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FORMULATION AND EVALUATION OF TASTE MASKING LORNOXICAM ORAL DISINTEGRATING TABLETS

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ABSTRACT

Recent development in Oral disintegration tablets have brought convenience in dosing to aged and youngsters WHO have bother in swallowing tablets. Lornoxicam is associate non-hormone medicament happiness to the category oxicams. It's extraordinarily bitter in style. the aim of this analysis was to arrange style masking Oral disintegrating tablets of poorly soluble lornoxicam by direct compression technique mistreatment kyron T-114 (cation exchange resin) as a style masking agent. With in numerous magnitude relations the Drug-resin ratio of 1:3 was found to supply best style masking. The super disintegrants utilized in formulation are Crosscaramellose atomic number 11, atomic number 11 Starch Glycolate and Cross Povidone. Among these cross povidone showed higher drug unharness. The tablets were evaluated for hardness, friability, weight variation, wetting time, disintegration time and uniformity of content. Optimized formulations were evaluated for *in-vitro* dissolution take a look at. Amongst all the formulations F-011 was found to be most palmy tablets ready by this system had disintegration time of 7 sec. And %CDR 93.80 within 30min. Hence, this approach is utilized for style masking of bitter pharmaceutical ingredients resulting in improved patient compliance.

KEYWORDS

Lornoxicam, kyron T-114, Superdisintegrants, Direct Compression technique and Oral Disintegration Tablets.

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INTRODUCTION

Oral route of drug administration have wide acceptance and thus up to 50-60% of total indefinite quantity forms are administered orally. Solid indefinite quantity forms are fashionable due to simple administration, correct indefinite quantity, self-medication, pain dodging and most significantly the patient compliance. The foremost fashionable solid indefinite quantity forms are being

tablets and capsules. But one among the constraints of those indefinite quantity forms for a few patients is that the issue to swallow. This issue in swallowing or upset is presently touching thirty five of general population. Drink plays a vital role within the swallowing of oral indefinite quantity forms. Usually times folks expertise inconv enience in swallowing standard indefinite quantity forms like once water isn't obtainable. For these reasons tablets that may simply dissolve or disintegrate within the mouth have attracted a good deal of attention. Oral disintegrating tablets aren't solely indicated for people that have swallowing difficulties, however are ideal for active people. European assemblage (5.0, 2005) adopted the term "orodispersible pill" as a tablet to be placed within the mouth wherever it disappears apace before swallowing, Stating a most DT of three min as determined in an exceedingly standard disintegration check equipmen t. ODT also are called fast dissolves, fast melts, quick dissolving, quick disintegrating, fast di ssolve or orally dissolving tablets 4. The bitter style of the medication that are orally administered usually contributes to patient non-compliance in taking medicines, particularly for youngsters and senior. Sadly, majority of the medication have a natural bitter style that may produce a burning feeling within the throat or within the mouth. Specifically, a bitter style will decrease the patient compliance and therefore reducing an efficient pharmacotherapy. Various techniques are developed to enhance style like chemical compound coatings ways, complexation with cyclodextrins, action resins, salt formation, mistreatment lipo somes, microencapsulation techniques and coating or granulation. Kyron T-114 (cation exchange resin) is generally used as a style masking agent derived from cros linked compound of 2-methylpropenoic acid. Strong bitter style of histamine blocker was covert with drug organic compound magnitude relation of 1:2, This approach is used for style masking of bitter pharmaceutical ingredients and might build eligible to typeulate mouth disintegrating indefinite quantity form. Lornoxicam could be a anti-inflammatory drug (NSAID) of the oxicam category with analgesic, medicinal drug and antipyretic properties. The mode of action of Lornoxicam is partially supported inhibition of autacoid synthesis (inhibition of the enzyme enzyme). Lornoxicam is absorbed apace and virtually utterly from the gastro-intestinal tract. Lornoxicam is extremely bitter in style. So to supply this drug in an exceedingly a lot of accessible and patient compliant type, within the gift study an endeavor has been created to mask its bitter style and formulate in to oral disintegrating pill.

