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## Development and Evaluation of Oral Fast Disintegrating Tablet Containing Levofloxacin Using Natural Super Disintegrant



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### ABSTRACT

The present work is to develop and evaluate the oral fast disintegrating tablet containing Levofloxacin that was prepared using natural disintegrant by direct compression method. Fast dissolving tablets were evaluated for physicochemical properties and *in-vitro* dissolution. The formulation containing Levofloxacin had the shortest wetting time and the pills disintegrated the fastest. The rate of drug release from fast dissolving tablets increases as the concentration of natural superdisintegrants rises, with a formulation including Levofloxacin achieving the highest levels.



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## INTRODUCTION

Fast dissolving tablets were solid single-dose forms that are placed in buccal and allowed to dissolve in the saliva without the usage of water, resulting in a rapid commencement of action<sup>1</sup>. As saliva travels down into the stomach, some medications are absorbed from the mouth, throat, and oesophagus<sup>2</sup>. In such instances, drug bioavailability is much higher than that reported with FDTs, which are preferred by a large segment of the population, notably youngsters and the elderly, who have trouble swallowing conventional tablets or capsules<sup>3</sup>. FDTs are made using a variety of methods, including direct compression, lyophilization, and moulding<sup>4</sup>.

Superdisintegrants are typically added to a medicine formulation to aid in the breakup or disintegration of tablets into tiny particles that dissolve more quickly than if they were not there<sup>5</sup>.

The orange book is classified as an FDTs by the US Food and Drug Administration's CDER, which interprets it as "a solid-dose form accommodate therapeutic synthetic that disintegrates rapidly, usually within seconds, when put on the tongue"<sup>6</sup>.

## MATERIALS AND METHODS

### Materials

The materials such as Levofloxacin, Guar gum, Mannitol, Starch, Magnesium stearate, Magnesium state, Talc of pharma grade, or the best possible Laboratory was used as supplied by the manufacturers. All materials (AR Grade) and instruments utilized in the work were sourced from various sources.

### Method

#### Preparation of Levofloxacin fast-dissolving tablets

The choice of superdisintegrant concentration and optimization of superdisintegrant concentration are essential parameters in the formulation of fast dissolving tablets. Fast dissolving tablets must break down or dissolve swiftly in the oral cavity in 15 - 60 seconds without the use of water and have a pleasant tongue feel. The super disintegrant (Guar gum) was used to formulate the tablets. All the ingredients as shown in Table No. 1 were co-ground in a pestle and motor and then talc and magnesium stearate was added and mixed for 10

minutes. The mixed blend of 1 drug-excipient was compressed by using a single punch tablet machine.

**Table No. 1: Formulation of the Levofloxacin.**

<b>Ingredients (mg/tablet)</b>	<b>F1</b>	<b>F2</b>	<b>F3</b>	<b>F4</b>
Levofloxacin	150	150	150	150
Guar gum	10	20	30	40
Mannitol	74	64	54	44
Starch	10	10	10	10
Talc	4	4	4	4
Magnesium stearate	2	2	2	2

### **EVALUATION PARAMETER**

- **Angle of repose**

It is used to assess the flow properties of powders, pellets, and granules. The angle of repose is determined by pouring the powder into a conical heap on a level, flat surface and measuring the inclined angle with the horizontal<sup>7</sup>.

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

Where h = height of a heap,

r = radius of a heap

- **Apparent density**

Weighed quantity of powder blend was taken in a graduated cylinder and bulk volume was measured and weight of blend was determined by

$$Dd = M/Vb$$

Where M is a mass of powder.

Vb is the tapped volume of the powder.

- **Tapped density**

Weighed the 10 gm of powder sample and transferred into a graduated cylinder containing a known mass of the sample and was tapped for 100 times using mechanical tapped density taster<sup>8</sup>.

$$Dt = M/Vt$$

Where M is a mass of powder.

Vt is a tapped volume of the powder.

- **Carr's index**

The compressibility index of the powder blend was determined by Carr's index simplest test to evaluate the bulk density and tapped density of the powder. The formula for Carr's index is given below:

$$\text{Carr's index} = \frac{\text{TD}-\text{BD}}{\text{BD}} \times 100$$

- **Hausner's Ratio**

A hausner ratio is a number that is corrected to the flowability of a powder or granular material.

$$\text{Hausner Ratio} = \text{TD}/\text{BD}$$

- **Tablet hardness and thickness**

It is usually expressed in Kg/cm<sup>3</sup>. The thickness of the tablet was calculated by using a screw gauge which indicates the strength of the tablet that withstands compression force applied<sup>9</sup>.

