WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.453
Volume 14, Issue 12, 719-735. Research Article ISSN 2277–7105

FORMULATION DEVELOPMENT OF MOUTH DISSOLVING FILMS OF QUETIAPINE

K. Senthilkumar[1]*, M. Pharm, PhD and Raj Priya Sennamanaidu[2], M. Pharm

[1]Department of Pharmaceutics, Ultra College of Pharmacy, Madurai, Tamil Nadu, India - 625020.

[2]Department of Pharmaceutics, Ultra College of Pharmacy, Madurai, Tamil Nadu, India - 625020.

Article Received on
03 May 2025,

Revised on 23 May 2025,
Accepted on 13 June 2025

DOI: 10.20959/wjpr202512-37241

***Corresponding Author**
Dr. K. Senthilkumar, M. Pharm, PhD
Department of Pharmaceutics, Ultra College of Pharmacy, Madurai, Tamil Nadu, India – 625020.

ABSTRACT

Objective: To enhance the solubility and bioavailability of Quetiapine fumarate (QF), a Biopharmaceutical Classification System (BCS) Class II drug, by formulating it into Mouth dissolving films (MDF) that provides rapid disintegration and improved patient compliance. **Methods:** Preformulation studies were conducted to evaluate organoleptic characters and drug - excipient compatibility by Fourier Transform Infrared spectroscopy (FTIR). MDF was prepared using Quetiapine fumarate - □-cyclodextrin (QF-β-CD) inclusion complexes, Hydroxypropyl methylcellulose (HPMC E-15) as a polymer, and Polyethylene glycol (PEG-400) as a plasticizer. The formulations were characterized for physicochemical properties, mechanical properties, Differential Scanning Calorimetry (DSC), Powder X-ray diffraction (PXRD), Scanning Electron Microscope (SEM) analysis and drug release in simulated saliva and gastric conditions. **Results:** The Quetiapine MDF showed excellent weight uniformity at 225 ± 0.5 mg, smooth surfaces, and a thickness of 41 ± 1.3 µm, with a dispersion time of 26 ± 1 s. The films had a neutral pH of 7, disintegrated quickly (9.2 ± 0.68 s), and contained 98.9 ± 0.31% of the drug. Mechanical tests indicated good flexibility, with a burst strength of 0.067 ± 0.06 N and a tensile strength of 3.21 ± 0.6 MPa. In vitro studies demonstrated 99.3% drug release in simulated salivary fluid (SSF) and 100% in 0.1M hydrochloric acid (HCl) within 30 minutes, confirming enhanced solubility. FTIR analysis showed no significant interactions between QF and excipients, while DSC, PXRD, and SEM confirmed reduced crystallinity and particle

size following the formation of the inclusion complex. **Conclusion:** The formulated Quetiapine MDF met United States Pharmacopeia (USP) standards, showing faster disintegration, enhanced dissolution, and higher bioavailability compared to commercially available immediate-release tablets. By bypassing first-pass metabolism, they improve absorption and patient compliance. The research demonstrated the potential for commercialization as an effective treatment.

KEYWORDS: Quetiapine fumarate, Mouth-dissolving films (MDF), Bioavailability, Inclusion complex, β-Cyclodextrin, Disintegration time, Drug release, Patient compliance.

INTRODUCTION

Oral dosage forms are the most common drug administration method due to the ease of administration, high patient convenience and compliance, minimum aseptic conditions, and flexibility in designing the dosage forms. However, there are several limitations for geriatric, pediatric, or dysphagic patients (people with difficulty in swallowing) and even animals. As an alternative method to overcome these limitations, orally disintegrating systems were developed, aiming for a fast release of the drug without water ingestion, also enabling drug absorption directly through oral mucosa to enter systemic circulation, avoiding first-pass hepatic metabolism.

MDFs, also called orodispersible films, are thin polymeric films with the size of a postage stamp that quickly hydrate and adhere to the mucosa wetted by saliva, disintegrate their matrices and release active compounds for absorption. They are thin, flexible, easy to handle and administrate, and stable for manufacturing, packaging, and transportation processes. They also provide acceptable taste and mouthfeel. The most common methods to produce MDFs include the solvent-casting method and hot- melt extrusion. Still, electrospinning and printing technologies have also been studied as alternative ways to create personalized MDFs.[1]

Quetiapine is within the chemical class of dibenzothiazepines and is used as an atypical antipsychotic drug for the treatment of bipolar disorder and schizophrenia. It is frequently prescribed to take twice / thrice a day to maintain the therapeutic plasma level because of its mean half-life of about 6 h. Quetiapine is a second-generation (Atypical antipsychotic) agent widely exploited in the effective management of schizophrenia. Interestingly, in contrast to olanzapine and risperidone, Quetiapine demonstrated significant neurocognition qualities and

expressed superior competence against positive and negative manifestations of schizophrenia. Clinically, Quetiapine has been reported to augment cognitive performance in many schizophrenia patients. It is known to be well tolerated in geriatrics. Together with its efficacy against a wide spectrum of ailments (mania, depression, bipolar disorders), Quetiapine has been approved as an ideal candidate for the first-line management of schizophrenia. Nonetheless, some major limitations of Quetiapine make it impractical to deliver via conventional means. In addition, Quetiapine is a BCS Class II agent with limited aqueous solubility, resulting in poor dissolution and limited absorption.[2]

AIM

The aim of this research work is to increase the solubility of Quetiapine fumarate and formulate that as a mouth dissolving film using solvent casting method and evaluate the physicochemical characteristics of the formulated film.

