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Research article

Formulation and development of orodispersible tablets of lornoxicam by using resinate inclusion complexes

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Abstract

Lornoxicam is a non-steroidal anti-inflammatory drug and it belongs to the class of oxicam. It is used for potent inhibitor of both COX-1 and COX-2. But it is a very bitter drug and insoluble in water. **Aim:** To mask the taste and to formulate into or dispersible tablet by complexation with ion exchange resins. Since, these tablets can be swallowed in the form of dispersion; they form a suitable dosage form for pediatric and geriatric patients. **Method:** A cation exchange resin like Kyron T- 134 was utilized for the complexation with drug. Drug-resinates was prepared in drug to resin ratio of 1:3.75. The prepared tablets were evaluated for general appearance, content uniformity, hardness, friability, taste evaluation, mouth feel, wetting time, disintegration time, and in-vitro dissolution studies. **Result:** Tablets with these resins have shown quick disintegrating features, i.e., within 20 seconds, which is very characteristic of orodispersible tablets. The dispersion not showing any bitter taste, indicate the capability of ion exchange resins used, both as taste masking and super disintegrating agents. Almost more than 90% of drug was released from both the formulations with in 1 hour. Further formulations were subjected to stability testing for three month at temperature at 40°C/ 75% RH.

Keywords: Taste masking, Super disintegrants, Lornoxicam, Orodispersibletablet, Ion-exchange Resins.

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1. Introduction

Oral route of drug administration have wide acceptance up to 50-60% of total people experience inconvenience in swallowing conventional dosage forms such as tablets when water is not available, in the case of motion sickness (kinetosis) and sudden episodes of coughing during the common cold, allergic conditions and bronchitis. Orodispersible tablets are not only indicated for people who have swallowing difficulties, but also are ideal for active people. Or dispersible tablets are also called as mouthdissolving tablets, melt-in-mouth tablets, fast dissolving tablets, rapimelts, porous tablets, quick dissolving etc [1].

Or dispersible tablets are those when put on tongue, disintegrates instantaneously, releasing the drug, which dissolves or disperses in the saliva. The faster the drug into solution, quicker the absorption and onset of clinical effect. Some drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach. In such cases, bioavailability of drug is significantly greater than those observed from conventional tablet dosage form

[2], [3].

Lornoxicam, [4], [5]. A member of the oxicam class of NSAIDs, showed efficacy in various clinical trials in the perioperative setting. Reduction of postoperative pain with Lornoxicam was demonstrated in gynecological, orthopedic, abdominal and dental surgery. Lornoxicam may offer potential as a better tolerated alternative or adjunct to opioid analgesics for the management of perioperative pain. Where oral treatment with NSAIDs is considered and fast onset of pain reduction is required, like oral/dental surgery and day-care surgery, the quick-release formulation of lornoxicam is a valuable alternative to the standard tablet.

2. Materials and methods

Lornoxicam was *a Kind* Gift sample *supplied by* Curex Pharma, Maharashtra, India. Avicel PH 102 and Aerosil were obtained from the Emcure ltd, Pune India as a gift sample. Tulsion 339; Indion 204, 214; Kyron T-134 were gifted by Thermax India Ltd., Ion Exchange India Ltd. and Corel Pharmachem Ltd. All other materials and solvents used in are of analytical grade.

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Preformulation studies:

1) Determination of threshold bitterness concentration of lornoxicam [6].

A panel of ten healthy human volunteers (age 20-25) was selected. A series of solutions of Lornoxicam in phosphate buffer of pH 6.8 of concentrations 5, 10, 20, 30, 40 and 50 g/ml were prepared. The volunteers held 10 ml of each solution in oral cavity for 60 sec and rated the taste on a scale from 0 to 4 (0: no bitterness, 1: threshold bitterness, 2: bitter, 3: moderate bitterness and 4: strong bitterness). Rinsing the mouth by distilled water and a gap of 30 min was given before next higher concentration was tasted. Based on the opinion of the volunteers, threshold bitterness concentration of Lornoxicam was judged.

2 Selection of method for taste masking of lornoxicam

Taste masking by formation of complexes with ion exchange resins

Tulsion 339; Indion 204, 214; Kyron T-134 were used in 1:1 drug: resin ratios. 100 mg of each resin was allowed to swell separately in 50 ml of deionized water for 90 min. 100 mg of Lornoxicam was added to each of them and stirred for 5 hrs. Each slurry was filtered and the residue i.e. resinate was washed again with 25 ml of deionized water. The combined filtrate was evaluated for drug content. The difference between amount of drug used initially and that remaining in the filtrate is the amount of drug loaded on the resin. The resin that showed optimum loading was subjected to optimization of drug loading process.

