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Formulation and Evaluation of Orodispersible Bilayer Tablet containing Fenoprofen Calcium

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ABSTRACT: Conventional compressed tablets are associated with certain limitations associated to their delayed plasma drug concentration and difficulty in swallowing (Dysphagia). Orodispersible tablets, seem to circumvent the above-mentioned limitation and can facilitate oral administration in pediatric and geriatric patients. Current work aimed to achieve rapid therapeutic effects; typically suggested for geriatric and paediatric patients because to enhanced compliance, bioavailability, simplicity of administration, and palatability. Fenoprofen Calcium orodispersible tablets were made using the direct compression method and a coprocessed superdisintegrant (Crospovidone + Ac-Di-Sol). The absorbance, MP, and FTIR spectra of the bulk drug were evaluated in order to characterise it. There was uniformity and repeatability in the measurements for tablet thickness, weight variation, percent drug, wetting time, in vitro disintegration time, and in vitro dissolution tests after compression. Within 25 minutes, all formulations (ODT1-ODT9) demonstrated a nearly 100% drug release rate. The fastest Fenoprofen Calcium release was recorded in the case of ODT9: in 10 min, 58.554%, and in 25 min, 98.72%. The current study concluded that increasing the amount of coprocessed superdisintegrants decreased tablet disintegration time and increased cumulative drug release, all of which resulted in increased absorption.

Keywords: Direct Compression, Fenoprofen Calcium, Coprocessed superdisintegrant, Factorial design.

INTRODUCTION

Orodispersible tablets (ODTs), according to the 10th edition of the European Pharmacopoeia, have a maximum disintegration time of 3 minutes and are a modern pharmaceutical formulation that patients readily accept (Deore *et al.,* 2021; Ingale *et al.,* 2021). Novel medicine administration methods, such as orodispersible tablets, are becoming more common (Eisa *et al.,* 2022). It is advantageous because this pharmaceutical formulation does not necessitate the use of water during administration (Borse *et al.,* 2022). The term "arthritis" is frequently used to describe any condition that has an impact on the joints. The knees, wrists, fingers, toes, and hips are examples of joints, which are areas of the body where bones meet. These illnesses are marked by inflammation (which manifests as redness, heat, swelling, and sensations like pain) and the loss of function of one or more physical structures that link or support the body (Bullock *et al.,* 2019). Pain, swelling, and stiffness are common symptoms. Osteoarthritis (OA) is an abnormal remodeling of joint tissue within the affected joint including pathologic changes such as degradation of the articular cartilage, thickening of the subchondral bone, formation of osteophytes, variable degrees of inflammation of the synovium, degradation of ligaments and hypertrophy of the joint capsule (Gupta, 2017). Knees, hips, spines and joints in the hands are the commonly affected anatomic sites. Knee OA is the most common joint disorder in elderly individuals (Taoyu *et al.,* 2019). Fenoprofen Calcium is the calcium salt version of the fenoprofen, a propionic acid derivative. It have anti-inflammatory, analgesic, and anti-rheumatic activities by inhibiting both isozymes of cyclooxygenase, resulting in inhibition of prostaglandin synthesis by blocking the conversion of arachidonic acid to prostaglandins (Wanasukapunt *et al.,* 1976). The half-life of plasma is approximately 3 hours. The two major urinary metabolites of offenoprofen, glucuronide and 4'-hydroxyglucuronide, contribute for approximately 90% of the oral dose's clearance within 24 hours. 99% of fenoprofen is linked with albumin (Patterson *et al.,* 2002). Orally, 200 mg every 4 to 6 hours is the suggested dosage for the management of mild to moderate pain in arthritis. Fenoprofen Calcium are available in the market as conventional Tablets and Capsules (Rihana *et al.,* 2019).

MATERIAL AND METHODS

Materials

Fenoprofen Calcium was purchased from Yarrow Chem Products (Mumbai, India). Avicel, Ac-di-sol and

Crospovidone were gifted by Banglore Fine Chemicals (Banglore), Bioven Ingredients (Noida) & Signet Chemicals (Mumbai). Analytical grade solvents and reagents were used through out the study.

Methods

FTIR spectra of the drug: By using an interferometer detector and a FTIR spectrometer (Perkin Elmer 1600), the spectra of pure Fenoprofen Calcium were captured. Samples were formed using the KBr disc method (2 mg of material in 100 mg of KBr), and they were then analyzed using the transmission mode (Mohamed *et al.*, 2018).