MATERIALS AND METHODS

Materials

Quetiapine fumarate was a gift sample from Orchid Healthcare in Chennai, Tamil Nadu, India. B- Cyclodextrin was procured from RP Chemicals, Chennai. Sucralose was generously donated by Par Pharmaceuticals. A mixed fruit flavour was kindly provided by Apex Laboratories, Chennai.

Drug-excipients compatibility study

A compatibility study of excipients with QF was conducted using FTIR spectroscopy to assess the interaction between the drug and the excipients. The FTIR spectra of the samples were recorded using the KBr disc method with a Shimadzu IRAffinity-1 spectrophotometer, employing IR solution software (Shimadzu, Japan). The sample powder was thoroughly mixed and triturated with potassium bromide in a glass mortar using a pestle, then compressed into a KBr disc with a hydraulic press. FTIR spectra for all samples were recorded over a spectral range of 4000 to 400 cm^{-1}, using 20 scans at a resolution of 4 cm^{-1}.

Preparation of QF - β-CD inclusion complex

Quetiapine fumarate - □-Cyclodextrin inclusion complex of weight ratio (1:1 gram) and molar ratio (1:1 molar) were prepared by the kneading method. QF and □-CD were triturated in a glass mortar with the pestle. Then small volume of distilled water was added to obtain slurry. Then it was kneaded for 45 min and then dried at room temperature. The dried complex

was passed through the # 60 ASTM Sieve.[3]

Optimization of Quetiapine MDF

The optimization trials were formulated with both types of QF - □-CD inclusion complex to optimize a suitable concentration of polymers and plasticizers as shown in Table 1.

Table 1: Optimization of Quetiapine MDF.

Batch Code	HPMC (Gram ratio)	HPMC (Molar ratio)	MD & PVA (Gram ratio)	MD & PVA (Molar ratio)
Ingredients	**Quantity / Film**			
QF - □-CD inclusion complex (mg)	814	932	814	932
HPMC E-15 (mg)	200	200		
Maltodextrin (mg)			200	200
Polyvinyl alcohol (mg)			200	200
Polyethylene glycol - 400 (mg)	400	400		
Polythene glycol (mg)			300	300
Distilled Water (ml)	5	5	5	5

Preparation of Quetiapine MDF

MDF of Quetiapine was prepared by solvent casting method using gram ratio QF-□-CD inclusion complex, the composition of which is given in Table 2. A homogenous solution of HPMC E-15 was prepared by continuous stirring of the polymer solution in distilled water. Sucralose, mixed fruit flavour - 148691, and PEG were added to the above solution and stirred well. Accurately weighed QF- □-CD inclusion complex was added and stirred well. Then it was poured in a petri dish and kept in Microwave oven for 45 min at 50 ^{0}C. Then the film was carefully removed from the petri dish, checked for imperfections and was cut into 3 x 3 cm square films to deliver the equivalent dose of 25 mg of QF per film. Then it was dried, and stored in Alu-Alu pouches and used for further evaluation studies.

Table 2: Composition of Quetiapine MDF.

Ingredients	Quantity / Film
QF-□-CD inclusion complex (mg)	814
HPMC E-15 (mg)	200
Sucralose (mg)	50
Mixed Fruit Flavour (ml)	0.025
PEG (mg)	400
Distilled Water (ml)	5

Evaluation of Quetiapine MDF

Formulated Quetiapine MDF were evaluated for appearance, uniformity of weight, thickness,

In vitro dispersion time, *In vitro* disintegration time, pH, folding endurance, tensile strength, burst strength, % elongation, Young's modulus, drug content, uniformity of dosage units, *In vitro* dissolution studies, DSC, PXRD, SEM.

Appearance

Homogeneity, colour, and transparency of films were tested visually.

Uniformity of weight

Each film was individually weighed on an analytical balance and the average weight of 3 films was found. A large difference in weight denotes the un-uniform distribution of a drug in the film.

Thickness of film

Thickness of the film was measured using Vernier Caliper by placing each film in different locations and the average thickness was calculated.

Mechanical properties

a) Burst strength

Film burst strength is the force required to break or rupture the film, which is an indicator of the flexibility of the film. The Burst strength of the film was studied using a 5 mm spherical stainless steel ball probe (P/5S) with the probe adapter which was connected to the load cell. A circular strip film with an area of 7.07 cm^2 was placed in the film supporting rig and the moving probe reached the surface of the film with the pretest speed of 2.0 mm/s. When the probe reached the surface of the film, the probe speed was changed to 1.0 mm/s test speed with the trigger load of 5 g and the data were recorded.

b) Tensile strength

The tensile strength of a film is an indicator of the toughness of the film. Films were cut into specimens with a width of 20 mm and a length of 60 mm. Film thickness was measured using a calibrated dial gauge with an accuracy of 0.001 mm at 5 different positions. The tensile strength of the film was determined with Tensile Grips (A/TG).

