RESEARCH PAPER

Formulation, Characterization, and Evaluation of Sildenafil Citrate and Fluoxetine Hydrochloride Immediate-Release Film and Suspension: A Pharmaceutical Development Study

Akash Patel[1], Upendra Patel[2], Bhavin Vasantray Bhimani[3], Harsh Jitendrabhai Trivedi[4], Ravi V. Patel[5]

1. Research Scholar, Swarrnim Startup and Innovation University, Gujarat, India. Email: aakash191996@gmail.com
2. Principal, Aarihant School of Pharmacy, Swarrnim Startup and Innovation University, Gujarat, India. Email: upendralpatel02@gmail.com
3. Research Scholar, Swarrnim Startup and Innovation University, and Associate Professor, Aarihant School of Pharmacy & BRI, Swarrnim Startup and Innovation University, Gujarat, India. Email: bvb3636@gmail.com
4. Professor, Aarihant School of Pharmacy & BRI, Swarrnim Startup and Innovation University, Gujarat, India. Email: harshtrivedi28@gmail.com
5. Professor, Aarihant School of Pharmacy & BRI, Swarrnim Startup and Innovation University, Gujarat, India. Email: rvp251985@gmail.com

Corresponding Author: Akash Patel, Research Scholar, Swarrnim Startup and Innovation University, Gujarat, India. Email: aakash191996@gmail.com

Abstract

Background: Oral films and suspensions are alternative oral dosage forms that can support flexible administration. This study describes the formulation and evaluation of immediate-release oral films and suspensions containing sildenafil citrate and fluoxetine hydrochloride. Methods: Nine film formulations (F1-F9) containing 50 mg sildenafil citrate and 20 mg fluoxetine hydrochloride per unit were prepared using hydroxypropyl methylcellulose E5 (HPMC E5), polyvinyl alcohol (PVA), and glycerol. Nine suspension formulations (S1-S9) containing the same drug amounts per 5 mL were prepared using sodium carboxymethylcellulose (Na-CMC) and xanthan gum. Physical properties, drug content, in-vitro release, and FTIR compatibility were assessed. Results: Film thickness ranged from 0.112 to 0.154 mm, folding endurance from 86 to 157 folds, tensile strength from 2.8 to 4.1 MPa, and disintegration time from 48 to 29 s. At 30 min, release ranged from 91.3% to 99.0% for sildenafil citrate and 93.5% to 99.5% for fluoxetine HCl. Suspension pH ranged from 6.4 to 6.6, viscosity from 185 to 410 mPa·s, and sedimentation volume from 0.72 to 0.93. At 30 min, release ranged from 90.0% to 99.0% and 92.0% to 99.5%, respectively. Conclusion: The reported results show formulation-dependent differences in film mechanics, suspension rheology, and release. F9 and S9 had the highest reported values for several measured attributes; selection of a final product requires confirmation against predefined quality criteria and verified experimental records.

Keywords: Sildenafil Citrate; Fluoxetine Hydrochloride; Oral Film; Oral Suspension; Immediate Release; Drug Release; FTIR.

How to cite this article: Akash Patel1 Upendra Patel2 Bhavin Vasantray Bhimani3 Harsh Jitendrabhai Trivedi4 Ravi V. Patel5. Formulation, Characterization, and Evaluation of Sildenafil Citrate and Fluoxetine Hydrochloride Immediate-Release Film and Suspension: A Pharmaceutical Development Study. Int J Drug Deliv Technol. 2026;16(90s):1263-1270. DOI: 10.25258/ijddt.16.90s.125.

1. Introduction

Oral dosage forms are widely used because they are convenient and familiar to patients. However, conventional solid dosage forms may be difficult to administer to individuals who have swallowing difficulties or require flexible dosing. Oral films provide a thin, rapidly wetting dosage form, while oral suspensions allow drug administration as a measured liquid dose [1-3]. The performance of these dosage forms depends on polymer selection, excipient concentration, drug distribution, and the physical characteristics of the formulation. Hydrophilic film-forming polymers such as HPMC and PVA can provide film integrity, while plasticizers such as glycerol can influence flexibility. In suspensions, viscosity-modifying agents such as Na-CMC and xanthan gum can affect sedimentation, redispersibility, and drug release [4-5]. The present study compares nine immediate-release oral-film formulations and nine oral-suspension formulations containing sildenafil citrate and fluoxetine hydrochloride. The formulations were evaluated for physical properties, drug content, in-vitro release, and FTIR spectral changes. The aim was to describe the observed formulation trends and identify candidates for further product development.