3) Optimization of various parameters for maximum drug loading

Drug loading process was optimized for maximum drug loading considering parameters as Follows [7].

Drug: resin ratio

For optimizing drug: resin ratio, 4 mg of Lornoxicam was added to each of the five beakers containing 04, 08, 10, 12 and 15 mg of resin swelled in 100 ml of deionized water. The mixture was stirred for 300 min. Drug Resin Complex was collected by filtration, washed with 50 ml of deionized water and evaluated for drug content.

Resin swelling time

Optimization of resin swelling time was carried out by keeping 100 mg of resin in each of the five beakers containing 100 ml of deionized water for 30, 60, 90, 120 and 180 min respectively. Drug Resin Complex was prepared as described above using 100 mg of Lornoxicam and percent drug loading was estimated [8].

Effect of pH

Loading pH was optimized by preparing Drug Resin Complex using 100 mg each of Lornoxicam and resin in 100 ml of deionized water and adjusting pH like 1.2, 3, 4, 5, 6, 7, 8 and 9 using standard solutions of hydrochloride and sodium hydroxide. Loading efficiency was determined at these conditions [9].

Stirring time

For optimizing stirring time, Drug Resin Complex was prepared by stirring 10 mg of Lornoxicam with 10 mg of resin in 10 ml of deionized water separately for 60, 120, 180, 240, 300 and 360 min and percent drug loading was evaluated.

4) Confirmation of complexation FTIR studies [10]

Lornoxicam, Kyron T-134 were subjected for FTIR studies. Samples were prepared using KBr disc method and spectra were recorded over the range 450 cm-1 to 4000 cm-1. Spectra were analyzed for drug- resin interactions and functional groups involved in the complexation process.

Thermal analysis

Differential scanning calorimetry (DSC) was performed using DSC instrument The samples were hermetically sealed in aluminum pans and heated over the temperature range 30° C to 300° C with heating rate of 10° C/min. Nitrogen gas was purged at rate of 40ml/min. to maintain inert atmosphere.

Estimation of drug content [11]

100 mg of Drug Resin Complex was stirred with 100 ml of 6.8 Phosphate buffer for 60 min so as to release the entire drug from Drug Resin Complex. The mixture was filtered and 1 ml of the filtrate was diluted to 100 ml using 6.8 Phosphate buffer. The absorbance of this solution was measured at 378 nm using 6.8 Phosphate buffer as blank and the content of Lornoxicam was estimated.

5) Formulation development of or dispersible tablets

Selection of superdisintegrant

To select superdisintegrant, a comparative study was carried out. Crospovidone, Croscarmellose Sodium were screened. Mouth Dissolving Tablets of Lornoxicam were prepared using one of these superdisintegrant, mannitol, Microcrystalline Cellulose, aspartame, flavor and colloidal sio2. Unit tablet weight was maintained at 150 mg. MDTs were evaluated for major parameters like disintegration time, wetting time and percent friability. Microcrystalline cellulose was selected as binder. Mannitol was selected as bulking agent because of its good compressibility, good flowing properties, good solubility in water, and a pleasant taste. More ever mannitol does not absorb water during storage. Aspartame as taste improvers. Aerosil was used as lubricant.

Selection of levels of materials

Or dispersible tablets, each containing Drug Resin Complex equivalent 4.0 mg of Lornoxicam were prepared. Amount of

Drug Resin Complex equivalent to 4.0 mg of Lornoxicam was determined from the content of Lornoxicam in Drug Resin Complex. For determining levels of superdisintegrant initial trial batches with different concentrations were carried out and evaluated for Disintegration Test and friability. Quantities of aspartame and flavor were limited to 0.1% w/w and 0.2% w/w as they were used only for the purpose of taste improvement. Magnesium stearate was used as a lubricant and initial trials showed 0.5% w/w was the optimum level for a good tablet surface and lubrication properties. Mannitol was used to make the total weight of the tablet to 150 mg.

