, they were re-

suspended in 2 ml of cryoprotectant solution (sucrose 2 w/w) and trehalose (5% w/w)), dried on a lyophilizer and stored at 4°C PLGA-Aripiprazole (PLGA-CIL) nanoparticles were prepared by an emulsification solvent evaporation/diffusion method. The method is ideal for encapsulation of hydrophobic compounds like Aripiprazole.[7]

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Prepare aripiprazole nanoparticles by the emulsion–solvent evaporation method as follows: dissolve the required amount of 50 mg of aripiprazole together with PLGA in 10 mL of dichloromethane (organic phase), and prepare an aqueous phase of 50 mL containing 1% w/v polyvinyl alcohol (PVA) as stabilizer; slowly add the organic phase into the aqueous phase under magnetic stirring to form a coarse O/W emulsion, then reduce droplet size by probe sonication using short pulses while keeping the dispersion in an ice bath to avoid heating. After sonication, transfer the emulsion to a magnetic stirrer and allow the organic solvent to evaporate under moderate stirring (about 2–4 hours) at room temperature or slightly elevated temperature (≤40–45 °C) until the volume and odor of solvent are gone and nanoparticles form, to remove residual solvent faster you may apply reduced pressure. Collect the nanoparticles by ultracentrifugation discard the supernatant wash the pellet 1–2 times with distilled water to remove excess PVA and unencapsulated drug, then redisperse in a small volume of water.[8]

EVALUATION

SEM analysis

The morphology of NPs was studied by a scanning electron microscope. For this purpose, the sample was lyophilized and placed on aluminium stubs and the surface was coated with a layer of gold particles using a sputter coater. The shape of the NPs was determined by scanning electron microscopy (SEM) (XL30, Philips, the Netherlands) at 15 kV and 750 mA.[9]

Particle Size and Zeta Potential

The particle size of the formulation was determined by photo correlation spectroscopy with a zeta master (Malvern Instruments, UK) equipped with the Malvern PCS software. Every sample was diluted with distilled water. The surface charge (Zeta potential) was determined by measuring the electrophoretic mobility of the nanoparticles using a Malvern zeta sizer (Malvern Instruments, UK). Samples were prepared by diluting with distilled water.[10]

Incorporate Nanoparticles into Oro dispersible films[11]

Hydrate polymer: Sprinkle polymers into distilled water under stirring and let hydrate 20–30 min (avoid lumps).

Add plasticizer & excipients: Add PEG 400, dissolve sweetener, disintegrating agent and flavour

Cool & add NPs: Cool the film solution to room temp. Slowly add the NP suspension under gentle stirring.

Cast: Pour 30 mL onto a levelled petri dish

Dry: Dry at ambient or controlled 35–40 °C till peelable (avoid >45 °C). Drying time depends on thickness.

Peel & cut: Peel film stored into the deccicators.

Table 2: Formulation Design of Aripiprazole Nanoparticles incorporate Oro dispersible films.

Formulation code	Aripiprazole Nanoparticles (mg)	Sodium alginate (mg)	HPMC (mg)	PEG (ml)	CCS (mg)	Aspartame (mg)
F1	5	100	-	1	5	3
F2	5	200	-	1	5	3
F3	5	300	-	1	5	3
F4	5	400	-	1	5	3
F5	5	-	100	1	5	3
F6	5	-	200	1	5	3

F7	5	-	300	1	5	3
F8	5	-	400	1	5	3

Evaluation of transdermal formulation

Physical appearance: All the prepared Oro dispersible films were observed for color, clarity, flexibility, and smoothness.[12]

Folding endurance: Folding endurance of the patches was determined by repeatedly folding at the same place till it broke. The number of times the patch could be folded at the same place without breaking is the folding endurance. This was repeated on all the patches for three times and the mean values plus standard deviation was calculated.[13]

Thickness of the film: The thickness of each patch was measured by using screw gauze. The thickness was measured at three different places on each patch and the average thickness of the patch was taken as the thickness of the patch.[14]

Weight uniformity: The prepared patches are to be dried at 60^0C for 4hrs before testing. A specified area of 4.52 cm^2 of patch is to be cut in different parts of the patch and weigh in digital balance. The average weight and standard deviation values are to be calculated from the individual weight.[15]

Drug content: The formulated Oro dispersible films were assayed for drug content in each case. Three patches from each formulation were assayed for content of drug. Each formulation was casted in triplicate and one patch from each was taken and assayed for content of drug.[16]