2. Materials and Methods

2.1 Materials

Sildenafil citrate and fluoxetine hydrochloride were selected as the active pharmaceutical ingredients. Hydroxypropyl methylcellulose E5 (HPMC E5) and polyvinyl alcohol (PVA) were used as film-forming polymers, and glycerol was used as a plasticizer. Sodium carboxymethylcellulose (Na-CMC) and xanthan gum were used as suspension stabilizers. Purified water was used as the aqueous vehicle. A suitable wetting agent, sweetener, flavouring agent, and preservative, where required, were selected during preliminary formulation studies. The selected excipients were used according to their intended functions in oral films and oral suspensions.

2.2 Formulation Design

Nine formulations were prepared for each dosage form. In the oral-film formulations, HPMC E5 and PVA concentrations were varied at three levels, while the glycerol concentration was adjusted according to the HPMC E5 concentration. In the suspension formulations, Na-CMC and xanthan gum concentrations were varied at three levels. The drug content was kept constant within each dosage-form series [6].

2.2.1 Immediate-Release Oral Films

Each film unit contained 50 mg of sildenafil citrate and 20 mg of fluoxetine hydrochloride. The composition of the film formulations is shown in Table 1.

Table 1. Composition of immediate-release oral-film formulations

Formulation	Sildenafil citrate (mg/unit)	Fluoxetine HCl (mg/unit)	HPMC E5 (mg)	PVA (mg)	Glycerol (mg)	Sweetener (mg)	Flavour (mg)
F1	50	20	100	1000	20	5	2
F2	50	20	100	1500	20	5	2
F3	50	20	100	2000	20	5	2
F4	50	20	150	1000	30	5	2
F5	50	20	150	1500	30	5	2
F6	50	20	150	2000	30	5	2
F7	50	20	200	1000	40	5	2
F8	50	20	200	1500	40	5	2
F9	50	20	200	2000	40	5	2

2.2.2 Immediate-Release Oral Suspensions

Each 5 mL of suspension contained 50 mg of sildenafil citrate and 20 mg of fluoxetine hydrochloride. The composition of the suspension formulations is shown in Table 2.

Table 2. Composition of immediate-release oral-suspension formulations

Formulation	Sildenafil citrate (mg/5 mL)	Fluoxetine HCl (mg/5 mL)	Na-CMC (mg)	Xanthan gum (mg)
S1	50	20	25.0	5
S2	50	20	25.0	10
S3	50	20	25.0	15
S4	50	20	37.5	5
S5	50	20	37.5	10
S6	50	20	37.5	15
S7	50	20	50.0	5
S8	50	20	50.0	10
S9	50	20	50.0	15

2.3 Preparation of Oral Films

HPMC E5 and PVA were accurately weighed and dispersed separately in portions of purified water. Each polymer was allowed to hydrate completely. The polymer solutions were then combined under continuous stirring. Sildenafil citrate and fluoxetine hydrochloride were weighed separately and incorporated into the polymeric solution using a suitable solution or dispersion method. Glycerol, sweetener, and flavouring agent were added, and the mixture was stirred until a uniform casting solution was obtained. The casting solution was deaerated and poured onto a level casting surface with a defined area. The films were dried under controlled temperature and humidity conditions. The dried films were carefully removed from the casting surface and cut into units of uniform dimensions. The film units were stored in moisture-protective packaging until evaluation [7-8].

2.4 Preparation of Oral Suspensions

Na-CMC and xanthan gum were accurately weighed according to the formulation composition. The polymers were gradually dispersed in a portion of purified water with continuous stirring and allowed to hydrate. Sildenafil citrate and fluoxetine hydrochloride were incorporated into the hydrated polymer dispersion using a suitable dispersion procedure. The selected wetting agent, sweetener, flavouring agent, and preservative, where required, were then added. The mixture was stirred until a uniform suspension was obtained. The suspension was transferred to a calibrated container and diluted to the final volume with purified water. The final

suspension was mixed thoroughly and filled into clean, tightly closed containers. The containers were shaken according to a standardized procedure before sampling [9].