MATERIAL AND METHODS

Material

Lornoxicam was obtained as a gift sample from KORES (INDIA) LIMITED; Navi Mumbai. Polyacrylic acid (kyron T-114) was a gift sample from Corel Pharma Chem, Ahmedabad. Sodium starchglycolate, Cross carmellose sodium, and Lactoe Monohydrate (SN 21) were obtained from DFE Pharma, Germany. Cross povidone was obtained from Nanhang Industrial, China. Sucralose was from Unisweet (ZIBO) Ltd, China. Lemon Flavour was from Givaudan, Switzerland. Colloidal Silicon Dioxide was from Wacker Chemie, Germany. Magnesium stearate was from Mayfield Heights, Ohio. All the other chemicals used were of Analytical grade.

Methods

Preparation of drug-resinate complex

The method used for masking the style of Lornoxicam was complexation with activity resins like Polyacrylic acid (Kyron T-114), as per the subsequent procedure:

Step I

Drug and rosin were accurately weighed

in needed quantitative relation.

Step II

Then suspension of rosin was created in enough am ount of demineralised water associated stirred for Half an hour at 500rpm, so as to permit the chemical compound structure to swell uniformly.

Step III

Then drug was value-added slowly beneath stirred condition to Step II.

Step IV

The drug rosin mixtures were then ceaselessly stirred for eight to10hrs at five hundred to 600rpm and therefore the volume was created up to 100ml.

Preparation of drug-resinate granules and Lubrication

After drug-resin mixtures were stirred for needed time, the drug-resinates were completely washed with demineralized water for many times then filtered by victimization Whatman's paper and dried. The pulverized drug-resinate particles are wetted, created into damp mass. Then had sieve no-16 and dried at 60°C for half-hour. The dried granules are once more had Sieveno-16 over sieveno-44 to get uniform granules. These dried granules were lubricated with the appropriate excipients and used for the compression of the Lornoxicam Orally disintegrating tablets. Type path No. F001 to F005, Trail No. F003 is taken into account for the more development as the style is found smart with the F003. Next many trails were created to settle the appropriate Disintegrant as shown within the Table No.2. when finalisation of the appropriate concentration of the Polyacrylic acid (Kyron T-114) and therefore the suitable disintegrating agent, many trails were taken with sweeteners and at last flavor to more improve the acceptance of the Lornoxicam. Orally disintegrating tablet dosage form as shown in the Table No.2.

EVALUATION PARAMETERS

Pre-formulation Studies

Fourier transform Infrared Spectroscopy

The fourier transform infra-red analysis was conducted for the structure characterization. FTIR spectra of the pure drug, polymers and formulations were recorded by BRUKER FTIR instrument. close to 1mg of sample were mixed with 100mg of qualitative analysis grade KBr Pellets, samples were scanned within the IR vary from five hundred to 3500 cm-1, with a resolution of 4 cm-1.

Pre-compression studies of quick dissolving tablets Bulk density

It is the quantitative relation of total mass of powder to the majority volume of powder. It had been measured by running the burden powder (passed through commonplace sieve #20) into a measurement cylinder and initial weight was noted. This primary volume is termed the majority volume. It is expressed in g/ml and is given by

$$Db = M / Vb$$

Where, M is that the mass of powder

Vb is that the bulk volume of the powder.

Tapped Density

It is the quantitative relation of the whole mass powder to the broached volume of the powder. It had been determined by inserting a graduate, containing a notable mass of drug-excipients mix. The cylinder was allowed to fall into its own weight onto a tough surface from the peak of 10cm at two second intervals. The sound was continued till no more modification i n volume was noted.

$$Dt = M / Vt$$

Where, M is the mass of powder

VT is the Tapped volume of the powder.

Angle of Repose

It is outlined as, the utmost angle attainable between the surface of the pile of the powder and also the horizontal plane. The angle of repose was resolute by the funnel methodology urged by Newman. Angle of repose is decided by the subsequent formula:

Tan θ = h/r

Therefore θ = Tan -1 h/r

Where θ = Angle of repose

h = height of the cone

r = Radius of the cone base.

Compress ability Index

The compressibility index has been planned as an indirect live of bulk density, size, shape, area, wet content and cohesiveness of materials as a result of all of those will influence the determined compressibility index.

