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Comparative Study of Natural and Synthetic Superdisintegrants in the Formulation of Oral Fast Disintegrating Tablets Using Levofloxacin HCl as Model Drug

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ABSTRACT

The main objective of the present study was to develop the oral fast disintegrating tablets of Levofloxacin HCl, using natural and synthetic disintegrants in order to find out the difference in the drug release from the dosage form.Levofloxacin is an antibiotic,which is used to treat a number of bacterial infections including acute bacterial sinusitis,pneumonia,urinary tract infections,chronic prostatitis and some types of gastroenteritis. Along with other antibiotics,it may be used to treat tuberculosis, meningitis, or pelvic inflammatory disease.We prepared Levofloxacin HCl fast disintegrating tablets FDT to treat bacterial infections.In the present study, we studied the use of natural and synthetic disintegrants in the preparation of Levofloxacin HCl tablets.The natural super disintegrant used for the formulation was Banana powder and the synthetic disintegrants used for the formulation were Sodium starch glycolate,Cross povidone,Cross carmellose sodium. We employed wet granulation and direct compression technique for the preparation of fast dissolving tablets.The prepared granules were evaluated for the flow properties like bulk density, true density, tapped density, Carr's index,Hausner's ratio etc. The prepared tablets were evaluated for hardness,friability, thickness,weight variation, disintegration time, dissolution time, and the disintegration time was compared with natural and synthetic disintegrant.The FT-IR studies revealed that there was no interaction between the drug and the polymer and the polymers selected were suitable for the formulation of fast disintegrating tablets.Among all the formulations, formulations containing banana powder exhibited the fast disintegration time and exhibited the drug release up to 95% whereas the drug release from synthetic disintegrant was found to be up to 88%. Hence it was concluded that natural superdisintegrant was superior compared to synthetic superdisintegrant for the formulation of Levofloxacin fast disintegrating tablets.

INTRODUCTION

Difficulty in swallowing is the common problem in many patients such as elderly, paediatrics, mentally retarded, uncooperative, patients suffering from nausea, and vomiting [1]. Many elderly persons face difficulties in administering conventional oral dosage forms because of incompliance and dysphasia[2]. The above drawbacks of conventional dosage forms lead to the development of fast dissolving tablets also called as Melt-in-mouth tablet which disintegrates /dissolves rapidly in saliva without the use of drinking water[4]. The Melt-in-mouth dosage form containing active ingredients disintegrates rapidly, usually in a matter of seconds, without the need of water, providing optimal convenience to the patient. Melt-in-mouth tablets are also called as Mouth dissolving tablets, Oro-dispersible tablets, fast dissolving tablets, fast disintegrating tablets, rapi-melts, porous tablets, quick dissolving tablets etc[5]. The Fast disintegrating tablet technology, makes the tablet to dissolve or disintegrate in the mouth without additional water intake. The FDT formulation is defined by the Food and Drug Administration (FDA) as "A solid dosage form containing medicinal substances which disintegrates rapidly, usually within a seconds, when placed upon the tongue[3].According to European Pharmacopoeia, "the FDT should disperse/disintegrate in less than three minutes. The basic approach in development of FDT is the use of superdisintegrants, which provide instantaneous disintegration of tablet after placing on tongue and release the drug in saliva. The fast dissolving tablets are rapidly dissolved or undergoes disintegration by the use of superdisintegrants[5].The faster the drug into solution, quicker the absorption and onset of clinical effect. Some drugs are absorbed from the mouth, as the saliva passes down into the stomach. In such cases, bioavailability of drug is significantly greater than those observed from conventional tablets dosage form. The advantage of mouth dissolving dosage forms are increasingly being recognized in both, industry and academics. The basic approach in development of FDT is the use of superdisintegrant like cross linked carboxymethylcellulose (croscarmellose), sodium starch glycolate (primogel, explotab), polyvinylpyrrolidone (polyplasdone) etc, which provides instantaneous disintegration of tablet after putting on tongue, thereby release the drug in saliva[6].

