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Formulation and Evaluation of Fast Dissolving Tablets of Fexofenadine

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ABSTRACT
In the present work, an attempt has been made to develop fast disintegrating tablets of fexofanadine, was as dehydrated banana powder, crosspovidone and Fenugreek Gum were employed as super disintegrating agents to enhance the solubility and dissolution rate of drug molecule. Formulations were prepared by direct compression method using 9.5mm punch on 8 station rotary tablet punching machine. The blend of all the formulations showed good flow properties such as angle of repose, bulk density and tapped density. The prepared tablets have shown good post compression parameters and they passed all the quality control evaluation parameters as per IP limits. Among all the formulations F6 formulation showed maximum percentage drug release i.e., 97.45 % in 15 min, hence it is considered as optimized formulation. The F6 formulation contains Crosspovidone as super disintegrate in the concentration of 30mg.

Keywords: Crosspovidone, Dehydrated Banana Powder, Fenugreek gum,Solubility, Dissolution rate

I. INTRODUCTION

Oral routes of drug administration have wide acceptance up to 50-60% of total dosage forms. Solid dosage forms are popular because of ease of administration, accurate dosage, self-medication, pain avoidance and most importantly the patient compliance. The most popular solid dosage forms are being tablets and capsules; one important drawback of this dosage forms for some patients, is the difficulty to swallow. Drinking water plays an important role in the swallowing of oral dosage forms. Often times people experience inconvenience in swallowing conventional dosage forms such as tablet when water is not available, in the case of the motion sickness (kinetics) and sudden episodes of coughing during the common cold, allergic condition and bronchitis [1].

For these reason, tablets that can rapidly dissolve or disintegrate in the oral cavity have attracted a great deal of attention. Or dispersible tablets are not only indicated for people who have swallowing difficulties, but also are ideal for active people. Fast dissolving tablets are also called as mouth-dissolving tablets, melt-in mouth tablets, Orodispersible tablets, rapimelts, porous tablets, quick dissolving etc. Fast dissolving tablets are those when put on tongue disintegrate instantaneously releasing the drug which dissolve or disperses in the saliva [2].
The basic approach in development of FDT is the use of Superdisintegrants like cross linked Carboxymethyl cellulose, Sodium starch glycolate, Polyvinylpyrrolidone etc, which provide instantaneous disintegration of tablet after putting on tongue, their by release the drug in saliva[3]

Concept of fast dissolving drug delivery system:-

The concept of Fast Dissolving Drug Delivery System emerged from the desire to provide patient with conventional means of taking their medication. Because of physiological changes associated with, especially, elderly and paediatrics are quite unable to swallow
(Dysphasia); rather, this is a common problem of all age groups patients.[4,5].

Criteria for Fast dissolving Drug Delivery System:-

The tablets should not require water to swallow, but it should dissolve or disintegrate in the mouth in matter of seconds. Be compatible with taste masking. Be portable without fragility concern. Have a pleasant mouth feel. Leave minimum or no residue in the mouth after oral administration. Exhibit low sensitive to environmental condition as temperature and humidity Allow the manufacture of the tablet using conventional processing and packaging equipments at low cost[6]

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Advantages of Fast Dissolving Tablet:-

Fast dissolving tablets (FDTs) are solid unit dosage form, so they provide precise dosing, and high drug loading is sanctioned in it, and it is an ideal dosage in case of geriatric and pediatric patients, and additionally it is an ideal alternative of conventional tablet[7]

It has fast action, as it is taken by the patient, it commences melting when it comes in contact with saliva, it rapidly absorbed in the oral cavity, and it rapidly melts and produces fast action.

Due to pregastric absorption, the bioavailability of the drugs is amended, and fewer doses are required, which amends the patient compliance, clinical reports are also amended. [8,9,]

II. MATERIALS AND METHODS

The is gift sample from ....., Crosspovidone is purchased from Kayel Medichem Pvt Ltd Delhi, Fenugreek Gum is purchased from Rama Gum Industries, magnesium sterate, Talc, Aspartame and Mannitol is purchased from sigma Aldrich

Preformulation Studies:-

Standardization of Drug:-

UV Spectrophotometric method for fexofenadine:-

Standard Calibration Curve of fexofenadine at 310 nm in pH 7.4 phosphate buffer by using UV Spectroscopy Method.