Carr's compressibility index (%) = [(Dt-Db) X 100] / Dt

Where Dt is the tapped density

Db is the bulk density

Hausner's ratio

Hausner's quantitative relation is an indirect index of the convenience of powder

Flow. It's calculated by the subsequent formula.

Hausner's ratio = Dt/Db

Where, Dt is the tapped density,

Db is the bulk density.

Post compression studies of Lornoxicam oral disintegrating tablets

Tablet thickness test

Randomly ten tablets were taken from every formulation trial batch and their thickness was measured employing a Vernier calipers.

Weight variation test

The weight variation take a look at is allotted so as to make sure uniformity within the weight of tablets in an exceedingly batch. The whole weight of twenty tablets from every formulation was resolute and also the average was calculated. The individual weights of the tablets were additionally determined accurately and also the weight variation was calculated.

Hardness Test

The hardness of tablet is a sign of its strength. The force is measured in weight unit and also the hardness of concerning 3-5 kg/cm2 is taken into account to be satisfactory for uncoated tablets. Hardness of ten tablets from every formulation was resolute by Monsanto hardness tester.

Friability test

It is measured of mechanical strength of tablets. Roche Friabilator is employed to work out the Friability by following procedure. Twenty tablets were weighed and placed in Roche Friabilator wherever the tablets were exposed to rolling and continual shocks ensuing from free falls at intervals the equipment. Once one hundred revolutions, tablets are removed, dedusted and weighed once more. The Friability was resolute because the share loss in weight of the tablets.

% Friability = (loss in weight / Initial weight) X 100

Disintegration Time

The USP device to check disintegration was six glass tubes that are "3 long, open at the highest, and control against 10" screen at the underside finish of the basket rack assembly. One tablet is placed in every tube and also the basket rack is positioned in one cubic decimeter beaker of water at 37± 2ºC, such the tablets stay below the surface of the liquid on their upward movement and descend not nearer than two.5cm from the underside of the beaker.

Taste evaluation

Taste analysis was done by a panel of half-dozen volunteers mistreatment time intensity methodology. 1 pill was control in mouth for 10 seconds bitterness levels were recorded instantly then at the top of 10seconds, 30seconds and 60seconds. Bitterness levels are once more noted and recorded and compared with F005 formulation that isn't having the taste masking agent. The knowledge was bestowed as shown within the Table No.4.

Mouth feel

The same human volunteers participated in taste analysis take a look at, were asked offer their opinion concerning the sensation of indefinite quantity type within the mouth and also the knowledge was bestowed as shown in Table No.4.

Assay

The assay of the planned methodology was observed by activity assay of the quality drug with relevance the sample drug. Ten tablets of marketed sample were taken and crushed. average weight is recorded. Combining weight to average weight is weighed and brought in to 100ml volumetrical flask. Little amount of pH 7.4 phosphate buffer is taken and sonicated for half-hour. Once sonication filter it and also the volume is adjusted with seven. 4 phosphate buffer to 100ml. The concentration was diluted to 10mcg/ml and also the asorbance was determined at 376nm. And the the troubles purity of the drug was caluculated mistreatment the formula

% purity= take a look at absorbance X Dilution prothrombinase Label claim commonplace absorbance

Drug content uniformity: 5 pills were taken arbitrarily and individual tablet was taken in an exceedingly 100ml volumetrical flask. Small amount of pH seven. 4 phosphate buffer is taken and sonicated for half-hour. Once sonication filter it and also the volume is adjusted with seven. 4 phosphate buffer to 100ml.the concentration was diluted to 10mcg/ml and also the asorbance was determined at 376nm. All the formulations were analysed spectrophotometrically. The mean and variance of all the formulations were caluculated.

***In vitro* dissolution studies**

In vitro dissolution of Lornoxicam quick dissolving tablets was studied in USP XXIII type-II dissolution equipment (Lab Asian country ds2800) using a paddle stirrer at fiftyrev mistreatment 900 millilitre of pH seven. 4 phosphate buffer at 37±0.5º as dissolution medium.