Ingredient	F1	F2	F3	F4	F5	F6	F7	F8	F9
Drug Complex	18.98	18.98	18.98	18.98	18.98	18.98	18.98	18.98	18.98
Sod.s Glycolate	5.0	5.5	5.5						
Crosca .Sodium				6.0	6.5	7.0			
Crospovidone							7.0	7.0	7.5
Micro.cellulose	45.0	45.0	45.0	45.0	45.0	45.0	45.0	45.0	45.0
Aspartame	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0
Mg.stearate	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0
Flavor	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Aerosil	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Mannitol	69.02	68.52	68.52	68.02	67.52	67.02	67.02	67.02	66.52
Total	150	150	150	150	150	150	150	150	150

Table no 1: manufacturing formula of batches

6) Pre compression parameters [12], [13]

Bulk density and tapped density were determined using a bulk density apparatus. Angle of repose, compressibility index and Hausner ratio were evaluated as per methods described in USP 30-NF25. In the recent years compressibility index and the closely related Hausner ratio have become the simple, fast and popular methods of predicting powder flow characteristics. The basic procedure to calculate the compressibility index and Hausner ratio involves measuring the bulk volume (V_0) and final tapped volume (V_f). A 250 ml volumetric cylinder with 100 gm of the material is used for this purpose.

7) Post compression parameters

All the batches of tablets were evaluated for various parameters like weight variation, friability, hardness, drug content, disintegration and dissolution.

Weight variation test

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

Hardness test

The hardness of the tablet was determined using Monsanto Hardness Tester.

Friability test

Six tablets from each batch were examined for friability using Roche Friabilator (Tropical Equipment Pvt. Ltd. Mumbai, India) and the equipment was run for 4min at 25 revolutions per minute. The tablets were taken out, dedusted and reweighted and % friability was calculated

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

Dimensions of tablet:

The thickness of the tablets was determined using a Micrometer Screw gauge. Five tablets from each formulation were evaluated and average values were calculated [14].

Weight variation

For weight variation, 20 tablets of each formulation were weighed individually on an electronic balance, average weight was calculated and individual tablet weight was then compared with the average value to find out the deviation in weight. The % Weight variation also calculates [14]

Uniformity of content

100 mg of Drug Resin Complex was stirred with 100 ml of 6.8 Phosphate buffer for 60 min so as to release the entire drug from Drug Resin Complex. The mixture was filtered and 1 ml of the filtrate was diluted to 100 ml using 6.8 Phosphate buffer. The absorbance of this solution was measured at 378 nm using 6.8 Phosphate buffer as blank and the content of Lornoxicam was estimated [15, 16]

Disintegration time

According to the European pharmacopoeia the fast disintegrating/ or dispersible tablets should disintegrate within 3 minutes without leaving any residue on the screen. However it is difficult to assess the disintegration rate even in small amounts of water. Further the conventional test employs a volume of 900 ml of test solution compared to the volume of saliva in humans, which is limited to a few ml. Thus the disintegration rate obtained from conventional test does not appear to reflect the actual disintegration rate in human mouth. To overcome these problems, several methods have been proposed. In this work, disintegration time was assessed by a simplest method. 6 ml of phosphate buffer of pH 6.8 that simulated the volume and pH of saliva present in mouth was taken in a 25 ml measuring cylinder at 37±2°C and a MDL was placed in it. Time required for complete disintegration of the tablet was recorded as DL [17], [18].

Dissolution studies

Dissolution test was carried out using USP Type II dissolution test apparatus at $37\pm2^{\circ}$ C and 50 rpm speed. 900 ml of 6.8 phosphate buffer was used as dissolution medium. Time interval was from 0 min. to 45 min [19]

3. Result and discussion

Determination of threshold bitterness concentration of lornoxicam

Threshold bitterness concentration is the minimum concentration at which bitterness starts to appear and continues to provoke after 30s. Most of the volunteers rated 20 μ g/ml as the threshold bitterness concentration for Lornoxicam as shown in Table no 2. It was found that the taste masked form of the drug should not release more than or equal to 30 μ g/ml of the drug in mouth within 2 minutes for satisfactory taste masking.

Table No 2: Rating by the volunteers for different solutions
of Lornoxicam on the scale of bitterness

Volunteer	Rating on the scale of bitterness					
No.	10µg/	20µg/	30µg/	40µg/	50µg/	
110.	ml	ml	ml	ml	ml	
1.	0	0	1	1	2	
2.	0	1	1	2	3	
3.	1	0	0	2	3	
4.	0	0	1	2	3	
5.	0	1	1	2	3	
6.	0	0	1	3	3	
7.	0	1	0	2	3	
8.	0	0	1	1	2	
9.	0	1	0	2	3	
10.	0	0	1	2	3	

(0: no bitterness, 1: threshold bitterness, 2: bitter, 3: moderate bitterness and 4: strong bitterness).