Physical drug Excipients Compatibility Studies:-

Fourier transforms infrared spectroscopy:-

FTIR study was performed to verify pure drug and polymer interaction. The study of pure drug Selegiline and Dehydrated Banana Powder, Crospovidone, Fenugreek Gum and Avicel101 The pure drug powder within potassium bromide and pellet was prepared by high pressure to 100kg/cm for 2min. The obtained tablet was investigate in FTIR 8400S, Shimadzu, Japan. KBr was investigated of samples. The process was repeated for determine of drug and Polymers [10].

DSC Studies:

The DSC thermo gram of physical mixture of fexofenadine and the polymers showed no characteristic peaks of polymers and Selegiline peaks were still present but slightly shifted from their original positions

Melting Point Determination:-

Melting point determination was done by using capillary tube.

Solubility:

In water soluble (0.3551 mg/L at 25 °C) but display special solubility in 0.1M HCl.

S.No.	Ingredients (mg)	No. of Formulation					
1.	fexofenadine (mg)	F1	F2	F3	F4	F5	F6
		120	120	120	120	120	120
2.	Dehydrated Banana Powder	15	30	-	-	-	-
3.	Fenugreek Gum	-	-	15	30	-	-
4.	Crospovidone	-	-	-	-	15	30
5	MCC	116	100	116	100	116	100
6.	Orange flavour	2	2	2	2	2	2
7.	Aspartame	2	2	2	2	2	2
8.	Talc	4	4	4	4	4	4
9.	Magnesium Stearate	QS	QS	QS	QS	QS	QS
10.	Mannitol	45	40	45	40	45	40
	Total weight	300	300	300	300	300	300

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Micrometry study of Powder:

Bulk density and tapped density:

Bulk density is calculated by adding know mass powder to a cylinder. The density is calculated as mass. Tapped density in this method firstly we have to weigh the known powder and then known powder transfer in a 10ml mechanically tapping cylinder. The tapping is started until the little further volume change is observed [11].

LBD = Wt powder/Vol powder
TBD = Powder wt/Tapped vol powder

Carr's index:

The fast dissolving of powder can be determined by differentiate LBD & TBD of powder & value at which crowded depressed [64].
Carr's index is deliberate by formula:-

$$\% \text{ Carr's index} = \frac{\text{TBD} - \text{LBD}}{\text{TBD}} \times 100$$

Hausner's ratio:

The Hausner's proportion of compose fast dissolving tablets dried power merge were resolve following equation [64].

$$\text{Hausner's ratio} = \frac{\text{TBD}}{\text{LBD}}$$

Angle of repose:

Angle of repose was investigated by using funnel method of following formula [12]. $\text{Tan}\theta = \frac{H}{R}$

Where,
θ = angle of repose
H = height of the pile
R= radius of the pile base

Preparation of Fast Dissolving Tablets of fexofenadine:

Fast Dissolving tablet containing fexofenadine were prepared by direct compression method by Containing 120 mg fexofenadine and polymers like (Dehydrated Banana Powder, Crospovidone, and Fenugreek Gum) were mixed completely using mortar & pestle. The Superdisintegrants were used in different proportions and in different combinations. All the ingredients were weighed accordingly specified in the formulation and mixed well except magnesium Stearate. Then the blend was passed through sieve no 60 which was used for the evaluation of flow properties. To the mixed blend of powder and excipients finally add magnesium stearate and then mixed for 5 min. The mixed blend was compressed with eight station tablet punching machine using 9.5 mm flat punches with break line. Four punches in the 9.5 mm station compressor are fixed with die cavity and remaining is fixed with
Round punch.

