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Formulation and Evaluation of Piroxicam dispersible tablets using Natural disintegrants

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Abstract
The objective of necessary work to develop Piroxicam dispersible tablets using natural disintegrants which would release the drug rapidly with predetermined rate. Six batches of Piroxicam dispersible tablets were prepared by using various natural disintegrating agents in order to get required theoretical release profiles. The influence of the disintegrant concentration and granulation technique on the release of Piroxicam was studied. The formulated batches were characterized by different physical parameters. The study reveals that the formulation prepared by direct compression F5 exhibits better dissolution, disintegration at low concentration of natural disintegrants. Physical parameters of all the formulated tablets were within the acceptable limits.
Key words: Dispersible tablets, Isapghula husk, Natural disintegrants. Piroxicam.

Introduction:

Isapghula husk consists of dried seeds of the plant known as plantago ovata. It contains mucilage, which is present in the epidermis of the seeds[1]. Plantago ovata seed husk has high swellability and gives uniform and slightly viscous solution. Hence, it is used as a suspending agent. Cassia tora which is non toxic in nature have nutritional value and used in food material.

Piroxicam is an effective non steroidal anti-inflamatory drug used for the treatment of rheumatoid arthritis and osteoarthritis [2]. The usual daily dose is 20 mg. Sometimes given in two doses, because of long period required to obtain steady state.

Piroxicam is readily observed after oral or rectal administration and accumulation after repeated doses to reach steady state after about 7 days. The drug is extensively metabolized to apparently inactive metabolites and has a half life of about 40 hrs. in man.

Peak plasma concentrations are attained about 2 hrs after a single oral dose. Due to extended plasma a half life of Piroxicam, plasma concentration remain very stable over the next 24-48 hrs.

Piroxicam is highly protein bound and thus might be expected to displace other protein bound drugs. Piroxicam is an effective anti-inflamatory agent, it is about equal in potency to indomethacin as an inhibitor of prostaglandin biosynthesis, in vitro.

The present investigation was carried out to prepare dispersible tablets of Piroxicam (DTP) using plantago ovata seed husk (Isapghula), cassia tora [3] and cross linked tragacanth [4] as disintegrants, and to compare the formulations with marketed products.

Materials and methods:

Piroxicam was obtained from Eros Pharmaceuticals, Bangalore. Lactose procured by New Modern Chemical Corporation, Mumbai. Tragacanth, magnesium stearate was procured from S.D. Fine Chemicals Ltd, Mumbai. Isapghula husk was procured by Pragathi Pharmaceuticals, Belgaum.

The isapghula husk was dried at 50 ^{0}c mixed and powdered and passed through sieve #100. Cassia tora seeds were procured from Pragathi Pharmaceuticals, Belgaum. The seeds were dried at 5 0^{0}c for 24hrs and then powdered and treated similarly as in case of isapghula husk.

Cross linking of tragacanth was done by mixing dry tragacanth powder and epichlorhydrin in ratios ranging from 1:0.2 to 1:0.8 were allowed to react at temperatures ranging from 37 ^{0}c to 105 ^{0}c. The reaction time was varied in between 45 to 120min. Other materials used in the formulation and evaluation were of Pharmacopoeial grade.

Preparation of dispersible tablets [5,6].

Dispersible tablets of Piroxicam were prepared using disintegrants isapghula husk, cassia tora seeds and cross linked

Table 1: Composition of Piroxicam dispersible tablets

Sl..No	INGREDIENTS	F1	F2	F3	F4	F5	F6
01.	Piroxicam	20 20 20	20 20 20				
02.	Isapghula husk	60	-- -- 15			-- --	
03.	Cross linked tragacanth	-- 60		-- -- 15			--
04. Cassia	tora	--	-- 60		-- -- 15		
05.	Starch paste	5.0 5.0	5.0 --			--	--
06.	Starch	-- -- --	5.0			5.0	5.0
07.	Lactose	205.0	205.0	205.0 250		250	250
08.	Talc	5.0 5.0	5.0 5.0	5.0 5.0			
09.	Magnesium stearate	5.0 5.0	5.0 5.0	5.0 5.0			
Total weight of each tablets		300	300	300	300	300	300

F1, F2 & F3 are prepared by wet granulation and F4, F5 & F6 are prepared by direct compression method.

