

## Formulation and Evaluation of Dispersible Tablets of Lomefloxacin HCl

Veerendra K. Nanjwade\*<sup>1</sup>, F. V. Manvi<sup>1</sup>, Basavaraj K. Nanjwade<sup>1</sup>

<sup>1</sup>Department of Pharmaceutics, KLE University College of Pharmacy, JN Medical College Campus, Belgaum – 590010, Karnataka, India.

### Abstract

In the present work an attempt has been made to prepare FDT of Lomefloxacin HCl with an view to enhance the patient compliance, and provide a quick onset of action, increasing the solubility and masking its bitter taste. Taste masking and solubility was enhanced by complexing Lomefloxacin HCl with hydroxyl propyl  $\beta$  cyclodextrin (HP- $\beta$ CD) by solvent evaporation method. Prepared complex was further compressed into tablets by direct compression using different superdisintegrant like Sodium starch glycolate, Croscarmellose sodium, Polyplasdone XL-10 in different concentration such as 1%, 1.5%, 2 % using aspartame as a sweetener and aerosil as lubricant. The drug release from FDT increase with increasing the concentration of superdisintegrants and was found to be highest with formulation F6 containing 1.5 % Croscarmellose Sodium and was consider to be the best formulation which release upto 100.68 % in 45 min. *In vivo* studies revealed that FDT of formulation (F 6) showed good bioavailability compared to conventional tablet. The fast dissolving tablet with HP- $\beta$ CD complex can be formulated using different superdisintegrants by Direct Compression technique and was found to be disintegrate less than 2 minute, which provide faster effect and better patient compliance.

\*Corresponding author, Mailing address:

**Mr. Veerendra K. Nanjwade** M. Pharm.  
Department of Pharmaceutics  
KLE University College of Pharmacy  
BELGAUM – 590010, INDIA  
E-mail: [vknanjwade@gmail.com](mailto:vknanjwade@gmail.com)

### Key words:

Lomefloxacin HCl, Superdisintegrants, Sodium starch glycolate, Croscarmellose sodium, Polyplasdone XL-10, Bioavailability studies.

### How to Cite this Paper:

**Veerendra K. Nanjwade\***, **F. V. Manvi**, **Basavaraj K. Nanjwade** “Formulation and Evaluation of Dispersible Tablets of Lomefloxacin HCl” *Int. J. Drug Dev. & Res.*, January-March 2013, 5(1): 103-113.

### Copyright © 2013 IJDDR, Veerendra K.

**Nanjwade et al.** This is an open access paper distributed under the copyright agreement with Serials Publication, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

### Article History:-----

**Date of Submission: 26-11-2012**

**Date of Acceptance: 08-01-2013**

**Conflict of Interest: NIL**

**Source of Support: NONE**

### INTRODUCTION

Improvement of API physicochemical and biopharmaceutical properties as well as in vivo performance and, hence, are a potential new alternative in the selection of optimal solid forms in drug product development.<sup>[1,2]</sup> Since the development

cost of a new drug molecule is very high, efforts are now being made by pharmaceutical companies to focus on the development of new drug dosage forms for existing drugs with improved safety and efficacy together with reduced dosing frequency, and the production of more cost effective dosage form.

For most therapeutic agents used to produce systemic effects, the oral routes still represents the preferred way of administration, owing to its several advantages and high patient compliance compared to many other routes. Tablets and hard gelatin capsules constitute a major portion of drug delivery systems that are currently available. However, many patients groups such as the elderly, children and patient who are mentally retarded, uncooperative, nauseated, or on reduce liquid-intake/diets have difficulties swallowing these dosage forms. And those who are travelling or have little access to water are similarly affected.

To fulfill these medical needs, pharmaceutical technologists have developed a novel oral dosage form known as Fast Dissolving Tablets (FDTs) which disintegrate rapidly in saliva, usually in a matter of seconds, without the need to it with water. Drug dissolution and absorption as well as onset of clinical effect and drug bioavailability may be significantly greater than those observed from the conventional dosage forms.<sup>[3]</sup>

The bitter taste of the drugs which are orally administered often contributes to patient non-compliance in taking medicines, especially for children and elderly. Unfortunately, majority of the drugs have a natural bitter taste that can create a burning feeling in the throat or in the mouth. In particular, a bitter taste can decrease the patient compliance and thus reducing an effective pharmacotherapy. In order to achieve an acceptable palatability, the addition of flavors or sweeteners is limited and may not be efficient enough to mask the taste buds of drugs and requires the use of technological processes. A number of taste masking approaches like the use of ion exchange resins, the

use of inclusion complexes with cyclodextrins, viscosity modifications and melt granulation.

Lomefloxacin HCl is a bactericidal fluoroquinolone agent with activity against a wide range of gram-negative and gram-positive organisms. The bactericidal action of lomefloxacin results from interference with the activity of the bacterial enzymes DNA gyrase and Topoisomerase IV, which are needed for the transcription and replication of bacterial DNA. In the present work an attempt has been made to prepare fast dissolving tablet of Lomefloxacin HCl with an view to enhance the patient compliance, and provide a quick onset of action, increasing the solubility and masking its bitter taste. Taste masking and solubility was enhanced by complexing Lomefloxacin HCl with hydroxyl propyl  $\beta$  cyclodextrin (HP- $\beta$ CD) in 1:1 molar ratio by solvent evaporation method. These complex were compressed into tablets by direct compression using different superdisintegrants.