The test film was fixed to the upper tensile grip and the load cell was tare to zero weight. The upper tensile grip was moved to the preset distance of 25 mm and the test film was securely clamped to lower grip. The tensile force was gradually applied to the test film till the film broke. The parameters maintained were 1 mm/s pretest speed, and 1 mm/s test speed, in

distance target mode. Tensile strength was calculated using the formula,

$$\text{Tensile Strength} = \frac{F_{max}}{A_{Film}}$$

Where "Fmax" is the maximum force at breakage (N) and "Afilm" is the initial cross-sectional area of the sample (mm^2).

c) Percentage elongation

When stress is applied to an MDF, the film will stretch and this event is referred to as strain. Strain is the term for the deformation of a film divided by the original dimension of the sample, as seen in the equation below. In general, the elongation of a film will increase as the content of the plasticizer increases. Percentage Elongation was calculated using the formula,

$$\% \text{ Elongation} = \frac{L - L_0}{L_0} \text{ x } 100$$

Where "$L0$" is the initial gauge length of the specimen (mm) and "L" is the length at the moment of rupture (mm).

d) Folding endurance

Folding endurance was measured manually for the prepared films. MDF was repeatedly folded at 180 ^{0}C angle of the plane at the same place until it broke. The number of times the film could be folded at the same place without breaking was noted for 3 films of the same batch.

e) Young's modulus

Young's modulus, also known as elastic modulus, refers to the degree of stiffness of the film. Typically, harder and brittle films will have a higher tensile strength and higher Young's modulus with a lower degree of elongation. Young's modulus was calculated using the formula,

$$\text{Young's modulus} = \left(\frac{F_{lin}}{A_{film}}\right) \text{ x } \left(\frac{1}{\varepsilon}\right)$$

Where "Flin" is the force at a corresponding strain of the linear section (N), "Afilm" is the initial cross- sectional area of the sample (mm^2), and ε is the corresponding strain.

Surface pH

To identify the surface pH of the film, it was placed in a Petri dish and was moistened with 0.5 ml of distilled water and kept for 30 s. The surface pH was measured using pH paper placed on the surface of swollen films. The average of 3 determinations for each formulation was found out.

***In vitro* dispersion time**

In vitro dispersion time was measured by the petri dish method. A film was dropped in a petri dish of 9 cm in diameter, containing 10 ml of distilled water. The mean *In vitro* dispersion time of 6 films was determined.

***In vitro* disintegration time**

In vitro disintegration time was determined using a disintegration test apparatus. 6 MDFs were placed in each of the six tubes of the basket and apparatus operated with 900ml of distilled water as immersion fluid, maintained at 37 ^{0}C. The time taken to complete the disintegration of the film with no palpable mass remaining in the apparatus was recorded in seconds.

Drug Content and Uniformity of dosage units

a) For drug content

Ten films were weighed and dissolved in 500 ml 0.1 M HCl in a 500 ml volumetric flask and were sonicated for 10 min. Then 1 ml was pipetted out and transferred to a 100 ml volumetric flask and made up to 100 ml with 0.1 M HCl. Then the solution was analysed against 0.1 M HCl as blank in UV Visible Spectrophotometer at 208 nm.

b) For uniformity of dosage units

A film is dissolved in 50 ml 0.1 M HCl in a 50 ml volumetric flask and was sonicated for 10 min. Then 1 ml was pipetted out and transferred to a 100 ml volumetric flask and made up to 100 ml with 0.1 M HCl. Then the solution was analysed against 0.1 M HCl as blank in UV Visible Spectrophotometer at 208 nm. Uniformity of dosage units was performed by the content uniformity method as per USP 36. Ten films were assayed individually and the acceptance value was calculated.

$$\text{Acceptance Value} = |M - X| + \text{ks}$$

Where M is the reference value; X is the mean of Individual contents; k is the acceptability

Constant [If n = 10 then k = 2.4]; s is the sample Standard deviation.

The requirements for dosage uniformity are met if the acceptance value of the first 10 dosage units is less than or equal to L1% (i.e. 15%).

***In vitro* dissolution studies**

Dissolution studies were performed in 900 ml of SSF as well as 0.1 M HCL using Lab India Disso 2000 dissolution (paddle) apparatus (Lab India Instruments Pvt. Ltd., India) at 37 ± 0.5 ^{0}C with paddle rotation speed at 50 rpm.

Differential scanning calorimetry

The powdered sample (5 mg) of QF, □-CD, QF-□-CD inclusion complex, and dry mix of Quetiapine MDF were hermetically sealed in aluminium pans and heated at a constant rate of 20 ^{0}C/min, over a temperature range of 30 ^{0}C - 300 ^{0}C. Thermogram of the samples was obtained using DSC - 4000, PerkinElmer, India. Thermal analysis data were analysed using Pyris Software. The indium standard was used to calibrate the DSC temperature and enthalpy scale. An aluminium pan with a lid was used for all samples. An empty aluminium pan was used as a reference.

Powder X-ray diffraction

The PXRD patterns of samples were obtained from an X-ray diffractometer (Rigaku MiniFlex 600, Japan) working with Cu-Kα radiation and in 2θ range of 5^0 - 80^0 at 40 kV and 15 mA. The scan duration time was 10 ^{0}/min with a step size of 0.020.

Scanning electron microscope

Morphological evaluations of the samples were performed by Tescan, Vega 3 S, Czech Republic. The samples were mounted onto aluminium stubs using carbon double- sided tape and examined at an excitation voltage of 5 Kv.[3,4,5]

RESULTS AND DISCUSSION

Drug-Excipients Compatibility Study

The FTIR spectra of QF and blend are presented in Figure 1. FTIR spectra of QF showed characteristic peaks -OH stretching at 3305.9 cm^{-1}, C-H stretching at 2889.3 cm^{-1}, N-H bending at 1593.2 cm^{-1}, C-H bending in plane at 1377 cm^{-1}, C-C stretching at 1068.5 cm^{-1}. FTIR spectra of the Quetiapine blend showed characteristic peaks at -OH stretching at 3338.7 cm^{-1}, C-H stretching at 2908.6 cm^{-1}, N-H bending at 1600.9 cm^{-1}, C-H bending in plane at