The bioavailability of some drugs may be increased due to absorption of drug in oral cavity and also due to pregastric absorption of saliva containing dispersed drugs that pass down into the stomach[10]. Moreover, the amount of drug that is subjected to first pass metabolism is

reduced as compared to standard tablet. The technologies used for manufacturing fast dissolving tablets are freeze-drying, spray-drying, tablet molding, sublimation, sugar based excipients, tablet compression, and disintegration addition. As a result of increased life expectancy, the elderly constitute a large portion of the worldwide population today. These people eventually will experience deterioration of their physiological and physical abilities[7]

Requirements of Fast Disintegrating Tablets:

Fast disintegration tablet should have following characteristics:

1. They should not require water or other liquid at the time of administration.

2. They should easily disintegrate and dissolve upon administration in the oral cavity.

3. These tablets mask or overcome unacceptable taste of drug by the addition of sweetening agents.

4. They should have high drug loading capacity.[13]

5. They should exhibit pleasant feel upon the administration in mouth.

6. They should have negligible or no residue in oral cavity after administration.

7. They should have low sensitivity against environmental conditions like moisture and temperature etc.

8. They provide the ease of administration for patients who are mentally ill, disable and uncooperative.

9. These tablets should be portable without fragility concern. [14]

10. They should be manufactured using conventional tablet processing and packing equipment

Advantagses of fast disintegrsting tablets:-

1. Administered without water, anywhere, any time.

2. Suitability for geriatric and pediatric patients, who experience difficulties in swallowing and for the other groups that may experience problems using conventional oral dosage form,

due to being mentally ill, the developmentally disable and the patients who are un-cooperative, or are on reduced liquid intake plans or are nauseated.

3. Beneficial in cases such as motion sickness, suede episodes of allergic attack or coughing, where an ultra rapid on set of action required.

4. An increased bioavailability, particularly in cases of insoluble and hydrophobic drugs, due to rapid disintegration and dissolution of these tablets.

5. Stability for longer duration of time, since the drug remains in solid dosage form till it is consumed. So, it combines advantage of solid dosage form in terms of stability and liquid dosage form in terms of bioavailability.

Disadvantages of fast dissolving tablets:

Fast disintegration tablet have following disadvantages

1. Most fast dissolving tablets lack the mechanical strength compared to traditional tablet. Many products are light in weight and fragile requiring them to be individually packaged. Patients should be advised not to push these tablets through the foil film, but instead, Peel the film back to release the fast dissolving tablet. [8]

2. Due to formation of fast dissolving tablets which are also more susceptible to degradation via temp, and humidity, some of newest fast dissolving tablet formulation is dispensed in a conventional stock bottle. Pharmacists are advised to take care when dispensing such formulation to ensure they are not exposed to high levels of moisture or humidity excess handling of tablet can introduce enough moisture to initiate dissolution of tablet matrix.

Superdisintegrants:

Disintegrating agents are substances routinely included in the tablet formulations to aid in the break-up of the compacted mass into the primary particles to facilitate the dissolution or release of the active ingredients when it is put into a fluid environment.[9] They endorse moisture penetration and dispersion of the tablet matrix. The major function of disintegrant is to oppose the efficiency of the tablet binder and physical forces that act under compression to structure the tablet[12]

Types of Superdisintegrants:

The Superdisintegrants can be classified into two categories on the basis of their availability:

1. Natural Superdisintegrants

2. Synthetic Superdisintegrants

The aim of the present work was to identify the change in disintegration time by using natural and synthetic disintegrant in the formulation of Levofloxacin HCl fast disintegrating tablets. Levofloxacin is a fluoroquinolone antibiotic and is the optical S-(-) isomer of the racemic drug substance ofloxacin. It has a broad spectrum of *in-vitro* activity against Gram-positive and Gram-negative bacteria, as well as certain other pathogens such as Mycoplasma, Chlamydia, Legionella and Mycobacteria spp. Levofloxacin is significantly more active against bacterial pathogens than R-(+)-ofloxacin. The FDT were prepared using Levofloxacin HCl using natural and synthetic disintegrant.The natural superdisintegrant employed in the preparation of FDT was banana powder and the synthetic disintegrant employed in the preparation were mixture cross carmellose sodium, sodium starch glycolate, crospovidone.

MATERIALS AND METHODS

MATERIALS:

Levofloxacin HCl was obtained as a gift sample from Hetero Laboratories Pvt. Ltd, Hyderabad. Sodium starch glycolate, Crospovidone, cross carmellose sodium from Loba Chemie Pvt.Ltd, Mumbai Microcrystalline cellulose from Saimera, Chennai. Banana powder was procured from local market. All other chemicals and reagent were of analytical grade. A UV-Visible spectrophotometer (Systronics, double beam UV-vis spectrophotometer) was used for drug analysis.