Evaluation Parameters of Compressed Tablet:

Tablet Hardness:

The fexofenadine tablets hardness was deliberate by using Monsanto hardness tester. From every group the defeat strength of 10 fast dissolving tablets with known weight was note in kg/cm2 and hardness of tablets was determined [13].

Tablet Thickness:

The thickness of fast dissolving tablets was deliberate 5 tablets were used and average value was measured by using Vernier caliper [14].

Friability:

Friability of tablet was stand way to estimate solidity by using Roche Friability tester. Firstly 20 tablets taken and weight accurately and transfer into Friability tester. The tester was operated at 25 rpm for 4 min or run up to 100 revolutions. % damage in mass friability was deserved by following formula [15].

F = Initial wt - Final wt/Initial wt × 100

TECHNIQUES FOR PREPARING

Weight variation:

This method is performed as weight variation of tablets. Twenty tablets were individually weighed in (gm) on electronic balance. After that calculated the average weight of tablet and checked for weight variation of tablets [16].
Calculation of percentage weight deviation:-
% Variation = Individual wt - Average wt/Average wt × 100

Wetting Time

A piece of tissue paper folded twice was placed in a small Petridis of 6.5cm in diameter containing 6ml of water. A pre weighed tablet was placed on the surface of tissue paper and allowed to completely wet. The time required for water to reach the upper surface of the tablet and to completely wet it was noted as the wetting time. The wetted tablet was then weighed. Water absorption ratio (R) was determined using the following equation [17, 18].
R = Wa-Wa/ Wb *X* 100
Where,
Wb - Weight of tablet before wetting.

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Wa - Weight of tablet after wetting.

2Dispersion Time:
Tablet was placed in 10 ml phosphate buffer pH 6.8 solution. Time required for complete dispersion of tablet was measured.

In-vitro dissolution studies:

In-vitro dissolution study was performed by using dissolution test apparatus (electro lab) at 50 rpm. Phosphate buffer pH 6.8, 900 ml was used as dissolution medium which time interval (2 min) and was filtered. The amount of drug dissolved was determined by UV spectrophotometer (Shimadzu 1800, Japan) by measuring the absorbance of the sample at Selegiline at 310 nm in pH 7.4 phosphate buffer by using UV Spectroscopy Method and Cumulative percentage drug releases are determined. Maintained at 37±0.50C Aliquot of dissolution medium (5 ml) was withdrawn at specific. The following procedure was employed throughout the study to determine the in vitro dissolution rate for all the formulations.

Dissolution parameters:-

- Apparatus used - Electro lab
- Temperature - 37± 0.50C
- RPM - 50 rpm
- Volume withdrawn - 5 ml for 5 minutes
- λ max - 310nm
- **Stability studies:**
- The stability studies of optimised formulation (F6) were carried out according to ICH guideline. The correct formulation was subjected to stability at 40±2°C/75±5% RH for 180 days. After then duration the product was evaluated for Colour, Hardness, Disintegration time & In-vitro release [19].

III. RESULTS

Preformulation Study-

UV Spectroscopy-

After scanning of the sample drug, the wave length was obtained about 310 nm in pH 7.4 phosphate buffers by using UV Spectroscopy Method Figure 6.1.

Table 1 Calibration of fexofenadine

S.No.	Concentration µg/ml	Absorbance 310nm
1.	0	0
2.	2	0.1251
3.	4	0.2249
4.	6	0.3411
5.	8	0.4714
6.	10	0.5812
7.	12	0.6812
8.	14	0.8232
9.	16	0.9829

Discussion FTIR Spectroscopy:-

Table .2 FT-IR Spectral Data of Pure fexofenadine with Excipients

S.No.	Wave Number (cm^1)	Functional Group
A	**fexofenadine**	
1	3408	Broad band of bonded OH
2	1637	C=O of aryl acids stretching
3	1458	C=N stretching
4	1420	Aromatic C=C stretching
5	1083	C-N stretching
6	754	CH_3 angular
B	**fexofenadine with fenugreek Gum**	

