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FORMULATION DEVELOPMENT AND EVALUATION OF FAMCICLOVIR ORALLY DISINTEGRATING TABLET

Dhananjay Patil, Momin Sanaurrehman*, Vinod Bairagi, Abdurrahman, Mohammed Awais, Shrivastav Karishma, Rajashri More.

Department of Pharmaceutics, K. B. H. S. S. Trust Institute of Pharmacy, Malegaon Camp, Nashik, Maharashtra, India

Abstract:

Orally disintegrating systems have an edge amongst the oral drug delivery systems due to the highest component of compliance they enjoy in patients especially the geriatrics and pediatrics. In addition, patients suffering from dysphagia, motion sickness, repeated emesis and mental disorders prefer these medications because they cannot swallow large quantity of water. Further, drugs exhibiting satisfactory absorption from the oral mucosa or intended for immediate pharmacological action can be advantageously formulated in these dosage forms. However, the requirements of formulating these dosage forms with mechanical strength sufficient to withstand the rigors of handling and capable of disintegrating within a few seconds on contact with saliva are inextricable. Therefore, research in developing orally disintegrating systems has been aimed at investigating different excipients as well as techniques to meet these challenges. Famciclovir is an antiviral drug used for the treatment of herpes simplex virus (HSV), mainly HSV-1 and HSV-2 and varicella zoster virus. It is a BCS class III drug. Hence an orally disintegrating tablet formulation of Famciclovir was prepared by wet granulation techniques after incorporating superdisintegrants sodium starch glycolate. Six formulations were prepared. The formulation (F3) showed excellent in vitro dispersion time and drug release as compared to other formulation. After study of formulations F3 showed short dispersion time with maximum drug release in 10 min. It is concluded that fast disintegrating famciclovir tablets could be prepared by wet granulation using superdisintegrants.

Keywords: *Famciclovir, ODT, Sodium starch glycolate (Primogel), Microcrystalline cellulose (Avicel pH102).*

Corresponding author:

Momin Sanaurrehman Azizurrehman,

K. B. H. S. S. Trust's Institute of Pharmacy, Malegaon, Dist- Nasik (MS)

E-mail: *ms.rahman278@gSmail.com*

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INTRODUCTION:

ODTs are also called as orodispersible tablets, quick disintegrating tablets, mouth dissolving tablets, fast disintegrating tablets, fast dissolving tablets, rapid dissolving tablets, porous tablets, and rapid melts. However, of all the above terms, United States pharmacopoeia (USP) approved these dosage forms as ODTs. The European Pharmacopoeia has used the term orodispersible tablet for tablets that disperses readily within 3 minutes in the mouth before swallowing. [2] United States Food and Drug Administration defined ODT as "A solid dosage form containing a medicinal substance or active ingredient which disintegrates rapidly usually within a matter of seconds when placed upon the tongue." The disintegration time for ODTs generally ranges from several seconds to about a minute. [1]

MATERIALS AND METHODS:

Famciclovir were kindly supplied by Macleods Pharma (Daman, India), Sodium starch glycolate was supplied by Vishal Chemicals (Mumbai, India) and Microcrystalline cellulose Reseach lab Fine chem (Mumbai). All the products and materials used in this study comply with the pharmaceutical and analytical standards, respectively.

All the research work was carried out at K. B. H. S. S. Trust Institute of pharmacy, Malegaon, Maharashtra during year 2016-2017.

1. IR Spectrum: Famciclovir was subjected to FT-IR study (SHIMADZU India) for characterization purpose. IR technique is one of the most powerful techniques which offer the possibility of chemical identification. Famciclovir was mixed with potassium bromide (KBr) in 1:100 proportions and spectrum was obtained in range of 400-4000 cm-1. Potassium bromide was used as a blank while running spectrum.

2. U. V. Spectrum: The Famciclovir was subjected to UV spectroscopic analysis (Lab India; 3000+) to find out the wavelength (λ max) at which it shows maximum absorbance. Famciclovir was accurately weighed and dissolved in solvent phosphate buffer pH 6.8 to obtain stock solution of 1000 µg/ml. This solution was then suitably diluted with same solvent to get solution of concentration 100 µg/ml and further diluted to10 µg/ml. Then the UV spectrum of this concentration was recorded over the wavelength range 200-400 nm.

3. Calibration Curve by U.V Spectroscopic Method

A. Preparation of stock solution of Famciclovir in phosphate buffer pH 6.8:

a) Preparation of phosphate buffer pH 6.8:

Weighed quantity of Potassium dihydrogen phosphate (KH_2PO_4), 2.722 g was dissolved in 100 ml distilled water (DW) and mixed properly. In another 100 ml of volumetric flask, solution of 0.2 M sodium hydroxide was prepared, by dissolving 0.8g NaOH in 100 ml DW. 50 ml of potassium dihydrogen phosphate was taken in 200 ml volumetric flask and specified volume of 0.2 N NaOH (22.4 ml), was added in it and the volume was adjusted with DW to 200 ml [3].

b) Standard stock solution of Famciclovir:

About 10 mg of drug was accurately weighed and transferred to calibrated 10 ml volumetric flask. It was dissolved in phosphate buffer pH 6.8 and volume was made up to 10 ml with phosphate buffer pH 6.8 to obtain a final concentration of 1000 µg/ml.

c) Working stock solution:

This standard stock solution was further diluted to get a working standard solution 100 µg/ml, by pipetting out 1ml from standard stock and diluting it up to 10 ml with phosphate buffer pH 6.8. A series of Telmisartan dilutions were made from working standard solution, by pipetting out 0.2, 0.6, 1, 1.4, 1.8 and 2.2 ml respectively into separate 10 ml volumetric flasks and diluting to volume with phosphate buffer pH 6.8 to produce the concentrations ranging from 2-22 µg/ml.