Selection of method for taste masking of lornoxicam

The taste masked form of the drug should release the drug quickly in gastric juice but not in saliva. For mouth dissolving tablets, mouth feel is as important factor as the taste masking. The tablet should not disintegrate into large particles that cause gritty feel. Considering these criteria, granulation and coating of the drug as well as microspheres were not selected as approaches for taste masking. Granulation and coating of the drug may also get ruptured or fractures by compression forces and chewing. So ion exchange complex was investigated.

Taste masking by formation of complexes with ion exchange resins

Batch process was used to load Lornoxicam on the ion exchange resins (1:1 drug: resin ratio) in the preliminary trials. Indion resins (204, 214,) showed very small loading of the drug (< 15%) and poor taste masking. Tulsion resin showed improved taste masking but low values of drug loading (<30%). Kyron T-134 showed excellent taste masking and high drug loading (>90%). The process was repeated to check reproducibility of the results and showed a small variation (standard deviation \pm 0.94). Based on these studies, Kyron T-134 was selected for masking the bitter taste of Lornoxicam.

Optimization of various parameters for maximum drug loading

Loading of Lornoxicam on Kyron T-134 was carried out by batch process. Batch process is the preferred method for

loading a drug into finely divided ion exchange resins. Higher swelling efficiency in the batch process makes more surface area available for ion exchange. So batch process was selected.

Effect of drug: resin ratio

It was thus observed that optimum loading of Lornoxicam on Kyron T-134 occurred when used in 1:2.75 ratios. Hence the drug resin ratio in 1:3.75 proportions was used for further study

Table No 3: Effect of drug resin ratio on loading.

Drug: resin Ratio	% Drug Loading
1:0.5	56.43±0.98
1:1.0	70.13 ± 0.88
1:1.5	78.64 ± 0.89
1:2.0	78.95 ± 1.08
1:2.75	79.09±0.96

Effect Resin swelling time



Figure No 1: Effect of swelling time on drug loading

The results reveal that a 90-minute swelling time of Kyron T-134 in deionized water gave the maximum drug loading of 88.02% wt/wt. The swelling and hydrating properties of Kyron T-134 affect the rate of ion exchange, which in turn affects the percentage drug loading. In unswollen resin matrix, the exchangeable groups are latent and coiled toward the backbone; hence less drug-loading efficiency may be observed. It was observed that a swelling time of 90 minutes was sufficient for maximum drug loading. As shown in figure No. 1

Effect of pH

Table No 5: Effect of Kyron T-134 pH on Drug Loading.

pН	% Drug Loading
4	65.42 ± 1.98
5	69.73 ± 0.99
5.5	77.45 ± 1.05
6	80.02 ± 0.97
6.5	82.07 ± 1.32
7	88.64 ± 0.99

Effect of pH on drug loading

It was observed that optimum drug loading was achieved at neutral pH and was not much increased at pH higher than this. Hence for maximum drug loading environment pH was maintained at 7.



Figure no.: 2 Effect of pH on drug loading

Table No 6: Effect of Stirring Time on Drug Loading

Time (hr)	% Drug Loading
0.5	51.78
1	55.61
1.5	60.48
2	64.6
2.5	73.75
3	76.53
3.5	82.63
4	87.62
5	87.93



Figure no.: 3 Effect of stirring time on drug loading

It was observed that as the stirring time increased, loading efficiency was increased up to 5 hours of stirring. Loading was not considerably increased after this, so 5 hours was considered as the optimum contact time between Lornoxicam and Kyron T-134. As shown in figure No. 3.

Characterization of drug resin complex (DRC).

In-vitro taste evaluation

The objective for this test was to check whether the DRC releases any drug at salivary pH during a time interval of 120 Sec. No detectable amount of Lornoxicam dissolved in the phosphate buffer of pH 6.8 was detected at the end of 120 S. Thus the DRC did not release any drug at salivary pH. From the outcomes of in-vitro evaluation, it was found that the taste masking of Lornoxicam by making an ion exchange complex with Kyron T-134 was complete and satisfactory.