## MATERIALS AND METHODS

### Materials

Lomefloxacin HCl was obtained as a gift sample from Simpex Pharma Pvt. Ltd. Kotdwara, India. Hydroxy Propyl- $\beta$ -Cyclodextrin (HP- $\beta$ CD) was obtained as a gift sample from Gangwal Chemicals Pvt. Ltd. Mumbai (India). Microcrystalline cellulose (Avicel), Crospovidone (Polyplasdone XL-10), Croscarmellose sodium (Ac-di-sol), Sodium starch glycolate, were obtained as gift sample from Sanofi- Aventis Pvt. Ltd Goa (India). Aspartame were obtained as gift sample from Dr. Reddy Pvt. Ltd., Hyderabad (India). All other excipients used were of analytical grade.

### Methods

#### Preparation of inclusion complexes

Inclusion complex of Lomefloxacin HCl and Hydroxy propyl  $\beta$ - cyclodextrin in 1:1 molar ratio was prepared by dissolving the drug and Hydroxy propyl  $\beta$  - cyclodextrin (HPBCD) in methanol with continuous stirring. The resulting solvent was then

completely evaporated at 40-45°C with continuous stirring to obtain dry granules. [4]

#### **Formulation of fast dissolving tablet containing a complex of Lomefloxacin HCl with HP-β-cyclodextrin**

Fast dissolving tablets were prepared by direct compression using Lomefloxacin HCl, HP-βCD inclusion complex prepared by Solid dispersion/co-evaporated dispersion method. As general identification and micromeritic study of drug are shown in the Table 1. The formula included variable amounts of superdisintegrants and other excipients are shown in Table 2. The equal amount of drug- HP-βCD were taken and then mixed with directly compressible diluents and superdisintegrant in a mortar with the help of pestle, then finally Aspartame as sweeter and Aerosil as lubricant was added. The blend was then compressed using a Rimek tablet press machine. The total weight of the tablet was maintained 1000 mg.

#### **Identification of pure drug**

Identification of Lomefloxacin HCl was carried out by Infrared Absorption Spectroscopy.

#### **Melting point determination**

Melting point of Lomefloxacin HCl was determined by open capillary Method

#### **Drug - Excipient Compatibility Studies**

#### **Fourier-Transform Infrared Spectrophotometry**

Infrared spectra of Lomefloxacin HCl, HP-βCD and its complexes were recorded by KBr method using Fourier Transform Infrared Spectrophotometer.

Method: In the present study, the potassium bromide disc method was employed. The powdered sample was intimately mixed with dry powdered potassium bromide. This mixture was then compressed into transparent disc under high pressure using special dies. This disc was placed in IR spectrometer and spectrums were recorded. The scanning range was 450-4000 cm<sup>-1</sup> and the resolution was 1 cm<sup>-1</sup>.

#### **X-ray diffraction (XRD) study**

The XRD patterns of pure drug, HPβCD and its inclusion complexes were reported on an X-ray diffractometer (PW 1729, Philips, The Netherlands). Method: The sample were irradiated with monochromatized CuKα radiation (1.542 Å) and analyzed between 2-40° 2θ. The voltage and current used were 30 kV and 30 mA, respectively. The range and the chart speed were 5 X 10<sup>3</sup> CPS and 10min/°2θ, respectively.

#### **Pre compression parameters [5]**

##### **Angle of repose**

Angle of repose was determined using fixed funnel method. The blend was poured through a funnel that can be raised vertically until a maximum cone height (h) was obtained. Radius of the heap (r) was measured and angle of repose was calculated using formula.

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

Where, θ is angle of repose, h is height of pile and r is the radius of the base pile.

##### **Bulk Density**

Apparent bulk density (δb) was determined by pouring blend into a graduated cylinder and measuring bulk volume (Vb). And weight (M) as it is  $\delta b = M/Vb$ .

##### **Tapped density**

The measuring cylinder containing known mass of blend was tapped for a fixed time. The minimum volume (Vt) occupied in the cylinder and weight (M) of the blend as measured. The tapped density (ρt) was calculated using the formula.

$$\delta t = M/Vt$$

##### **Carr's compressibility index**

The simplest way of measurement of free flow property of powder is compressibility, an indication of the ease with which a material can be induced to flow is given by % compressibility which is calculated as follows:

$$C = (\delta t - \delta b) / \delta t \times 100.$$

### Hausner's ratio

Hausner's ratio is an index of ease of powder flow, it is calculated by following formula. Hausner's ratio =  $\delta t / \delta b$

Where,  $\delta t$  is tapped density and  $\delta b$  is bulk density.

### Post compression parameters

#### Weight variation test<sup>[6]</sup>

Twenty tablets were taken and their weight was determined individually and collectively on a digital weighing balance. The average weight of one tablet was determined from the collective weight.

#### Hardness test<sup>[6]</sup>

Six tablets were randomly picked and analyzed for hardness. The hardness of the tablets was determined using Monsanto hardness tester. The mean and standard deviation values was calculated and expressed in kg/cm<sup>2</sup>.