2.5 Preliminary Compatibility Assessment

Fourier-transform infrared spectroscopy (FTIR) was performed for sildenafil citrate, fluoxetine hydrochloride, selected excipients, and representative drug-excipient mixtures. The spectra were compared for changes in characteristic absorption bands, including shifts, broadening, disappearance, or changes in intensity. A suitable analytical method was used to quantify sildenafil citrate and fluoxetine hydrochloride separately in the film and suspension formulations. The method was evaluated for specificity, linearity, accuracy, precision, and suitability for drug-content and drug-release analysis [10].

2.6 Evaluation of Oral Films

2.6.1 Appearance and Surface Characteristics

The films were examined for colour, transparency, uniformity, surface smoothness, cracks, air bubbles, edge defects, and visible drug or excipient deposits. Tackiness, brittleness, and difficulty in removing the films from the casting surface were also recorded [11].

2.6.2 Thickness

Film thickness was measured at several evenly distributed points on each film unit using a calibrated micrometer. The mean thickness and standard deviation were calculated for each formulation.

2.6.3 Weight Variation

Individual film units of identical dimensions were weighed using an analytical balance. The mean weight, standard deviation, and percentage deviation from the mean were calculated [12].

2.6.4 Folding Endurance

A film strip of defined dimensions was folded repeatedly at the same location until visible cracking or breakage occurred. The number of folds completed before failure was recorded as the folding endurance.

2.6.5 Tensile Strength and Percentage Elongation

A film strip of defined dimensions was clamped in a tensile-testing instrument and pulled at a constant speed until breakage. The force at break, film width, film thickness, initial length, and length at break were recorded [13]. Tensile strength was calculated using Equation 1:

$$\text{Tensile strength} = \frac{\text{Force at break}}{\text{Film width Film thickness}}$$

$$\%\text{Elongation} = \frac{\text{Length at break} - \text{Initial length}}{\text{Initial length}} \text{ X } 100$$

2.6.6 Surface pH

A film unit was placed on a suitable support and moistened with a predefined volume of purified water. After equilibration, the surface pH was measured using a calibrated pH meter equipped with a suitable electrode. The same wetting volume and equilibration time were used for all formulations [14].

2.6.7 Disintegration Time

Each film unit was placed in the selected disintegration medium at a controlled temperature. The time required for the film to break apart or lose its structural integrity was recorded.

2.6.8 Drug Content and Content Uniformity

Individual film units were dissolved or extracted using a suitable solvent system. The extracts were clarified, diluted where necessary, and analysed for sildenafil citrate and fluoxetine hydrochloride using the validated analytical method. Drug content was calculated using the appropriate calibration curves and expressed as the amount of drug per film unit and as a percentage of the target content. Content uniformity was determined using individual film units [15].

2.6.9 In Vitro Drug-Release Study

Film units were tested using a suitable drug-release apparatus and medium. The release medium, volume, temperature, agitation speed, sampling schedule, and sample-replacement procedure were standardized. At each sampling interval, a measured volume of the release medium was withdrawn and replaced with an equal volume of fresh medium. Samples were clarified using a validated procedure and analysed separately for sildenafil citrate and fluoxetine hydrochloride. Cumulative drug release was calculated as a percentage of the measured drug content in each film unit. Corrections were applied for the removal and replacement of the release medium [16].

2.7 Evaluation of Oral Suspensions

2.7.1 Appearance and Homogeneity

The suspensions were examined for colour, odour, visible aggregation, caking, phase separation, and other physical changes. Each sample was mixed using a standardized procedure before evaluation.

2.7.2 pH

The pH of each suspension was measured using a calibrated pH meter at a controlled temperature. The electrode was rinsed between measurements [17].

2.7.3 Viscosity

Viscosity was measured using a suitable viscometer at a specified temperature. The spindle, rotational speed, equilibration time, and sample volume were kept constant for all formulations.

2.7.4 Sedimentation Volume

A measured volume of suspension was transferred to a graduated cylinder and stored under defined conditions. The sediment volume and original suspension volume were recorded at specified time intervals.