METHODS:

Preparation of Banana Powder:

The collected fresh whole bananas were cleaned from the debris and weighed. The skin peeled bananas were dipped in ethanol in 5 minutes. Then banana was weighed and squashed to paste, this paste was added with citric acid (2-3%) to remove the sticky nature. Then water was separated by centrifugation and processing. The pressed mass was subjected to drying in

tray-dryer. The dried substances were milled and screened in sieve (#80) to get fine powder.[16]

Table 1: Formulation Table of Fdt Using Natural Disintegrant

Formulation Code	Drug (mg)	Banana powder (%)	Lactose (mg)	Primojel (%)	Mannitol (mg)	Ethanol (ml)	Magnesium stearate (%)	Talc (%)
FN1	150	8	32	8	148	q.s	2	2
FN2	150	12	24	12	160	q.s	2	2
FN3	150	4	40	4	148	q.s	2	2
FN4	150	12	16	12	156	q.s	2	2
FN5	150	8	32	8	148	q.s	2	2

Table 2: Formulation Table of FDT using Synthetic Disintegrant

Formulations	Drug (mg)	Cross carmellose sodium(%)	Sodium starch glycolate (%)	Cross povidone (%)	Microcrystalline cellulose (mg)	Talc (%)	Magnesium stearate (%)
FS1	150	4	-	2	190	2	2
FS2	150	2	4	-	190	2	2
FS3	150	8	8	4	176	2	2
FS4	150	4	-	8	184	2	2
FS5	150	-	2	2	192	2	2

Formulation of Oral disintegrating tablet using synthetic disintegrant:

Oral disintegrating tablets containing Levofloxacin HCl using synthetic disintegrant were prepared by direct compression technique. Compositions of different formulations are shown in Table 2. All the ingredients except magnesium stearate and talc were mixed uniformly by geometric dilution method, followed by addition of magnesium stearate and talc, and then all

the ingredients were passed through sieve # 60. The prepared powder blend was evaluated for various pre-compression parameters like bulk density, tapped density, Hausner's ratio, Carr's Index and angle of repose. After evaluation of powder blend, the tablets were compressed by using rotary tablet compression machine.[18]

Formulation of oral disintegrating tablets using natural disintegrant:

Oral disintegrating tablets containing Levofloxacin HCl using natural disintegrant were prepared by wet granulation method. All the ingredients except magnesium stearate and talc were weighed and mixed in the mortar and pestle. The granulating mass was prepared by using ethanol. the prepared mass was passed through the #10 to obtain granules. The granules were dried and remaining ingredients were added and the tablets were compressed by using rotary tablet compression machine.

Pre-compression Parameters:

The granules prepared initially were evaluated for flow properties such as bulk density, true density, Car's index, Hausner's ratio, angle of repose.

Bulk density[4, 5]Bulk density is the ratio of the total mass of powder to the bulk volume of powder. It is measured by pouring the weighed powder (passed through a standard sieve # 20) into a measuring cylinder and the initial volume (bulk volume) was noted. From this, the bulk density is calculated. Tapped density is the ratio of the total mass of powder to the tapped volume of powder. It was measured by pouring the weighed powder into a measuring cylinder and then it was subjected to 500 tapings from a height of 2 inches. The volume was measured, tapped density is calculated. Three determinations were done for each formula.

Bulk density = mass/bulk volume

Hausner's Ratio and Compressibility index or Carr's index (%) [11]

Hausner's ratio is the ratio of tapped density to bulk density. It was measured by pouring the weighed powder into a measuring cylinder and the initial volume was noted and then it was subjected to 500 tapings from a height of 2 inches. Hauser's ratio was calculated by noted tapped density and poured density values.

Hausner's ratio= Tapped density/bulk density

Carr's index: Carr's index was calculated as 100 times the ratio of the difference between tapped density and bulk density to the tapped density. It was measured by calculated tapped density and poured density values. Determinations were carried out in triplicate.

Carr's index =[Tapped density-Bulk density]/Tapped density ×100

Angle of repose [12]: It is defined as the maximum angle possible between the surface of a pile of powder and the horizontal plane; it was measured by pouring the weighed powder mixture into the funnel which was fixed to stand at a definite height (h). The drug excipient blend was allowed to flow through the Funnel freely onto the surface and placed on a graph sheet. Then the height and diameter of the heap formed were noted, the angle of repose was calculated. Three determinations were performed.

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

Post compression parameters:

Hardness [20]: Hardness or tablet crushing strength is the force required to break a tablet in a diametric compression. Hardness of the tablet was determined using the Pfizer hardness tester. A tablet was placed between two anvils of the hardness tester, and force was applied to the anvils, and the crushing strength that caused the tablet to break was recorded.The hardness was computed by deducting the initial pressure from the final pressure. Three tablets were randomly picked up from each formulation and the mean and standard deviation values were calculated.