#### Friability<sup>[6]</sup>

Six tablets from each batch were examined for friability using Roche Friabilator and the equipment was run for 4 min at 25 revolutions per minute. The tablets were taken out, de-dusted and reweighed and % friability was calculated

$$\% \text{Friability} = (\text{Loss in weight} / \text{Initial weight}) \times 100$$

#### *In vitro* dissolution studies

*In vitro* release studies were carried out using tablet dissolution test apparatus USP XXIII at 75 rpm, using Phosphate buffer pH 6.4 as a dissolution medium maintained at  $37 \text{ }^{\circ}\text{C} \pm 1 \text{ }^{\circ}\text{C}$ . Samples were withdrawn at various time intervals, diluted and assayed at 281 nm, using UV spectrophotometer. Two objectives in the development of *in vitro* dissolution tests are to show (1) that the release of the drug from the tablet is as close as possible to 100% and (2) that the rate of drug release is uniform batch to batch and is the same as the release rate from those batches proven to be bioavailable and clinically effective. The following procedure was employed throughout the study to determine the *in vitro* dissolution rate for all the formulations.

The various parameters related to dissolution which are evaluated in the present work are as follows:

1. Drug release
2. Cumulative percentage drug release
3. Cumulative percentage drug retained.

#### *In Vivo* Absorption Studies<sup>[7, 8, 9]</sup>

The protocol according to form B was approved by Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) and Institutional Animal Ethics Committee (IAEC). The central animal facility of the institute provided male albino rabbits with mean weight of 2.5 to 3 kg. In the present study, 6 healthy male albino rabbits weighing (2.5 to 3 kg) were used. Optimized formulation F6 and conventional marketed tablet were gently broken into small pieces, which would be suitable for oral administration followed by 5ml tap water. Oral delivery was performed using flexible plastic tube attached to stainless steel gavage. Animals were housed individually under standard conditions and were fasted overnight and allowed to free access of water. Six rabbits were divided into two groups each. Formulations were administered to rabbits by gastric intubation method and 2 ml of blood samples were withdrawn from marginal ear vein of rabbits at 0.25, 0.5, 1, 2, 3, 4, 5, 6, 7 and 8 hours. Frozen serum sample were thawed at a ambient temp  $25 \pm 1^{\circ}\text{C}$  for 60 min. Plasma (ml) was placed in glass tube. And concentration of 2  $\mu\text{g}/\text{ml}$  was added to 15 ml conical centrifuge tube. Borate buffer (1 M, pH 9.0, 100 $\mu\text{g}/\text{ml}$ ) was added and the solution was mixed well. One ml of chloroform was added, and sample mixture was vortex- mixed for 1 min and centrifuged for 5 min at 1100 rpm. The organic layer was carefully transferred to 5ml conical centrifuge tube and evaporated to dryness in an evaporator. The mobile phase and 20 $\mu\text{l}$  was injected onto the column.

#### Comparison with conventional marketed product

The promising formulation was compared with marketed product (Maxaquin 400 mg Tab Pfizer

India Ltd) formulation by checking various physicochemical parameters.

#### Stability studies

In the present study, stability studies were carried out at 40°C /75% RH for a specific time period up to 3 months for selected formulation. Reproduced large scale batch F6 was placed for stability study at 40 °C/75 % RH for 3 month. Sample was collected at every 1 month interval and evaluated for Drug content.

### RESULTS AND DISCUSSION

#### Compatibility studies Fourier-Transform Infrared Spectrophotometry studies

Infrared studies reveal that both characteristic bands were present in all spectra. While no new bands or shift in characteristic peaks appeared. IR spectra are shown in Figure 1, 2 and 3.

#### X-ray diffraction study

Lomefloxacin HCl, HP-βCD and inclusion complex of drug with HP-βCD prepared by solid dispersion / co-evaporated dispersion method were subjected to XRD analysis and shown in Figure 4 and 5. From the figure, it was evident that pure drug existed as microcrystalline particles, as many broad peaks of very low intensity were observed. However no sharp peaks were detected. The X-ray diffraction pattern for inclusion complexes was characterized by complete absence of any diffraction peak for the drug, suggesting probable transformation of microcrystalline from into an amorphous state.

#### Pre-compression parameters

Granules ready for compression containing drug and various excipients was subjected for pre-compression parameters (Micromeritic properties) to study the flow properties of granules, to achieve uniformity of tablet weight. The data obtained for angle of repose for all the formulations were tabulated in Table 3 and the values were found to be in the range of 24°.51' to 29°.65'. The formulations of direct compression revealed poor flow property and formulations of wet granulation had good flow

property. Loose bulk density (LBD) and tapped bulk density (TBD) for the blend is shown in Table 3. The loose bulk density and tapped bulk density for all the formulations blend varied from 0.56 gm/cm<sup>3</sup> to 0.62gm/cm<sup>3</sup> and 0.63 gm/cm<sup>3</sup> to 0.69 gm/cm<sup>3</sup> respectively. The result obtained for hausners ratio of all formulations were found to be in the range of 1.098 - 1.182. All formulations showed the hausners ratio within the range as shown in table 3, which indicates a good flow property of the granules.