Drug and Excipient Compatibility Study using FTIR: To determine whether the drug and the polymer were compatible, an FTIR study was carried out. By using a Fourier transform infrared spectrophotometer and the KBr scattering technique, the infrared spectra of Fenoprofen Calcium were measured. Baseline correlation should be performed using dry potassium bromide. The spectra of the drug, that of potassium bromide, dry mixture of the drug and different polymers were all analyzed using an FTIR spectrophotometer. The maximum absorption of the test material in the spectrum matches the maximum absorption of the reference spectrum in position and intensity (Mohamed *et al.*, 2018).

Powder Characterization: The bulk and tapped densities (Da, Dt) were calculated in accordance with Chapter 2.9.34 of the Ph. Eur. 10. The powders belonging to the 9 formulations projected were characterised in terms of Carr Index (CI), Hausner Ratio (HR), and Angle of Repose (^{0}). The tapped density was determined using an electronic densimeter (MZ-P3000 electronic densimeter, China) (Roa *et al.,* 2019; Khan *et al.,* 2015).

The angle of repose: The angle of repose can be used to calculate the frictional forces present in a loose powder. It is described as the largest angle that can be formed between the powder pile's surface and the horizontal plane (Roa *et al.,* 2019; Khan *et al.,* 2015).

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

Where θ is the angle of repose "h" is the height in cms, "r" is the radius in cms.

Bulk density: Pre-sieved (100 mesh) bulk drugs are poured into a graduated cylinder via a large funnel, and the volume and weight are measured to calculate the bulk density (Da) (Roa *et al.,*2019; Khan *et al.,*2015).

$$\text{Bulk Density (Da)} = \frac{\text{Mass of powder (M)}}{\text{Bulk volume of the powder (V)}}$$

Tapped density: A known mass of mix was placed in the measurement cylinder, which was then tapped 100 times using density equipment. Following tappings, the blend weight and constant minimum volume of the cylinder were calculated. The tapped density was calculated using the formula (Dt) (Roa *et al.,*2019; Khan *et al.,* 2015).

$$\text{Tapped Density (Dt)} = \frac{\text{Weight of powder (W)}}{\text{Tapped volume of the powder (V)}}$$

Carr's index: In order to quantify the ability of a powder to be compressed, the Carr's Index (CI) was developed; as a result, it measures the relative significance of inter-particulate interactions (Roa *et al.,*2019; Khan *et al.,*2015).

$$\text{Carr's index (\%)} = \frac{\text{Tapped Density - Bulk Density}}{\text{Tapped Density}} \times 100$$

Hausner's ratio: Hausner's ratio (HR) is an indirect indicator of powder flow acceptance. It was calculated by the following formula (Roa *et al.,* 2019; Khan *et al.,* 2015).

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

Lower Hausner's ratio (<1.25) indicates better flow properties than higher ones.

Experimental Design: The ODTs (ODT1- ODT9) development utilized a 3^2 full factorial design. The composition of the nine can be found in Table 1, while the independent variables can be found in Table 2.

Table 1: Formulations of orodispersible tablets of Fenoprofen Calcium.

Ingredients(mg)	ODT1	ODT2	ODT3	ODT4	ODT5	ODT6	ODT7	ODT8	ODT9
Fenoprofen Calcium	200	200	200	200	200	200	200	200	200
Ac-di-sol	8	8	8	16	16	16	24	24	24
Crospovidone	8	16	24	8	16	24	8	16	24
Avicel PH102	231	223	215	223	215	207	215	207	199
Lactopress	200	200	200	200	200	200	200	200	200
Mannitol	120	120	120	120	120	120	120	120	120
Talc	16	16	16	16	16	16	16	16	16
Magnesium Stearates	16	16	16	16	16	16	16	16	16
Sunset Yellow Lake	1	1	1	1	1	1	1	1	1
Tablet Weight (mg)	800	800	800	800	800	800	800	800	800

Table 2: Selected independent factors with their levels.