Weight variation: This test was carried out according to Indian Pharmacopoeia. Twenty tablets were selected at the random and average weight was determined. Then individual tablets were weighed and the individual weight was compared with an average weight.[18]

Thickness: Three tablets were selected randomly from each batch and thickness was measured by using Vernier Calipers. The tablet was placed between two arms of Vernier Calipers and thickness was measured.[19]

Friability: The Roche friability test apparatus (Roche Rich Pharma, Mumbai) was used to determine the friability of the tablets. This device chamber revolves at 25 rpm. About 10 tablets were selected randomly, de-dusted and weighed. Then they were placed in a drum and rotated for 100 times over a period of 4 minutes. Then tablets were deducted to remove loose

dust and were reweighed. The percentage loss in weight was calculated and taken as a measure of friability.[15]

$$\textbf{\% Friability=} [W_{initial} - W_{final}]/W_{initial} \times 100$$

Rapidly Disintegrating Property: To evaluate the tablets for their rapid disintegration properties, following tests were carried out.

Wetting time: Five circular tissue papers of 10 cm diameter were placed in a Petri dish with a 10 cm diameter. Ten millimetres of water-containing methylene blue, a water-soluble dye, was added to Petri dish. A tablet was carefully placed on the surface of the tissue paper. The time required for water to reach upper surface of the tablet is noted as a wetting time.[17]

Modified disintegration test: The standard procedure of performing disintegration test for these dosage forms has several limitations and they do not suffice the measurement of very short disintegration times. The disintegration time for ODT needs to be modified as disintegration is required without water, thus the test should mimic disintegration in salivary contents. For this purpose, a Petri dish (10cm diameter) was filled with 10 ml of water. The tablet was carefully put in the centre of Petri dish and the time for the tablet to completely disintegrate into fine particles was noted.

Water absorption Ratio: A piece of tissue paper folded twice was placed in a small Petri dish containing 6 ml of water. A tablet was put on the paper and the time required for complete wetting was measured. The wetted tablet was then weighed. Water absorption ratio, R, was determined using following equation,

$$R=10(Wa/Wb)$$

Where, Wb is weight of tablet before water absorption & Wa is weight of tablet after water absorption.

***In-vitro* dispersion time:** Tablet was added to 10 ml of phosphate buffer solution, pH 6.8 at 37+0.5ºC, Time required for complete dispersion of a tablet was measured.

Wetting time: A small piece of tissue paper was folded twice and placed in a small petri dish (internal diameter 5 cm) containing 6 ml of water. A pre-weighed tablet was put on the paper and the time required for complete wetting was measured, the wetted tablet was then

weighed. The water uptake characteristic allows the evaluation of both the intrinsic swelling and the wettability of the superdisintegrating agents' water uptake were performed at room temperature. Three tablets from each formulation were performed and standard deviation was also determined.

***In-vitro* drug Release studies:**

In-vitro dissolution of melt in mouth tablets of Levofloxacin HCl was studied in USP type-II dissolution apparatus (Lab India) employing a paddle stirrer at 50 rpm. 900 ml of pH1.2 buffer solution was used as dissolution medium. The temperature of dissolution medium was maintained at 37±0.5ºC throughout the experiment. One tablet was used in each test. Samples of dissolution medium (5ml) were withdrawn by means of syringe fitted with pre-filter at known intervals of time and analyzed for drug release by measuring the absorbance at 293nm. The volume withdrawn at each time interval was replaced with the fresh quantity of dissolution medium. The dissolution studies were carried out in triplicate. A cumulative percent drug released was calculated and plotted against time.

Dissolution test parameters for melt in the mouth tablets of Levofloxacin hydrochloride

Medium: 900 ml of 0.1N hydrochloric acid

Rpm: 50

Time: 5, 10,15,20,25 min.

Apparatus: Paddle

λ_{max}: 293nm

Temperature: 37 ˚C ± 0.5˚C

RESULTS AND DISCUSSION

The preformulation studies revealed that the granules of Levofloxacin HCl exhibited good flow properties, and the infrared spectrum of the drug as well as the individual excipinents showed that there was no interaction between the peaks, which indicates that the polymers selected for the preparation of FDT were suitable and stable. As the percentage weight variation was within the pharmacopoeial limits of ±7.5%. It is related to tooling of the

compression machine, head pressure, machine speed and flow properties of the powder. Inconsistent powder or granulate density and particle size distribution are common sources of weight variation during compression. In all the formulations, hardness test indicated good mechanical strength, as the hardness of the FDTs was found in the range of 3.0 to 4.4 kg/cm2.High hardness values increase the disintegration time and reduced dissolution values. By exploiting the correlation between hardness, disintegration, dissolution, friability, percentage defective and weight variation, improves the quality of the tablets.