Moisture absorption studies: The films were weighed accurately and placed in a desiccator containing aluminum chloride to maintain 79.50% RH. After 3 days, the patches were taken out and weighed.[17] The percentage of moisture uptake was calculated using the following formula.

$$\text{Perentage moisture uptake} = \frac{\text{Final weight} - \text{Initial weight}}{\text{Initial weight}} \times 100$$

Moisture loss studies: Three films were weighed individually and kept in a desiccator containing calcium chloride at 37^0C for 24 hrs. Then the final weight was noted when there was no further change in the weight of the patch. The percentage of moisture loss was calculated using the following formula.[18]

$$\text{Percentage moisture loss} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Final weight}} \times 100$$

Disintegration time: Use the USP disintegration tester baskets. Replace or cover basket mesh with a finer mesh or use small film holders so the film remains in the basket but can contact medium. Fill the disintegration vessel with simulated saliva pre-warmed to 37 ± 0.5 °C. Set the apparatus to operate at the standard stroke (e.g., 30 cycles/min) Place a single film into each tube and start the apparatus and the stopwatch simultaneously. The end point is when the film completely disintegrates and no coherent film remains in the basket (pieces pass through mesh). Record time for each sample.[19]

***in-vitro* Drug release studies:** The *in-vitro* study of drug permeation through the Dialysis membrane was performed using a modified Franz type glass diffusion cell. The modified cell having higher capacity is (10 ml) is used to maintain sink condition. The samples were analyzed for drug content spectrophotometrically. The receptor phase was replenished with an equal volume of phosphate buffer at each sample withdrawal.[20]

Percentage of drug release was determined using the following formula.

$$\text{Perentage drug release} = \frac{Da}{Dt} \times 100$$

Where, Dt = Total amount of the drug in the patch

Da = The amount of drug released

Release kinetics[21]

The release kinetics can be understand basically by applying the obtained data to the release kinetics models.

Zero order kinetics

$$C = K0t$$

K0 - rate constant for Zero-order (concentration/time) t - Time (h).

First order kinetics

$$\text{Log } C = \text{Log}C0 - Kt / 2.303$$

Where C0 - Initial concentration of drug K = constant first order and t = Time (h)

Higuchi Model

$$Qt = Kt1/2$$

Where Qt - Amount of the drug release drug in time t K- Kinetic constant and t- is time in hrs.

Korsmeyer Pappas Model

$$Mt / M = Kt\ n$$

Where, Mt - amount of the released drug at time t, M- Overall drug amount released after 8 hrs. K- Diffusion constant n- Diffusion exponent mechanism of release of drug.

Stability study[22]

Stability studies of prepared Nanoparticle Oro dispersible film were carried out, by storing optimized formulation at 4°C ±1°C and 30°C ± 2°C in stability chamber for 90 days. The samples were analyzed at 0, 1, 2, and 3 months for their drug content, drug release rate (t50%) as well as any changes in their physical appearance (ICH Q1A (*R*2) 2003).

RESULTS AND DISCUSSION

FT-IR Spectrum of Aripiprazole

All the formulations were uniform in drug content and the FTIR spectra of Aripiprazole and its Oro dispersible films are identical. The principle FTIR absorption peaks of Aripiprazole Oro dispersible films were observed and found to be identical with the spectra of Aripiprazole pure drug. Thus, from the spectra it was understood that there was no interaction between Aripiprazole and the polymers used in the preparation of Oro dispersible films.