One pill was employed in every take a look at. Aliquots of dissolution medium (5 ml) were withdrawn at mere intervals of your time (5, 10, 15, 20, 30 min respectively) and analyzed for drug content by measurement the absorbance at 376nm. The volume withdrawn at on every occasion interval was replaced with recent amount of dissolution medium. Additive % Lornoxicam free was calculated and afore thought against the clock.

RESULTS AND DISCUSSION

Excepient Compatibility study

The possible interaction between the drug and the ion exchange resin was studied by FT-IR Spectroscopy.

FT-IR Spectroscopy

The possible interaction between the drug and the polymers was studied by FT-IR spectroscopy. In FTIR spectra similar peaks were obtained for pure Lornoxicam and Lornoxicam with kyron T-114 indicating that there are no physical or chemical interactions between drug and excepients the spectra is as follows:

FORMULATION OF LORNOXICAM ORAL DISINTEGRATINGTABLETS

Orodispersible tablets were prepared using Lornoxicam and Kyron T-114 complexes which were prepared by Physical mixture method, variable concentrations of super disintegrants and other excipients.

Table No.1: Drug content of prepared complex

S.No	Drug-resin complex ratio	%Drug release
1	1:1	85.20
2	1:2	84.8
3	1:3	85.25
4	1:4	75.10

On the basis of these observations Drug-kyron ratio 1:3 was finalized for further study.

Table No.2: Composition of all the trails taken during the development of the taste masked Lornoxicam Orally disintegrating tablets

S.No	INGREDIENTS	F-001	F-002	F-003	F-004	F-005	F-006	F-007	F-008	F-009	F-010	F-011
1	Lornoxicam	8	8	8	8	8	8	8	8	8	8	8
2	Kyron T-114	8	16	24	32	-	24	24	24	24	24	24
3	Water	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
4	LACTOSE SN21	128	120	112	104	136	97	97	97	91	91	91
5	SSG	-	-	-	-	-	15	-	-			-
6	CCS	-	-	-	-	-	-	15	-			-
7	CP	-	-	-	-	-	-	-	15	15	15	15
8	SUCRALOSE	-	-	-	-	-	-	-	-	2	4	4
9	LEMON FLAVOUR	-	-	-	-	-	-	-	-	-	-	2
10	AEROSIL	4	4	4	4	4	4	4	4	4	4	4
11	MG-STERATE	2	2	2	2	2	2	2	2	2	2	2
Total tablet weight (mg)		150	150	150	150	150	150	150	150	150	150	150

SSG = Sodium starch glycolate; CCS = Cross carmellose sodium; CP = Cros povidone.

Table No.3: Results of flow properties of different formulations of the Lornoxicam

S.No	Parameter⟶Batch No.	Angle of repose (θ)	Bulk density (g/cc)	Tapped Density (g/cc)	Compressibity index	Hausner ratio
1	F-001	19.35	0.293	0.331	11.48	1.13
2	F-002	24.32	0.289	0.321	12.03	1.11
3	F-003	21.06	0.285	0.324	14.46	1.14
4	F-004	21.01	0.280	0.317	14.05	1.13
5	F-005	25.35	0.284	0.322	13.43	1.15
6	F-006	21.16	0.283	0.325	12.96	1.15
7	F-007	23.32	0.284	0.323	12.03	1.13
8	F-008	19.11	0.285	0.312	11.82	1.15
9	F-009	24.12	0.293	0.324	11.23	1.13
10	F-010	24.18	0.289	0.312	11.15	1.10
11	F-011	23.12	0.280	0.320	11.98	1.10

Table No.4: Thickness, Diameter, Hardness, Friability, weight variation and *In-vitro* disintegration time