- **Tablet friability**

Friability is used to determine the friability test on OFDTs. Twenty tablets were picked from each formulation. The tablets were initially weighed and transferred into a friabilator. For 4 minutes, the drum was turned at 25 rpm. After the rotation, the tablets were removed. If any loose dust was removed from the tablets as before and the tablets weighed again then the percentage friability was calculated by<sup>10</sup>.

$$\frac{W_{\text{initial}} - W_{\text{final}}}{W_{\text{initial}}} \times 100$$

$$W_{\text{initial}}$$

Where,

F = % friability of tablets less than 1% are regarded as acceptable.

- **Weight Variation**

The weight variation test of tablets was conducted by weighing 10 tablets randomly. Calculate the average weight and individual weight by comparing the individual tablet to an average tablet<sup>11</sup>.

- **Wetting time test**

The tablet is placed near the center of the Petri dish on tissue paper, and the tablets begin to absorb water. The soaking time is defined as the time when the tablets are completely soaked<sup>12</sup>.

- ***In-vitro* Dissolution studies**

For this reason, the USP 2 paddle apparatus is utilized, which is the most ideal and common choice for OBTs, with a paddle speed of 100 rpm and a medium–water temperature of 37 + 0.5°C<sup>13</sup>.

## **RESULT AND DISCUSSION**

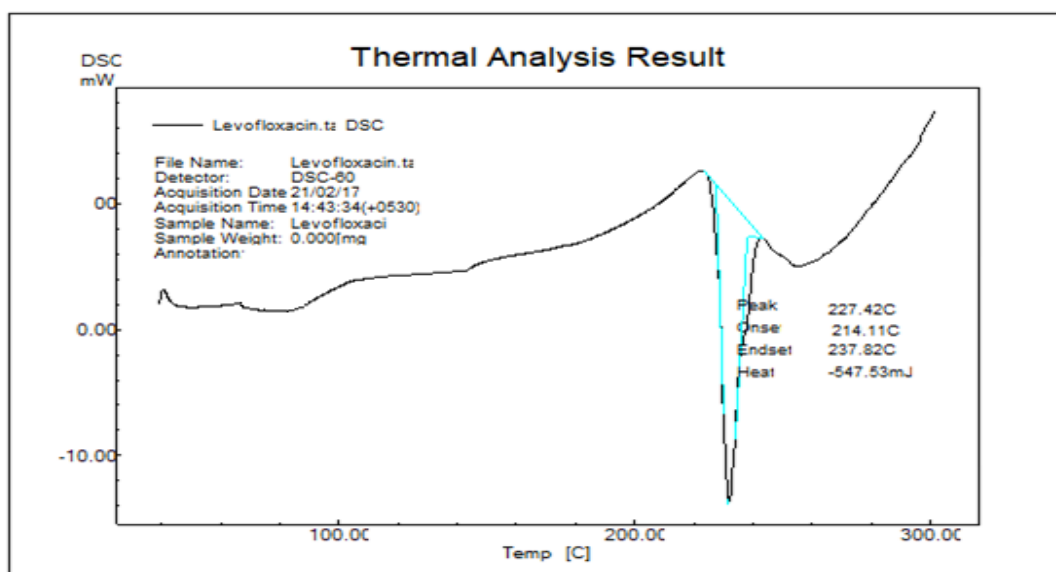
The specific objective of this study is to develop an oral fast disintegrating tablet of Levofloxacin by using natural super disintegrants like guar gum and to study antibacterial effects and urinary tract infection. In this regard formulation studies were carried out and the results for the experiment conducted are as follows.

**Preformulation studies**

**a. Melting point determination**

**Table No. 2: Melting point of Levofloxacin**

Reported	Method	Observed
224 - 227 <sup>0</sup> C	Thiel's tube	224 <sup>0</sup> C
	DSC	227 <sup>0</sup> C