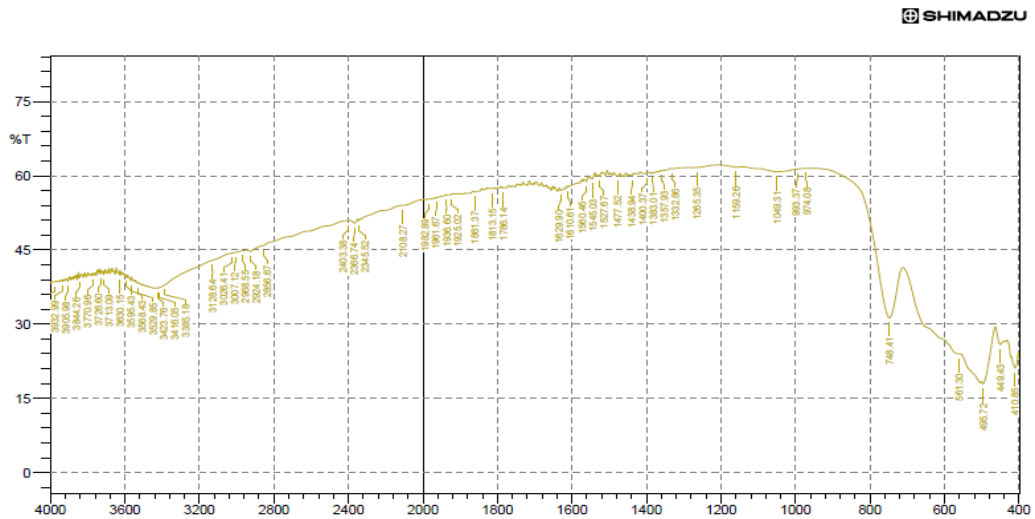

Fig. 1: FT-IR Sample for Aripiprazole.

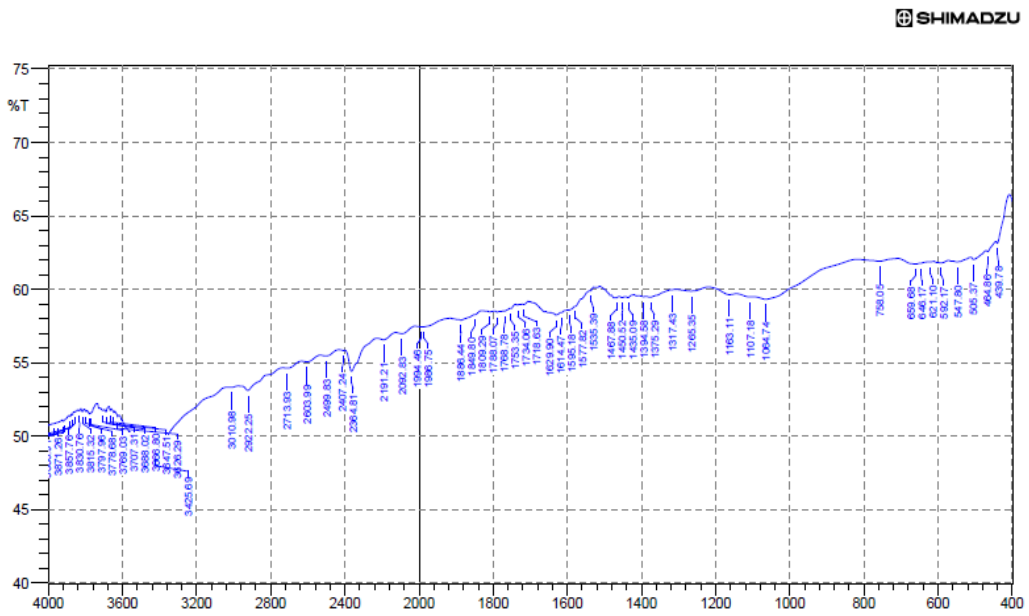

Fig. 2: FT-IR Sample for Optimized formulation.

Particle size

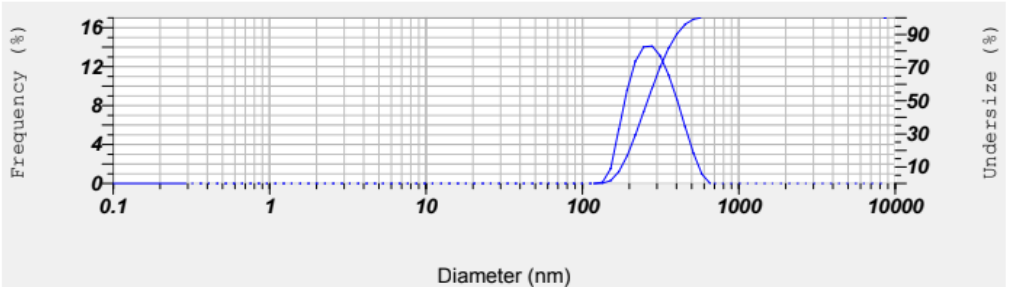

Fig. 3: Particle size of nanoparticles.

The mean particle size of optimized Nanoparticles was found to be 261 nm.