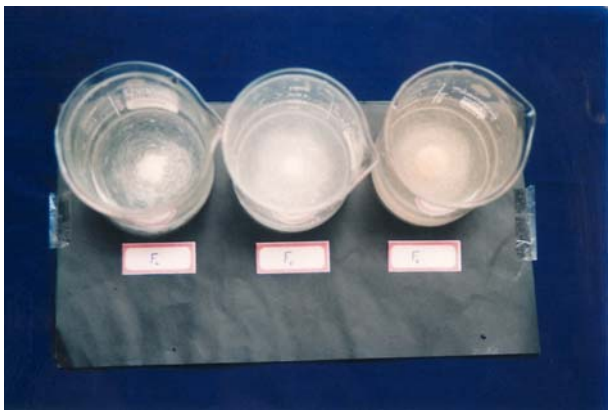


Fig 1: Dispersion patterns of for mulations of F1 F2 F3 after 120 sec

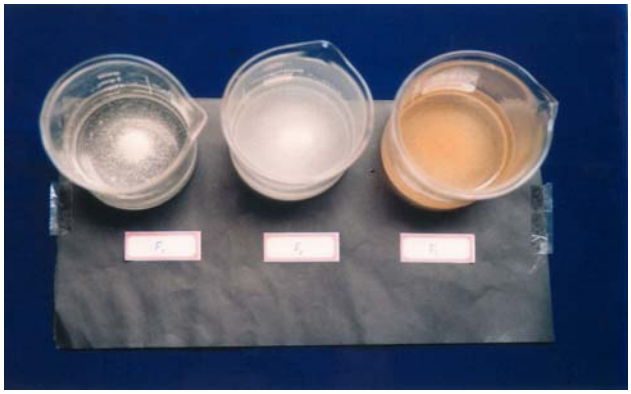


Fig 2: Dispersion patterns of for mulations F4 F5 F6 after 50sec

tragacanth (prepared as mentioned earlier) 5% in direct com pression and 20% in wet granulation in each for mulation. The composition of for mulation is given in Table-1. The ingredients are thoroughly mixed, sieved and lubricated and compressed. In wet granulation methods the ingredients are thoroughly m ixed and passed through sieve # 22. Granules thus obtained were compressed by tablet punching machine.

Evaluation of dispersible tablets of Piroxicam [7,8**].**

Dispersible tablets were evaluated under these parameters such as weight variation, hardness, f riability loss, disintegration, drug content uniform ity and dispersion patterns [9]. Disintegration tim e was determined using Electrolab tab/cap disintegration apparatus distilled water as a disintegration m edium. Each for mulation was t ested for uni form dispersion as per official standards. One tablet was placed in a beaker containing 25m l of water at 37 ± 2^0c. After disintegration, beaker was shaken and this fluid was passed through the sieve # 22. Hardness of the tablet was tested using a Pfizer h ardness tes ter and friability b y Roche f riabilator. Drug content w as dete rmined using UV spectrophotometer (UV 1201, Shim adzu Japan) at 333nm . The evaluation parameters were shown in Table-2.

Dissolution studies [10].

In vitro dissolution studies were c arried out on USPXXXIII table t dis solution apparatus using pH 1.2 buffer 900m l at 100rpm at 37±5 ^{0}c, em ploying paddle method. Single tablet from each formulation was used for the studies. Samples were withd rawn and diluted appropriately to get concentr ation 2 to 12mcg/ml. The withdrawn sam ple replaced with buffer solution to maintain

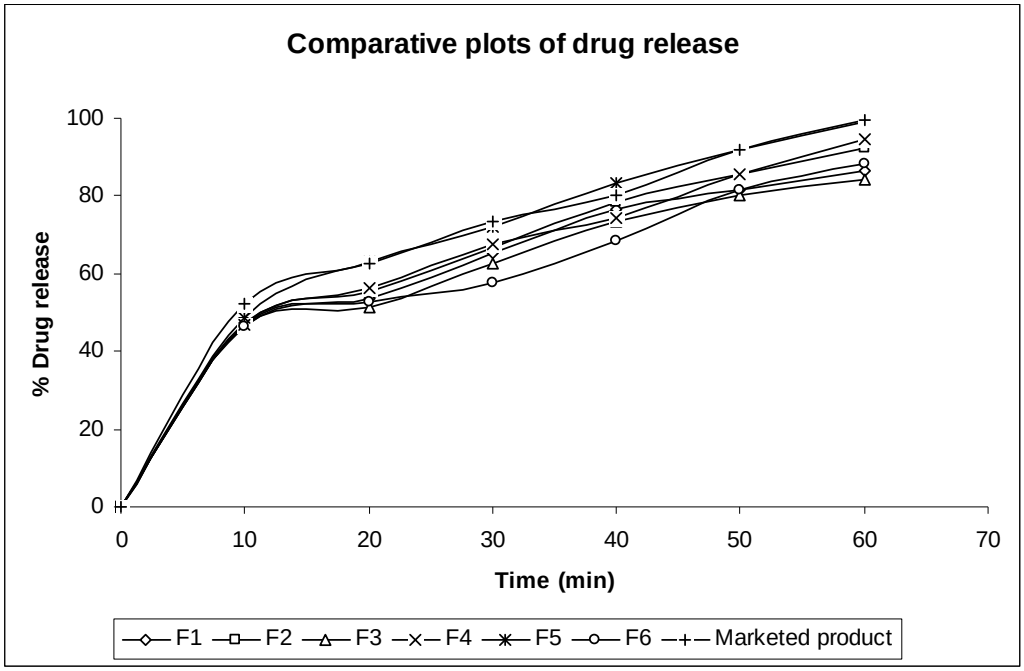
Table 2: Results of various physical evaluation parameters of Piroxicam dispersible tablets.