Sedimentation volume was calculated using Equation 3: $F = V_u / V_o$, where V_u is the ultimate sediment volume and V_o is the original suspension volume. F is dimensionless [18].

2.7.5 Redispersibility

After the defined storage period, each container was inverted or shaken using a standardized procedure. The number of inversions required to redisperse the sediment uniformly was recorded.

2.7.6 Particle-Size Distribution

Particle-size distribution was determined using a suitable method, such as laser diffraction or microscopy. The dispersion conditions, dilution medium, instrument settings, and reported particle-size parameters were recorded.

2.7.7 Drug Content

The suspension was mixed thoroughly before sampling. A measured volume was withdrawn and the drugs were extracted using a suitable solvent system. The extract was clarified, diluted where required, and analysed separately for sildenafil citrate and fluoxetine hydrochloride. Drug content was expressed as the amount of each drug per 5 mL and as a percentage of the target content.

2.7.8 In Vitro Drug-Release Study

A measured quantity of suspension corresponding to the defined test dose was introduced into the selected release apparatus containing the release medium. The temperature, agitation speed, medium volume, sampling intervals, and sample-replacement procedure were standardized. Samples were prepared using a validated procedure and analysed separately for both drugs. Cumulative percentage release was calculated using the measured drug content as the reference value, with correction for the volume removed and replaced during sampling [19].

3. Results and Discussion of Oral Films

3.1 Physical and Mechanical Evaluation

The physical and mechanical results for formulations F1-F9 are summarized in Table 3. Film thickness ranged from 0.112 ± 0.006 mm in F1 to 0.154 ± 0.007 mm in F9. The increase in thickness was associated with the higher total polymer content of the formulations. Weight variation ranged from 2.4% to 3.2%, indicating relatively consistent film mass across the tested formulations. Folding endurance increased from 86 ± 5 folds in F1 to 157 ± 8 folds in F9, while tensile strength increased from 2.8 ± 0.2 MPa to 4.1 ± 0.2 MPa. These findings indicate that the later formulations exhibited greater resistance to repeated folding and improved mechanical strength. However, the individual contributions of HPMC E5, PVA, and glycerol could not be established because their concentrations varied simultaneously. Disintegration time decreased from 48 ± 4 s in F1 to 29 ± 2 s in F9, indicating faster disintegration in the later formulations. Surface pH values ranged from 6.5 to 6.7, showing minimal variation among the formulations. F9 exhibited the highest reported folding endurance and tensile strength, together with the shortest disintegration time.

Table 3. Physical and mechanical properties of film formulations F1-F9

Formulation	Thickness (mm)	Weight variation (%)	Folding endurance (folds)	Tensile strength (MPa)	Surface pH	Disintegration time (s)
F1	0.112 ± 0.006	3.2 ± 0.8	86 ± 5	2.8 ± 0.2	6.5 ± 0.2	48 ± 4
F2	0.121 ± 0.005	2.9 ± 0.7	98 ± 6	3.0 ± 0.2	6.5 ± 0.2	44 ± 3
F3	0.130 ± 0.006	2.7 ± 0.6	112 ± 7	3.2 ± 0.2	6.6 ± 0.2	40 ± 3
F4	0.124 ± 0.006	2.8 ± 0.7	105 ± 6	3.1 ± 0.2	6.5 ± 0.2	43 ± 3
F5	0.133 ± 0.005	2.5 ± 0.6	124 ± 6	3.4 ± 0.2	6.6 ± 0.1	38 ± 3
F6	0.142 ± 0.006	2.6 ± 0.7	139 ± 7	3.7 ± 0.3	6.6 ± 0.2	34 ± 3
F7	0.136 ± 0.006	2.7 ± 0.6	131 ± 7	3.5 ± 0.2	6.6 ± 0.2	37 ± 3
F8	0.145 ± 0.005	2.5 ± 0.6	146 ± 8	3.8 ± 0.3	6.7 ± 0.2	33 ± 2
F9	0.154 ± 0.007	2.4 ± 0.5	157 ± 8	4.1 ± 0.2	6.7 ± 0.2	29 ± 2

3.2 Drug Content

The drug-content results for formulations F1-F9 are presented in Table 4. Sildenafil citrate content ranged from 96.8 ± 1.4% to 99.2 ± 0.7% of the target content, while fluoxetine hydrochloride content ranged from 97.2 ± 1.3% to 99.4 ± 0.6%. Formulation F9 showed the highest reported content for both drugs. The relatively low standard deviations indicate limited variability in the measured drug content. Content uniformity was assessed using individual film units to evaluate the distribution of both drugs within each formulation.