Zeta potential

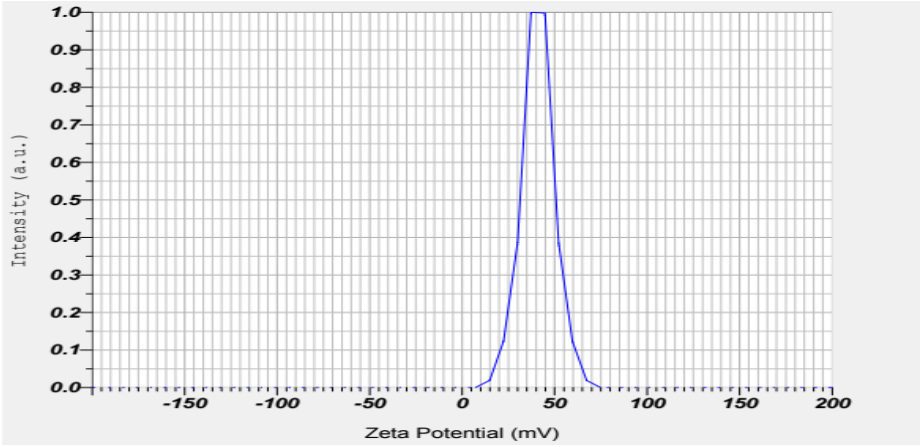

Fig. 4: Zeta potential analysis of Optimized Nanoparticles.

Table 3: Evaluation Studies of particle size and Zeta potential Nanoparticles.

F. No	Particle size (nm)	Zeta potential
F1	301	-21
F2	326	-25
F3	298	-29
F4	319	-23
F5	355	-27
F6	285	-20
F7	261	-22
F8	275	-26

Surface morphology

According to scanning electron microscopy (SEM), the polymeric nanoparticles were round, smooth, and free of any aggregation.

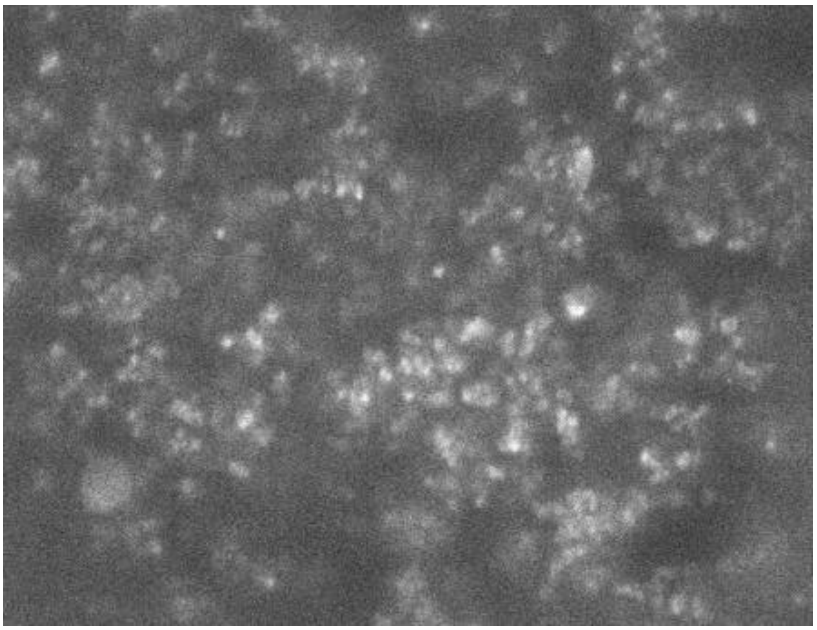

Fig. 5: SEM analysis of Optimized polymeric nanoparticle.

The particle size of nanoparticles plays a crucial role in determining their drug release rate, stability, and bioavailability. The mean particle size of the optimized Aripiprazole nanoparticles (F7) was found to be 261 nm, indicating successful formation of nanosized particles within the desired range. All formulations exhibited particle sizes between 261 nm and 355 nm. The variation in particle size among the formulations could be attributed to differences in polymer concentration, surfactant levels, and stirring speed during the emulsion solvent evaporation process. Generally, an increase in polymer concentration tends to increase particle size due to higher viscosity of the organic phase, leading to reduced dispersion efficiency.

The zeta potential values of the formulations ranged from –20 mV to –29 mV, indicating moderately stable nanoparticle suspensions. The optimized formulation (F7) exhibited a zeta potential of –22 mV, suggesting sufficient electrostatic repulsion between particles to prevent aggregation. Higher absolute zeta potential values (more negative) typically enhance the stability of the nanoparticles by minimizing inter-particle attraction. The negative charge can be attributed to the presence of carboxyl groups in the polymer or surfactant molecules adsorbed onto the nanoparticle surface. Scanning Electron Microscopy (SEM) analysis further confirmed that the optimized nanoparticles were spherical, smooth-surfaced, and discrete, without signs of aggregation or irregular morphology. The uniform surface indicates proper encapsulation of the drug within the polymer matrix and efficient solvent removal during the drying process.