Category	Independent Factor		Level (mg)		
			-1	0	1
Coprocessing Technology	X_1	Ac-di-sol	8	16	24
	X_2	Crospovidone	8	16	24

ODT Manufacturing Steps

Coprocessed Super disintegrants: The coprocessed superdisintegrant was prepared as follows: Blends of Ac-di-sol and crospovidone in various ratios were added to 50 ml of isopropyl alcohol in a full factorial design at 3^2 levels (1:1, 1:2, 1:3, 2:1, 2:2, 2:3, 3:1, 3:2, 3:3) (Nagendrakumar *et al.,* 2010). A magnetic stirrer was used to stir the contents of the beaker at 50 rpm. The temperature was kept between 65-70°C, and the stirring was kept going until the majority of the isopropyl alcohol evaporated. The wet, cohesive mixture was sieved through Sieve No. 80. The moist powder was dried in a tray dryer at 60°C for 20 minutes. Before storing the dried powder in an airtight container, it was sifted through a 80-mesh sieve (Rangu *et al.,* 2018).

Direct Compression: In this process, all ingredients were accurately weighed and passed through sieve number 80, then mixed to form a powder blend and then compressed using a 12 mm concave punch on a multiple station tablet compression machine (Haque *et al.,* 2016). By removing the tablet machine's one-side rise-up cam and inserting the coloured and non-colored parts in two distinct hoppers, bilayer tablets were created. The hardness of the tablets was maintained at 3–4 kg/cm^2. The tablet weight was maintained at 800 mg (Varghese *et al.,* 2022).

Evaluation of the Dependent Parameters

Thickness: Individual tablet thickness was tested using a micrometre, which allows for consistent measurement and offers information on variation between tablets (Jire *et al.,* 2021).

Hardness: Tablet hardness is also known as tablet crushing strength. It may vary due to the powder's poor flow characteristics. The tablets' hardness was tested using a Monsanto hardness tester (Rao *et al.,* 2021).

Friability: Twenty tablets were chosen at random from each batch and weighed. These tablets were friability tested for 100 revolutions using a friabilator (Roche type) (25 rpm for 4 min.). Tablets were removed, de-dusted and weighed again (Rao *et al.,* 2021).

$$\text{Average \% F} = \frac{\text{Initial Weight - Final Weight}}{\text{Initial Weight}} \times 100$$

Weight variation: The weight variation test would provide a reliable way to assess the uniformity of the drug content. According to USP, twenty tablets were weighed one at a time, with the average weight being calculated and the individual tablet weights being compared to it. One tablet's average weight was computed. The percentage deviations from the mean value were calculated (Rajeswari *et al*., 2020; Patil *et al*., 2016).

$$\text{Average weight of tablet} = \frac{\text{Total weight of 20 tablet}}{20}$$

$$\text{Deviation (\%)} = \frac{\text{Weight of each tablet} - \text{Average weight of tablets}}{\text{Average weight of tablets}} \times 100$$

Determination of drug content: The tablets were ground into a fine powder in a glass mortar and pestle after ten randomly chosen tablets were weighed and their average weight computed. The weight of powder corresponding to 200 mg of fenoprofen calcium was measured. 100 ml of Sorenson's buffer (pH 6.8) was used to dissolve the weighed quantity, and the resulting solution was filtered. Sorenson's buffer (pH 6.8) was used to dilute an aliquot of 2.0 ml of this solution to 10 ml in a different volumetric flask. At 270 nm, the content of each formulation was measured spectrophotometrically (Govind *et al.*, 2016).

Disintegration test: The action of saliva causes orodispersible tablets to disintegrate in the mouth, however the amount of saliva in the mouth is limited, and neither the USP nor the IP contain any tablet disintegration tests to mimic in vivo conditions.The disintegration period of the tablets was calculated using a modified disintegrating instrument method. In a cylindrical tank, a 10-mesh screen was positioned so that it would only be covered by 4 ml of a dissolving or disintegrating media (Fig. 1). 6 ml of Sorenson's buffer (pH 6.8) were added to the jar so that 4 ml of the media were below the sieve and 2 ml were above the sieve in order to measure the disintegration time. The tablet was then put on the sieve, and everything was then put on a shaker. The tablet's disintegration time was determined to be when all of the particles passed through the sieve. The composite samples' six tablets were picked at random, and the average value was calculated (Govind *et al.,*2016).

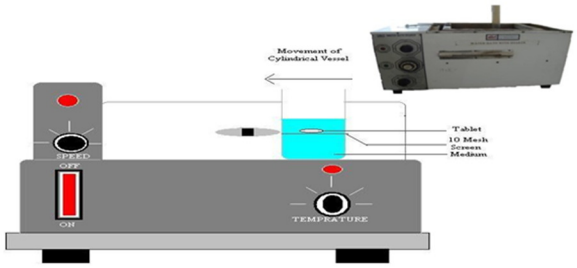

Fig. 1. Modified disintegration test apparatus.