The results of Carr's consolidation index or compressibility index (%) for all the formulations blend ranged from 8.99 to 15.44. The results for all the formulations were recorded in Table 3.

#### Post-compression Parameters

The tablets prepared were subjected for evaluation according to various official specifications and other parameters. Hardness, friability, weight variation, disintegration time, *in vivo* taste, and disintegration were performed. The hardness of the tablets was found in the range of 4.70 kg/cm<sup>2</sup> to 6.87 kg/cm<sup>2</sup>, respectively. The mean hardness test results are tabulated in Table 4. Friability of the all the formulation was in the range of 0.18 to 0.26. The obtained results were found to be well within the approved range (<1%) in all designed formulations. The results are shown in Table 4. The content uniformity was performed for all the formulations and results are tabulated in Table 4. The weight variation for all the formulations is shown in Table 4. All the tablets passed the weight variation test; average percentage weight variation was found within the pharmacopoeial limits of ± 10 %. The obtained results were found to be 998.9 mg to 1001.0 mg.

#### In vitro dissolution studies

All the nine formulations were subjected for the *in vitro* dissolution studies using tablet dissolution tester USP XXIII. The samples were withdrawn at different time intervals and analyzed at 281 nm. Cumulative drug release was calculated on the basis of mean amount of Lomefloxacin HCl present in the



respective tablet. The plots of cumulative % drug release V/s. time and the results obtained in the *in vitro* drug release for the formulations F1 to F3, F4 to F6 and F7 to F9 are shown in Figure 6.

The dissolution rate was found to increase linearly with increasing concentration of superdisintegrant. Formulations F1, F2 and F3 which contained increasing concentrations of Sodium starch glycolate from 1 % w/w to 2 % w/w, have recorded drug release 95.60%, 96.89% and 97.99% respectively, at the end of 45 minutes. Formulations F4, F5 and F6 which contained increasing concentrations of Croscarmellose sodium from 1 % w/w to 2 % w/w, have recorded drug release 96.28 %, 98.89% and 100.68% respectively, at the end of 45 minutes. Formulations F7, F8 and F9 which contained increasing concentrations of Polyplasdone XL-10 from 1 % w/w to 2 % w/w, have recorded drug release 94.89%, 98.84% and 99.42% respectively, at the end of 45 minutes. In all the formulations the drug release was near to 100% within 45 minutes. The relative efficiency of different superdisintegrants to improve the dissolution rate of tablets was in order, Croscarmellose sodium > Sodium starch glycolate > Polyplasdone XL-10.

In comparative study of the formulations F6 showed 100.68% drug release respectively at the end of 45 minutes, graphical representation is shown in Figure 6.

#### **Comparison with conventional marketed product**

The marketed product gave 68.83 of drug release in 45 minutes of dissolution study. *In vitro* dissolution profile of marketed product in comparison to the formulated batches were shown in Figure 7 and showed that the formulation F6 with 98.49% of drug release has better control over release of drug in comparison to marketed product.

#### **In Vivo absorption studies**

The study was carried out to compare the the pharmacokinetics of Lomefloxacin HCl selected FDT

formulation (F6) to conventional commercial available marketed tablet following the administration of single dose equivalent to 400 mg. Plasma were periodically collected upto 8 hrs after administration of one tablet containing 400 mg of Lomifloxacin HCl. FDT Lomifloxacin HCl reached a maximum 7 µg/ml in 1 hr after administration and therefore the plasma level declined with a elimination half life time of 8 hrs, and AUC 51 µgh/ml as shown in Table 7.

#### **Stability studies**

The formulations F6 were selected for stability studies on the basis of their high cumulative % drug release and also results of *in vitro* disintegration time, wetting time, and *in vivo* disintegration time. The stability studies were carried out at 40°C/75% RH for the selected formulations up to 3 months shown in Table 8. For every 1 month time interval the tablets were analyzed for drug content uniformity, hardness, *in vitro* disintegration time, friability and wetting time up to 30 days. These formulations showed not much variation in any parameter. From these results it was concluded that, formulation F6 was stable and retained its original properties.

#### **CONCLUSION**

From the results obtained it can be concluded that the fast dissolving tablet with hydroxyl propyl beta cyclodextrin (HP-βCD) complex can be formulated using different superdisintegrants like, Croscarmellose Sodium, Crospovidone, Sodium Starch Glycolate by Direct Compression technique and was found to be disintegrate less than 2 minute, which provide faster effect and better patient compliance.

The formulated tablets showed compliance for various physiochemical parameters viz. tablet dimensions, hardness, friability, weight variation, content uniformity and disintegration. The *in vitro* studies revealed that formulation F6 showed maximum drug release. From the above it can be concluded that the formulation F6 containing 2%

Croscarmellose Sodium is the best formulation which release upto 100.68% in 45 min. *In-vivo* studies revealed that FDDT of formulation (F-6) showed good bioavailability compared to conventional tablet.

The result of stability studies indicated that formulations F6 were stable at 40°C/75% RH and there was no significant change in evaluated parameters.