Confirmation of complexation

Formation of an ion exchange complex between Lornoxicam and Kyron T-134 was confirmed by FTIR and given peaks are reveled with final formulation as peak shows 3067 cm⁻¹-NH Stretching.,1646 cm⁻¹-C=O Group.,1597 cm⁻¹, 1559 cm⁻¹- N-H Group.,1157 cm⁻¹,1146 cm⁻¹,1173 cm⁻¹-O=S=O Group.,829 cm⁻¹-CH Stretching .,765 cm⁻¹-C-Cl bending vibration. DSC studies. Objective was to study the interaction between drug and resin.

FTIR Studies





Figure No 4: FTIR spectra of Lornoxicam (A), Kyron T-134(B) and DRC(C).

DSC Studies

The thermo gram of Lornoxicam shows a sharp peak at 230°C corresponding to melting of pure drug and its crystalline nature (Fig. 4A). The thermo gram of Kyron T-134 indicates its amorphous nature. (Fig.4B). Thermo gram of DRC indicates its amorphous nature and shows the absence of endothermic peak of melting of the drug (Fig. 4C). The formation of DRC and entrapment of Lornoxicam in the polymer matrix of Kyron T-134was thus confirmed from the findings of these thermo grams. Formulation of drug resin complex was confirmed by FTIR, and DSC studies. The IR spectrum of the complex showed absence of characteristic peaks of Lornoxicam and Kyron T-134. It was observed that the -COOK group of Kyron T-134 was involved in the complexation. The complex showed absence of sharp peaks of the drug and indicated entrapment of drug in the resin polymer matrix. Thermo grams of Kyron T-134 and drug resin complex indicated amorphous nature and absence of endothermic peak of Lornoxicam. Thus formation of drug resin complex was confirmed.



Figure no.:-5 DSC thermo grams of Lornoxicam



Figure no.:-6 DSC thermo grams of Kyron T-134



Figure no.:-7 DSC thermo grams of drug resin complex. (DRC)

Estimation of drug content

When DRC was prepared using all of the optimized parameters; percent of drug content was 48.12% w/w.

Evaluation of tablet blends

The nine batches tablet blends prepared were analyzed for various micromeritic and flow properties. Values of compressibility index were less than 15. Hausner ratio was between 1 and 1.17. Angle of repose was less than 30°. The compressibility index has been proposed as an indirect measure of bulk density, size and shape, surface area, moisture content and cohesiveness of materials because all of these can influence the observed compressibility index. The outcomes of these parameters indicated excellent flow properties and the blends were suitable for direct compression.

Table No 7: Evaluation of physical properties of tablet blends

Batches	Bulk density	Tapped density	Hausner's ratio	Compressibility index	Angle of repose
F1	0.594 ± 0.0084	0.7258 ± 0.0082	1.221	18.16	30.84±0.66
F2	0.6164 ± 0.006	0.7564 ± 0.009	1.224	18.49	32.40±0.287
F3	0.5921±0.0055	0.7258 ± 0.0082	1.225	18.41	34.39±0.674
F4	0.629 ± 0.0062	0.7826 ± 0.0095	1.243	19.57	32.99±1.072
F5	0.6428 ± 0.0065	0.7826 ± 0.0095	1.217	17.85	33.34±0.240
F6	0.6569 ± 0.0068	0.7965 ± 0.01	1.212	17.50	32.06±0.607
F7	0.6716 ± 0.0071	0.7665 ± 0.01	1.183	15.67	31.44±0.264
F8	0.7200 ± 0.0082	0.8258±0.011	1.146	12.79	28.64±0.564
F9	0.6809±0.0101	0.7759±0.009	1.136	12.23	28.56±0.531

The bulk density & tap density were found to be ranging from 0.592 ± 0.05 to 0.7200 ± 0.02 , 0.7258 ± 0.07 to 0.8258 ± 0.06 respectively. Hausner's ratio was found to be ranging from 1.136 to 1.243, and compressibility index was found to be ranging from 12.23 to 19.57

Evaluation of tablets

Table No 8: Physical evaluation of tablet formulations.