Dissolution test: A modified method was used to dissolution profile of the tablets resembling conditions similar to mouth cavity or oral cavity absorption as used in determination of disintegration of tablets. For determination of dissolution profile of tablets 6 ml Sorenson's buffer (pH 6.8) with 1% w/v SLS (sinking agent) at 37±0.5° C, was placed inside the vessel in such way that 2 ml of the media was below the sieve and 4 ml above the sieve. Tablet was placed on the sieve and the whole assembly was then placed on a shaker. Samples (1.0 ml) were withdrawn at different time intervals and replaced with same fresh media. Samples

were filtered and diluted with Sorenson's buffer (pH 6.8) and analyzed UV spectrophotmetrically at 270 nm (Govind *et al.,* 2016).

Quantification of the Released Fenoprofen Calcium. Determination of λ max [Preparation of Sorenson's Buffer (pH 6.8)]**:** 24.5 ml of 0.2 M dibasic sodium phosphate and 0.2 M 25.5 ml of monobasic sodium phosphate was placed in 100 ml volumetric flask, and make up the volume 100 ml by water. UV spectra absorption in the rage 200 to 400 nm of a 50 µg/ml solution in Sorenson's buffer (pH 6.8) was measured. The absorption maxima (λmax) of fenoprofen calcium (50 µg/ml) in the solution was found to be 270 nm (Purnachand *et al.,*2016; Nyola *et al.,* 2012).

Preparation of Calibration Curve: Fenoprofen Calcium (100 mg) was dissolved in small amount of Sorenson's buffer (pH 6.8) in a 100 ml of volumetric flask and final volume was made with the Sorenson's buffer. 10 ml of this solution was diluted to 100 ml with Sorenson's buffer (pH 6.8) in a 100 ml volumetric flask to obtain a stock solution of 100 µg/ml. Aliquots of 1, 2, 3, 4, 5 and 6 ml were taken from stock solution in 10 ml volumetric flasks and volume was made up to 10 ml with buffer (pH 6.8) to obtain stock solutions of 10, 20, 30, 40, 50, 60 µg/ml. The absorbance of these solutions was measured by UV Spectrophotometer (Shimadzu-1700 spectrophotometer) at 270 nm (Vallabhaneni *et al.,* 2017).

RESULTS AND DISCUSSION

Determination of absorbance maxima (λ max): It was determined that the maximum absorbance was 270 nm. The observed absorbance at 270 nm is shown in Fig. 2.

FTIR of Fenoprofen Calcium: The quality of the Fenoprofen Calcium was examined using FTIR technology. The FTIR study was used to validate the sample. Fig. 3 displays the FTIR spectrum of Fenoprofen Calcium.

FTIR for Drug excipients compatibility study: The sample pellet was placed in the FTIR (Perkin Elmer 1600) compartment and scanned at 4000–500 cm^{-1} wavelength. The FTIR spectra of pure fenoprofen calcium (Fig. 3) revealed a pattern of distinctive absorption peaks (696, 1546, 3286, and 3601 cm^{-1}). According to Fig. 4, no changes in the major bands of a drug were identified, revealing the physical and chemical compatibility between drug and excipients.

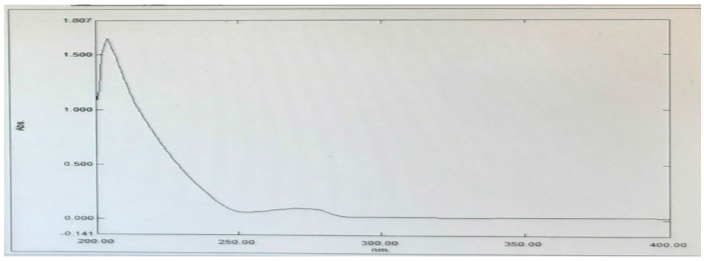

Fig. 2. UV spectrum of Fenoprofen Calcium.

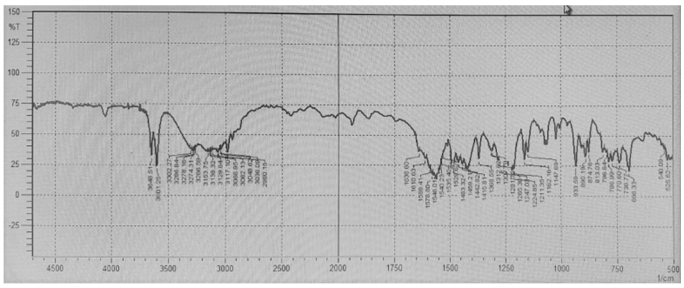

Fig. 3. FTIR Spectra of Fenoprofen Calcium.