**Table 1:** Identification and micromeritic study of drug

Identification test	Result of sample obtained	Reported standards	Parameter	Lomefloxacin HCL
Appearance	Solid	Solid	Bulk density(g/ml)	0.334
Color	Pale yellow	Pale yellow	Tapped density(g/ml)	0.488
Odor	Odorless	Odorless	Compressibility Index(%)	31.68
Taste			Hausner ratio	1.463
Melting point			Angle of Repose(θ)	38.58

**Table 2:** Composition of fast dissolving tablets of Lomefloxacin HCL

Ingredients(mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Lomefloxacin	400	400	400	400	400	400	400	400	400
HPβCD	400	400	400	400	400	400	400	400	400
Lactose monohydrate	68	63	58	68	63	58	68	63	58
Avicel-102	92	92	92	92	92	92	92	92	92
SSG(1, 1.5,2%)	10	15	20	-	-	-	-	-	-
Croscarmellose sodium (1, 1.5, 2%)	-	-	-	10	15	20	-	-	-
Crospovidone (1, 1.5, 2%)	-	-	-	-	-	-	10	15	20
Magnesium stearate	10	10	10	10	10	10	10	10	10
Aspartame	10	10	10	10	10	10	10	10	10
Aerosil	10	10	10	10	10	10	10	10	10
Total	1000	1000	1000	1000	1000	1000	1000	1000	1000

\*all quantities are taken in mg/tablet

**Table 3:** Micromeritic study of granules

Code	Angle of repose (θ)	Bulk density (gm/cm <sup>3</sup> )	Tapped density (gm/cm <sup>3</sup> )	Hausner ratio	Carr's Index
F1	27.528±0.235	0.561±0.032	0.634±0.043	1.130	11.51
F2	24.512±0.290	0.567±0.045	0.660±0.057	1.164	14.10
F3	27.210±0.352	0.574±0.058	0.652±0.083	1.135	11.96
F4	27.050±0.252	0.582±0.026	0.674±0.048	1.158	13.64
F5	24.625±0.374	0.575±0.048	0.680±0.061	1.182	15.44
F6	28.561±0.380	0.624±0.043	0.691±0.053	1.107	9.69
F7	24.840±0.972	0.607±0.057	0.667±0.063	1.098	8.99
F8	29.653±0.784	0.605±0.086	0.682±0.049	1.127	11.29
F9	28.462±0.850	0.611±0.048	0.679±0.057	1.111	10.01

**Table 4:** Various Evaluation Parameter of Formulations of Lomefloxacin HCl (all quantities are taken in mg/ tablet)

Formula Code	Avg. wt. (mg)	Avg. Hardness (kg/cm <sup>2</sup> )	Avg. Thickness (mm)	Friability (%)	Disintegration time
F1	1000±3.2494	6.866±0.1527	6.086±0.079	0.202±0.0302	4.33±1.03
F2	1000±1.6484	5.466±0.208	6.059±0.1004	0.205±0.06500	2.51±1.02
F3	1000±1.7451	6.733±0.1553	6.038±0.0944	0.221±0.1105	2.29±0.65
F4	1000±1.9948	5.466±0.2516	6.020±0.0871	0.228±0.0480	1.87±0.84
F5	1000±1.5730	4.866±0.2081	6.013±0.0736	0.244±0.0966	1.26±0.35
F6	1000±3.9841	4.633±0.0577	6.047±0.1011	0.204±0.0853	1.03±0.53
F7	1000±3.1401	6.833±0.1527	6.012±0.1088	0.216±0.0861	1.55±0.56
F8	1000±2.1278	6.766±0.2081	6.035±0.1098	0.260±0.0547	1.48±0.73
F9	1000±2.1137	6.533±0.1527	6.045±0.0892	0.181±0.0269	1.56±0.44

**Table 5:** Cumulative percent drug release profiles of formulations of Lomefloxacin HCl containing different Disintegrants

Time (mins)	Percent cumulative drug released (Mean ± S.D)								
	Formulation code								
	F1	F2	F3	F4	F5	F6*	F7	F8	F9
5	63.68±0.73	65.28±0.96	66.94±1.24	70.84±0.80	74.28±1.28	80.23±0.51	62.28±0.64	70.73±0.79	74.41±0.56
10	70.66±0.46	74.96 ±1.12	78.04±0.42	81.21 ±1.06	82.66±1.56	86.21±1.25	67.66±1.45	76.85±1.21	80.04±1.38
15	77.80±0.29	79.93±0.22	81.98±0.80	82.99±1.49	90.73±0.78	92.88±0.46	74.73±1.87	80.98±0.68	86.92±0.33
20	80.62±0.95	84.91±0.49	86.81 ±1.57	90.51±0.77	92.91±0.39	96.51±2.51	83.91±0.48	86.30±1.26	92.64±1.61
30	89.43±1.31	92.91±1.18	93.32±1.49	94.38±0.93	96.91±2.65	100.38±1.22	9.91±2.39	94.17±2.34	96.37±1.17
45	5.60±0.65	96.89±0.80	97.99±0.47	96.28 ±1.25	98.89±0.85	100.68±0.58	94.89±0.96	98.84±1.10	99.42±1.35

