Formulation and Evaluation of fast dissolving tablets of Lornoxicam

Ravi Kumar Nayak*¹, Narayana Swamy VB², Senthil A¹, Thakkar Hardikkumar¹,

Dave Mehul Kumar¹, Mahalaxmi R³

¹Department of Pharmaceutics, Karavali College of Pharmacy, Mangalore-575028, Karnataka, India, ²Department of Pharmacognosy, Karavali College of Pharmacy, Mangalore-575028, Karnataka, India, ³Department of Pharmaceutics, Manipal College of Pharmaceutical Sciences, Manipal -576104, Karnataka, India.

***For correspondence** Ravi Kumar Nayak, Assistant Professor

Dept. of Pharmaceutics,

Karavali College of Pharmacy, Mangalore-575028, Karnataka,

E-mail: ravikumar300@gmail.com

Phone No: 9886735735

Summary

Orodispersible tablets are the fast growing and highly accepted drug delivery system in now a day mainly to improve patient compliance. Orodispersible tablets have number of advantages over conventional dosage forms, because of that Orodispersible tablets have emerged as an alternative to conventional dosage forms. Lornoxicam is a non steroidal anti-inflammatory drug with analgesic properties and belongs to the class oxicams. Orodispersible tablets of Lornoxicam were prepared using superdisintegrants viz; crospovidone, croscarmellose sodium and sodium starch glycolate using the direct compression method. The tablets prepared were evaluated for thickness, uniformity of weight, hardness, friability, wetting time, in vitro disintegration time and in vitro dissolution time. The different formulations showed disintegration time between 18 to 75 s. Drug release showed time between the ranges of 10 to 12 min. Among all the formulations, F3 (containing 4% of crospovidone) showed 99% drug release within 12 min and it showed least disintegration time (18s). Thus, F3 was considered best among the other formulations. The stability study was conducted as per the ICH guidelines and the optimized formulation (F3) was found to be stable, with insignificant change in hardness, drug content and disintegration time. Therefore the main objective of the present work is to develop orodispersible tablets of Lornoxicam to improve bioavailability, disintegration time, dissolution efficacy and patient compliance.

Keywords: Oral disintegrating tablet, Lornoxicam, direct compression, Superdisintegrants, Disintegration time.

Introduction

Oral route of drug administration have wide acceptance of 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 compliance¹. The most popular solid dosage forms are being tablets and capsules. However one important drawback of these dosage forms for some patients is the difficulty to swallow². This difficulty in swallowing or dysphasia is currently affecting 35% of general population³. 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 when water is not available⁴. For these reasons tablets that can easily dissolve or disintegrate in the oral cavity have attracted a great deal of attention. Orodispersible tablets are not only indicated for people who have swallowing difficulties, but also are ideal for active people⁵. Orodispersible tablets are also known as mouth dissolving tablets, melt-in-mouth tablets, fast dissolving tablets, rapimelts, porous tablets and quick dissolving tablets⁶.

We often see that patient find difficulty in swallowing the conventional tablets especially the geriatrics, pediatric patients, and patients suffering from various diseases, are the major problem. Hence it is the necessary criterion to develop a dosage form that will provide rapid and quick action. Thus the development of Met-In-Mouth tablet, which disintegrate rapidly without the need of drinking water providing convenience of administration, patient compliance and quick onset of action⁷⁻⁸.

Lornoxicam is a non steroidal anti-inflammatory drug with analgesic properties used in rheumatoid arthritis, post-traumatic pain, masculo-skeletal and joint disorders, belongs to the class oxicams. The mode of action of Lornoxicam is partly based on inhibition of prostaglandin synthesis (inhibition of the cyclo-oxygenase enzyme). Lornoxicam is absorbed rapidly and almost completely from the gastro-intestinal tract⁹. Lornoxicam is very bitter in taste and yet no oral disintegrating taste-masked preparation is available in market, which might be helpful in pediatric and geriatric patients. Therefore, to provide this drug in a more accessible and patient compliant form, in the present study an attempt has been made to mask its bitter taste and formulate it into oral disintegrating tablet¹⁰⁻¹¹.