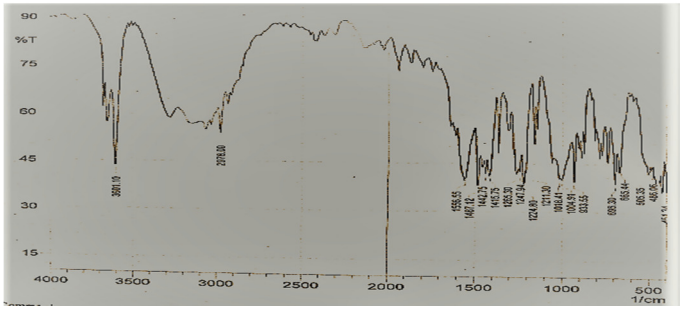

Fig. 4. FTIR Spectra of Fenoprofen Calcium and Polymer (Physical Mixure).

Powder Evaluation: The CI (Table 3) ranged from 5.96 (ODT1) to 8.1 (ODT9). Usually, a low CI indicate better compressibility. Further, The flow character can be identified with the help of HR. In this approach, it was discovered that all powders conforming to the proposed formulation offered values of <1.25. The following mixtures are considered very free flow according to Ph. Eur. 10. Least HR observed with ODT1. With the help of Angle of repose, additional information regarding flow properties can be determined. In this manner it was observed that ODT1,ODT2,ODT3,ODT4,ODT5,ODT9 presented excellent flow ability (values < 25), while ODT6,ODT7,ODT8 presented good flowability (values between 25-30).

Table 3: The powder evaluation for FC ODTs

Formulation Parameters	ODT1	ODT2	ODT3	ODT4	ODT5	ODT6	ODT7	ODT8	ODT9
Bulk Density (gm/ml)	0.396 ±0.004	0.390 ±0.003	0.393 ±0.004	0.401 ±0.003	0.397 ±0.004	0.392 ±0.004	0.398 ±0.005	0.408 ±0.003	0.397 ±0.003
Tapped Density (gm/ml)	0.421 ±0.005	0.424 ±0.004	0.427 ±0.005	0.435 ±0.003	0.421 ±0.004	0.424 ±0.003	0.432 ±0.002	0.440 ±0.005	0.432 ±0.004
Hausner's Ratio	1.063 ±0.011	1.087 ±0.014	1.086 ±0.011	1.084 ±0.016	1.060 ±0.013	1.081 ±0.017	1.085 ±0.015	1.078 ±0.008	1.088 ±0.012
Compressibility Index (%)	5.96 ±0.872	8.01 ±0.865	7.96 ±0.863	7.81 ±0.859	5.70 ±0.871	7.54 ±0.869	7.87 ±0.854	7.27 ±0.721	8.10 ±0.621
Angle of Repose (^{o})	24.16 ±0.042	24.09 ±0.038	24.22 ±0.040	24.82 ±0.037	24.16 ±0.040	25.62 ±0.036	25.42 ±0.038	25.72 ±0.026	24.27 ±0.032

±SD; *n=6*

Evaluation of Post Compression Parameters: To establish the dimensional parameters of the FC ODTs, the following parameters were determined: Weight variation and thickness: the results of the previously mentioned dimensional parameters are found in Table 4.

Table 4 : Result of Post-Compression parameters.

Batch code	Thickness (mm)	Hardness (Kg/cm^2)	Weight variation (mg)	Friability (%)	Disintegration time (s)
ODT1	6.937±0.037	3.4±0.121	794.72±3.308	0.627±0.016	150±1.57
ODT2	6.957±0.042	3.3±0.127	798.84±3.318	0.510±0.048	129±0.83
ODT3	6.948±0.038	3.2±0.132	796.72±3.308	0.290±0.046	121±2.32
ODT4	6.952±0.035	3.4±0.118	800.82±3.102	0.669±0.025	141±6.53
ODT5	6.935±0.035	3.3±0.125	794.89±3.238	0.579±0.043	120±1.21
ODT6	6.942±0.042	3.2±0.122	797.42±3.234	0.379±0.025	104±1.17
ODT7	6.912±0.033	3.4±0.132	799.18±3.221	0.763±0.014	136±9.85
ODT8	6.964±0.037	3.3±0.128	796.27±3.232	0.655±0.016	115±1.78
ODT9	6.972±0.040	3.3±0.124	798.32±3.187	0.465±0.011	94±2.33