**Table 6:** Comparison of drug release from marketed product with optimized formulation

Time (min)	Percent cumulative drug released (Mean ± S.D) (n=6)	
	Formulation code	
	MR	F6*
5	30.74 ±0.728	80.23±0.51
10	48.09 ±1.540	86.21±1.25
15	59.11 ±0.512	92.88 ±0.46
20	73.56 ±1.358	96.51±2.51
30	82.09± 1.446	100.38 ±1.22
45	98.21 ±0.910	100.68 ±0.58

**Table 7:** Pharmacokinetic parameters of Lomefloxacin HCL by Fast dissolving tablet of F6 and Conventional tablet.

Parameter	F6 formulation	Conventional tablet
AUC (µg h/ml)	51	26.1
Tmax (hr)	1	1.5
Cmax (µg/ml)	7	2.8

**Table 8:** Selected formulations for stability studies F6 stored at 40 °C/75% RH.

Formulation Code	Tested after time (in days)	Hardness (kg/cm <sup>2</sup> )	Disintegration time (sec)	Wetting time (sec)	Drug content (n=5)	Friability %
		Mean ± SD (n=3)				
F6	30	4.41±0.21	14.38±2.19	20.21±1.43	5.00±0.046	0.2451
	60	4.39±0.19	14.31±2.20	20.15±1.43	5.00±0.021	0.2439
	90	4.21±0.15	14.19±2.21	20.11±1.47	4.991±0.011	0.2431