Materials and Methods

Materials

Lornoxicam is procured from Glenmark generics Ltd, Mumbai, India. Croscarmellose sodium (CCS), Crospovidone (CP), and Sodium Starch Glycolate (SSG), Aspartame and Strawberry flavor were received as gift samples from Zydus Research centre, Ahmedabad, India, Microcrystalline Cellulose pH 102 (Avicel PH 102) was gift sample from Emcure labs Ltd. Pune. Talc, Aerosil and Magnesium stearate were procured from Apex Chemicals (Ahmedabad, India). All other reagents and chemicals used were of analytical grade.

Methods

Characterization of drug and excipients

Fourier transform infra red spectroscopy (FTIR)

FTIR spectra of pure Lornoxicam and physical mixture of drug and excipients were recorded on Shimadzu Corporation, (Tokyo, Japan) Model-1601 PC. Potassium bromide pellet method was employed and background spectrum was collected under identical situation. Each spectrum was derived from single average scans collected in the region 650- 4000 cm⁻¹ at spectral resolution of 2cm⁻² and ratio against background interferogram. Spectra were analyzed by software supplied by Shimadzu.

Differential Scanning Calorimetry (DSC)

Thermal properties of the pure Lornoxicam and the physical mixture of drug and excipients were analyzed by Shimadzu DSC-60, Shimadzu Limited Japan. The samples were heated in a hermetically sealed aluminum pans. Heat runs for each sample were set from 25 to 350° C at a heating rate of 10° C/min, using nitrogen as blanket gas.

Formulation of melt in mouth tablets of Lornoxicam

Tablet each containing 8 mg Lornoxicam were prepared as per composition given in Table1. The drug and excipients were passed through sieve (#80) to ensure the better mixing. Microcrystalline Cellulose was used as a direct compressible vehicle. Super disintegrants like Sodium Starch Glycolate, Crospovidone and Croscarmellose Sodium were used in different ratios. All the materials were transferred

to glass mortar and triturated till it mixed uniformly. The resulting powder mixture was subjected to various precompression parameters.

Ingredients (mg)*	F1	F2	F3	F4	F5	F6	F7	F8	F9
Lornoxicam	8	8	8	8	8	8	8	8	8
Sodium starch glycolate							4	6	8
Crospovidone	4	6	8						
Croscarmellose sodium				4	6	8			
Microcrystalline cellulose	173	171	169	173	171	169	173	171	169
Aspartame	6	6	6	6	6	6	6	6	6
Magnesium stearate	2	2	2	2	2	2	2	2	2
Talc	4	4	4	4	4	4	4	4	4
Strawberry flavor	2	2	2	2	2	2	2	2	2
Aerosil	1	1	1	1	1	1	1	1	1
Total weight	200	200	200	200	200	200	200	200	200

 Table No. 1- Composition of orodispersible tablets of Lornoxicam

*All the quantities are in mg

Pre Compression Parameters¹²

Angle of repose

Angle of repose was determined by using funnel method. Powder was poured from a funnel that can be raised vertically until a maximum cone height, h, was obtained. Diameter of heap, D, was measured. The angle of repose, Θ , was calculated by formula

$$\tan \Theta = \mathbf{h} / \mathbf{r}$$

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

Where, Θ is the angle of repose, h is the height in cm and r is the radius.

Bulk Density

Apparent bulk density was determined by pouring pre- sieved drug excipient blend into a graduated cylinder and measuring the volume and weight "as it is". It is expressed in g/ml and is given by

$$\mathbf{D_b} = \mathbf{M} / \mathbf{V_0}$$

Where, M is the mass of powder and V_0 is the Bulk volume of the powder

Tapped density

It was determined by placing a graduated cylinder, containing a known mass of drug- excipient blend, on mechanical tapping apparatus. The tapped volume was measured by tapping the powder to constant volume. It is expressed in g/ml and is given by

$$\mathbf{D}_{\mathbf{t}} = \mathbf{M} / \mathbf{V}_{\mathbf{t}}$$

Where, M is the mass of powder and V_t is the tapped volume of the powder.

Powder flow properties

The flow properties were determined by

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i) Carr's Index (I)

It is expressed in percentage and is expressed by

 $\mathbf{I} = \mathbf{D}_{t} - \mathbf{D}_{b} / \mathbf{D}_{t}$

Where, D_t is the tapped density of the powder and D_b is the bulk density of the powder.