±SD; *n=6*

The average weight was within the acceptable uniformity criteria, and all of the tablets had a standard deviation of less than 5% when compared to the average weight of each formulation (Table 4). Considering that the maximum limit is 5%, we concluded that all of the produced tablets meet the requirements for average mass uniformity from Ph. Eur.10. The thickness of the tablets in the developed FC-ODTs ranged between 6.912 mm - 6.972 mm for ODT7 and ODT9 formulation, respectively (Table 4). The friability test was passed by all formulations (Table 4), with all evaluated formulations exhibiting values less than 1%. The lowest figure (0.29%) was found in the case of the ODT3 formulation. The ODTs with the highest proportion of Crospovidone had the lowest friability values. The measured hardness values were between 3.2 - 3.4 kg/cm^2, however greater values for this mechanical attribute are acceptable if an ODT with a higher crushing strength and a short disintegration time is created. Furthermore, an increase in crushing strength does not necessitate special storage conditions, which might be regarded an advantage. The ODTs with a higher proportion of Ac-di-sol presented the highest values regarding hardness. The values observed for the disintegration time were between 94 -150 sec. The lowest value was observed in the case of the ODT9 formulation (94 sec). The ODTs with a higher proportion of crospovidone presented the lowest values regarding the disintegration time. The amount of FC released in 25 minutes was evaluated, and all formulations released a concentration of FC more than 80%. The fastest FC release was documented in the case of ODT9: 58.554% of FC was released in 10 minutes. The quantity of crospovidone, which may be responsible for the fast release of the API in the formulations ODT3, ODT6, and ODT9, is one factor that may produce a fast release of the API. The dissolving behaviour data are shown in Tables 5, 6, and 7, as well as in Fig. 5.

Table 5: In vitro drug release data of formulations ODT1-ODT3.

Time (min)	ODT1 Cumulative % drug release	ODT2 Cumulative % drug release	ODT3 Cumulative % drug release
0	0	0	0
5	26.732 ±0.432	29.456±0.423	29.983±0.786
10	47.126 ±1.009	52.784±1.011	54.845±1.002
15	68.901±0.574	78.674±0.498	79.345±0.474
20	74.375±0.383	83.387±0.412	85.765±0.456
25	84.732±0.468	95.853±0.454	96.732±0.435

±SD; *n=6*

Table 6: In vitro drug release data of formulations ODT4-ODT6.

Time (min)	ODT4 Cumulative % drug release	ODT5 Cumulative % drug release	ODT6 Cumulative % drug release
0	0	0	0
5	27.856±0.464	30.706±0.438	31.655±0.447
10	48.845±1.007	54.662±1.017	56.167±1.014
15	69.732±0.598	79.267±0.552	82.756±0.511
20	77.456±0.421	88.763±0.476	90.365±0.464
25	85.827±0.402	96.934±0.435	97.832±0.474

±SD; *n=6*

Table 7: In vitro drug release data of formulations ODT7-ODT9.

Time (min)	ODT7 Cumulative % drug release	ODT8 Cumulative % drug release	ODT9 Cumulative % drug release
0	0	0	0
5	29.434±0.402	32.576±0.456	33.212±0.439
10	50.934±1.012	55.311±1.005	58.554±1.011
15	71.522±0.612	80.776±0.601	83.432±0.569
20	80.378±0.421	90.211±0.408	92.675±0.416
25	87.375±0.398	97.232±0.425	98.724±0.467

±SD; *n=6*

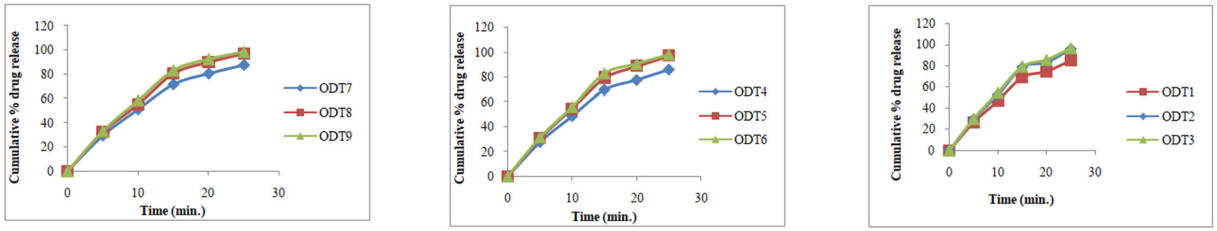

Fig. 5. Dissolution profile of the FC ODT formulations.