4. Drug-Polymers compatibility studies:

I. Drug content: The successful formulation of a stable and effective solid dosage form depends on the careful selection of the excipients, which are added to facilitate administration, to promote the consistent release and bioavailability of the drug and protect it from degradation. API and excipients were thoroughly mixed in 1:1 ratio and passed through the 60# sieve. The blend was filled in transparent glass vials and were closed with gray colored rubber stoppers and further sealed with aluminum seal. Vials were kept in stability chamber at room and aggravated temperature and humidity conditions (37±0.5°C, 45±0.5°C temperature and 75±5%RH for 30 days).

Similarly, API was also kept at all condition as for the samples. Samples were withdrawn for analysis within two day of sampling date as per the compatibility study and evaluated for FTIR. The films were tested for drug content uniformity by UV spectrophotometric method. Films were cut from three different places from the casted films.

Each film was placed in 100 ml volumetric flask and dissolved in pH 6.8 phosphate buffer and filtered through whatman filter paper. From the solution 1 ml was taken and diluted with pH 6.8 phosphate buffer upto 10 ml, to make final concentration of 10µg/ml. The absorbance of the solution was measured at 224 nm using UV/visible spectrophotometer (R2=0.998). The percentage drug content was determined using the standard graph and the same procedure was repeated for three tablet of each formulation.

II. Infrared Spectroscopy: A compatibility study for Famciclovir was carried out with potential formulation excipients to determine possibility of any drug-excipients interaction/incompatibility. Excipients studied included Avicel pH102, Primogel, Starch, Saccharin sodium, Talc, Magnesium stearate, (Aerosil) Fumed silicon dioxide, Dicalcium phosphate and physical mixture of drug with these excipients. These samples were subjected to compatibility studies and stored for 30 days at elevated temperature and humidity conditions of 40 ± 2 °C / 75 ± 5 % RH. IR spectra of these stored samples were then obtained after 30 days [4,5,6].

5. Formulation and Development of ODTs:

Table no. 1: Composition of Famciclovir ODTs:

Sr. No.	Name of ingredients	F1 mg	F2 mg	F3 Mg	F4 Mg	F5 Mg	F6 Mg
1	Famciclovir	250	250	250	250	250	250
2	Sodium starch glycolate (Primogel)	110	115	120	125	130	135
3	Microcrystalline cellulose. (Avicel) pH 102	40	35	30	25	20	15
4	Starch	40	40	40	40	40	40
5	Saccharin sodium	25	25	25	25	25	25
6	Talc	3	3	3	3	3	3
7	Magnesium stearate	2	2	2	2	2	2
8	Fumed silicon dioxide (Aerosil)	3	3	3	3	3	3
9	Dicalcium phosphate	77	77	77	77	77	77
	Total weight	**550**	**550**	**550**	**550**	**550**	**550**

6. Evaluation of Famciclovir ODTs: [7,8,9]

The Famciclovir ODTs were evaluated for the following properties:

1. Physical Appearance: The thickness of tablet as a dimensional variable was evaluated. The tablet thickness was controlled within average value. The colour, odours and any other flaws like chips, cracks, surface texture, etc. are other important morphological characteristics were observed.

2. Hardness: Tablet hardness is defined as force required to crushing the tablet in diametric compression test. The hardness was measured with Pfizer hardness tester. The tablets were placed diametrically between two plungers and the lower plunger is kept in contact of tablet to read as zero. The upper plunger is forced against a spring by turning the screw until tablet fractures.

3. Friability:

Twenty tablets were weighed and subjected to friability test in Roche friabilator. The pre-weighed sample was placed in friabilator which revolves at 25 rpm for 4 minutes dropping the tablets through a

distance of 6 inch with each revolution. This process was repeated for all formulations and the percentage friability was calculated.

% loss = Initial wt. of tablets - Final wt. of tablets / Initial wt. of tablets x 100

Where; W1 = Initial weight of tablet

W2 = weight of tablet after rotation

4. Weight Variation: For Tablet weighing 250 mg or more, not more than two tablets differ from the average weight by 10 % deviation. The percent deviation in weight variation from average value for all formulation of design batches were within limit. The weight variation within limits indicates uniformity in tablet compression and consequently content of drug in a unit. 20 tablets were taken and average weight of the tablet was determined. The tablets were weighed individually and the weight variation was determined.

5. Thickness and Diameter: Thickness and diameter of tablets was important for uniformity of tablet size. The thickness and diameter of tablets were determined with the help of Vernier caliper. The average diameter and thickness of the tablet was calculated. The test passed if none of the individual diameter and thickness value deviated by ± 5% of the average.

6. Drug Content: From each batch of prepared tablets, ten tablets were collected randomly and powdered. A quantity of powder equivalent to 250 mg was transferred to 250 ml volumetric flask. 50 ml of pH 6.8 phosphate buffer was added and then the solution was subjected to Sonication for a period of about 30 min. The solution was made up to 250 ml with 6.8 phosphate buffer. The solution was filtered and suitable dilutions were prepared with pH 6.8 phosphate buffer and then drug content was estimated by recording the absorbance at 224 nm by using UV-visible spectrophotometer.

7. *In vitro* Dissolution Studies:

The dissolution study of the developed drug delivery system was planned on the basis of physiological condition oral cavity. The media for dissolution is as follows:

- ✓ pH 6.8 phosphate buffer

The volume of media was kept 900 ml to maintain sink condition. The apparatus for dissolution used was USP-II (Paddle) at 100 rpm. Aliquots were withdrawn at 1, 2, 4, 6, 8, 10-minute interval from a zone midway between the surface of dissolution medium and top of the rotating paddle not less than 1 cm apart from the suitable replacements with fresh medium was also made. Each sample solution was filtered through Whatman no. 41 filter paper. The absorbance was measured at 224 nm using spectrophotometer.