Hausner ratio

It is expressed in percentage and is expressed by

 $H= D_t / D_b$

Where, D_t is the tapped density of the powder and D_b is the bulk density of the powder. Lower Haunser ratio (< 1.25) indicates better flow properties than higher ones6 (>1.25).

Compression of tablet

After evaluation of powder blend were then compressed into tablets using flat face round tooling on Rimek compression machine equipped with 8 mm round punch by direct compression technique. A minimum of 50 tablets was prepared for each batch.

Evaluation of tablet

All the tablets were evaluated for following different parameters which includes;

General appearance

Five tablets from different batches were randomly selected and organoleptic properties such as color, odor, taste, shape, were evaluated.

Hardness

For each formulation, the hardness of five tablets was determined using the Monsanto hardness tester (Cadmach).

Weight Variation

Twenty tablets from each formulation were selected at a random and average weight was determined. Then individual tablets were weighed and was compared with average weight.

Friability

Friability of the tablets was determined using Roche Friabilator. This device subjects the tablets to the combined effect of abrasion and shock in a plastic chamber revolving at 25 rpm and dropping the tablets at a height of 6 inches in each revolution. Pre weighed sample of tablets was placed in the friabilator and were subjected to100 revolutions. Tablets were de dusted using a soft muslin cloth and re weighed.

The friability (f) is given by the formula. Friability (f) = 100 (Wo - W) / Wo

Where Wo is weight of the tablets before the test and W is the weight of the tablet after the test

In vitro Disintegration time

The disintegration time for all formulations was carried out using tablet disintegration test apparatus. Six tablets were placed individually in each tube of disintegration test apparatus and discs were placed. The water was maintained at a temperature of $37^{\circ}\pm2^{\circ}$ C and time taken for the entire tablet to disintegrate completely was noted¹³.

Thickness

Thickness of the tablets was determined using a Vernier caliper. Five tablets from each batch were used, and average values were calculated.

Drug content

Five tablets were weighed individually and powdered. The powder equivalent to average weight of tablets were weighed and extracted in water and concentration of drug was determined by measuring absorbance at 378 nm by Ultra Violet (UV) spectrophotometer (Schimadzu 1601).

In vivo disintegration time

The *in vivo* disintegration time was measured in six human volunteers. A tablet was placed on the tongues of the volunteers and time required for complete disintegration in the mouth was noted and also taste and mouth feel was observed¹⁴.

Wetting time

The wetting time of the tablets was measured using a simple procedure. Five circular tissue papers of 10cm diameter were placed in a petridish with a 10 cm diameter. Ten milliliters of water containing eosin, a water-soluble dye, was added to the petridish. A tablet was carefully placed on the surface of tissue paper. The time required for water to reach the upper surface of the tablets was noted as the wetting time.

Dissolution studies

In vitro release of Lornoxicam from tablets was monitored by using 900 ml of simulated intestinal fluid, SIF (USP phosphate buffer solution, pH 7.4) at $37\pm0.5^{\circ}$ C and 50 rpm using programmable dissolution tester [Paddle type, model TDT-08L, Electrolab, (USP), India]. 5 ml Aliquots were withdrawn at one minute time intervals and were replenished immediately with the same volume of fresh buffer medium. Aliquots, following suitable dilutions, were assayed spectrophotometrically (UV- 1601, Shimadzu, Japan) at 378 nm. The dissolution experiments were conducted in triplicate¹⁵.

Mouth feel

The same human volunteers participated in taste evaluation test, were asked to give their opinion about the feeling of smoothness or grittiness of the dispersion soon after the tablet got disintegrated.

Taste evaluation

Taste evaluation was done by a panel of six volunteers using time intensity method. One tablet was held in mouth for 10 s bitterness levels were recorded instantly and then at the end of 10 s, 30 s, 1 min, and 2 min, bitterness levels are again noted and recorded.

Test for dispersion

This test is carried out for dispersible tablets. Two tablets were placed in 100 mL of water and stirred gently until it was completely dispersed and smooth dispersion was obtained. The dispersed liquid was passed through sieve no. 22. No residue should remain over the sieve.

Stability Studies

The stability study of optimized formulation (batch F3) was carried out as per ICH (International Conference on Harmonization) guidelines at $40 \pm 2^{\circ}$ C / 75 \pm 5% RH using stability chamber for three month. The effects of temperature and time on the physical characteristics of tablets were evaluated for assessing the stability of prepared formulations. The samples were collected monthly and different parameters like hardness, uniformity of weight, friability, drug content and disintegration time were studied¹⁶.