S.No	Batch no.: ⟶ Parameter	Thickness (mm)	Diameter (mm)	Hardness (kg/cm^2)	Friability (%w/w)	Weight variation (mg)	*In-vitro* disintegration time
1	F-001	3.9 ± 0.04	10.02	5.4 ± 0.5	0.421	146 ± 2	45
2	F-002	3.9 ± 0.03	10.01	5.5 ± 0.5	0.480	148 ± 2	52
3	F-003	3.9 ± 0.02	10.01	5.4 ± 0.5	0.453	147 ± 2	55
4	F-004	3.9 ± 0.02	10.02	5.5 ± 0.5	0.465	147 ± 2	53
5	F-005	3.9 ± 0.03	10.01	5.7 ± 0.5	0.458	148 ± 2	48
6	F-006	3.9 ± 0.05	10.02	5.8 ± 0.5	0.455	152 ± 2	15
7	F-007	3.9 ± 0.05	10.02	5.8 ±0.5	0.456	151 ± 2	12
8	F-008	3.9 ± 0.04	10.02	5.5 ± 0.5	0.476	153 ± 2	7
9	F-009	3.9 ± 0.05	10.01	5.7 ± 0.5	0.468	152 ± 2	7
10	F-010	3.9 ± 0.04	10.01	5.7 ± 0.5	0.476	149 ± 2	7
11	F-011	3.9 ± 0.03	10.02	5.8 ± 0.5	0.477	152 ± 2	7

Table No.5: Taste evaluation and Mouth feel for final formulation

Trail. No.	Volunteer.No.	Bitterness	Mouth feel
F- 011	1	a	++
	2	a	++
	3	a	++
	4	a	++
	5	a	++
	6	a	++