Table 4. Drug content of film formulations F1-F9

Formulation	Sildenafil citrate (% of target)	Fluoxetine HCl (% of target)
F1	96.8 ± 1.4	97.2 ± 1.3
F2	97.4 ± 1.2	97.8 ± 1.1
F3	98.1 ± 1.0	98.4 ± 0.9
F4	97.6 ± 1.2	97.9 ± 1.1
F5	98.5 ± 0.9	98.8 ± 0.8
F6	98.9 ± 0.8	99.1 ± 0.7
F7	98.0 ± 1.0	98.3 ± 0.9
F8	98.7 ± 0.9	99.0 ± 0.8
F9	99.2 ± 0.7	99.4 ± 0.6

3.3 In Vitro Drug Release

Drug release increased with time for all formulations. At 30 min, sildenafil citrate release ranged from 91.3% in F1 to 99.0% in F9. Fluoxetine hydrochloride release ranged from 93.5% in F1 to 99.5% in F9. Formulation F9 showed the highest release at each sampling time, whereas F1 showed the lowest release. Fluoxetine hydrochloride release was slightly higher than sildenafil citrate release at the measured time points. The differences among formulations may be related to changes in polymer content and film structure. However, the independent effects of HPMC E5, PVA, and glycerol require statistical analysis based on the formulation design.

3.3.1 Sildenafil Citrate Release

Table 5. Cumulative release of sildenafil citrate from film formulations F1-F9

Time (min)	F1	F2	F3	F4	F5	F6	F7	F8	F9
5	24.5	28.0	31.5	27.0	32.0	36.0	30.0	35.0	38.0
10	46.8	52.0	57.0	50.0	59.0	65.0	56.0	63.0	68.0
15	65.2	70.0	75.0	68.0	77.0	83.0	74.0	82.0	87.0
20	79.4	84.0	88.0	82.0	90.0	94.0	87.0	93.0	96.0
30	91.3	94.0	96.0	93.0	97.0	98.0	95.0	98.0	99.0

3.3.2 Fluoxetine Hydrochloride Release

Table 6. Cumulative release of fluoxetine hydrochloride from film formulations F1-F9

Time (min)	F1	F2	F3	F4	F5	F6	F7	F8	F9
5	27.2	30.0	33.0	29.0	34.0	38.0	32.0	37.0	40.0
10	49.5	55.0	60.0	53.0	62.0	68.0	59.0	66.0	71.0
15	68.1	73.0	78.0	71.0	80.0	86.0	77.0	85.0	90.0
20	82.3	87.0	91.0	85.0	93.0	96.0	90.0	95.0	98.0
30	93.5	96.0	98.0	95.0	98.0	99.0	97.0	99.0	99.5

3.4 FTIR Analysis

The FTIR spectra of the individual drugs, selected excipients, and representative film formulation are compared in Figure 1. In the displayed film spectra, the principal bands attributed to sildenafil citrate and fluoxetine HCl remain observable in the representative film spectrum. The figure labels bands near 3326 and 3402 cm^{-1} for the individual drugs and corresponding broad bands near 3345 cm^{-1} in the film mixture; bands in the fingerprint region are also retained, although some overlap and modest shifts are visible. This pattern is consistent with retention of recognizable drug-associated absorptions and does not, by itself, establish chemical compatibility or exclude interactions. The exact peak assignments and shifts should be confirmed from the original spectral files and reported with instrument conditions.