EVALUATION PARAMETERS OF NANOPARTICLE INCORPORATED IN ORODISPERSIBLE FILMS

Evaluation of Oro dispersible film formulation

Physical appearance

The prepared oro dispersible film were found to be uniform, smooth, flexible and homogenous.

Folding endurance

The folding endurance values were 140–153, which indicates that all formulations had sufficient flexibility and mechanical strength to withstand repeated folding without breaking. F7 showed the highest folding endurance (153), suggesting superior film strength and elasticity.

Weight and Thickness

The film weights ranged between 127–138 mg, with thicknesses from 0.31–0.49 mm. The results show that the films were of uniform weight and thickness, indicating good reproducibility of the casting technique. Slight variations may be attributed to differences in polymer concentration and solvent evaporation rates.

Drug content

Drug content ranged from 75.69% (F1) to 90.12% (F7). Lower values in F1–F3 may be due to drug loss during film preparation or non-uniform distribution, whereas F6–F8 showed

higher content, indicating improved entrapment and homogeneity. Among all, F7 exhibited the highest drug content (90.12%), suggesting it to be the most optimized formulation.

Moisture Loss and Moisture Absorption

Moisture loss was 8.1–8.9%, while absorption was 9.1–10.5% across formulations. These values reflect moderate hygroscopic nature, which ensures film stability without becoming too brittle or sticky. F8 showed slightly higher absorption (10.5%), possibly due to hydrophilic excipients.

Tensile Strength

The tensile strength values varied between 14.6–16.8 MPa, indicating that the films possessed good mechanical integrity. F7 again showed the highest strength (16.8 MPa), which correlates with its high folding endurance, confirming that the formulation can resist mechanical stress during handling and administration.

Disintegration Time

Disintegration times ranged from 12–20 seconds. F7 showed the fastest disintegration (12 sec), followed by F4 and F6 (15–16 sec), indicating rapid film hydration and breakdown. Formulations with longer disintegration (F1 = 20 sec) may have higher polymer concentrations or lower hydrophilicity.

Table 4: Physicochemical evaluation of oro dispersible films.

Formulation code	Weight (mg)	Thickness (mm)	Folding endurance	Drug content (%)	% Moisture loss	% Moisture absorption	Tensile strength (Mpa)	Disintegration time (sec)
F1	127	0.43	149	75.69	8.5	9.1	14.6	20
F2	136	0.46	150	78.82	8.9	9.6	15.7	17
F3	129	0.35	146	79.52	8.1	9.5	14.9	19
F4	138	0.38	147	81.23	8.7	9.5	15.3	15
F5	128	0.31	143	83.26	8.3	10.1	15.8	18
F6	136	0.42	140	85.19	8.2	9.9	16.3	16
F7	132	0.45	153	90.12	8.6	10.3	16.8	12
F8	135	0.49	151	89.36	8.5	10.5	15.9	15

***In vitro* release study**

Phosphate buffer pH 6.8 was used as medium for the release studies and good linearity was observed in the plotted standard graph with a correlation coefficient of 0.997. The drug release profiles of films containing HPMC polymer. It was cleared from the release profiles of formulations, that the drug release was governed by polymer nature and content.

Table 5: *In vitro* drug release profiles of Nanoparticles Oro dispersible film(F1-F8).

Time (min)	F_1	F_2	F_3	F_4	F_5	F_6	F_7	F_8
0	0	0	0	0	0	0	0	0
5	25.69	26.89	24.57	23.39	28.25	29.26	30.15	31.29
10	36.85	38.96	39.60	37.48	34.67	35.10	42.91	40.25
15	48.92	50.25	52.22	49.84	50.12	49.86	50.21	52.25
20	67.95	68.52	65.15	59.82	63.27	60.27	62.79	60.15
25	81.26	82.26	80.20	78.95	80.25	79.86	81.26	80.16
30	92.56	93.68	94.57	90.12	92.79	94.33	98.85	96.37