a = absent, ++ indicates more pleasant feeling

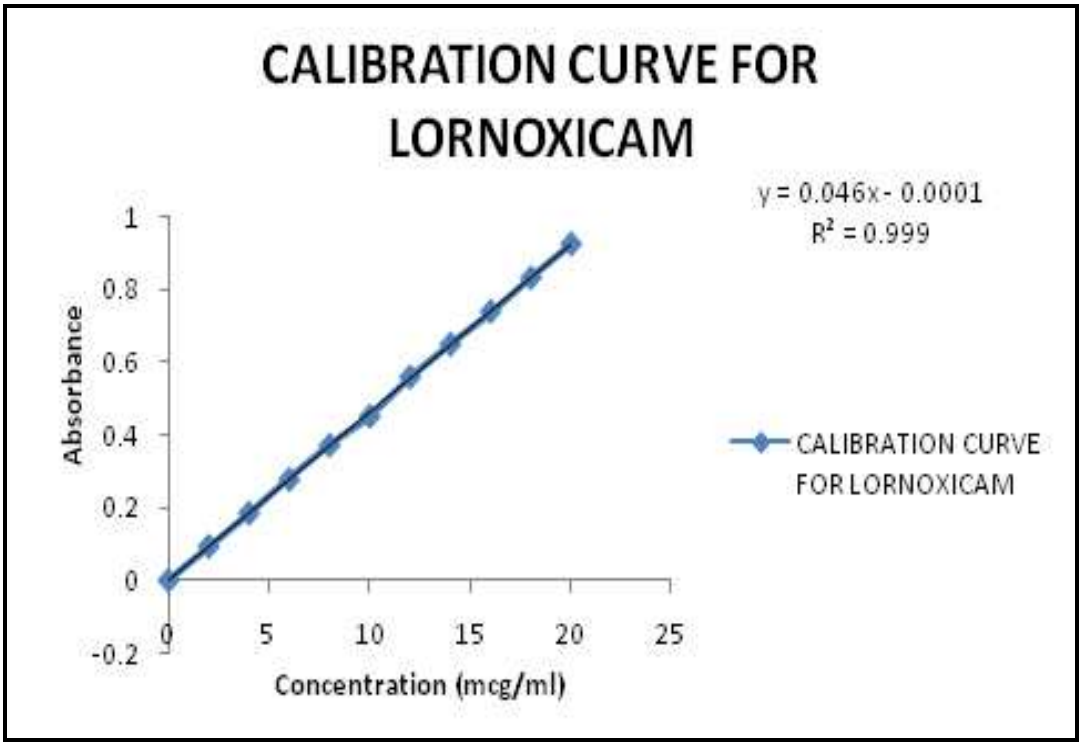

Figure No.1: Calibration curve for Lonoxicam

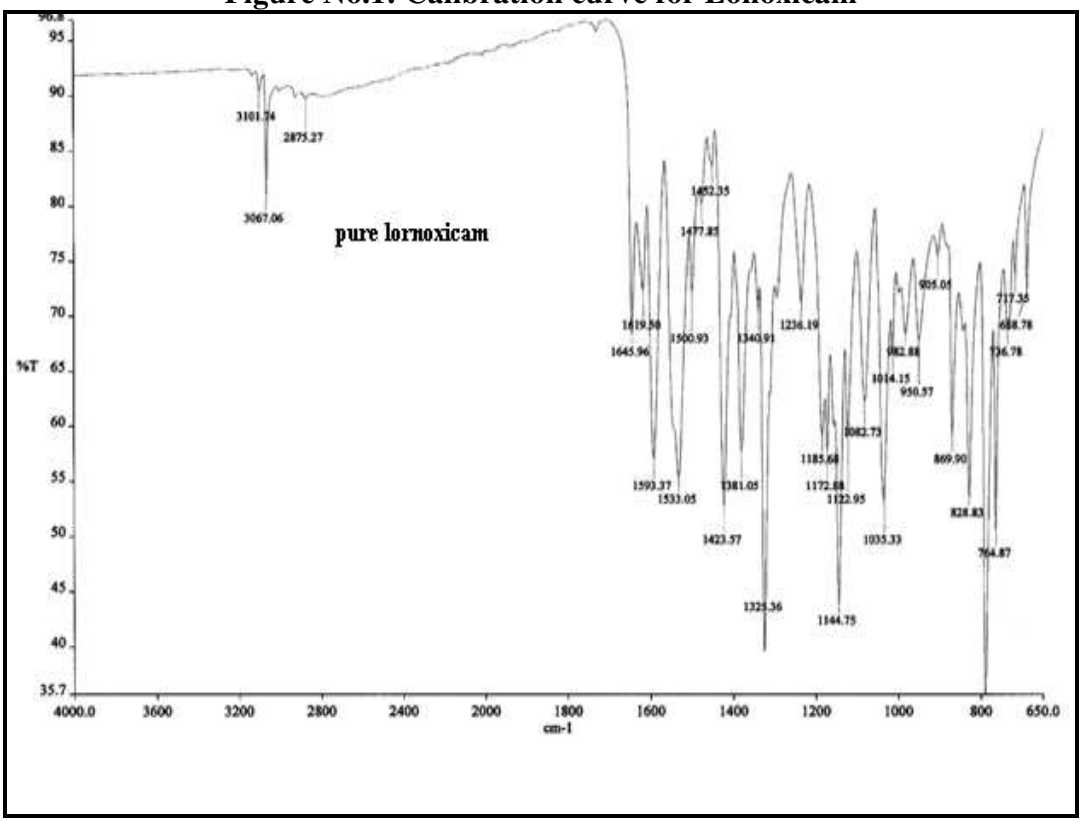

Figure No.2: FT-IR Spectra of Pure Loroxicam

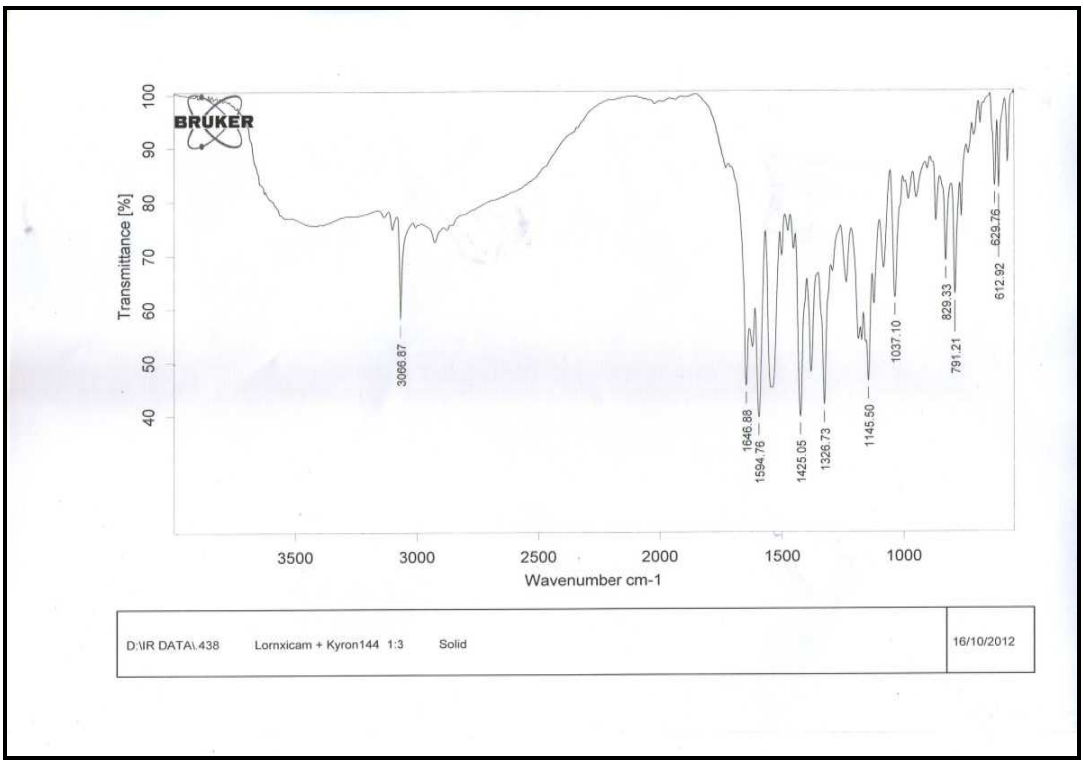

Figure No.3: FT- IR Spectra of Lornoxicam and Kyron T-114

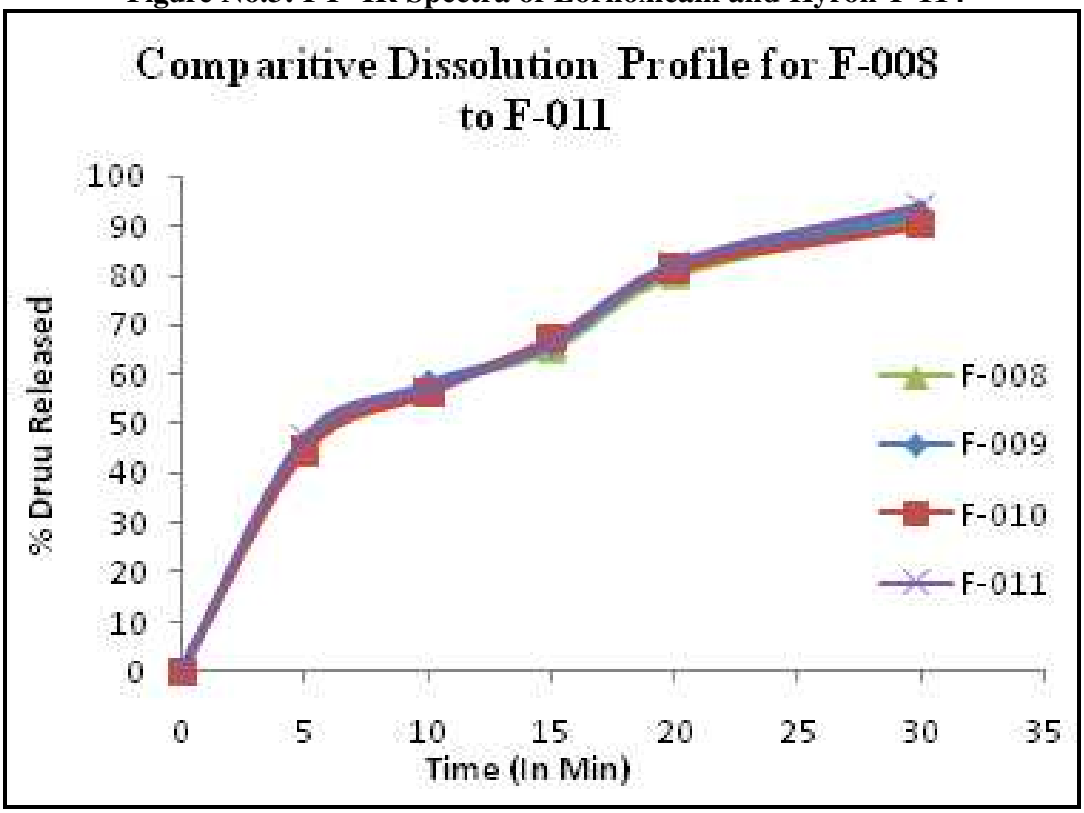

Figure No.4: Comparitive Dissolution profiles for cross povidone formulations