Results and Discussion

In recent decades, a variety of pharmaceutical research has been conducted to develop new dosage forms. Considering quality of life, most of these efforts have been focused on ease of medication. Among the various dosage forms developed to improve the ease of administration, the oral disintegrating tablet (ODT) is the most widely preferred commercial products. Attempt was made in the present investigation to make a fast dissolving tablet of Lornoxicam by direct compression method. Formulation was carried out using three different types of super disintegrants and optimized the concentration and hardness of the tablet to give the minimum disintegration time and get maximum drug release.

Characterization of drug and excipients

The formulation additives in concentrations used did not affect the stability and Ultraviolet absorbance of the drug.

Fourier transform infra red spectroscopy (FTIR)

The interaction study between the drug and excipients in different formulations were performed using FTIR spectrophotometer. The pellets were prepared on KBr press. The spectra were recorded over the wave number range of 4000 to 650 cm⁻¹. The FTIR spectrum of lornoxicam showed a characteristic peak

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at 3,090 cm⁻¹ corresponding to NH stretching vibration. Intense absorption peak was found at 1,642 cm⁻¹ due to the stretching vibration of the C=O group in the primary amide. Other peaks were observed at 1,597 and 1,559 cm⁻¹ and were assigned to bending vibrations of the N–H group in the secondary amide. The stretching vibrations of the O=S=O group appeared at 1,157, 1,387, and 1,336 cm⁻¹. Other prominent peaks appeared at 827.94 cm⁻¹ corresponding to CH aromatic ring bending and heteroaromatics and at 766.8 cm⁻¹ due to the C–C₁ bending vibration, which indicates groups is match with structure of drug and confirm the purity of the drug. FTIR-spectra of drug and its physical mixture with excipients are exactly same, and there is no shift of peaks or disappearance of principle peaks or modification of the principle peaks indicating that there is no interaction between the drug and excipients. FT-IR spectrum of pure drug and its physical mixture is represented in Figure 1 and Figure 2.



Fig.1- Infrared Spectrum of pure lornoxicam

Fig.2- Infrared Spectrum of physical mixture of lornoxicam and excipients



Differential Scanning Calorimentry (DSC)

Any possible drug polymer interaction can be studied by thermal analysis. The DSC thermogram of lornoxicam was typical of a crystalline substance, exhibiting a sharp exothermic peak at 232.9°C corresponding to its melting and decomposition. The thermograms of the physical mixtures of lornoxicam with other excipients (1:1) showed the existence of the drug exothermic peak which could indicate the

absence of interaction between lornoxicam and other excipients. The DSC thermogram of pure drug and its physical mixture is represented in Figure 3.

Pre-compression parameters of Lornoxicam powder blend

Since the flow properties of the powder mixture are important for the uniformity of the mass of the tablets, the flow of the powder mixture was analyzed before compression of the tablets. The results of angle of repose and compressibility index (%) ranged from $(24.58\pm0.04^{\circ} \text{ to } 28\pm0.01^{\circ})$ and $(16.1\pm0.03 \text{ to } 26.53\pm0.01)$, respectively. The results of bulk density and tapped bulk density ranged from $(0.48\pm0.01 \text{ g/cm}^3)$ to $0.58\pm0.01 \text{ g/cm}^3$ to $0.58\pm0.01 \text{ g/cm}^3$) and $(0.58\pm0.03 \text{ g/cm}^3)$ to $0.73\pm0.03 \text{ g/cm}^3$), respectively. The results of Hausner ratio ranged from 0.08 ± 0.01 to 1.32 ± 0.01 . The results of angle of repose (<30) and compressibility index indicates good flow properties of powder blend (Table 2).