8. Solubility (S):

Procedure: 25 mg of sample was accurately weighed and transferred into 25 ml volumetric flask and volume was made up to the mark with methanol. From this 1 ml was taken in 10 ml volumetric flask and volume is adjusted up to mark with same solvent. The absorbance of the solution was measured at 224 nm using appropriate blank. The drug content of Famciclovir was calculated using calibration curve.

9. Kinetics of drug release: [10]

'In vitro' dissolution has been recognized as an important element in drug development. Under certain conditions it can be used as a surrogate for the assessment of bioequivalence. Several theories or a kinetic model describes drug dissolution from immediate and modified release dosage forms.

The quantitative interpretation of the values obtained in dissolution assay is facilitated by the usage of generic equation that mathematically translates the dissolution curve in function of some parameters related with the pharmaceutical dosage forms.

In most cases the theoretical concept does not exist and some empirical equations have proved to be most accurate or appropriate. The kind of drug its polymorphic form, crystallinity, particle size, solubility and amount in that pharmaceutical dosage form can influence the release kinetics. A water soluble drug incorporated in a matrix is mainly released by diffusion while for low water soluble drug the self-erosion of the matrix will be the principle release mechanism.

Zero-Order Kinetics: F=K0t, where F represents the fraction of drug released in time t and K0 is the zero-order release constant.

First-Order Kinetics: ln (1-F) = Ktt, where F represents the fraction of drug released in time t and Kt is the first-order release constant.

The model with the highest correlation coefficient was considered to be the best fitting one. [12]

10. Accelarated Stability Studies: [11]

On the basis of In vitro evaluation of all the formulation batches for the various parameters, formulations were packed in thick aluminum foil and stored in ICH certified stability chambers for the accelerated stability studies. The tablets were stored in the stability chamber at the controlled conditions of temperature and relative humidity. The stability of the tablets was studied for the duration of 30 days at temperature 400C ± 20 C and 75% ± 5% relative humidity and room temprature. The tablets was then evaluated for various parameters viz. weight

variation**,** thickness,diameter, hardness, friability, drug content and release studies.

RESULTS AND DISCUSSION:

1. IR Spectrum:

For characterization of pure Famciclovir FTIR studies were carried out. The observed and reported characteristic peaks of functional group have been shown in table 8.1 and IR spectrum is shown in (Fig.1).

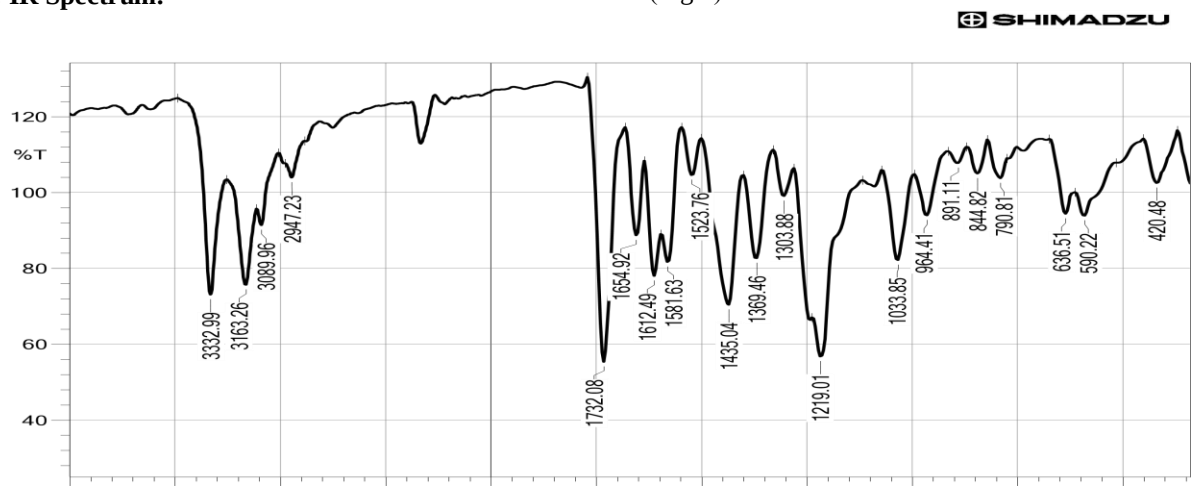

Fig.no. 1: IR Spectrum of Famciclovir (pure drug)

Table no. 2: Reported and observed principal peaks of Famciclovir in IR

Functional group	Characteristics	Observation
C-H (Stretching)	3000-2800	2947
Ester	1750-1730	1732
C=C	1680-1600	1654
N-H (bending)	1640-1550	1581
C-N (Amine)	1300-1000	1219

2. U. V. Spectrum:

Famciclovir shown absorbance at 224 nm in phosphate buffer solution pH 6.8 (Fig.8.2). While reported λ max of drug is 224 nm.