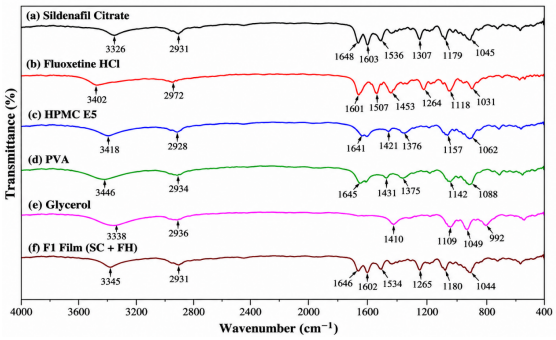


Figure 1. FTIR spectra of sildenafil citrate, fluoxetine hydrochloride, HPMC E5, PVA, glycerol, and the F1 immediate-release oral film formulation.

4. Results and Discussion of Oral Suspensions

4.1 Physical Evaluation

The physical-property results for suspension formulations S1-S9 are presented in Table 7. All formulations appeared as uniform, pale suspensions, with pH values ranging from 6.4 to 6.6. Viscosity increased from 185 ± 8 mPa·s in S1 to 410 ± 18 mPa·s in S9. Sedimentation volume also increased

with increasing Na-CMC and xanthan gum concentrations, reaching 0.93 ± 0.02 in S9. The number of inversions required for redispersion decreased as viscosity increased. These observations suggest that higher polymer concentrations improved resistance to sedimentation, while also increasing resistance to pouring and redispersion.

Table 7. Physical properties of suspension formulations S1-S9

Formulation	pH	Viscosity (mPa·s)	Sedimentation volume	Redispersion (inversions)
S1	6.4 ± 0.1	185 ± 8	0.72 ± 0.03	8 ± 1
S2	6.4 ± 0.1	215 ± 9	0.78 ± 0.03	7 ± 1
S3	6.5 ± 0.1	250 ± 11	0.83 ± 0.02	6 ± 1
S4	6.4 ± 0.1	235 ± 10	0.77 ± 0.03	7 ± 1
S5	6.5 ± 0.1	275 ± 12	0.84 ± 0.02	6 ± 1
S6	6.5 ± 0.1	320 ± 14	0.89 ± 0.02	5 ± 1
S7	6.5 ± 0.1	295 ± 13	0.82 ± 0.03	6 ± 1
S8	6.5 ± 0.1	350 ± 15	0.90 ± 0.02	5 ± 1
S9	6.6 ± 0.1	410 ± 18	0.93 ± 0.02	4 ± 1

4.2 Drug Content

The drug-content results for suspension formulations S1-S9 are presented in Table 8. Sildenafil citrate content ranged from 96.5 ± 1.5% to 98.8 ± 0.8%, while fluoxetine hydrochloride content ranged from 96.9 ± 1.4% to 99.0 ± 0.7%. Formulation S9 showed the highest reported content values for both drugs. The relatively low standard deviations indicate limited variability in the measured drug content among the tested suspension samples.

Table 8. Drug content of suspension formulations S1-S9

Formulation	Sildenafil citrate (%)	Fluoxetine HCl (%)
S1	96.5 ± 1.5	96.9 ± 1.4
S2	97.0 ± 1.3	97.3 ± 1.2
S3	97.6 ± 1.2	97.9 ± 1.1
S4	97.2 ± 1.3	97.5 ± 1.2
S5	98.0 ± 1.0	98.3 ± 0.9
S6	98.5 ± 0.9	98.7 ± 0.8
S7	97.8 ± 1.1	98.0 ± 1.0
S8	98.4 ± 0.9	98.7 ± 0.8
S9	98.8 ± 0.8	99.0 ± 0.7

4.3 In Vitro Drug Release

Both drugs showed progressive release over 30 min. Sildenafil citrate release at 30 min ranged from 90.0% in S1 to 99.0% in S9. Fluoxetine hydrochloride release ranged from 92.0% in S1 to 99.5% in S9. The higher-polymer formulations showed increased viscosity and improved sedimentation behaviour. The release profiles also differed among the formulations. These differences may be related to the physical structure and viscosity of the suspension vehicle. Formulations with higher polymer concentrations showed a modified early-release pattern compared with the lower-polymer formulations.