Fig.3- DSC Thermogram of physical mixture of lornoxicam and excipients



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Formulati on code	Angle of repose(θ)	Bulk density (g/cm ³)	Tapped density (g/cm ³)	Carr's index (%)	Hausner ratio (H _R)	Flowability
F1	28.0±0.01	0.57±0.01	0.69±0.01	17.6±0.05	1.24±0.04	good
F2	24.58±0.04	0.510±0.02	0.610±0.01	21.32±0.03	0.112±0.02	good
F3	27.5±0.02	0.57±0.02	0.67±0.02	20.8±0.03	1.26±0.04	good
F4	25.1±0.03	0.52±0.04	0.68±0.01	16.1±0.03	1.29±0.04	good
F5	25.1±0.02	0.56±0.02	0.71±0.03	24.7±0.04	1.22±0.02	good
F6	26.1±0.01	0.58±0.01	0.73±0.01	21.1±0.02	1.32±0.01	good
F7	25.1±0.03	0.52±0.04	0.68±0.01	16.1±0.03	1.29±0.04	good
F8	26.1±0.01	0.58±0.01	0.73±0.01	21.1±0.02	1.32±0.01	good
F9	25.41±0.02	0.483±0.01	0.587±0.03	26.53±0.01	0.088±0.01	good

Table No. 2- Results of Precompression Flow Properties of Lornoxicam powder blend

*All values are expressed as mean \pm SD, n=3

Post-compression parameters of Lornoxicam fast dissolving tablets

The melt in mouth tablets of Lornoxicam were off-white, smooth, flat shaped, and one side break line in appearance with zero defects. The results of post compression parameters of different batches of Lornoxicam fast dissolving tablets are given in (Table 3). Tablet mean thickness was almost uniform in all the formulations. The thickness varies between 2.8±0.02 mm to 3.2±0.02 mm. The prepared tablets in all the formulations possessed good mechanical strength with sufficient hardness in the range of 2.8±0.12 kg/cm^2 to 3.1±0.05 kg/cm². Friability values below 1% were an indication of good mechanical resistance of the tablets. All the tablets from each formulation passed weight variation test, as the % weight variation was within the Pharmacopoeial limits of $\pm 7.5\%$ of the weight. The weight variation in all the formulations was found to be 198±0.03 mg to 201±0.04 mg. The percentage drug content of all the tablets was found to be between 97.15±0.05 to 101.21±0.02 percent of Lornoxicam which was within the acceptable limits. Wetting time is used as an indicator of the ease of tablet disintegration. The wetting time for all the formulations was performed in triplicate. The time for all formulations varied between 25±1.23 to 79±1.26 s. The wetting time of the tablets were also considerably reduced in tablets containing crosscarmellose sodium which may be attributed due to the wicking and swelling type of disintegrants thus facilitating the faster disintegration. The result in vitro disintegration were within the prescribe limit and comply with the criteria for orally disintegrating tablets, the value were with 18 ± 2.14 to 75 ± 3.41 . Due to highly porous structure of crospovidone, it draw large amount of water by water wicking mechanism into porous network of tablet and thus crosscarmellose sodium swells very little, yet rapidly absorbs water into its network. Due to this with increase in concentration of crospovidone, improved water uptake and reduction in disintegration time was observed with all four formulation containing crospovidone, as compared to other batch.

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Formulation code	DT*in vitro (s) (n=3)	Thickness (mm) (n=5)	Hardness (kg/cm ²) (n=5)	Friability (%) (n=5)	Drug content (%) (n=5)	Weight variation (mg) (n=20)	Wetting time (s) (n=3)	DT <i>in vivo</i> (s) (n=3)
F1	52±2.21	3.2±0.02	3.1±0.05	0.44±0.01	101.21±0.02	198±0.01	59±1.43	69±2.41
F2	55±3.32	2.8±0.02	2.9±0.09	0.55±0.04	97.56±0.02	197±0.02	58±1.17	61±2.21
F3	18±2.14	3.0±0.01	3.0±0.05	0.45±0.05	99.89±0.06	201±0.04	25±1.23	26±2.45
F4	75±3.41	3.0±0.02	3.0±0.02	0.41±0.03	98.35±0.05	200±0.03	79±1.26	81±3.10
F5	62±1.32	3.0±0.01	3.2±0.1	0.42±0.01	99.45±0.02	199±0.01	66±1.21	70±2.12
F6	56±1.10	3.1±0.02	2.8±0.12	0.42±0.02	99.98±0.03	200±0.01	60±1.32	66±1.25
F7	69±1.41	2.9±0.01	2.8±0.03	0.58±0.05	97.15±0.05	198±0.03	71±1.28	72±2.61
F8	53±1.61	3.0±0.02	3.0±0.04	0.45±0.01	99.15±0.02	198±0.03	56±1.24	59±1.32
F9	43±2.34	2.9±0.02	3.0±0.08	0.41±0.03	98.32±0.03	201±0.02	49±1.12	50±3.14