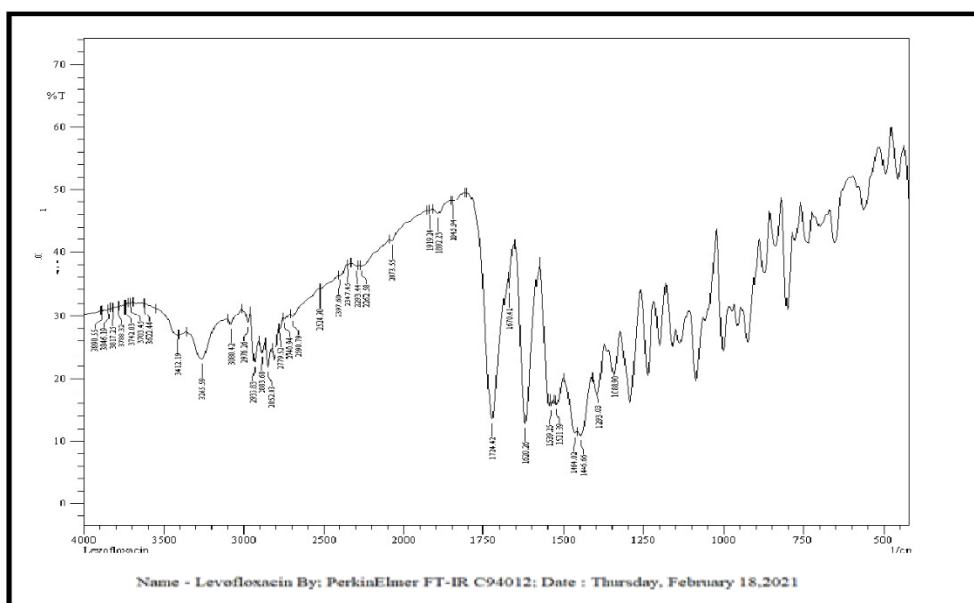


**Figure No. 1: DSC Thermograph of Levofloxacin**

**b. Solubility analysis**

Levofloxacin was found to be slightly soluble in water, sparingly soluble in methanol, practically soluble in phosphate buffer pH 7.4. The obtained results are in agreement with other researchers i.e., Levofloxacin is slightly soluble in water highly soluble in phosphate buffer pH 7.4.

**c. Compatibility studies by FTIR**



**Figure No. 2: FTIR spectra of Levofloxacin**

**Preformulation parameters**

**Micromeritic characters of oral fast disintegrating tablets of Levofloxacin:**

**Table No. 3: Micromeritic characters of oral fast disintegrating tablets**

Code	Bulk density (g/cm <sup>3</sup> )	Tapped density (g/cm <sup>3</sup> )	Hauser's ratio	Carr's index (%)	Angle of repose (°)
F1	0.347	0.353	1.08	6.30	31.38
F2	0.346	0.375	1.122	8.33	32.26
F3	0.348	0.362	1.081	6.098	34.15
F4	0.350	0.389	1.098	10.93	35.07

Post compression parameter of fast disintegrating tablets:

Table No. 4: Results of hardness, thickness, friability, and weight variation formulations F1 - F4

Formulation batches	Thickness (mm)	Hardness (kg/cm <sup>2</sup> )	Friability (%)	Weight variation
F1	0.37	2.92	0.240	99.5
F2	0.37	2.45	0.264	99.7
F3	0.37	2.32	0.228	99.2
F4	0.37	3.23	0.267	99.8

Table No. 5: results of wetting time and disintegration time of F1 - F4

Formulations	Disintegration time (sec)	Wetting Time (sec)
F1	22	15
F2	25	17
F3	23	16
F4	23	16

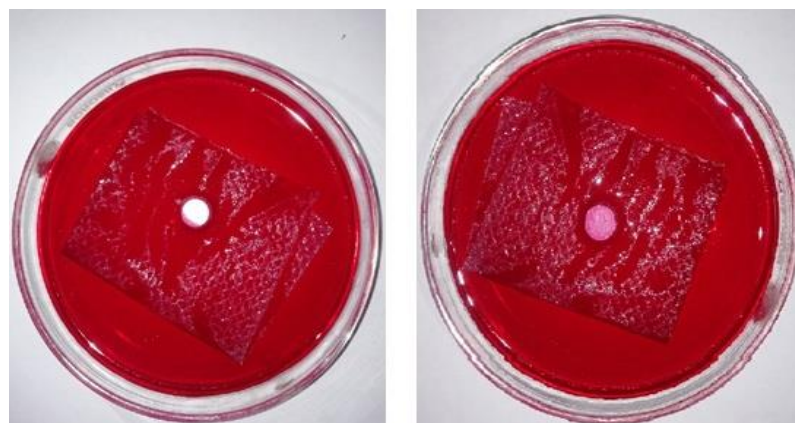


Figure No. 3: Wetting time for optimized formulation F4



**Table No. 6: *In-vitro* drug release study of formulations F1 - F4 in phosphate buffer pH 6.8**

Percentage drug release				
Time (min)	F1	F2	F3	F4
0	0	0	0	0
1	5.05	6.47	6.736	7.47
3	20.63	26.61	28.05	30.42
6	31.15	36	39.47	42.52
9	46.26	48.57	51.73	53.57
12	60.63	65.73	65.8	69.1
15	88.1	90.68	92.84	94.78

## CONCLUSION

- Levofloxacin of oral fast disintegrating tablets was successfully formulated.
- When the prepared FDTs were evaluated for Micromeritic characters it confirmed that powder blends have good flow properties.
- The prepared FDTs were evaluated for post formulation parameters indicating that all the formulations were found within the specified limits.
- The *in-vitro* release of Levofloxacin fast disintegrating tablets was done.
- Among the four formulations, F4 showed the faster drug release. Hence, the F4 formulation is considered an optimized formulation.

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