1392.6 cm^{-1}, C-C stretching at 1060.8 cm^{-1}. The FTIR spectrum of the Quetiapine blend designates that all the prominent peaks of QF were present in the spectrum. It specifies that the drug has retained its identity without losing its characteristics.[3]

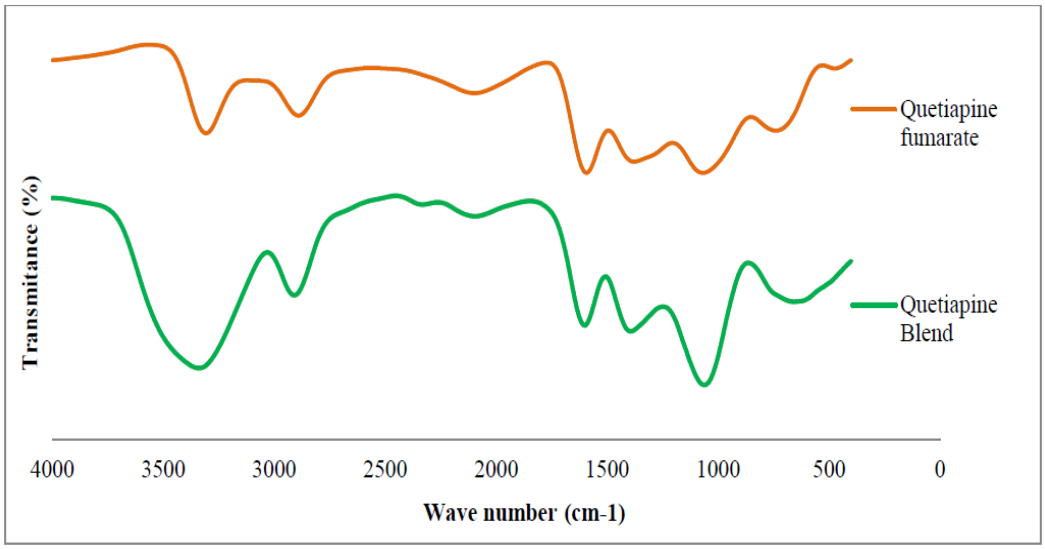

Figure 1: FTIR spectra of Quetiapine fumarate and Quetiapine blend.

Optimization of Quetiapine MDF

Prepared films were evaluated for uniformity of weight, thickness and *in vitro* dispersion time and the results were shown in Table 3. Except for film formulated with HPMC (gram ratio), all the films showed higher variation in weight, thickness and dispersion time, which might be due to un-uniform distribution. Hence, further formulation development was carried out with HPMC, PEG and gram ratio of QF - □-CD inclusion complex.

Table 3: Physicochemical properties of optimization of Quetiapine MDF.

Batch code	HPMC Gram ratio	HPMC Molar ratio	MD & PVA Gram ratio	MD & PVA Molar ratio
Weight (mg)	225 □ 0.5	253.5 □ 1.2	126.5 □ 1.7	205 □ 2.3
Thickness (□m)	41 □ 1.3	54 □ 1.9	76 □ 2.4	88 □ 3.7
Dispersion time (sec)	26 □ 1	37 □ 1.5	31 □ 2.3	40 □ 3.3

Evaluation of Quetiapine MDF

The evaluation results are depicted in Table 4.

Appearance

The appearance of films was found to be a homogenous, off-white and smooth surface.

Uniformity of weight

Weight variation was found to be minimum as indicated by a small standard deviation of about 0.5 mg. The observation also shows the uniform distribution of the ingredients in MDF.

Thickness of film

The maximum thickness of MDF was about 45 m and the calculated standard deviation values are very low which suggests that the prepared film was uniform in thickness indicating that added substances were uniformly distributed.

Mechanical properties

Results of mechanical properties indicate that Quetiapine MDF was found to have less flexibility. Results are presented in Table 4, Figure 2 and Figure 3.

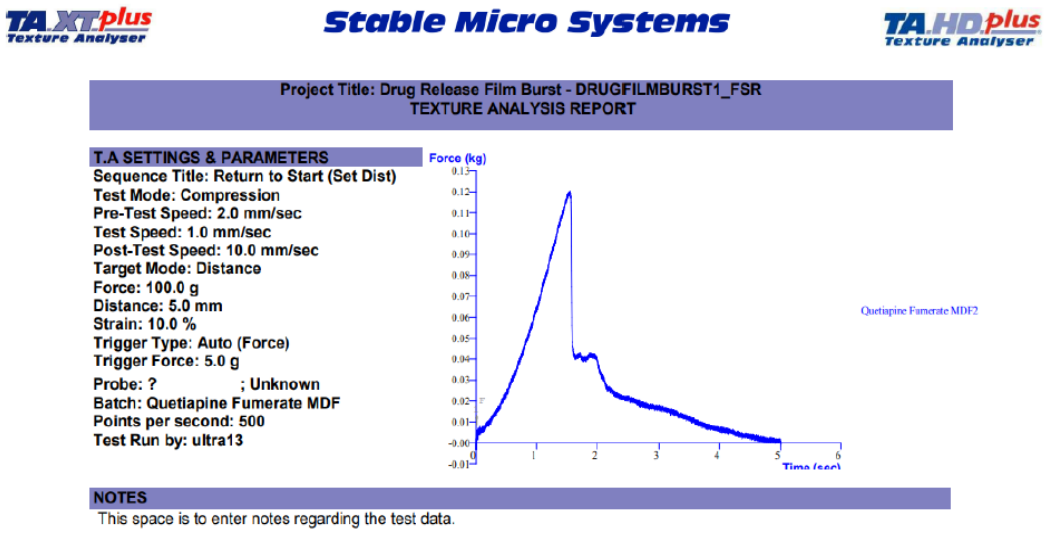

Figure 2: Texture analysis graph for Burst Strength of Quetiapine MDF.