Table No. 3- Results of Post Compression Properties of Lornoxicam tablets

Effect of concentration of superdisintegrant on the dissolution release rate

In vitro dissolution profiles of different batches are shown in figure 4, 5 and 6. The cumulative % of drug release increased as the time increases up to 15 min with increased in the concentration of superdisintegrants. Among all formulations, F3(contains 4% crospovidone) formulation considered as better as it gives disintegration time 18s which fulfills official requirement (less than 30s as per USFDA Guideline) for orodispersible tablets and also it Shows highest drug release 98% at 12 minutes compared to the other formulations. Formulation containing crospovidone showed faster release rate than other formulation containing crospovidone showed faster release than marketed preparations. Formulation containing crospovidone showed 100% drug release within 12 min. Whereas formulation containing Crosscarmellose sodium (F4 to F6) showed 100% drug release within 14 min. Formulation F7 to F9 (containing Sodium starch glycolate as the superdisintegrant) showed slow rate of release as compared to crospovidone and Crosscarmellose sodium that is 100% release within 15 min. All the formulations showed improvement in dissolution rate with increasing the amount of superdisintegrant. Slow release of the formulation containing Sodium starch glycolate.

Stability study

During storing the tablets at $40 \pm 20C/75 \pm 5\%$ RH for 3 m, the tablets were tested for their hardness, uniformity of weight, friability, drug content and disintegration time monthly. Formulation F-3 which showed promising results, were subjected to stability studies at $40 \pm 20C/75 \pm 5\%$ RH for 3 m. After 3 m, Lornoxicam fast dissolving tablets did not show any change in physical appearance or drug content. In the formulation using superdisintegrant with the concentration of 4% and hardness range of 2.7 to 3.0 kg/cm², disintegration time was found to be 16-20 s and. Percentage friability and % drug content were found to 0.45 ± 0.05 to 0.48 ± 0.06 % and 99.89 ± 0.06 to 96.68 ± 0.01 %, respectively and were within the acceptable limit(table 4).





Fig.5- Comparison of *in vitro* dissolution profile of Crosscarmellose sodium formulations (F4-F6)





Fig.6- Comparison of *in vitro* dissolution profile of sodium starch glycolate formulations (F7-F9)

Table No. 4- Stability Study of Optimized Batch (F6) of Lornoxicam Fast Dissolving Tablets

Sr.	Time	Parameters							
No.		Hardness (Kg/cm ²)	Uniformity of weight	Friability (%)	<i>In vitro</i> disintegration time (s)	Drug content (%)			
1	0 week	3.0±0.01	201±0.04	0.45±0.05	18	99.89±0.06			
2	4 week	2.9±0.01	201±0.02	0.46±0.02	17	98.80±0.05			
3	8 week	2.8±0.04	201±0.03	0.47±0.01	20	97.76±0.02			
4	12 week	2.7±0.02	201±0.01	0.48±0.06	16	96.68±0.01			

Conclusion

In the present study a stable, effective and pleasant tasting mouth disintegrating tablet, exhibiting an excellent disintegration time and dissolution profile, was formulated using different concentrations of superdisintegrants. Even though the excipients employed are well known and established, they have not been used with Lornoxicam for formulating mouth disintegrating tablets. Also such formulation is not

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available in the market. The formulation was developed with the aim of providing patients suffering from rheumatoid arthritis, post-traumatic pain, masculo-skeletal and joint disorders, a convenient means of taking their medication, whenever and wherever needed, for immediate relief of rheumatoid arthritis, post-traumatic pain, masculo-skeletal and joint disorders. It was observed that when crospovidone used at 4% concentration (formulation F3) percentage drug release was maximum in 12 min and disintegration time was least (18s). And in stability testing of batch F3, tablets did not show any change in physical appearance or drug content. Therefore it is concluded that croscarmellose sodium can be effectively used as superdisintegrant in Lornoxicam fast dissolving tablets. The main motive was to achieve fast disintegration and immediate drug release, using an economic, industry feasible method involving conventional tabletting equipments. Undoubtedly, all the formulations showed good disintegration time, apart from fulfilling all compendial and other standard specifications, and exhibited higher release rates of Lornoxicam.

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