Ingale *et al*. (2021) conducted a study in which captopril successfully formulated as mouth dissolving tablets using various superdisintegrants in different concentrations by direct compression method. The formulation containing 10% of crospovidone as superdisintegrants was found to be outstanding than other formulations in terms of disintegration time and rate of dissolution (Ingale *et al.,* 2021). In terms of friability, disintegration time, and dissolution behaviour, the results obtained in our investigation are equivalent to those found in the literature.

CONCLUSIONS

The idea of creating fenoprofen calcium rapid disintegration and dissolution characteristics of orodispersible bilayer tablets with coprocessed super disintegrants are appropriate and useful. Studying the absorbance, melting point, and FTIR spectroscopy allowed researchers to characterise fenoprofen calcium. ODT1, ODT2, and ODT3 formulations were prepared with 8 mg of Ac-di-sol and 8 mg, 16 mg, and 24 mg of Crospovidone, resulting in a % drug release in the order ODT1<ODT2<ODT3. ODT4, ODT5, and ODT6 formulations were prepared with 16 mg of Ac-di-sol and 8 mg, 16 mg, and 24 mg of Crospovidone, resulting in a % drug release in the order ODT4<ODT5<ODT6. ODT7, ODT8, and ODT9 formulations were prepared with 24 mg of Ac-di-sol and 8 mg, 16 mg, and 24 mg of Crospovidone, resulting in a % drug release in the order of ODT7<ODT8<ODT9. The fastest Fenoprofen Calcium release was recorded in the case of ODT9: in 10 min, 58.554%, and in 25 min, 98.72%. The orodispersible tablets of Fenoprofen Calcium with an improved drug release profile were successfully developed in the current experiment. It has been determined that using more superdisintegrants and a

bilayer design speeds up drug absorption by reducing the time it takes for tablets to dissolve, shortening the time they take to moisten, and increasing the cumulative percentage of drug release.

FUTURE SCOPE

Owing to the enhancement technological developments, the coming ODTs future trends will bring greatly different disciplines within the pharmaceutical market. Development of future ODTs serving controlled release drug delivery system, especially with short half lived drugs is considered an important future target. These advances are expected to lead to further significant progress in the orodispersible drug delivery of drugs with large individual doses and improve patient outcomes and quality of life.

ABBREVIATIONS

MP: Melting point, FTIR: Fourier-Transform Infrared, ODT: Orodispersible Tablet, USP: United State Pharmacopoeia, IP: Indian Pharmacopeia, Ph. Eur.: European Pharmacopoeia, UV: Ultraviolet, HR: Hausner ratio, CI: Carr's Index, FC: Fenoprofen Calcium.

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Conflict of Interest. None.

REFERENCES

Borse, L. B., Bendale, A. R. and Jadhav, A. G. (2022). Formulation and Evaluation of Mouth Dissolving Tablet Rivaroxaban and its Validation. *Biosci Biotech Res Asia, 19*(4).

Bullock, J., Rizvi, S. A. and Rais, A. (2019). Rheumatoid Arthritis: A Brief Overview of the Treatment. *Med Princ Pract, 27*(6), 501–507.

Eisa, A. M., Nagia, A. and Nahas, H. M. (2022). Formulation and evaluation of fast dissolving tablets of haloperidol solid dispersion. *Saudi Pharmaceutical Journal, 30*(11), 1589-1602.

Govind, A., Menden, M. B., Kmar, R. and Swamy, N. (2016). Formulation and Evaluation of Mouth Dissolving Tablets of Deflazacort. *Asian J. Pharm.Tech., 6*(2), 91-98.

Gupta, B. M. (2017). Arthritis Research in India: A Scientometric Assessment of Publications Output during 2007-16. *SF J Orthopedic Rheumatol,1*,1.

Haque, I., Kumar, R., Narayanaswamy, V. B. and Hoque, M. (2016). Formulation and Evaluation of Montelukast Sodium Fast Dissolving Tablets. *Asian J. Pharm. Res., 6*(3), 159-169.

Ingale, A. S., Ahire, S. S. and Patil, P. R. (2021). Formulation and evaluation of fast dissolving tablets of captopril. *GSC Biological and Pharmaceutical Sciences, 17*(02), 123–130.