Friability was observed less than 1%, indicated that FDTs had a good mechanical resistance. It is designed to evaluate the ability of the tablet to withstand abrasion in packaging, handling and shipping. The wetting time was rapid in all the formulations. Wetting is closely related to inner structure of tablets, this may be due to ability of swelling and also capacity of absorption of water. Among all the formulations FN4 showed less wetting time. The capacity of disintegrates to swell in presence of little amount of water were found to be in the range of 42-80 %. The water absorption ratio that is the up taking of water was very fast and the ratio was found higher. This rapid disintegration of the FDTs was due to the penetration of saliva into the pores of the tablet, which leads to the swelling of superdisintegrants to create enough hydrodynamic pressure for quick and complete disintegration of the tablet. Banana Powder when comes in contact with water it quickly wicks water into the tablet through capillary action to create internal pressure that disintegrates tablet. Formulations FN1 containing superdisintegrant Banana powder (8%), and FN2 containing superdisintegrant Banana powder (12%) showed a release of 75.33% and 78.09%, FN3 containing superdisintegrant Banana (4%) while FN4 containing Banana powder (12%) showed a release of78.09 % and95.34%. Formulation FN5 containing superdisintegrant Banana powder (8%) showed a drug release of 92.23%.so formulations FN4, FN5 were regarded as best formulations in case of natural super disintegrant. Among all the formulations prepared using synthetic disintegrant, formulations FS3, FS4 were regarded as best formulations with a % drug release of 88.89 % and 92.34% respectively. Hence it was concluded that use of natural superdisintegrant increased the disintegration time and helped in rapid disintegration of tablet. Hence, exhibited the therapeutic effect.

Table 3: Preformulation Parameters for Granules of Levofloxacin HCl using Synthetic Disintegrants

Formulations	Angle of Repose(θ) (degree)	Bulk Density(gm/cm3)	Tapped density	Hausners ratio	Carrs index
FS1	26.56	0.47	0.56	1.14	16.07
FS2	26.69	0.46	0.55	1.13	16.36
FS3	27.56	0.45	0.54	1.09	16.66
FS4	26.55	0.43	0.60	1.16	20.11
FS5	29.01	0.48	0.59	1.15	27.11

Table 4: Preformulation Parameters for Granules of Levofloxacin HCl using Natural Super Disintegrant.(Banana Powder)

Formulation	Angle of Repose (θ) (degree)	Bulk Density(gm/cm3)	Tapped density	Hausner's ratio	Carr's index
FN1	26.56	0.51	0.56	1.14	8.92
FN2	26.69	0.51	0.55	1.13	7.27
FN3	27.56	0.56	0.54	1.09	370
FN4	26.55	0.57	0.59	1.15	3.52
FN5	29.01	0.48	0.60	1.16	12.5

Table 5: Physicochemical Parameters of Levofloxacin FDT using Natural Super Disintegrant (Banana Powder)

Formulation	Hardness($Kg/cm^{2)}$	Friability (%)	Disintegration time (sec)	Wetting time (sec)	Weight variation	Water absorption ratio
FN1	3.8	0.76	34	15	293	62.35
FN2	3.6	.081	29	18	329	67.87
FN3	3.5	0.75	22	27	323	75.45
FN4	4.0	0.90	12	36	345.25	79.67
FN5	3.8	0.96	10	35	349.57	80.34

Table 6: Physicochemical Parameters of Levofloxacin FDT using Synthetic Super Disintegrants

Formulation	Hardness (Kg/cm^2)	Friability (%)	Disintegration time (sec)	Wetting time (sec)	Weight variation	Water absorption ratio
FS1	3.0	0.76	34	15	203	42.35
FS2	3.9	.061	39	8	309	57.87
FS3	4.4	0.95	22	27	350.49	75.05
FS4	4.0	0.90	12	36	345.25	79.67
FS5	3.6	0.86	40	15	329.57	60.34

Table 7: Dissolution Data of Levofloxacin FDT using Synthetic Super Disintegrants

Time (min)	FS1	FS2	FS3	FS4	FS5
0	0	0	0	0	0
5	34.45	23.34	39.45	44.97	23.34
10	45.67	32.56	48.95	51.29	39.94
20	52.34	39.23	57.67	69.21	43.56
30	67.89	45.21	69.54	75.24	54.34
45	69.28	55.76	75.34	85.29	64.34
60	75.23	65.34	88.89	92.34	71.23

Table 8: Dissolution Data of Levofloxacin FDT using Natural Super Disintegrant (Banana Powder)

Time (min)	FN1	FN2	FN3	FN4	FN5
0	0	0	0	0	0
5	24.53	28.34	29.75	44.37	43.54
10	35.72	30.56	38.05	51.79	59.34
20	42.42	35.83	47.37	69.31	63.16
30	57.91	42.21	59.94	75.44	74.04
45	69.82	57.68	65.74	85.98	84.49
60	75.33	65.49	78.09	92.34	95.23