Batches	Weight Variation (mg)	Hardness (kg/cm ²)	Diameter (mm)	Thickness (mm)
F1	150.11 ± 1.61	4.9 ± 0.20	8 ± 0.05	2.8 ± 0.03
F2	150.17 ± 1.32	4.0 ± 0.25	8 ± 0.03	2.7 ± 0.02
F3	150.22 ± 1.47	4.2 ± 0.17	8 ± 0.03	2.6 ± 0.02
F4	149.82 ± 1.46	4.0 ± 0.50	8 ± 0.00	2.7 ± 0.01
F5	150.87 ± 2.11	4.5 ± 0.63	7.9 ± 0.04	2.5 ± 0.04
F6	150.42 ± 1.68	4.5 ± 0.52	8 ± 0.03	2.7 ± 0.02
F7	151.11 ± 1.20	4.5 ± 0.24	8 ± 0.06	2.8 ± 0.04
F8	149.25 ± 1.42	4.5 ± 0.57	8 ± 0.03	2.5 ± 0.03
F9	150.56 ± 1.63	4.6 ± 0.27	8 ± 0.03	2.6 ± 0.05

The tablets were within limits of weight variation allowed by I.P. 1996. Hardness of the tablets was within 4.0- 4.9 kg/cm². Diameter of the tablets was close to 8 mm (7.9-8). Thickness varied from 2.5-2.8 mm. Hardness of the tablets was within 2.9- 3.6 kg/cm². Formulation F1-F9 showed 4.5 ± 0.57 kg/cm² of hardness these hardness values show the good mechanical strength of tablet. The friability decreases from sodium starch glycolate > Crosscarmellose sodium > Crosspovidone Thus Crosspovidone is shows less friability hence good mechanical strength.

Batches	Disintegration Time (s)	Friability	% Assay	Wetting time
F1	42±1.02	1.12±0.02	98.44±1.02	32±0.65
F2	38±0.89	0.77±0.01	99.21±1.26	28±0.20
F3	33±1.21	0.8 ± 0.04	98.17±0.85	24±0.90
F4	28±0.67	0.53±0.02	99s.90±0.62	25±0.70
F5	26±0.96	0.46±0.03	98.53±1.08	23±0.83
F6	25±0.82	0.52 ± 00.02	98.02±0.96	21±0.22
F7	23±0.69	0.54 ± 0.01	97.93±1.21	24±0.47
F8	21±0.77	0.51±0.03	99.28±1.05	19±0.19
F9	20±0.81	0.48 ± 0.01	99.73±0.85	16±0.26

Table no. 9 Evaluation of various parameters of tablets

Summary and conclusion

The crucial aspect in the formulation of Or dispersible tablets is to mask the bitter taste and to minimize the disintegration time while maintaining a good mechanical strength of the tablet. To achieve the desired goal three disintegrates were studied such as sodium starch glycolate in concentration 2, 4, and 6%. Croscarmellose sodium in 1, 2 and 3%. And Crospovidone in 2, 3, and 4% the desired D.T. was not obtained with sodium starch glycolate and the compressibility was also low. In case of Crosscarmellose sodium till the D.T. was not satisfactory hence used the crospovidone which

showed less disintegration and also good mechanical strength was also seen as increase in concentration of Crospovidone, but higher % of crospovidone hampers the D.T. and also drug release. The tablets were prepared by direct compression method as it is less expensive and less time consuming process.

The final formulations of best batch was forwarded for the stability study and also the results of stability study were satisfactory but to establish the safety and efficacy of the formulation further stability studies are needed. The Experiment relates to formulation and development of oral pharmaceutical or dispersible tablet of Lornoxicam for administration of therapeutically effective amount of antiinflammatory drug substance to obtain a relatively fast or quick onset of action. Experiment conclude that or dispersible tablet is suitable for delivering drug with or dispersible drug delivery system which gives quick and rapid release of drug and to shows or dispersible release pattern

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Disintegration test

It was observed that Disintegration time of batches containing Crosspovidone was less as compared to the sodium starch glycolate and Crosscarmellose sodium. From disintegration data shown in table no.17, it is observed that 3% concentration of Crosspovidone shows the least DL. As the concentration of Crosspovidone increases above 3% it retards the DL. Wetting time was found in the range of 16 ± 0.19 sec to 22 ± 0.65 sec.

Dissolution test

Dissolution test was carried out using USP Type II dissolution test apparatus at $37\pm2^{\circ}$ C and 50 rpm speed. 900 ml of 6.8 phosphate buffser was used as dissolution medium at 378 nm. Time interval was from 0 min. to 45 min. formulation F1 showed 85.08% drug release at the end of 45 min. formulation F2,F3,F4,F5,F6,F7,F8,F9 showed 88.58%, 99.52%, 97.0%, 97.72%, 98%,98.51% drug release at the end of 45 min.respectively.



Figure no.: 8 Dissolution profile of batch F1-F9.

mouth dissolving tablet of Tramadol having adequate mechanical strength AAPS PharmSciTech,vol 10 no.2 june 2009:574-581

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