Parameter	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**X**
Diameter(mm) ± S.D (n=3)	10.06 ±0.030	10.08 ±0.029	10.08 ±0.029	10.11 ±0.028	10.08 ±0.029	10.06 ±0.030	10.08 ±0.029
Thickness(mm) ± S.D (n=3)	2.266 ±0.0086	2.263 ±0.0061	2.266 ±0.003	2.261 ±0.005	2.244 ±0.009	2.255 ±0.008	2.242 ±0.009
Content uniformity ± S.D (n=3)	98.33 ±1.14	99.06 ±1.33	92.86 ±2.48	100.99 ±3.11	101.02 ±2.44	99.61 ±1.75	99.99 ±1.33
Weight variation (mg) % Deviation	300.3 ±1.01	299.4 ±0.998	295.1 ±0.983	298.3 ±0.994	300.4 ±1.004	297.3 ±0.991	300 ±1.13
Disintegration test (sec) ± S.D (n=3)	160 ±0.03	150 ±0.09	170 ±0.02	70 ±0.01	60 ±0.03	80 ±0.19	50 ±0.03
Test for dispersion	Passes Passes		Passes	Passes Passes Passes Passes			
Hardness (kg/cm^2) ± S.D (n=10)	4.2 ±0.16	4.3 ±0.22	4.1 ±0.25	3.1 ±0.18	2.6 ±0.14	3.2 ±0.10	2.5 ±0.25
Friability %	0.67	0.65	0.64 0.81 0.82 0.85 0.82				
Tensile strength]	0.092	0.096	0.087 0.085 0.081 0.078 0.071				
Wetting time (sec) ± S.D (n=3)	475 ±3.3	460 ±2.6	490 ±1.1	260 ±2.7	245 ±2.08	270 ±1.7	240 ±2.08
Water sorption ratio ± S.D (n=3)	5.09 ±1.01	7.78 ±0.09	3.89 ±0.04	8.01 ±0.05	8.67 ±0.25	7.18 ±0.08	8.52 ±0.25
Dissolution efficiency %	60.46	62.47	58.95 62.32 67.54 58.25 67.54				

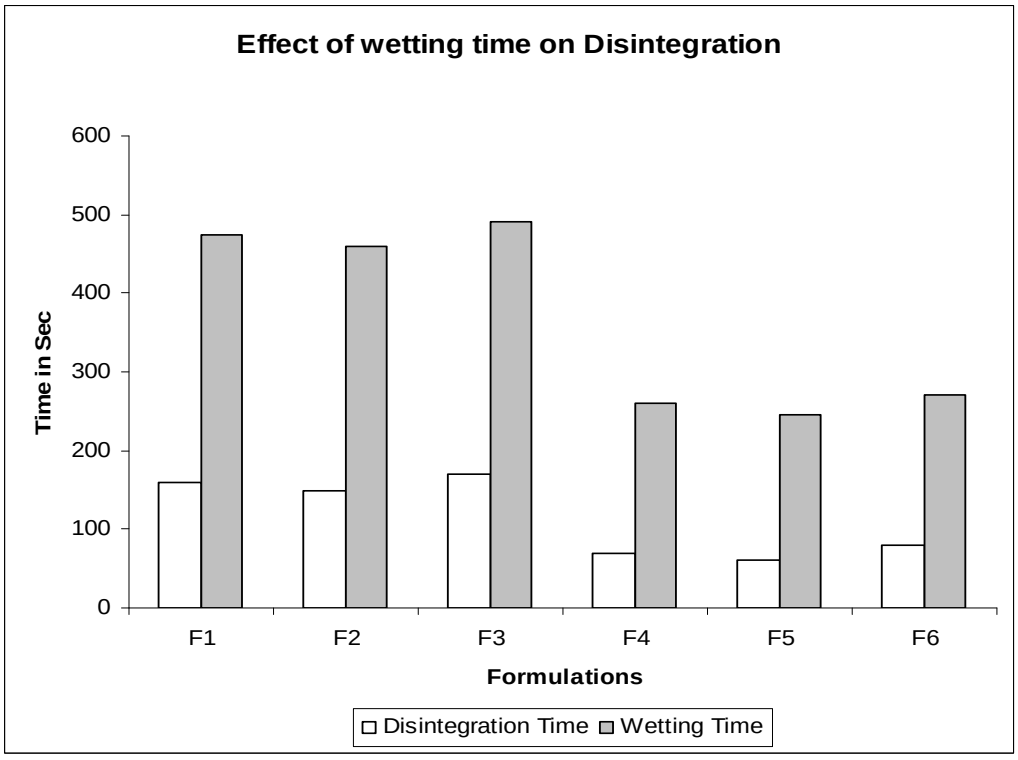
sink conditions. The absorbance was recorded on UV spectrophotometer at 333nm. All dissolution studies were carried out in triplicate. Dissolution data's were shown in Table-2.