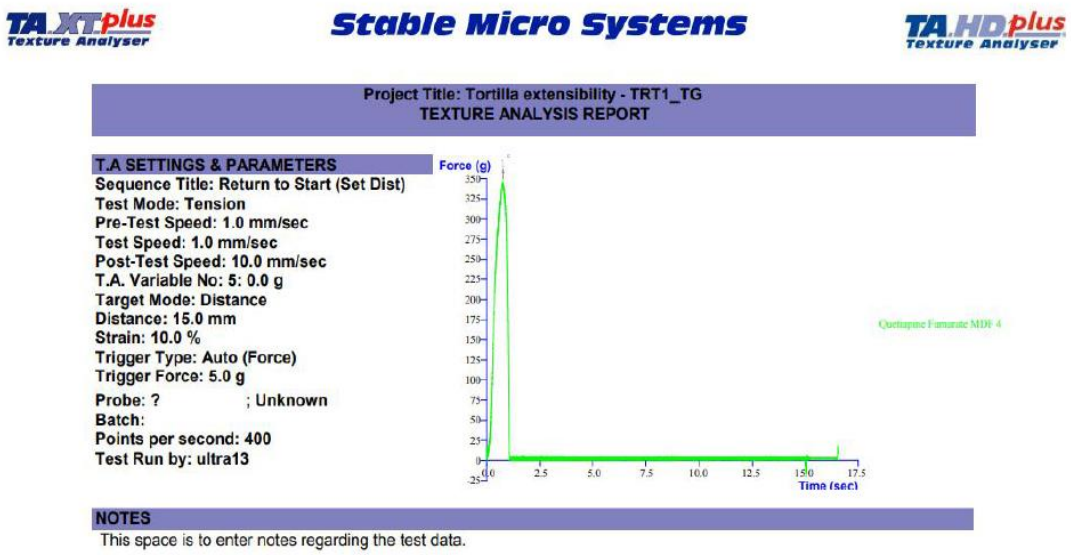

Figure 3: Texture analysis graph for Tensile Strength of Quetiapine MDF.

Surface pH

The film's surface pH was found to be in the range of 6.8 - 7. As the surface pH of the film was around the neutral pH, irritation would not be produced when administered.

In vitro dispersion time

The maximum *in vitro* dispersion time of the MDF was about 27 s, which indicates films were rapidly dispersible in the mouth.

In vitro disintegration time

The maximum *In vitro* disintegration time of the MDF was about 9.2 s. FDA recommends a disintegration time of 30 seconds or less for ODTs based on the USP disintegration test. The observed disintegration values of MDF were well below the limit and passed the disintegration test.

Drug content and UOD

The percentage drug content in all the formulations varied between 98.7 and 99.5, as depicted in Table 4. The uniformity of dosage units of formulation showed an L1 value of less than 15 indicating the accuracy and uniform distribution of quetiapine fumarate in the formulated MDF.

Table 4: Physicochemical and mechanical properties of Quetiapine MDF.

Parameters	Quetiapine MDF
Weight (mg)	230 □ 0.5

Thickness (□m)	45 □ 1
Burst Strength (N)	0.067 □ 0.06
Tensile Strength (MPa)	3.21 □ 0.6
% elongation	3.59 □ 0.27
Folding endurance	4 □ 1.1
Young's modulus (MPa)	24.6 □ 2.32
Surface pH	7
Drug content (%)	98.9 □ 0.31
UOD (Acceptance Value)	1.29
In vitro dispersion time (s)	27 □ 1.2
In vitro disintegration time (s)	9.2 □ 0.68

In vitro dissolution studies

In vitro drug release studies of Quetiapine MDF were carried out in SSF and 0.1 N HCl for 30 min. Quetiapine MDF showed rapid release in SSF. In 0.1 N HCl, release is rapid and complete. Dissolution profiles are given in Figures 4(a) and 4(b), respectively.

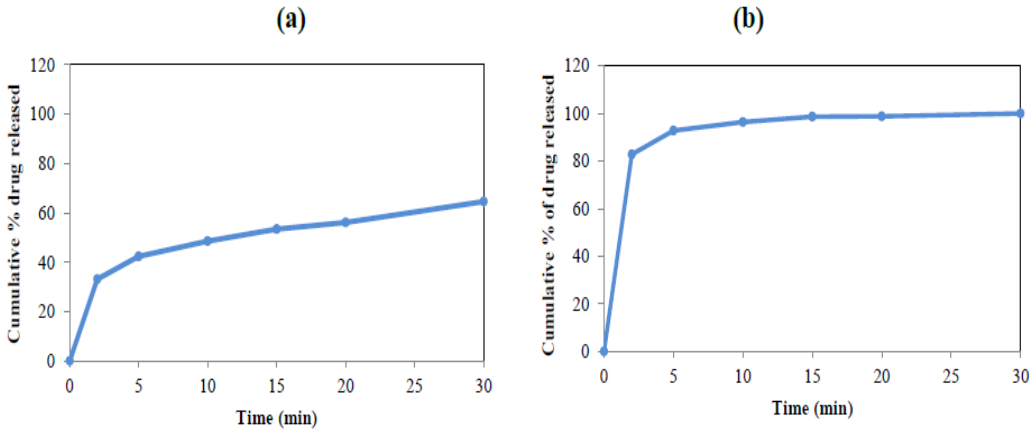

Figure 4: *In vitro* dissolution profiles of Quetiapine MDF in (a) SSF (b) 0.1 M HCl.