4.3.1 Sildenafil Citrate Release

Table 9. Sildenafil citrate release from suspension formulations S1-S9

Formulation	5 min (%)	10 min (%)	15 min (%)	20 min (%)	30 min (%)
S1	22.5	43.0	62.0	77.0	90.0
S2	25.0	47.5	67.0	82.0	93.0
S3	28.0	52.0	72.0	87.0	96.0
S4	24.0	45.5	65.0	80.0	92.0
S5	27.5	51.0	71.0	86.0	95.0
S6	31.0	57.0	78.0	92.0	98.0
S7	26.0	49.0	69.0	84.0	94.0
S8	30.0	56.0	77.0	91.0	97.0
S9	33.0	61.0	82.0	95.0	99.0

4.3.2 Fluoxetine Hydrochloride Release

Table 10. Fluoxetine hydrochloride release from suspension formulations S1-S9

Formulation	5 min (%)	10 min (%)	15 min (%)	20 min (%)	30 min (%)

S1	24.0	45.0	64.0	79.0	92.0
S2	26.5	49.0	69.0	84.0	95.0
S3	29.5	54.0	74.0	89.0	97.0
S4	25.5	47.5	67.0	82.0	94.0
S5	29.0	53.0	73.0	88.0	96.0
S6	32.5	59.0	80.0	94.0	99.0
S7	27.5	51.0	71.0	86.0	95.0
S8	31.5	58.0	79.0	93.0	98.0
S9	34.5	63.0	84.0	96.0	99.5

4.4 FTIR Analysis

The FTIR spectra of the individual drugs, selected excipients, physical mixture, and optimized suspension are compared in Figure 2. In the displayed suspension spectra, drug-associated bands remain visible in the physical mixture and optimized suspension traces, including broad bands around 3346-3348 cm^{-1} and multiple fingerprint-region bands. The apparent retention of these features is consistent with the presence of both drugs in the excipient matrix. Because the plotted spectra are not accompanied by raw spectral data, replicate scans, or validated peak assignments, FTIR alone cannot confirm absence of interaction; the conclusion should be limited to no obvious major spectral change in the displayed traces.

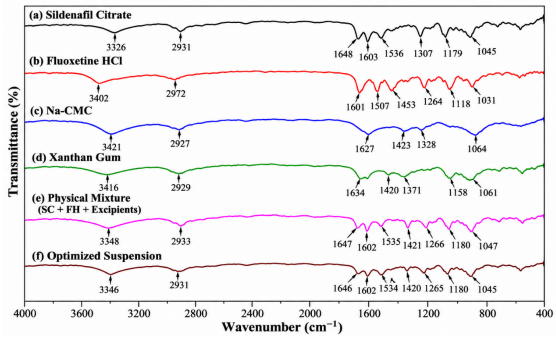


Figure 2. FTIR spectra of sildenafil citrate, fluoxetine hydrochloride, Na-CMC, xanthan gum, their physical mixture, and the optimized immediate-release suspension formulation.

5. Conclusion

Immediate-release oral films and oral suspensions containing sildenafil citrate and fluoxetine hydrochloride were prepared using polymeric excipients. The film formulations showed acceptable physical properties, increasing mechanical strength with increasing polymer concentration, short disintegration times, consistent drug content, and progressive release of both drugs. The suspension formulations showed uniform appearance, pH values in the range of 6.4-6.6, increasing viscosity with increasing polymer concentration, improved sedimentation volume, and satisfactory redispersibility. Both drugs demonstrated progressive release from the suspension formulations. Among the tested formulations, F9 showed the highest tensile strength, folding endurance, drug content, and drug release among the film formulations. S9 showed the highest viscosity, sedimentation volume, drug content, and drug release among the suspension formulations. Final formulation selection should be based on the complete experimental dataset, statistical analysis, stability results, dose uniformity, ease of administration, and predefined product-quality criteria.