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1	3421	Broad band of bonded OH
2	2131	C-H Stretching for methyl
3	1639	C-N vibration
	1531	C=C stretching
4	1280	C=N stretching
5	509	Aromatic
C	**fexofenadine with Crospovidone**	
1	3485	OH Stretching
2	3410	Aliphatic C-H
3	2947	C=O Stretching
4	2710	C-N Stretching
5	754	C-H Methane
6	441	CH2 Group

DSC Studies:

DSC Studies Fexofenadine:

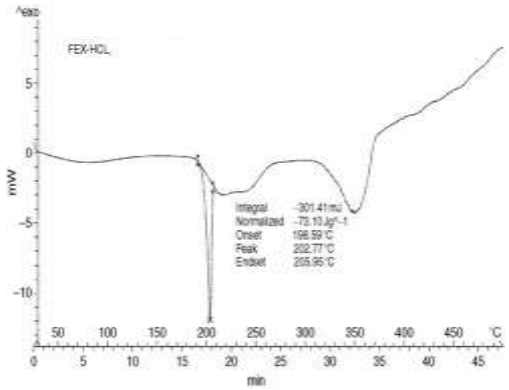

Figure 1 Differential Scanning Calorimetry of fexofenadine

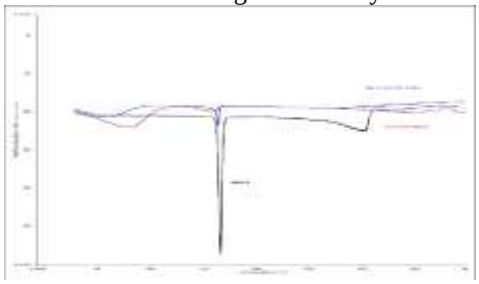

Figure 2 Differential Scanning Calorimetric of fexofenadine with Excipients

Evaluation of Powders for Fast Dissolving Tablet:

The physical mixtures for fast dissolving tablet were evaluated with respect to Angle of repose was found between 26.36±1.06 to 30.86±0.48and Carr's index values were found 19.50±0.8 to 28.68±0.8% the powder of all batches excellent to poor flow ability and compressibility. Hausner ratio was found to be 1.19±0.18 to 1.40±0.20. Bulk density ratio 0.58±0.44 to 0.64±0.68 and tapped density ratio 0.69±0.02 to 0.78±0.54for all the batches indicating that possible and poor flow properties.

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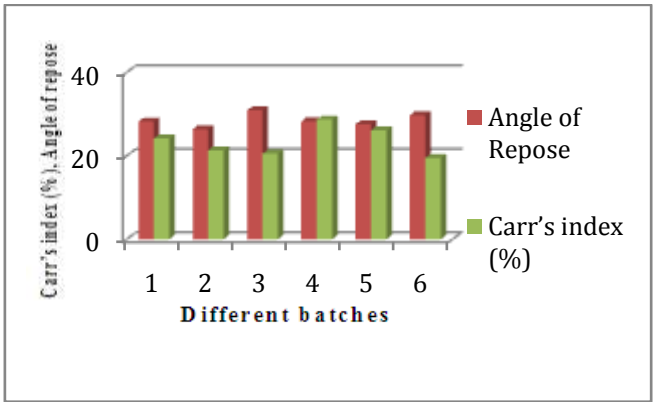

Figure 3 Carr's index and Angle of repose

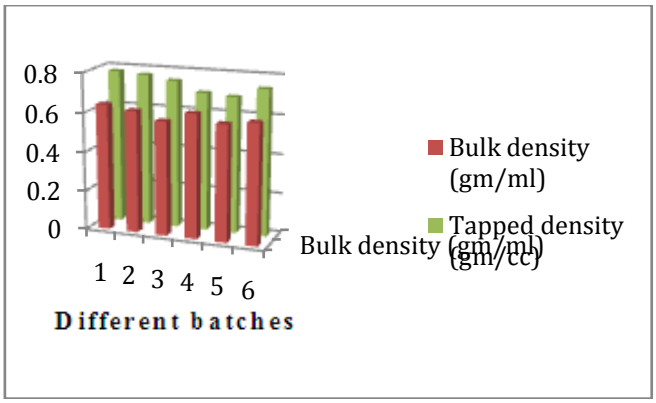

Figure 4 Bulk density and Tapped density

Evaluation Parameters of Compressed Tablet:

The physical parameters Hardness of tablets were found to 4.0±0.5 to 5.0±0.5 kg/cm2. The friability of all prepared tablets was found to 0.32% to 0.63 %. The Thickness was found range 4.07±0.4 to 4.17±0.4 mm. The weight variations of all tablets were established to be 292±306 to 295 to 309mg. The Wetting time 23±1 to 62±1, disintegration 31±1 to 31±1, and Dispersion Time found to be about 36±0.6to 87±0.4.

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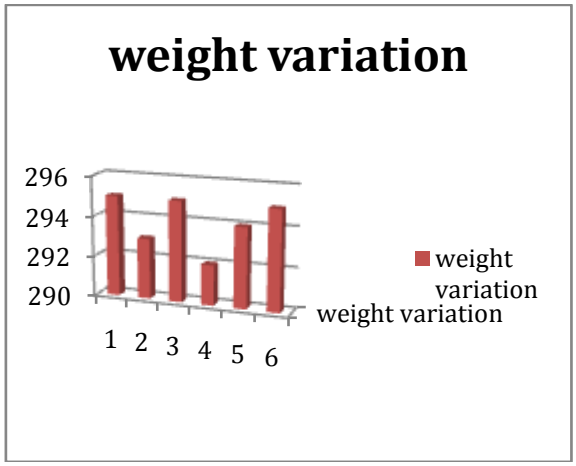

Figure 5 Weight variation

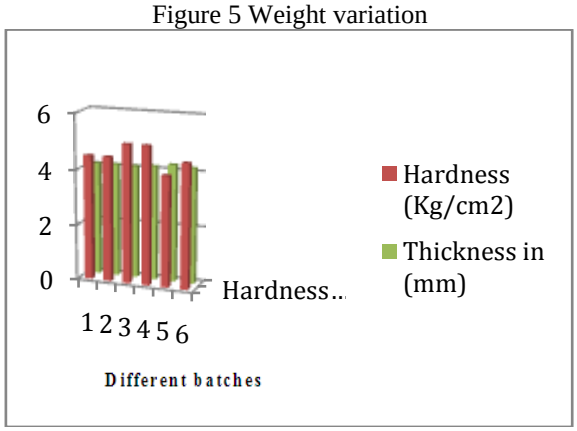

Figure 6 Hardness and Thickness

In-Vitro Drug Release Studies:

Table 3.Release studies F1-F6

Time/Min	% Release drug					
Formulation	F1	F2	F3	F4	F5	F6
0	0	0	0	0	0	0
3	51.75±2.4	50.3±0.28	51.65±0.24	50.04±0.96	53.4±0.72	58.42±1.30
6	56.56±2.2	55.55±0.99	56.46±0.48	59.52±1.33	56.85±0.88	67.78±1.25
9	61.78±2.3	58.04±0.90	59.52±0.76	63.13±1.28	57.58±1.24	73.47±1.20
12	69.25±0.9	70.56±0.36	65.32±0.82	69.49±1.22	61.44±1.45	85.89±1.18
15	76.52±0.5	78.78±1.25	79.7±0.91	72.21±0.98	72.98±1.30	97.45±0.97

±standard Deviation (n = 3)

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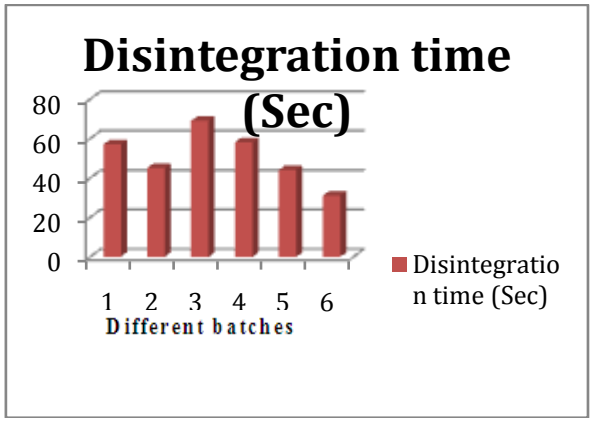