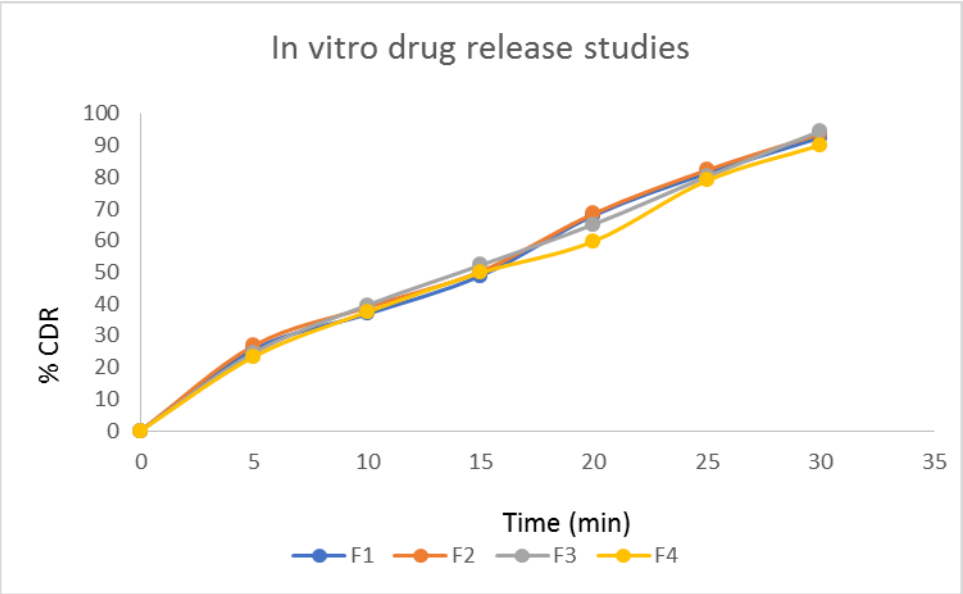

Fig. 7: Drug release for (F1-F4) formulations.

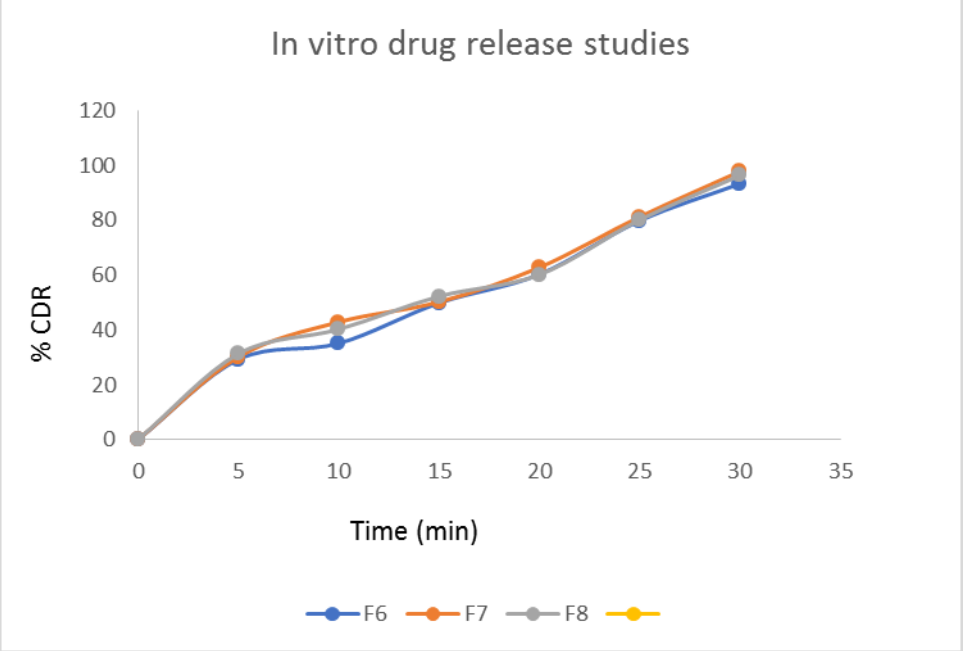

Fig-8: Drug release for (F5-F8) formulation.

Kinetic models

Dissolution data of above two methods was fitted in Zero order, First order and Higuchi equations. The mechanism of drug release was determined by using Higuchi equation.