References

1. Xu LL, Shi LL, Cao QR, Xu WJ, Cao Y, Zhu XY, et al. Formulation and in vitro characterization of novel sildenafil citrate-loaded polyvinyl alcohol-polyethylene glycol graft copolymer-based orally dissolving films. Int J Pharm. 2014;473(1-2):398-406. doi:10.1016/j.ijpharm.2014.07.037.
2. Hosny KM, El-Say KM, Ahmed OA. Optimized sildenafil citrate fast orodissolvable film: a promising formula for overcoming the barriers hindering erectile dysfunction treatment. Drug Deliv. 2016;23(1):355-61. doi:10.3109/10717544.2014.916763.
3. Yadagiri DJ, Kuchukuntla M, Konatham M, Gorle MT, Bakshi V, Jadi RK. Development and characterization of sildenafil citrate oral thin films. Int J Pharm Sci Drug Res. 2021;13(2):147-51.
4. Malviya V, Pande S. Development and evaluation of fast dissolving film of fluoxetine hydrochloride. Res J Pharm Technol. 2021;14(10):5345-50. doi:10.52711/0974-360X.2021.00932.
5. Dadey E. Bioequivalence of 2 formulations of sildenafil oral soluble film 100 mg and sildenafil citrate (Viagra) 100 mg oral tablets in healthy male volunteers. Am J Ther. 2017;24(4):e373-80. doi:10.1097/MJT.0000000000000302.
6. Kim EY, Lee SY, Jeon JY, Im YJ, Kim Y, Kim HI, et al. Pharmacokinetics of a new orally soluble film formulation of sildenafil administered without water. Int J Clin Pharmacol Ther. 2014;52(6):437-45. doi:10.5414/CP201995.
7. Shaw A, Lawrence TE, Yan T, Liu M, Summers N, Daggumati V, et al. Bioequivalence studies of sildenafil citrate orodispersible film administered with and without water vs Viagra film-coated tablets in healthy male volunteers. Curr Ther Res Clin Exp. 2023;99:100708. doi:10.1016/j.curtheres.2023.100708.
8. Mewada V, Shah J, Jacob S, Shah H, Boddu SHS, Nair AB. Improvement of bioavailability of sildenafil citrate through taste masked orodispersible film for pulmonary hypertension management. AAPS PharmSciTech. 2024;25(7):194. doi:10.1208/s12249-024-02905-8.

9. Borges AF, Silva C, Coelho JFJ, Simões S. Oral films: current status and future perspectives: II—Intellectual property, technologies and market needs. J Control Release. 2015;206:108-21. doi:10.1016/j.jconrel.2015.03.012.
10. Borges AF, Silva C, Coelho JFJ, Simões S. Oral films: current status and future perspectives: I—Galenical development and quality attributes. J Control Release. 2015;206:1-19. doi:10.1016/j.jconrel.2015.03.006.
11. Silva BMA, Borges AF, Silva C, Coelho JFJ, Simões S. Mucoadhesive oral films: the potential for unmet needs. Int J Pharm. 2015;494(1):537-51. doi:10.1016/j.ijpharm.2015.08.038.
12. Dixit RP, Puthli SP. Oral strip technology: overview and future potential. J Control Release. 2009;139(2):94-107. doi:10.1016/j.jconrel.2009.06.014.
13. Preis M, Woertz C, Kleinebudde P, Breitkreutz J. Oromucosal film preparations: classification and characterization methods. Expert Opin Drug Deliv. 2013;10(9):1303-17. doi:10.1517/17425247.2013.804058.
14. Karki S, Kim H, Na SJ, Shin D, Jo K, Lee J. Thin films as an emerging platform for drug delivery. Asian J Pharm Sci. 2016;11(5):559-74. doi:10.1016/j.ajps.2016.05.004.
15. Kumar P, Verma M. Pharmaceutical suspensions: an updated patent review on novel suspending agents and recent advancement. Recent Adv Drug Deliv Formul. 2023;17(3):193-209. doi:10.2174/0126673878246149231010085610.
16. Allen LV Jr, Popovich NG, Ansel HC. Ansel's pharmaceutical dosage forms and drug delivery systems. 10th ed. Philadelphia: Wolters Kluwer; 2014.
17. Aulton ME, Taylor KMG, editors. Aulton's pharmaceutics: the design and manufacture of medicines. 5th ed. Edinburgh: Elsevier; 2018.
18. Sinko PJ, editor. Martin's physical pharmacy and pharmaceutical sciences: physical chemical and biopharmaceutical principles in the pharmaceutical sciences. 6th ed. Philadelphia: Lippincott Williams & Wilkins; 2011.
19. United States Pharmacopeial Convention. General chapter : uniformity of dosage units. In: United States Pharmacopeia and National Formulary (USP 47-NF 42). Rockville (MD): United States Pharmacopeial Convention; 2024.