Figure 7 wetting time and Water absorptions

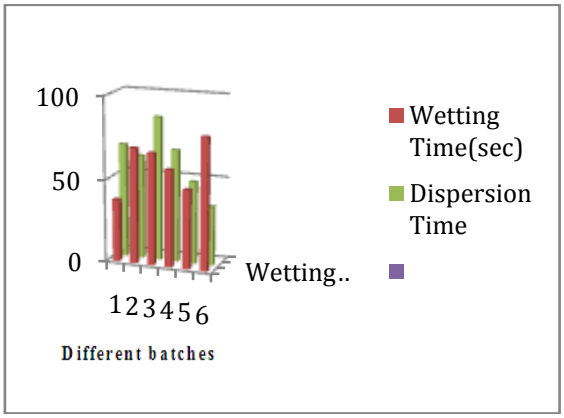

Figure 8 Disintegration time Microcrystalline cellulose

IV. DISCUSSION:-

The percentage of drug released from the formulation F1, 2 and 3 was found to be 51.75±0.51 t0 76.52±0.5% and 50.37±0.28% to 78.78±1.25 and 51.65 ±0.24 to79.7±0.91 The % of drug

Released from the formulations F4, 5 and 6 was found to be 50.04±0.96 to 72.21±0.98%, 53.4±0.72 to 72.98±1.30% and F6, 58.42±1.30 to 97.45±0.97 % for respectively. It was observed that The formulation F6 containing best concentration of Superdisintegrants than the other formulations so it is give the batter release within 15min than the other formulations.

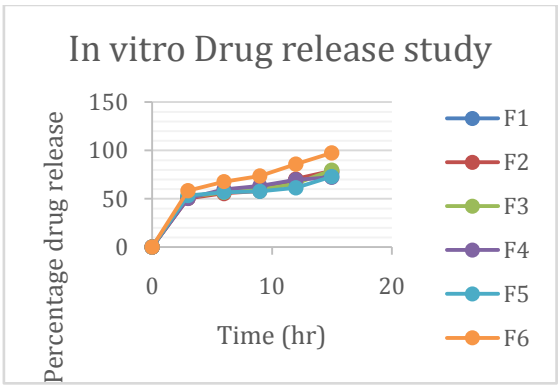

Figure 9 Cumulative Percentage drug release of fexofenadine

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Stability Studies:

The duration of stability studies of the Formulation 6, there is no change in colour, but found the minor variation in hardness, Disintegration time and In vitro drug release. All data evaluated according to ICH guidelines at 40±2°C/75±5% RH for 180 days.

V. CONCLUSION

The Fast disintegrating tablets of fexofanadine were prepared by dry granulation method using different Superdisintegrants such as Crospovidone, Karaya gum, dehydrated banana powder and in different concentration. The Mannitol was stick to dies and punch therefore ball mill is use to prepare Coground mixtures of Crospovidone and Mannitol to improve the compatibility and stability of product. The FTIR, DSC analysis revealed that the fexofanadine and polymer used were compatible with fexofanadine. Disintegration time decrease with increase in the concentration of Superdisintegrants. Among all formulation, Crospovidone (in concentration 15, 30 mg) as Superdisintegrants is fulfilling all the parameters satisfactorily. In vitro release studies that almost 97.45 % of drug was release from formulation F6 within 15 minutes in comparison to other formulation. Thus in this research, Crospovidone was found to play a most important role in fast release of drug, other disintegrants and Mannitol to improve the compatibility and stability of product. In present work fast dissolving tablets have been synthesized to overcome drawbacks associated with allergic.

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