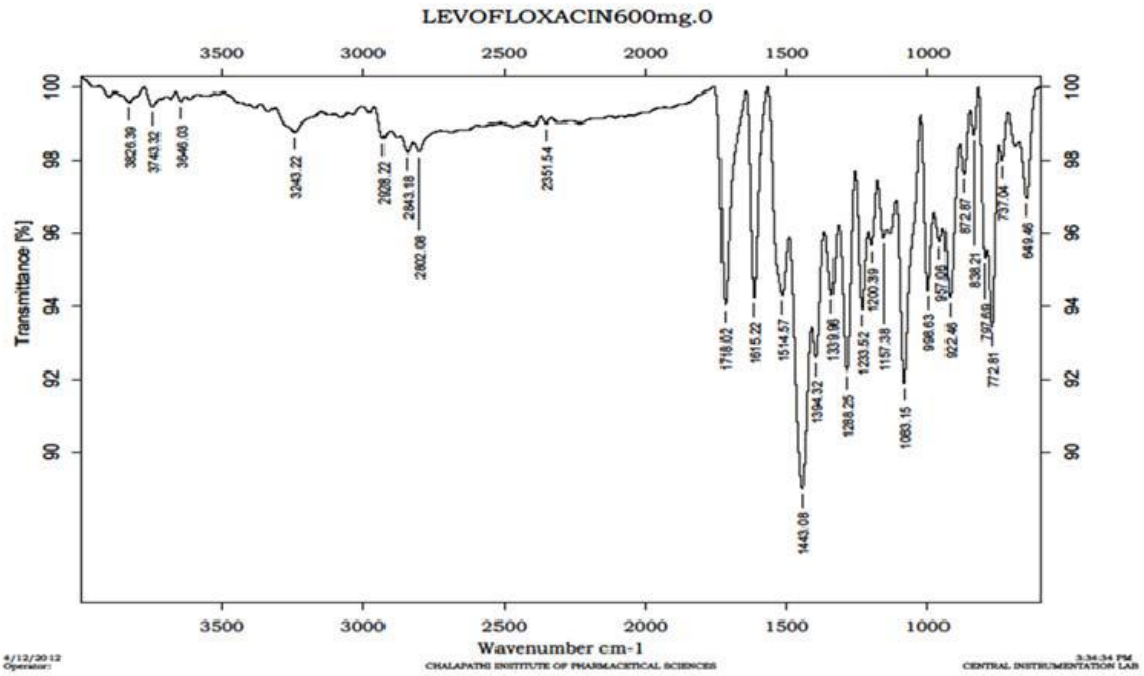

Figure 1: Infrared Spectrum of Levofloxacin HCl

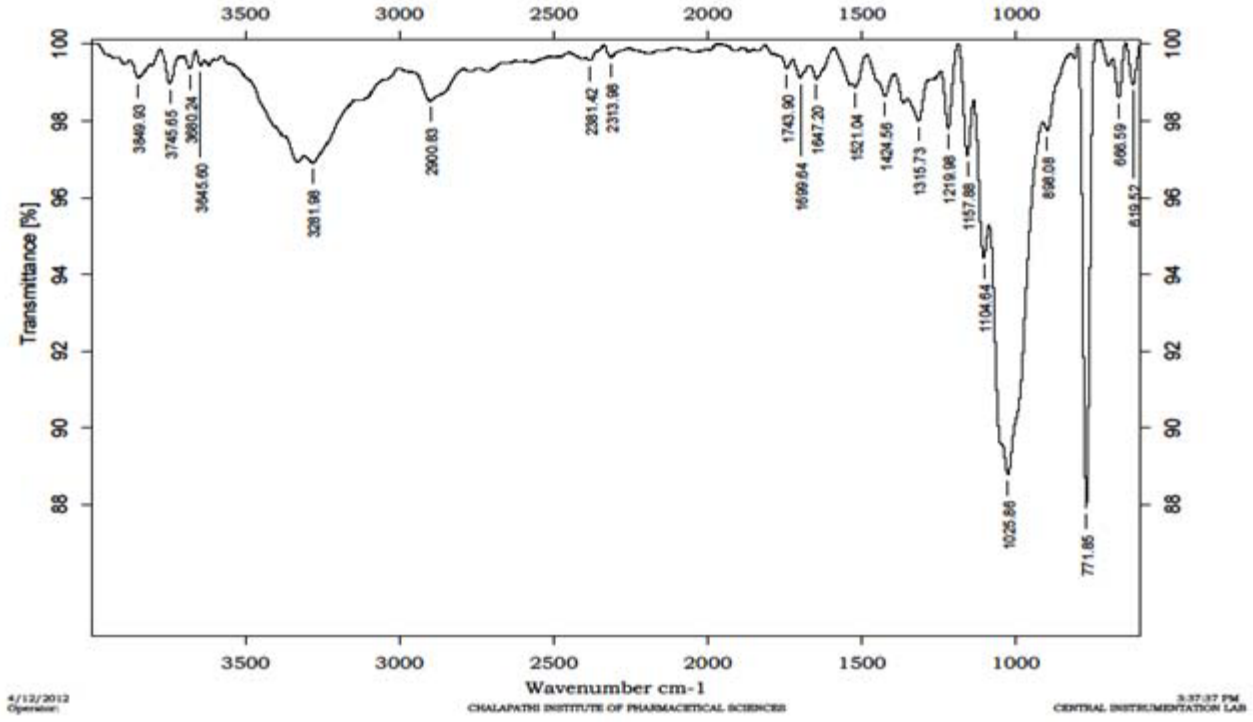

Figure 2: IR Combination Spectrum of Drug and All Super Disintegrants

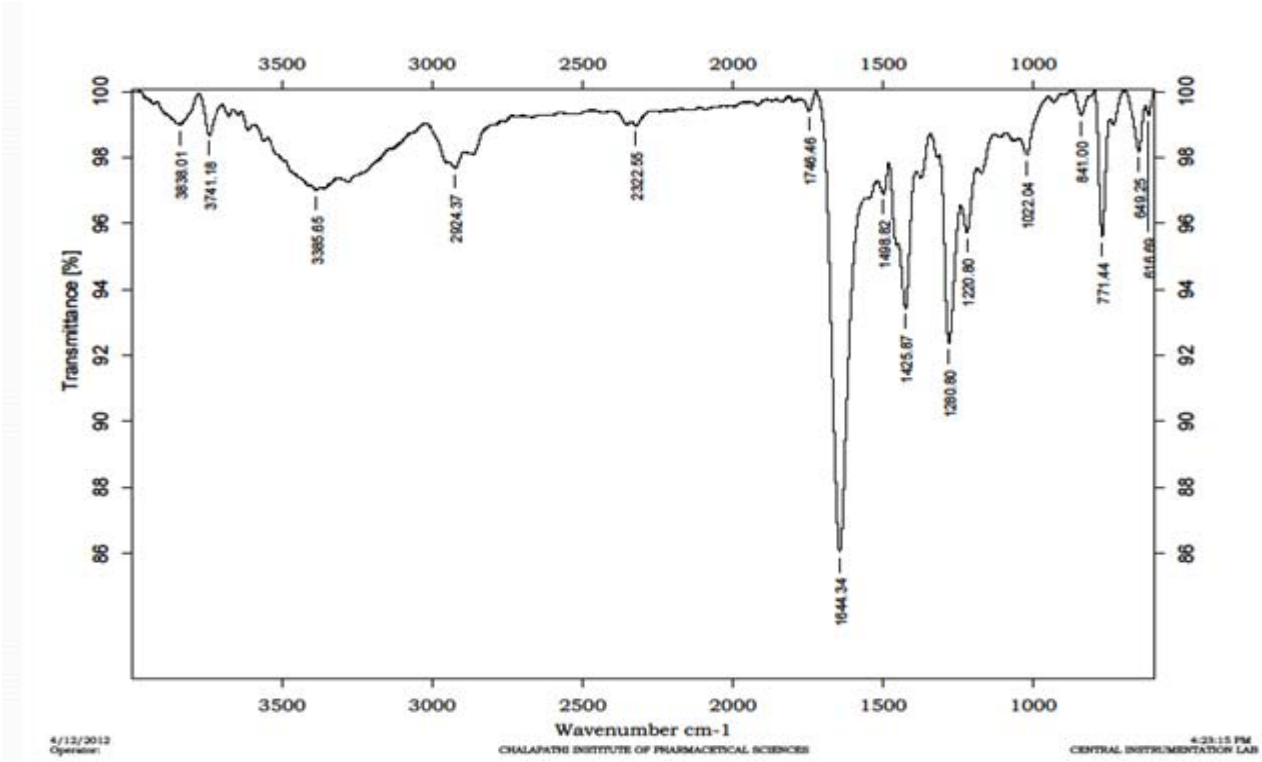

Figure 3: Combination Spectrum of Drug and Natural Superdisintegrant

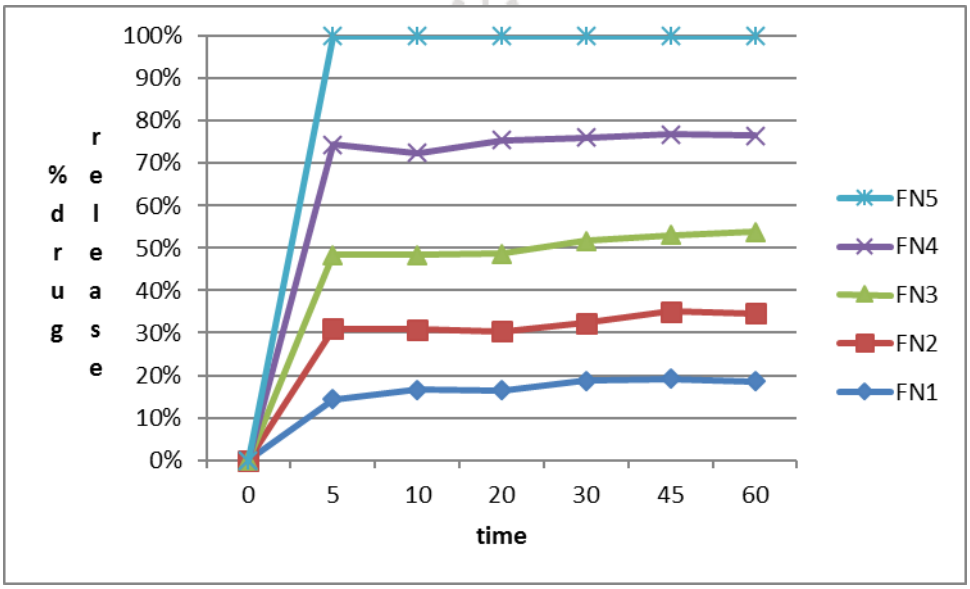

Figure 4: Dissolution Profile of Levofloxacin FDT using Natural Superdisintegant

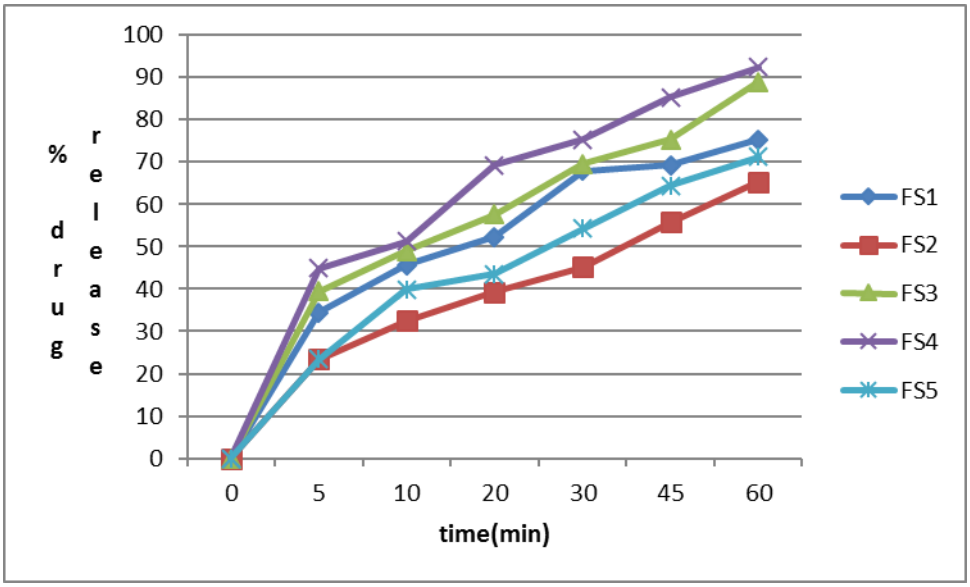

Figure 5: Dissolution Profile of Levofloxacin FDT using Synthetic Superdisintegrant

Figure 6: Disintegration of Levofloxacin FDT Using Natural Superdisintegrant

Figure 7: Disintegration Of Levofloxacin FDT using Synthetic Superdisintegrant

CONCLUSION

The fast dissolving tablets of Levofloxacin HCl were prepared using natural and synthetic superdisintegrants and the change in the disintegration time, dissolution time between the natural and synthetic disintegrants was evaluated using banana powder as natural superdisintegrant and mixture of croscarmellose sodium, crospovidone, sodium starch glycolate as synthetic superdisintegrants respectively. The use of natural disintegrant increased the disintegration time as well as dissolution time and hence improved the bioavailability and aqueous solubility of the drug. Hence, it was concluded that natural superdisintegrants were superior over synthetic disintegrant, among all the prepared formulations formulation FN4, FN5 were found to be best in case of tablets prepared using natural disintegrant, where formulations FS3, FS4 were considered as best formulations in case of tablets prepared using synthetic disintegrant.

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