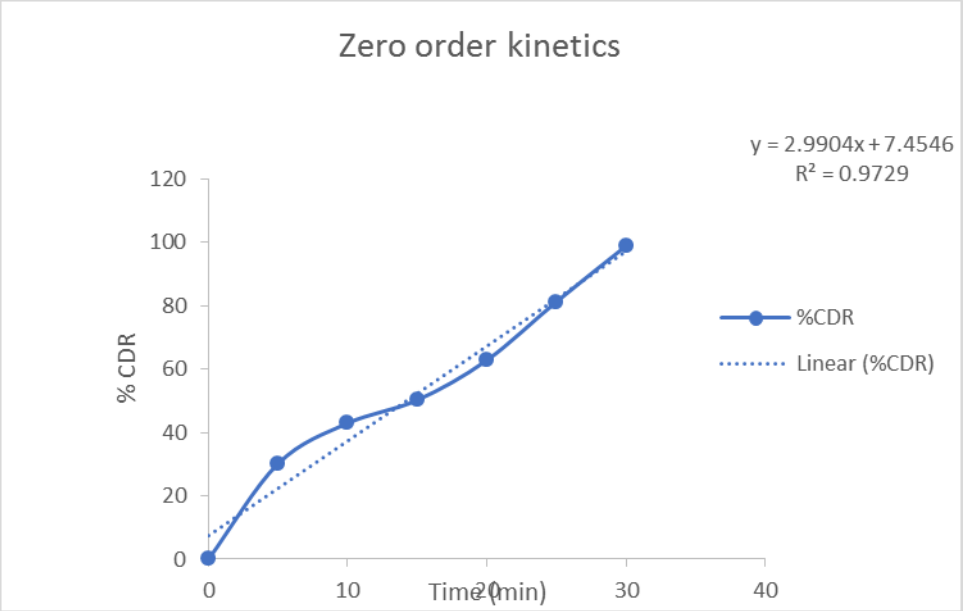

Fig. 9: Zero order kinetics of optimized formulation.

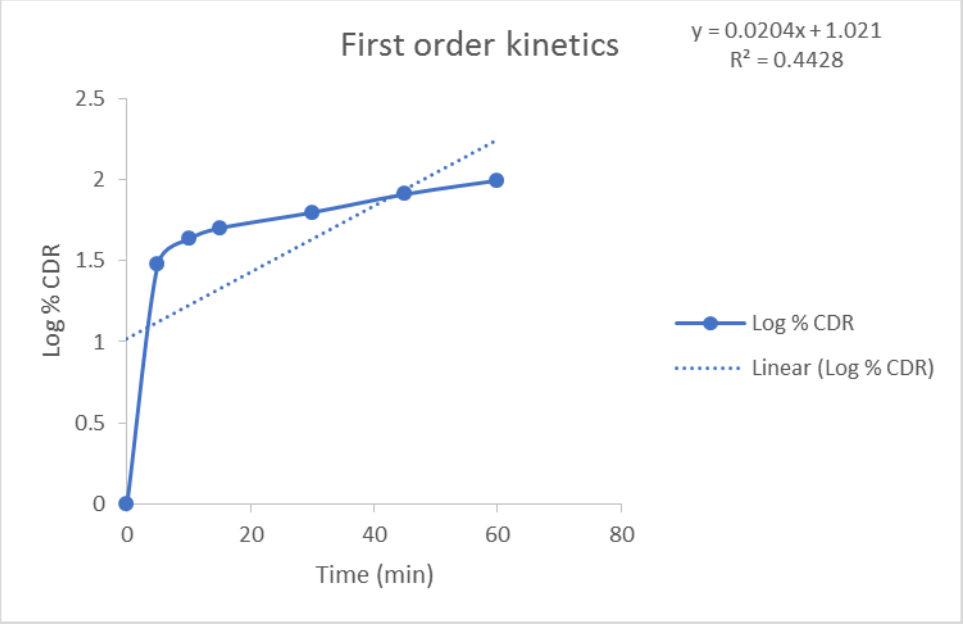

Fig. 10: First order kinetics of optimized formulation.