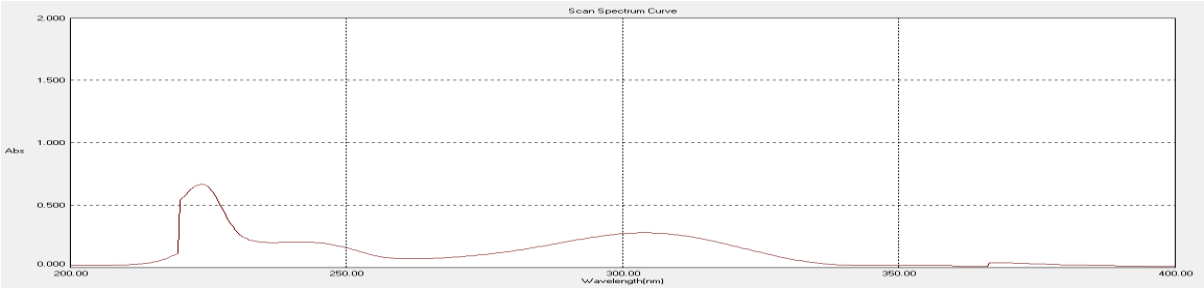

Fig.no. 2: UV spectrum of Famciclovir in Phosphate buffer pH 6.8

3. Calibration Curve by UV Spectroscopic Method:

1. Calibration curve in phosphate buffer pH 6.8:

A linear relationship was obtained in Beer-Lamberts plot of Famciclovir (y =0.0965x+0.0139, R2=0.998). The calibration data is given in Table 8.2 and graph obtained after plotting absorbance (y) vs. concentration (x) is shown in Fig.3.

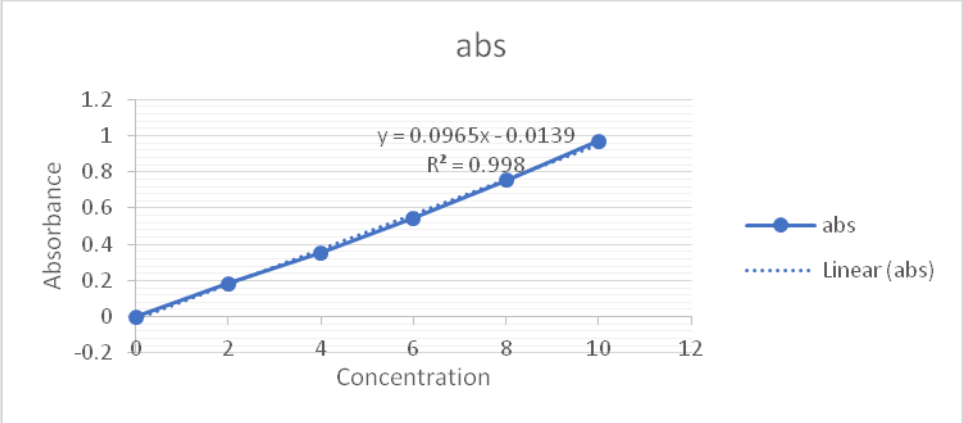

Fig.no. 3: Calibration curve of Famciclovir in PBS 6.8 by UV

Spectroscopic method:

Table no. 3: Calibration data of Famciclovir in PBS 6.8 by UV spectroscopic method

Sr.No	Concentration	Absorbance
1	0	0
2	2	0.185
3	4	0.355
4	6	0.546
5	8	0.755
6	10	0.971

4. Drug-Polymers compatibility study:

A) Infrared Spectroscopy:

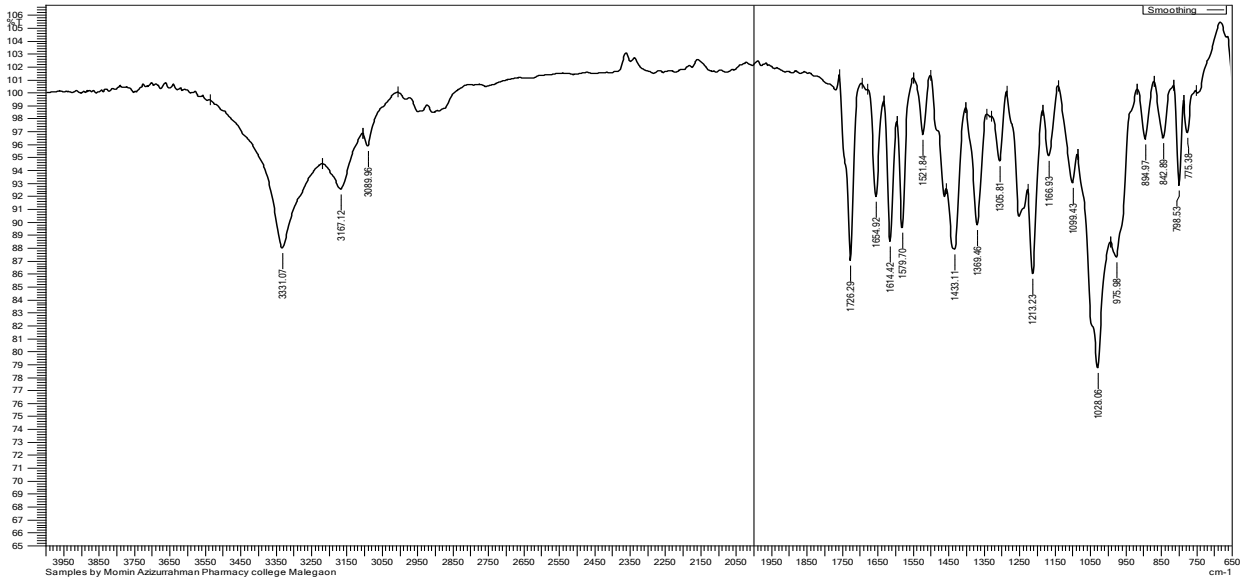

Fig. no.4: IR spectrum of Famciclovir with Avicel pH102

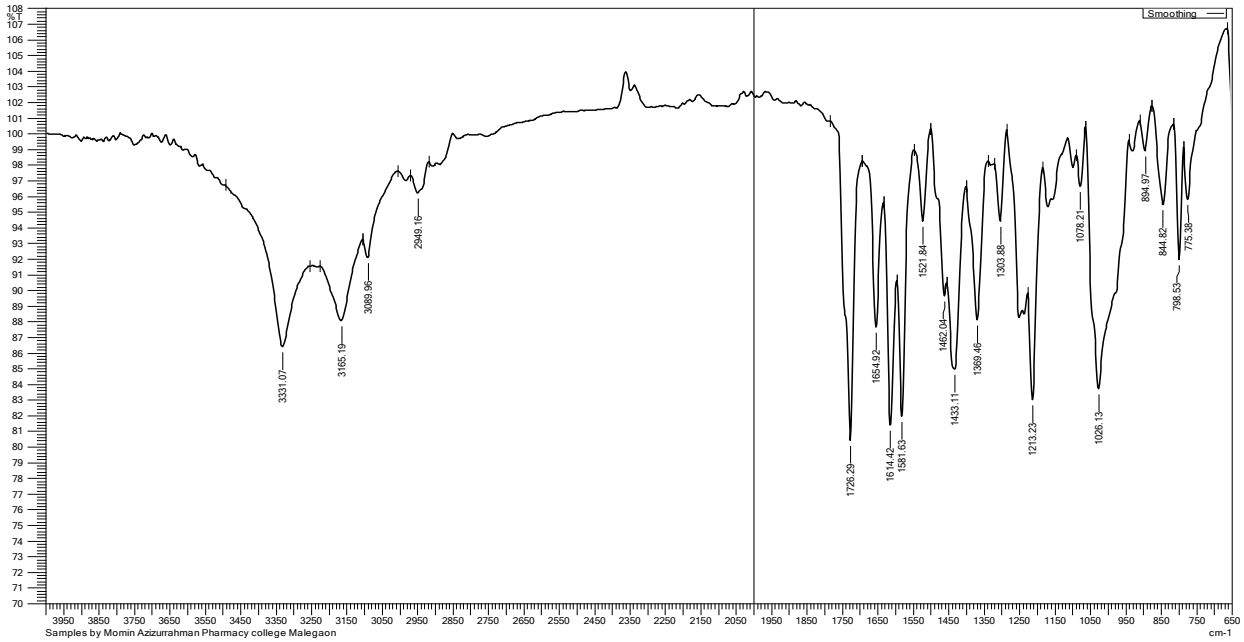

Fig. no.5: IR spectrum of Famciclovir with Primogel

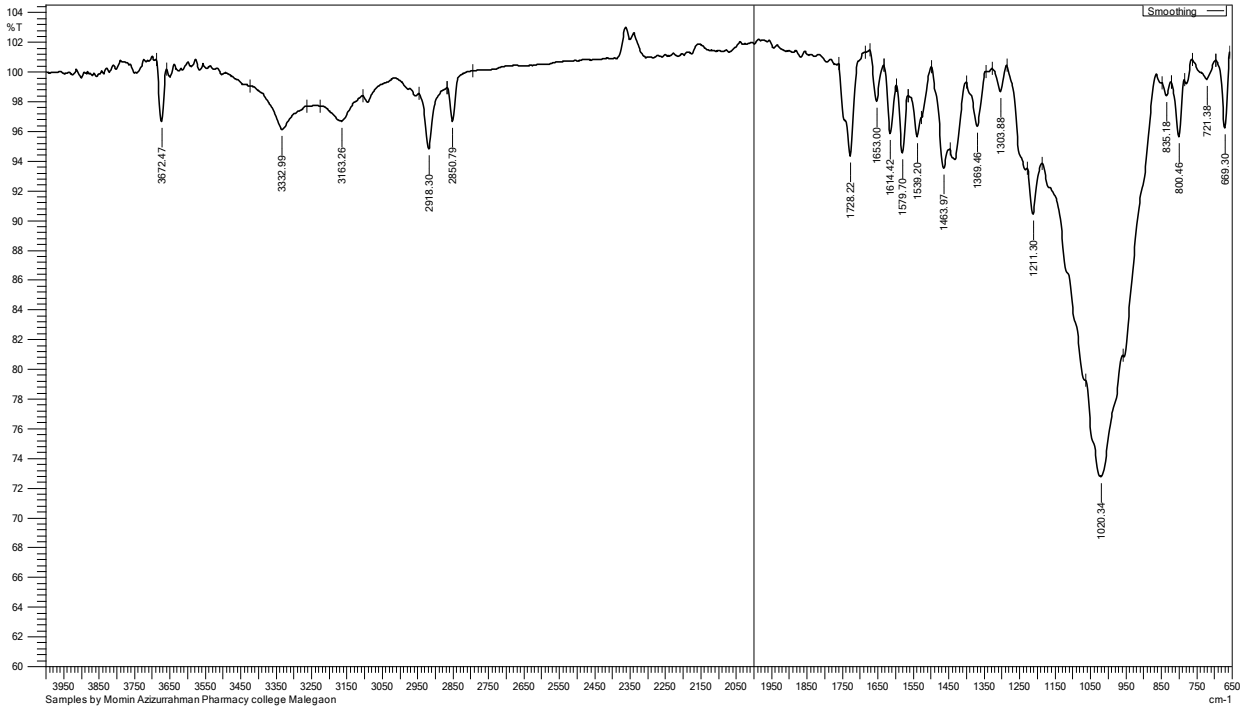

Fig. no.6: IR Spectrum of Famciclovir and mixture of Excipients (Avicel, Primogel (S.G.S), Starch, Saccharine sodium, Talc, Magnesium stearate, Aerosil, Dicalcium phosphate.)

The Drug-excipients interaction study had shown no interaction between Famciclovir and selected polymers as there was no significant shift of peaks in IR spectrum. Also the characteristic peaks of drug Famciclovir were observed in IR spectrum of drug-excipients and in physical mixture sample. From these IR spectra, it was concluded that the selected excipients were compatible with drug Famciclovir.