Differential scanning calorimetry

DSC of QF, □- CD and QF-□-CD inclusion complex were shown in Figure 5. The thermal behaviour of the QF-□-CD inclusion complex was studied using DSC to confirm the formation of the solid complexes. When guest molecules are included in the □-CD cavity their melting, boiling & sublimation points usually shift to a different temperature or disappear. Thus, the decrease in peak area suggests that the complexation efficiency was enhanced. The DSC thermogram of QF exhibited an endothermic peak at 180.36 ^{0}C and □-CD showed a very broad endothermic peak at 116.76 ^{0}C. Thermograms of QF-□-CD complex show a broad endothermic peak at 107.19 ^{0}C due to dehydration of the complex, and another sharp peak at 177.10 ^{0}C which still reflect the presence of a few drug crystals in the

preparation. However, these thermogram peaks appeared more broadened and reduced in intensity, suggesting an interaction of drug & □-CD.[6]

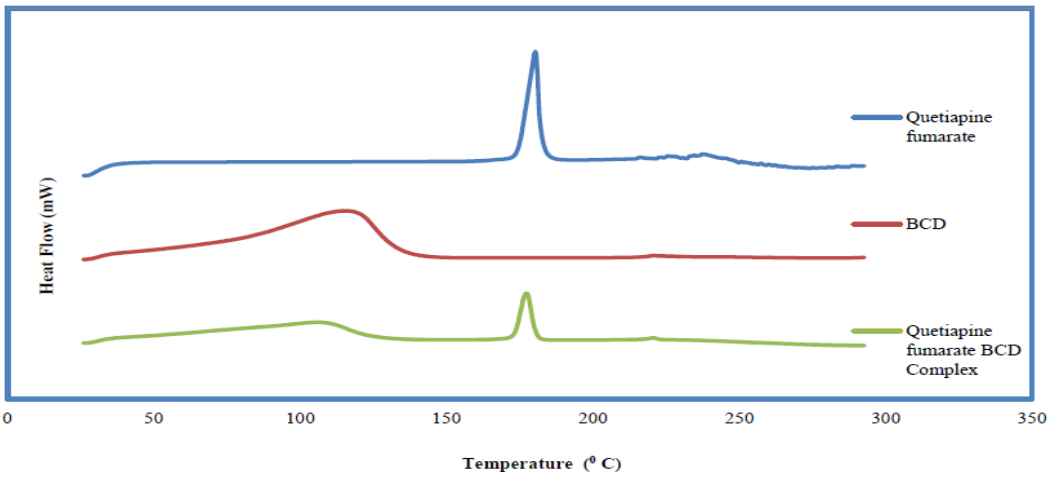

Figure 5: DSC of Quetiapine fumarate, □ - Cyclodextrin and QF - □ - CD inclusion comple.

Powder X-ray diffraction

QF, □-CD, and QF-□-CD were characterized by PXRD and the diffractogram of all samples was represented in Figure 6. PXRD of QF reveals many distinct reflections in its diffractograms, pointing to its highly crystalline nature. Various diffraction peaks of drug crystals can be traced in spectrum of the pure drug at 2□ values of 7.3, 9.1, 11.5, 13.2, 15.2, 16.1, 16.5, 17.5, 19, 19.9, 20.1, 21, 21.7, 22.2, 23.2, 24.2, 24.9, 25.5, 25.9, 26.9, 28.4, 29.3, 29.7, 30.5, 31.3,32.6, 33.1, 33.6, 35.1, 38, 38.9, 40.1, 41.5, 42.7, 43, 45.3, 45.8, 46.7, 47.2, 47.7, 50.8 and 57.6. The significant diffraction patterns demonstrated the existence of Form I polymorph in QF. β-CD showed many distinct reflections in its diffractograms, pointing to its crystalline nature. Various diffraction peaks of drug crystals can be traced in spectrum of pure drug at 2□ values of 6.1, 8.9, 9.7, 10.5, 11.4, 12.3, 13.3, 14.5, 15.2, 15.9, 16.9, 17.6, 18.6, 19.4, 20.6, 21.2, 22.5, 23.4, 24, 25, 26.3, 26.8, 28.3, 30, 30.8, 31.7, 33.8, 34.5, 35.6, 43.8, and 51. Diffractogram of QF-□-CD inclusion complex showed disappearance of prominent peaks at 2□ values of 16.5, 25.9, 29.3, 29.7, 30.5, 31.3, 32.6, 33.6, 38, 40, 41.5, 43, 45.3, 45.8, 46.7, 50.8 and 57.6 and newer peaks appeared at 9.6, 10.6, 12.4, 35.2, 39 and 47.1.

The intensity of peaks and peak height is reduced at 2□ values of 7.3, 11.5, 16.1, 17.5, 19.9, 21.7, 24.9 and 25.5 and showed an increase in width. Decrease in the crystalline (reduction in peak intensity), shifts and disappearance of peaks, and appearance of new peaks of a complete diffuse pattern might be related to possible amorphisation.[3]