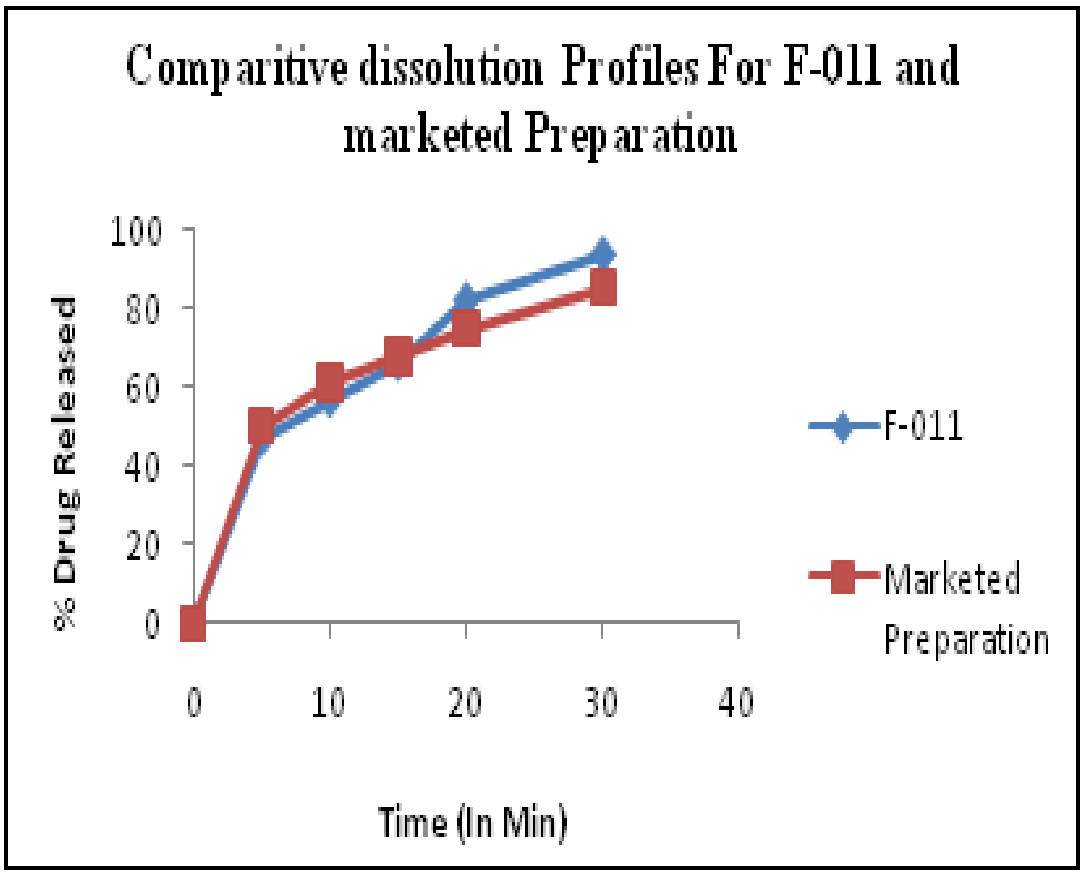

Figure No.5: Comparitive dissolution profiles for F-011 and marketed preparation

CONCLUSION

One of the issues encountered within the preparation of ODTs of Lornoxicam was the bitter style of the drug. Results advised that by complexing drug with Kyron T-114 in 1: three ratios disguised the bitter style of drug. Overall results advised that F-011 formulation containing crosspovidone in tenth concentration was higher and satisfy all the standards of ODTs and therefore the *In vitro* dissolution studies showed a drug unharness up to ninety three.8% in half-hour, that was found to be higher than an advertisement product (85.25%).

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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