5. Evaluation of flow properties of powder blends:

The characterization of flow properties of powder blends is important in tablet compression. The powder blends with good flow properties gives uniform die fill and consequently it gives the uniform tablet weight. The values are given in table no. 4**.**

Table 4: Flow properties of powder

Formulation	Bulk Density (gm/cm2)	Tapped Density (gm/cm2)	Carr's Index (%)	Hausner Ratio	Angle of Repose (0)
F1	0.5412± 0.013	0.6601± 0.062	21.4366± 1.831	1.3472± 0.238	27.64± 1.224
F2	0.4512± 0.013	0.5265± 0.088	25.8133± 1.626	1.5493± 0.304	28.56± 0.871
F3	0.4135± 0.024	0.5152± 0.051	38.1650± 0.816	1.2727± 0.125	19.45.15± 1.115
F4	0.4662± 0.015	0.5033± 0.038	26.9250± 0.880	1.3723± 0.0890	26.42± 0.733
F5	0.5281± 0.031	0.4907± 0.069	31.8207± 1.201	1.5111± 0.2987	28..17± 1.426
F6	0.4171± 0.01	0.4920± 0.032	16.9122± 0.816	1.256± 0.146	23.15± 2.849

1. Angle of repose

The angle of repose can be correlated with type of flow of powder. The angle of repose below 25º indicates excellent flow properties. The angle of repose was found to be within the range of 19º to 28º indicating good flow properties.

2. Bulk density

The bulk density of powder is important parameter in the compressibility of the powder. The bulk density was between 0.41 to 0.54gm/cm2.

3. Tapped density

The tapped density of powder is important parameters in the compressibility of the powder. The tapped density was found to be 0.49 to 0.66 gm/cm2.

4. Carr's index

The Carr's index is indicator of compressibility. The value below 21 % shows good compressibility. It was found to be 16 to 38 %. indicating good compressibility.

5. Hausner's ratio

The Hausner ratio is another parameter indicating the flow properties. The value of ratio below 1.25 indicates good flow while above 1.25 indicates the poor flow. It was found to be 1.25 to 1.54 indicating poor flow ability**.**

6. Evaluation of Tablets:

The tablet parameter like weight variation, Hardness, thickness, diameter, friability, and drug content were evaluated and values are given in table no.5**.**

Table 5: Evaluation of Tablets

Formulation	Weight variation mg±SD	Hardness (Kg/cm2) ±SD	Thickness (mm) ±SD	Diameter (mm) ±SD	Friability (%)	Drug content (%)
F1	549.25± .153	3.6±0.2	4.93 ± 0.21	11.26 ± 0.15	0.2811	96.26± 0.230
F2	552.35± .758	3.6±0.26	4.72 ± 0.06	11.31 ± 0.43	0.1696	98.62± 3.602
F3	551.20± .125	3.4± 0.21	4.05 ± 0.12	11.23 ± 0.13	0.4121	96.54±1.325
F4	548.95 ± 2.064	3.5± 0.2	4.61 ± 0.06	11.29 ± 0.15	0.1801	97.98±1.876
F5	549.5± 2.212	3.6± 0.26	4.58 ± 0.06	11.42 ± 0.18	0.3032	94.67±0.933
F6	552.65± 1.094	3.7± 0.25	4.66 ± 0.31	11.27 ± 0.12	0.3751	99.85±1.445

1.

Weight variation

The weight variation of the formulation F1 to F6 ranged from 548.95 to 552.35 mg and percentage deviation ranged from 1.09 to 3.15 **%.** The percentage deviations of the tablets have to be specific, and they should not differ ± 5**%** according to IP specification**.**

2. Hardness and Friability

The Hardness of the formulation F1 to F6 ranged from 3.4 to 3.7 Kg/cm2**.** However, hardness alone cannot be considered as absolute indicator of the tablet strength**.** Hence another parameter measured was the friability of the tablets**.** The friability of the tablets was found to be less than 1 **%** which was considered within the limit **[**USP**].** The measure of these two parameters gives the strength of the tablets during handling, packaging, shipping etc**.**

3. Thickness and Diameter

The percentage deviation of thickness and diameter of the formulation F1 to F6 ranged from 0.05 to 0.21 and 0.12 to 0.43 respectively**.** These parameter of the tablets have to be specific, and they should not differ ± 5**%** of the average value**.** The tablet evaluated showed within the limit and thus passes the test**.**

4. Drug content

The uniformity in the drug content is an important measure**.** It gives the percentage of drug present per unit dosage form**.** The content uniformity was found within 94.62 to 99.85 **%** of the 250 mg of Famciclovir**.** Hence the tablets prepared showed good content uniformity**.**

Table no. 6. Result of disintegration time, wetting time of Orally Disintegrating Tablets.

Batches	Parameter	
	Disintegration time (sec)	**Wetting time (sec)**
1	95.53± 2.00	68.00 ± .1145
2	120.25± 3.00	75.00 ± 2.00
3	175.00±1.00	125.45±3.56
4	119.22± 1.02	98.33 ± 2.12
5	165.00 ± 2.08	85.33 ± 2.89
6	90.51± 0.48	65.45 ± 0.67

4. ***In- vitro*** **drug release studies:**

Table no.7: Percent cumulative drug from formulation F1 to F6

Time [mint]	**% Cumulative Drug Release**					
	Batch Code					
	F1	**F2**	**F3**	**F4**	**F5**	**F6**
0	0	0	0	0	0	0
1	34.56	44.06	38.66	36.50	39.09	43.83
2	44.52	63.89	43.91	44.04	46.72	73.82
4	60.34	72.66	57.40	60.63	57.13	78.72
6	73.28	81.42	70.97	72.70	70.98	82.10
8	76.62	84.38	84.75	79.51	81.74	94.21
10	82.30	93.92	91.98	85.27	87.59	98.14

% cumulative drug releases of all batches:

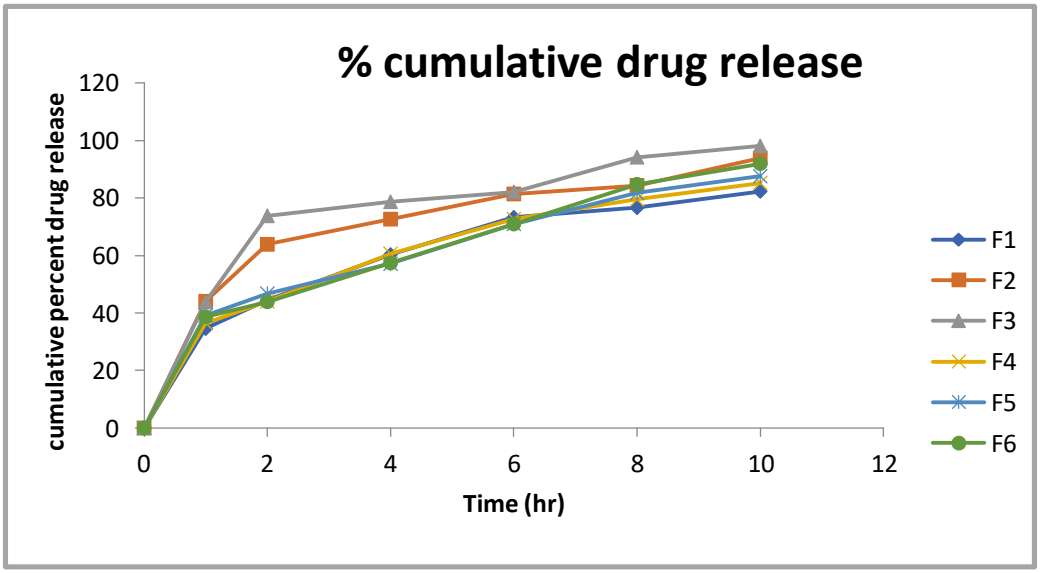

Fig.no. 7. % Cumulative drug release of all batches

5. Kinetics of drug release:

The value of coefficient of regression for different models of optimized formulation is given in table. no. 9. The coefficient of regression value was found to be highest for First order model and hence the release mechanism was found to follow First order kinetics.

Zero order equation:

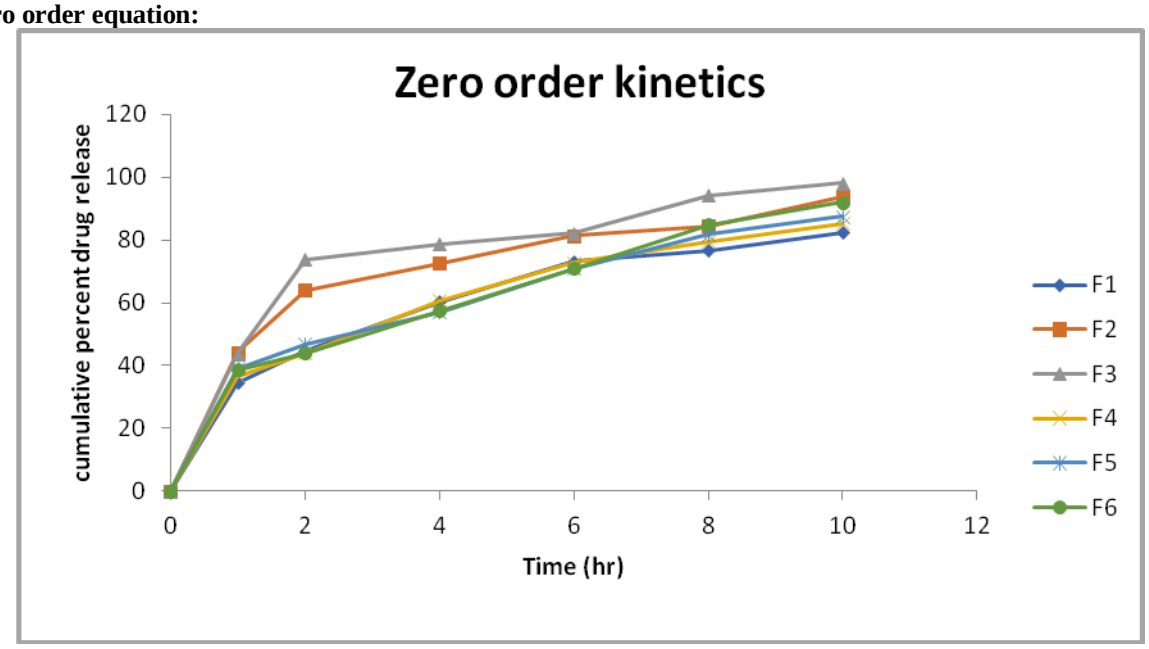

Fig. no. 8. Zero order kinetics model of formulation F1-F6

First order equation:

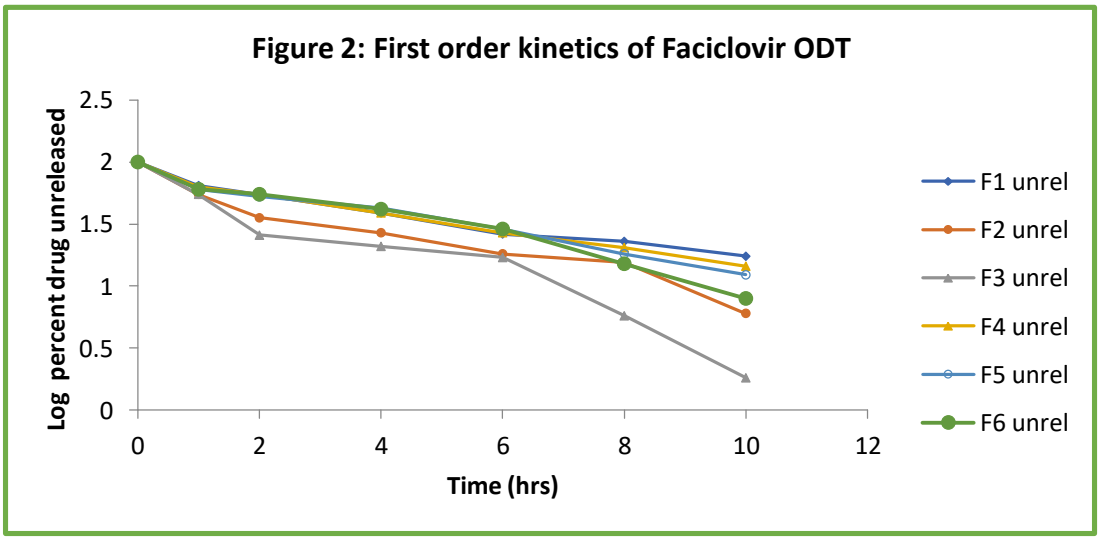

Fig. no.9. First order kinetics model of formulation F1-F6

8. Curve Fitting analysis for different formulation:

The in-vitro release studies data was quantified to determine the release mechanism, to fit various mathematical models and to determine the best fit model for formulation**.** The parameters like regression co-efficient **(**R2**)** were calculated in the set of data, the model showing highest values of R2 was considered as best fit model**.**

The kinetic data of orally disintegrating tablets formulation are shown in table no8**.**11**.** when the data were plotted according to zero order equation and first order equation showed correlation coefficient values between 0**.**7039 -0**.**8855and 0**.**9407 -0**.**9806 respectively**.** Hence, the results revealed that all the orally disintegrating**s** tablets formulation release the drug by First order kinetics as R2 close to one**.**

Table no.9: Regression coefficient (r2) different kinetic models of formulation F1 to F6.

Formulation	**Regression**	
	Zero order	**First order**
F1	0.8461	0.9616
F2	0.7323	0.9413
F3	0.7039	0.9407
F4	0.8461	0.9806
F5	0.8516	0.9776
F6	0.8855	0.9704

9. Accelerated stability studies:

The results of stability study are as follows.

1) There was no change in the physical appearance of the tablet.
2) The total drug content was

Table no.9. Stability study

Formulation	**Drug content before stability study**	**Drug content after stability study**
F6	99.62 %	99.85 %

3) The release pattern of the drug was studied by dissolution studies in same way as done previously. The results obtained were compared with the previous data, the comparative data shown in graph is as follow.

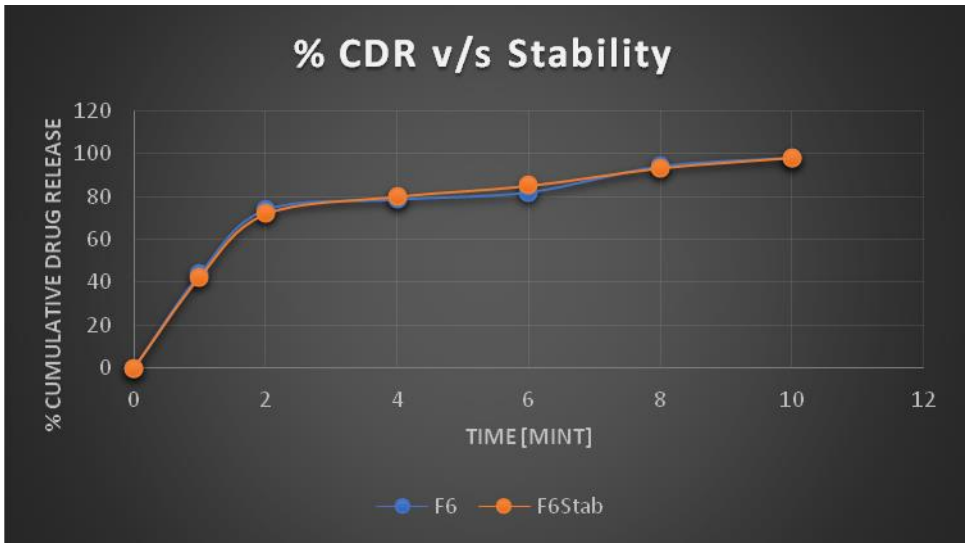

Fig: no.10. In vitro dissolution profile for stability study

From the graph it is observed that the drug release pattern after stability (F6) study was nearly same as before stability (F6) with little difference.

Thus the formulation showed the characteristics of stable dosage form with no change in the physiochemical characteristics and release pattern.

CONCLUSION:

The Orally Disintegrating Tablets have potential advantages over conventional dosage forms, with their improved patient compliance; convenience bioavailability and rapid onset of action had drawn the attention of many manufacturers over a decade. The preparation process of wet granulation tablets includes granule formation of all the excipients before compression, resulting the increase in the solubility due to the reduction in the effective particle size of the drug following increase in the wetting of drug particle by the excipients and improved dissolution of drugs by wet granulation.

In conclusion, overall results suggest that the ODTs of Famciclovir (F6) shows best results as compared to other formulations in terms of percent drug release, compressibility index, and hardness and disintegration time. This work concluded that F6 was found best formulation because it is having good disintegration time (90.51±0.48) and dissolution responses (98.14 %) in 10 mints as compared to other concentration of superdisintegrants. Thus, ODTs may be developed for Famciclovir, for quick onset of action without need of water for swallowing or administration, however further studies are investigations are needed to confirm the in vitro efficiency and for the development of ODT of Famciclovir. This work gives idea about the selection and compatibility of the superdisintegrants with respect to the drug.

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