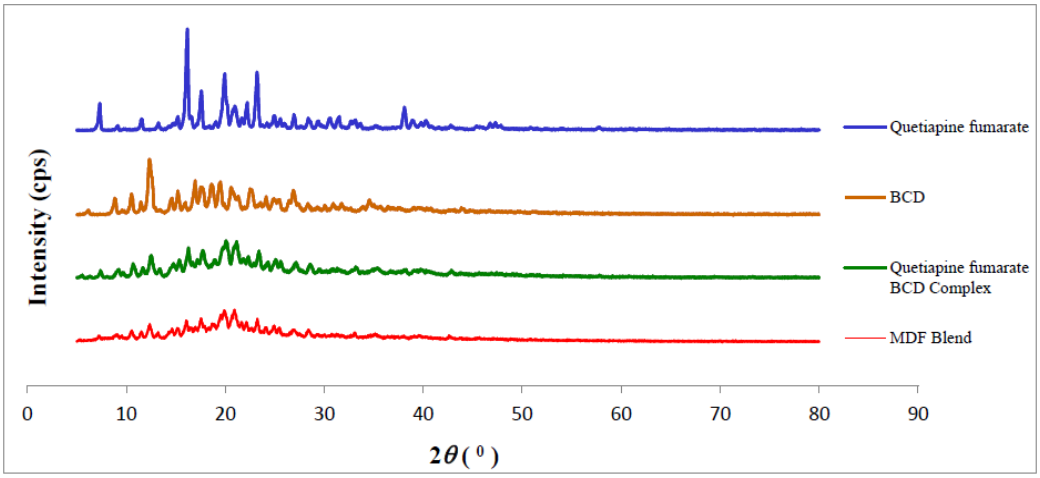

Figure 6: PXRD of QF, □ - CD, QF - □ - CD inclusion complex and Quetiapine MDF Blend.

Scanning electron microscope

SEM morphology of QF, □-CD, QF-□-CD inclusion complex and Quetiapine MDF were characterized by SEM and SEM images of all the samples were presented in Figure 7 a - d respectively. The morphology of QF observed by the SEM shows that particles are hard and crystalline. The particles consisted of discrete, short rod-like structures with sharp edges and some structures are large with rectangular shapes. The morphology of □-CD observed by the SEM shows that particles are hard and thick. Also, particles present in □-CD are large and parallelogram in shape. Particles are soft and thin. Agglomerates are observed with particles clumping to each other. The original morphology of raw material disappeared and particle size reduction was observed. The hard and crystalline nature of QF disappeared on dissolving with amorphous HPMC. Film morphology showed a rough and uneven surface with circular pits. Results of DSC, PXRD & SEM confirm the reduction in particle size of Quetiapine fumarate after forming a QF - □-CD inclusion complex. Further results ensure that loss of crystallinity.[3]

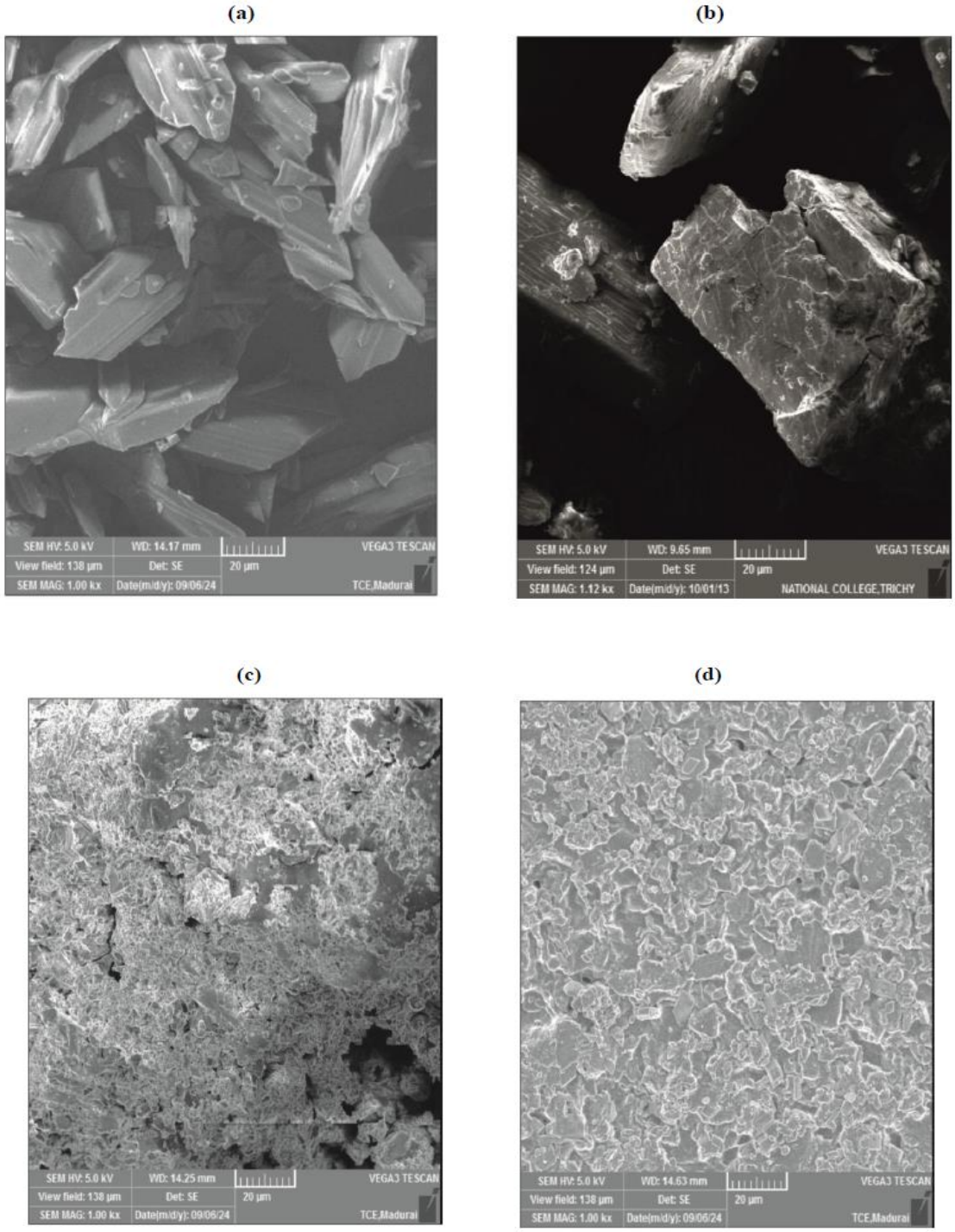

Figure 7: SEM images of (a) QF, (b) □ - CD, (c) QF - □ - CD inclusion complex and (d) Quetiapine MDF Blend.