**Figure 1:** IR spectra of Lomefloxacin HCl-F3

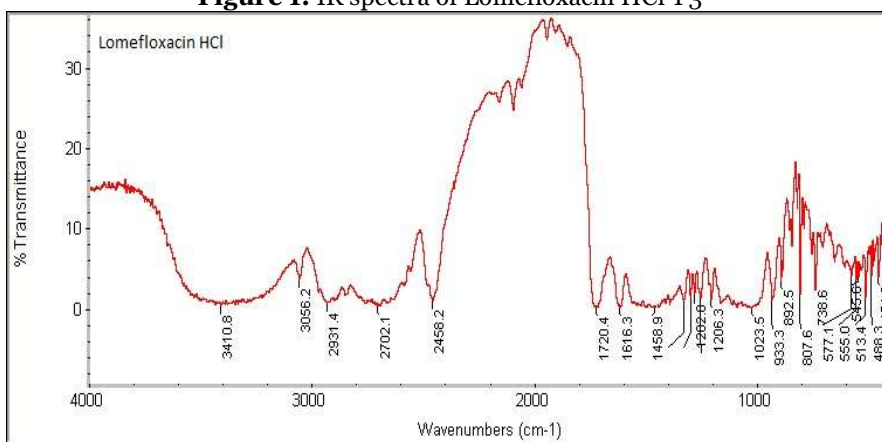




Figure 2: IR spectra of Lomefloxacin HCl-F6

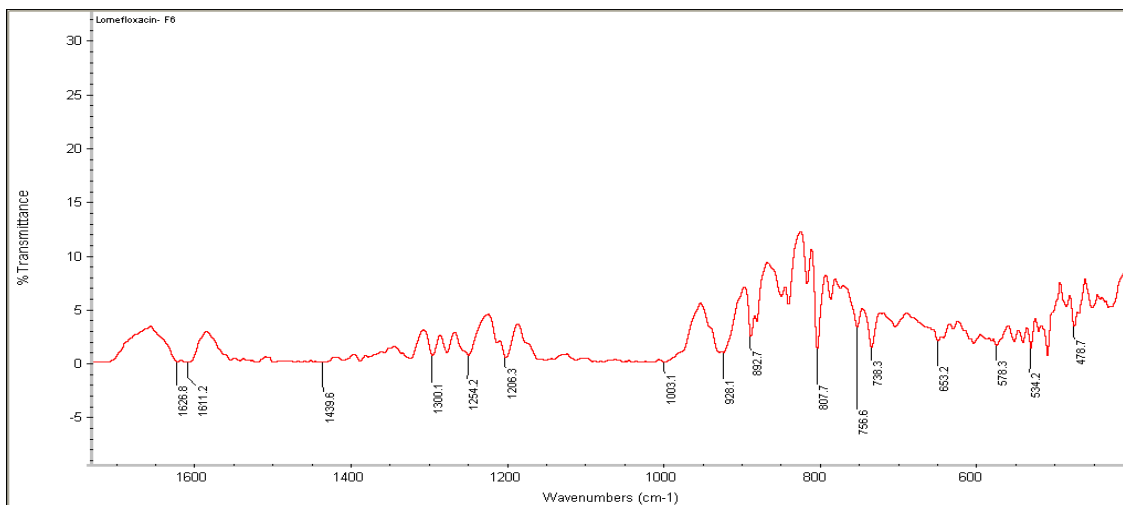


Figure 3: IR spectra of Lomefloxacin HCl-F9

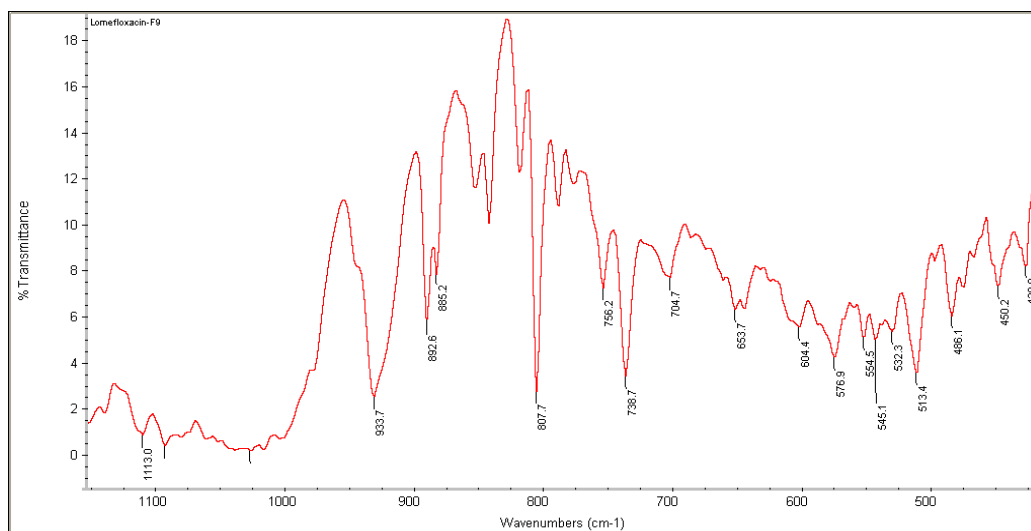


Figure 4: p-XRD of Lomefloxacin HCl + HP $\beta$ CD

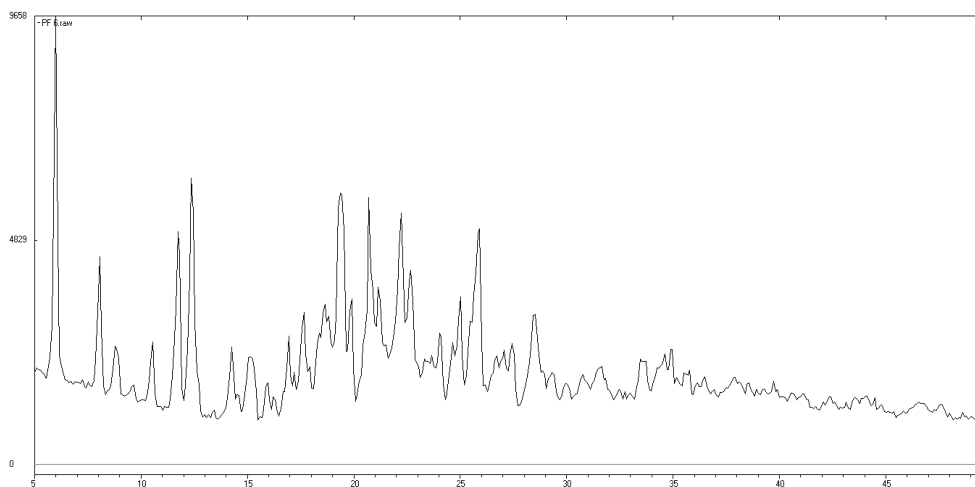


Figure 5: p-XRD of Lomefloxacin HCl – F6

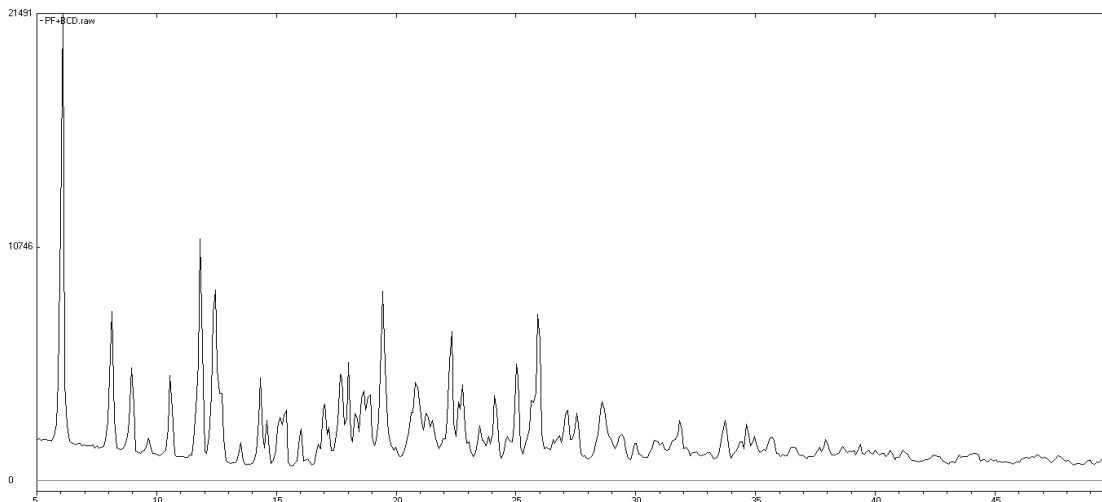


Figure 6: Dissolution Profile of Lomefloxacin HCL Complex of various formulations