Jire, D. S., Gosavi, N. S., Badhe, R. B. and Jagdale, D. H. (2021). Mouth Dissolving Tablet: A Novel Drug Delivery System. *Asian Journal of Pharmaceutical Research, 11*(3), 180-186.

Khan, M. Y., Roy, M., Ahmad, I. and Panday, M. (2015). Formulation and Evaluation of Efavirenz 600 mg Tablet. *Asian J. Res. Pharm Sci., 5*(3), 153-167.

Mohamed, M., Frag, E., Hathoot, A. and Shalaby, E. (2018). Spectrophotometric determination of fenoprofen calcium drug in pure and pharmaceutical preparations. Spectroscopic characterization of the charge transfer solid complexes. *Spectrochim Acta A Mol Biomol Spectrosc, 189,* 357-365.

Nagendrakumar, D., Raju, S.A. and Shirsand, S. B. (2010). Design of fast dissolving granisetron HCL tablets using novel co-processed superdisintegrants. *International Journal of Pharmaceutical Sciences Review and Research, 1*(1), 58-62.

Nyola, N., Kumawat, M., Kalra, N. and Singh, G. (2012). Simultaneous estimation of famotidine and ibuprofen in pure and phatmaceutical dosage form by UV-Vis Spectroscopy. *IRJP, 3*(4), 227-280.

Patil, R., Patil, N., Patil, A., Dange, V. N., Magdum, C.S. and Mohite, S. K. (2016). Preparation and Evaluation of Fast Dissolving Tablet Tramadol Hydrochloride. *Asian J. Pharm. Tech, 6*(3), 183-185.

Patterson, J., Bary, A. and Rades, T. (2002). Physical stability and solubility of the thermotropic mesophase of fenoprofen calcium as pure drug and in a tablet formulation. *Int J Pharm, 247*(24), 147-57.

Pratiksha, Deore, S., More, Y. M. and Maru, A. D. (2021). Formulation and Evaluation of Orodispersble Tablet. *Asian Journal of Research in Pharmaceutical Sciences, 11*(4), 267-272.

Purnachand, D., Veerareddy, A., Ramadevi, B. and Madhusudhanreddy, B. (2016). Development and Validation of Stability Indicating RP-HPLC Method for Determination of Related Substances in Fenoprofen Calcium. *Journal of Chemical and Pharmaceutical Research, 8*(5), 251-259.

Rajeswari, K. R., Brungi, V., Bennuru, S. and Gupta, V. (2020). Studies on the development of Orally Disintegrating Tablets of Irbesartan. *Asian J. Pharm. Res, 10*(1), 01-07.

Rangu, N., Akula, G. and Jaswanth, A. (2018). Formulation and Evaluation of Metoprolol Orodispersible Tablets by Super Disintegration Method. *Asian J. Pharm. Res., 8*(3), 119-124.

Rao, A. H. O. P., Kumar, R. S., Kandukuri, S., Ramya, M. (2021). Optimization of starch glycolate as novel superdisintegrant in the formulation of glipizide fast dissolving tablets through 23 factorial design. *International Journal of Applied Pharmaceutics, 13*(5), 244–251.

Rao, M. R., Sonavane, V., Kulkarni, S. and Karanjkar, P. (2019). Design of transdermal patch of ketoprofen by full factorial design for treatment of rheumatoid arthritis. *J. Drug Delivery Ther, 9*(2), 197-205.

Rihana, S., Suneetha, A. and Chaitanya G. A. (2019). Development and validation of an RP-HPLC method for estimation of fenoprofen in bulk drug. *WJPR, 8*(2), 874-886.

Taoyu, M. D., Jianjun, W. and Xiaochun, W. (2021). The global state of research in pain management of osteoarthritis (2000–2019). Medicine, 100(2), 239-44.

Vallabhaneni, M., Yerramilli, A. and Chinnapillai, R. (2017). Development and Validation of UPLC Method for the Determination of Related Substances in Fenoprofen Calcium. *J. Chem. Pharm. Res., 9*(10), 286-293.

Varghese, N. and Komala, M. (2022). Analysis of in vitro disintegration and dissolution effect of Cucurbitamaxima starch in Losartan FDT. *International Journal of Applied Pharmaceutics, 14*(4), 163-170.

Wanasukapunt, S., Lertratanakul, Y. and Rubinstein, H. M. (1976). Effect of fenoprofen calcium on acute gouty arthritis. *Arthritis Rheum, 19*(5), 933-935.

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