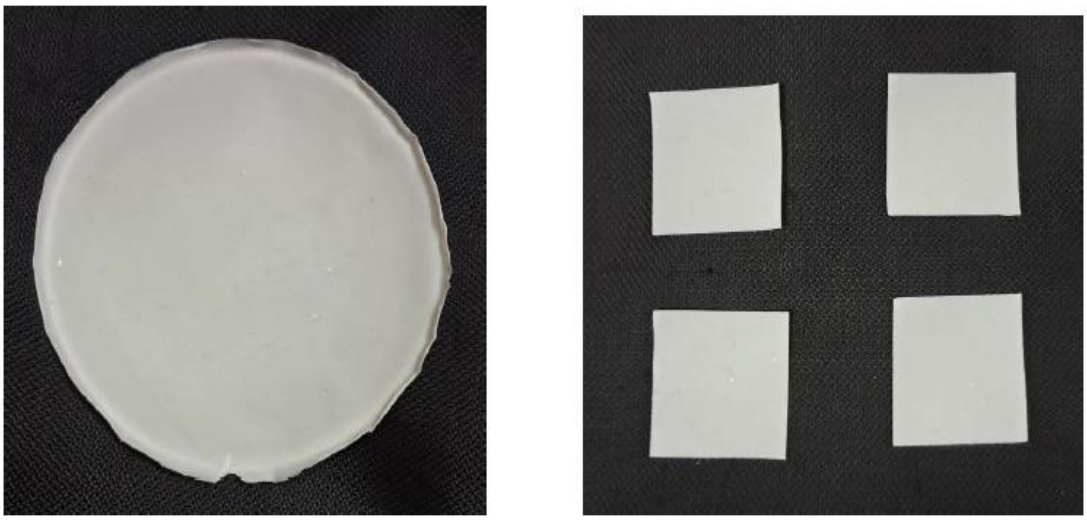

Figure 8: Photographic images of Quetiapine MDF.

CONCLUSION

The formulation of Quetiapine mouth-dissolving films meets all the requirements of mouth-dissolving films as per USP standards was successfully formulated. MDF prepared in this study was found to have higher dissolution rates compared to commercially available immediate-release tablets of Quetiapine fumarate. Quetiapine MDF showed faster disintegration, and enhanced solubility in oral and gastric pH. Since QF has a high permeability. By pregastric absorption, QF may bypass the first-pass metabolism and result in enhanced bioavailability. So, it was concluded that the intent of this research was successfully made and after requisite stability and clinical studies, this patient-friendly dosage form can be made commercialised which will result in great patient compliance and a more effective treatment.

ACKNOWLEDGEMENT

I would like to express my gratitude to the Department of Chemistry at Thiagarajar College of Engineering, Madurai, for conducting the SEM analysis. I also thank the BSR - Basic Scientific Research Instrumentation Centre at Jayaraj Annapackiam College for Women (Autonomous), Periyakulam, for performing the FTIR and PXRD analyses, and the Science Instrumentation Centre at The Standard Fire Works Rajaratnam College for Women, Sivakasi, for conducting the DSC analysis.

Additionally, I sincerely thank my peers: S. Barani Ganesh, B. Pharm; B. Ponpriyadharsini, B. Pharm; S. Janani, B. Pharm; K. Nandhana, B. Pharm; and K. Vandhana, B. Pharm, for their camaraderie and cooperation.

REFERENCES

1. Murilo Santos Pacheco, Douglas Barbieri, Classius Ferreira da Silva and Mariana Agostini de Moraes, A review on orally disintegrating films (ODFs) made from natural polymers such as pullulan, maltodextrin, starch, and others. Int J Biol Macromol, 2021; 1: 504 - 513.
2. Gaurav SP, Sopan NN, Dilip AP, Dinesh DB and Ganesh BP. Design of quetiapine fumarate loaded polyethylene glycol decorated graphene oxide nanosheets: *In vitro-ex vivo* characterization. An Pharm Fr, 2024; 82(5): 848 - 864.
3. Senthilkumar K and Vijaya C. Formulation Development of Mouth Dissolving Film of Etoricoxib for Pain Management. Int J Adv Pharm, 2015.
4. Sanjay P, Vishal GN, Gowda DV and Praveen Sivadasu. Formulation and Evaluation of Oral Disintegrating Film of Atenolol. Asian J Pharm Clin Res, 2018; 11(8).
5. Sinha VR, Anitha R, Ghosh S, Nanda A and Kumria R. Complexation of Celecoxib with b-Cyclodextrin: Characterization of the Interaction in Solution and in Solid State. J Pharm Sci, 2005; 94(3): 676 - 687.
6. Arjun Narala and Kishan Veerabrahma. Preparation, Characterization and Evaluation of Quetiapine Fumarate Solid Lipid Nanoparticles to Improve the Oral Bioavailability. J Pharm, 2013.