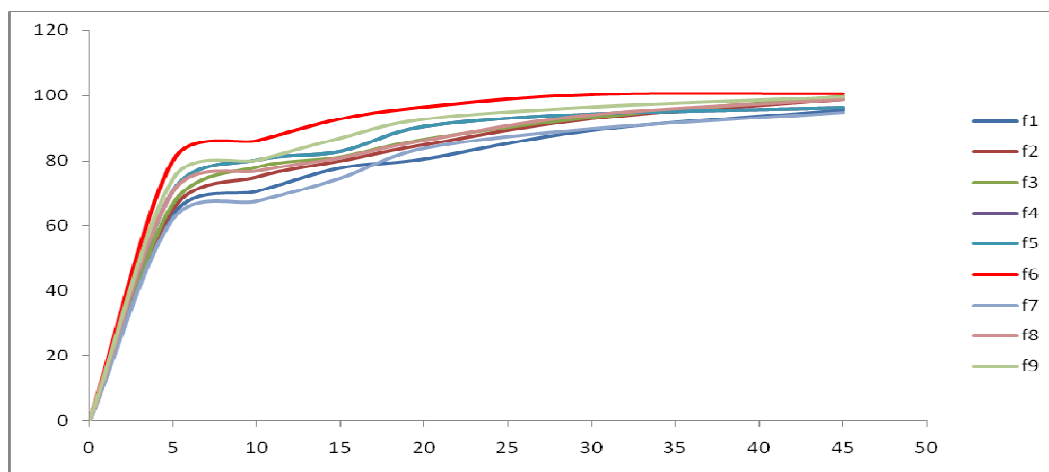
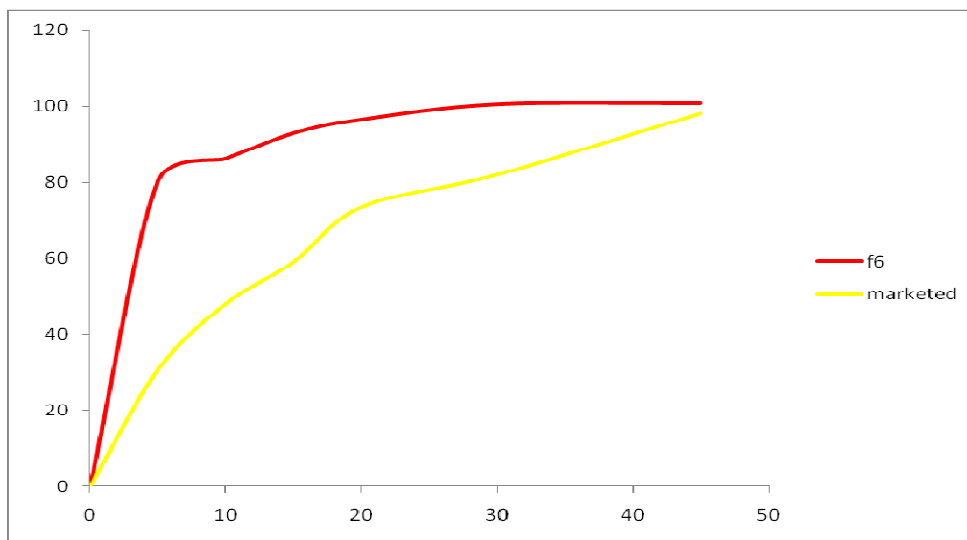


Figure 7: Comparison of marketed product with optimized formulations



#### ACKNOWLEDGEMENT

We are very grateful to the vice-chancellor and registrar of KLE University and also would like to thank all staff of KLE university college of Pharmacy, Belgaum for providing constant support and enthusiasm to carry out this work.

#### REFERENCES

- 1) Schultheiss N, Newman A. Pharmaceutical cocrystals and their physicochemical properties. *Cryst. Growth Des* 2009; 9: 2950-67.
- 2) Jung MS, Kim JS, Kim MS. Bioavailability of indomethacin-saccharin cocrystals. *J Pharm Pharmacol* 2010; 62: 1560-68.
- 3) Hirani JJ, Rathod DA, Vadalia KR. Orally disintegrating tablets: A Review. *Tropical Journal of Pharmaceutical Research* 2009; 8:161-72.
- 4) Maski N, Arulkumaran GK, Ghode P, Randive S, Pal R. Studies on the preparation, characterization and Solubility of  $\beta$ -cyclodextrin-diacerein inclusion complexes. *Int J Pharmacy and Pharm Sci* 2009; 1:121- 35.
- 5) Subramanyam CVS. Textbook of Physical Pharmaceutics, Vallabh Prakashan, 2<sup>nd</sup> edn; 2001. p. 210-28.
- 6) Gohel MC Bansal G, Bhatt N. Formulation and evaluation of orodispersible taste masked tablets of Famotidine. *Pharma Biol World* 2005;3:75-80.
- 7) Shoukri RA, Ahmed IS, Shamma RN. In vitro and in vivo evaluation of nimesulide lyophilized orally disintegrating tablets. *Eur J of Pharmaceutics and Biopharmaceutics* 2009; 73: 162-71.
- 8) McClure N. Stability studies in overview of ICH guidelines for drug products. Matrix Pharmaceutical Inc. 1997. (<http://www.mcclurenet.com>).
- 9) Shanmugapandiyam P, Selvaraj B, Malarvizhi P, Udayakumar T. Design and evaluation of fast dispersible aceclofenac tablets. *Int. J. Pharm & Ind. Res* 2011; 1: 214-18.