Results and discussion:

Dispersible tablets each containing 20mg of Piroxicam were prepared employing three natural disintegrants namely isapghula husk, cassia tora and cross linked tragacanth using both direct compression and wet granulation method. The DT prepared was evaluated to compare the fast dissolving efficiency of the natural disintegrants for the release of Piroxicam. All the DT prepared contains Piroxicam within ±5 % of the labelled claim. Hardness and friability of tablets were within official (IP) and GMP limits. All the batches of the tablets prepared fulfilled the official (IP) tests for weight variation. The percentage deviation in the weight of the tablet was less than 3% in all the batches. All the tablets prepared were found to be disintegrating in water. As such the prepared dispersible tablets were of good quality with regard to weight variation, hardness, friability, drug content, thickness and diameter. The Piroxicam from all the dispersible tablets prepared was studied in an acidic medium of 0.1N HCl at pH 1.2.



Graph 1: Drug release profiles of Dispersible Piroxicam tables.



Graph 2: Effect of wetting time on Disintegration of Piroxicam dispersible tables.

The released data were given in T able-2 and drug release profiles of various tablets were shown in Fig-3. All the released parameters indicated variations or differences in the drug relea se f rom the tablets formulated with the different natural dis integrants. All the disintegrants were used at sam e concentration i.e., 20% in wet granulation method and 5% in direct compression.

The study reveals that form ulation prepared by direct compression F5 exhibits highest dissolution, disintegration at low concentration of natural disintegrant. Disintegration pattern of all the formulations showed satisfactory and uniform dispersion (Fig-1 and Fig-2).

Conclusion:

Piroxicam dispersible tablets using natural disintegrants which would release the drug rapidly with predetermined rate. The study reveals that the for mulation prepared by direct compression exhibits better dissolution, disintegration at low concentration of natural disintegrants.

Acknowledgements

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References:

[1] Wallis,T.E.,(2005)., Text b ook o f Pharmacognasy., 5 th ed : CBS Pub lishers an d Distributors. 208-209.

[2] Gupta,G.D., Gau d,R.S., (2 000 Sep-Oct),Formulation and Eval uation of Dispersible Tablets Using Natural Disintegrants; Ind.J. Pha.Sci.62(5).339-342.

[3] Kirtikar,K.K., Basu,B .D.,(1980). Indian Medicinal Pl ants. 2nd ed. Lalith Mo han Basu MB; Vol II. P. 110-111.

[4] Martindale-The Ext ra P harmacopoeia,(1996)., 31st ed. The Royal Pharmaceutical Society. 80-81.

[5] Kuchekar,B.S., Bhise,S.B ., Arumugan,V.,(2001 Oct- Dec), Desig n of Fast Dissolution Tablets;Ind.J. Pha.Edu.35 (4). 150-152.

[6] Chakrabarti,P.K, Khodape ,D.T., Bhattacharya,S., Naik,S.R ., (1991 May-J un). Dispersible Ta blet Dosa ge Form –ß-Lactum Antibiotics; Ind.J.Pha.Edu., 107-109.

[7] Leon Lachman., He rbert,Lieberman,A., Joseph.,Kani.L.,(1987)., T he Theory and Practice of Indust rial Pharm acy. Tablets. 3 rd ed. Varghese Publishing House, Bombay. 293-303.

[8] Banker,G.S., Rhodes,C .T., (1990)., Modern Pharmaceutics.. 2 nd ed. Marcel Dekker, 375-377.

[9] Indian Pha rmacopoeia.,(1996)., M inistry of Health an d Welfare, Delhi. Gov ernment o f India,. Vol II., 376.

[10] Chowdary,K.P.R, Su jatha R ao,D.,(1992 Jan - Feb).,Formulation and Eval uation of Dispersible T ablets of poorly Sol uble Drugs. Ind.J.Pha.Sci.,. 31-32.