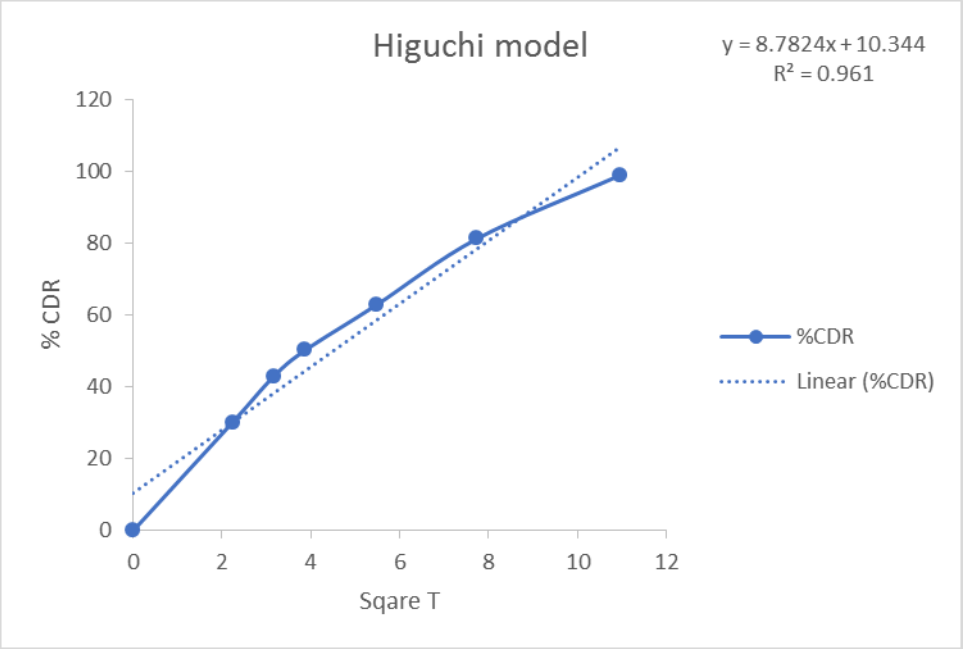

Fig. 11: Higuchi model of optimized formulation.

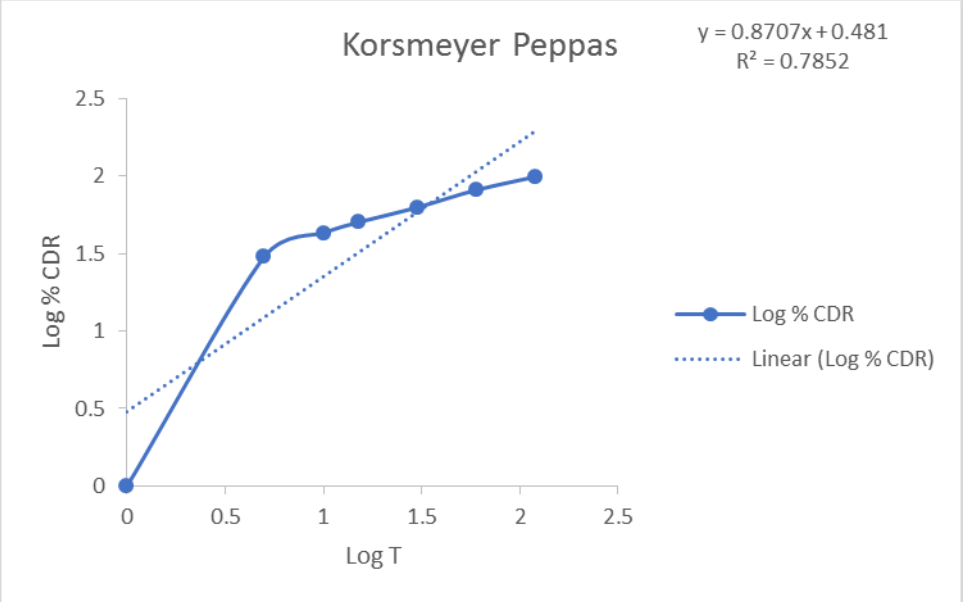

Fig. 12: Korsmeyer peppas of optimized formulation.

The values of in vitro release were attempted to fit into various mathematical models. Plots of zero order, first order, Higuchi model, Korsmeyer Peppas.

Regression values are higher with Zero order release kinetics. Therefore, all the orodispersible film follows Zero order release kinetics.

Table 6: Stability studies of optimized formulations at 40 ± 2 ^{0}C and 75 ± 5% RH for 3 months.

Time in days	Drug content (%)	Folding endurance	Physical appearance	% Cumulative drug release
0	90.12	153	No change in colour	98.85
0	89.69	512	Slight yellowish colour	97.50

Phosphate buffer pH 6.8 was used as medium for the release studies and good linearity was observed in the plotted standard graph with a correlation coefficient of 0.997. The drug release profiles of Orodispersible film containing HPMC. It was cleared from the release profiles of formulations, that the drug release was governed by polymer nature and content.

CONCLUSION

The study successfully demonstrated that Aripiprazole nanoparticles could be efficiently formulated using the emulsion solvent evaporation technique and incorporated into oro-dispersible films to enhance drug solubility, dissolution, and bioavailability. Therefore, Aripiprazole nanoparticle-loaded ODFs represent a promising alternative to conventional oral dosage forms, especially for patients with swallowing difficulties, ensuring improved therapeutic efficacy, patient compliance, and faster onset of action.

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