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Design and evaluation of fast dissolving tablet of mefenamic acid

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ABSTRACT

The demand for fast disintegrating tablets has been growing during the last decade especially for geriatric and pediatric patients because of swallowing difficulties. Mefenamic acid is mainly indicated for to overcome the inflammation, however, it is also prescribed for the prophylaxis of premenstrual migraine headache. Hence, in the present work an attempt has been made to formulate fast dissolving tablets of Mefenamic acid by direct compression technique using various concentrations of super disintegrants like cross carmellose sodium (Ac-Di-Sol), fenugreek and plantago ovate. The formulated tablets were evaluated for crushing strength, friability, thickness, diameter, weight variation, wetting time, water absorption ratio, disintegration time, and percentage of drug release. All formulations showed satisfactory result. Among them formulation F_5 containing 2% of fenugreek exhibited complete disintegration time was within 20seconds. Dissolution data was exhibited an acceptable value >50. All parameters were within the limit of acceptance.

Keywords: Mefenamic acid, Fast Dissolving Tablet, Superdisintegrants, Fenugreek, Plantago ovate, Croscarmellose Sodium, Drug Release.

1. INTRODUCTION

Mefenamic acid belongs to NSAIDs group of drug. Chemically it is a derivative of benzoic acid. Its IUPAC name is 2-(2, 3-dimethylphenyl) aminobenzoic acid. Orally, its bioavailability is 90% with a protein binding of 90%. It is mainly metabolized in the liver with CY P_2 C_9 enzyme system and excreted via renal and fecal route [1-3]. It is mainly indicated for to overcome the inflammation, however, it is also prescribed for the prophylaxis of perimenstrual migraine headache [2, 3]. The conventional immediate release tablets have some limitation as dosage form such as frequent side effects and non compliance of the patients towards dosage regimen [4, 5]. In order to overcome such problems, the Mefenamic acid is now-a-days available as controlled release dosage form [6-8]. The aim and focal point of this study is to design and formulate the fast dissolving tablets of Mefenamic acid by using natural and synthetic superdisintegrants like Plantago ovate, Fenugreek and Croscarmellose sodium to release the drug [9, 10]. In vitro dissolution release profile of the fast dissolving Mefenamic acid tablets was evaluated.

2. MATERIALS AND METHODS

2.1. Chemicals and Instrumentation

The Chemical materials used in the research work included Sodium Hydroxide (Merck, Germany), Mono basic potassium phosphate (Merck, Germany), Mefenamic Acid (Gift sample from Micro labs, Hosur), Mannitol and Magnesium stearate (from the manufacturer of Ferro, Roquette), and natural superdisintegrants are collected from local market at Erode. The instruments used during the manufacturing and evaluations of tablet were Dissolution Apparatus (Pharma Test), Weighing Balance (Sartorius BT 4202 S (Max 420g)), Tablet punching machine (Rimek Mini Press – II, Cadmach Compression Machine), UV-Visible spectrophotometer (UVIDEC-1601 Shimadzu, Japan), Friability Tester (Electrolab EF- 2 - USP), Hardness Tester (Dr. Schleuniger). Disintegration tester (Electrolab ED – 2 AL - USP) and Tap density tester (Electrolab ETD – 1020 - USP)

2.2. Physical Analysis of Mixed Powder

For physical analysis, the mixed powder of drug and superdisintegrant was evaluated using numerous QC tests. The angle of repose was determined using funnel method. And the compressibility index was calculated by cylindrical method. All these tests were performed as per USP guidelines are tabulated in table no 1.

2.3. Formulation of Fast Dissolving Tablets

Fast dissolving tablets containing 200 mg of mefenamic acid were prepared by direct compression method, each tablet containing 60 mg of mefenamic acid was prepared by using Direct compression as per Formula given in Table no 2. The superdisintegrant Plantago ovata (5%, 10%, 15%), Fenugreek (5%, 10%, 15%) and Croscarmellose sodium (5%, 10%, 15%) were used in different proportion and in different combination. All the ingredients were passed through sieve # 85and kept in hot air oven at 60°C to make anhydrous and accurately weighed. The drug, superdisintegrant, MCC, Mannitol were mixed to improve drug distribution and content uniformity and triturated well in a mortar. Then Mg. Stearate and Talc was passed through sieve # 85, mixed and blended well with the initial mixture. The mixed blend of Drug and Excipient was compressed using single Punching Machine to produce tablet weighing 200 mg having diameter 4.5mm of FDT of mefenamic acid were prepared.

Table - 1: Physical analysis of Mixed powder

F.Code	Bulk Density (gm/ml)	Tapped Density (gm/ml)	Void Volume	Porosity	Haussner Ratio	Carr's Index (%)	Flow Property
F_1	0.4011	0.6823	24	0.4352	2.6987	28.45	Poor
F_2	0.4065	0.5971	13	0.2017	1.2398	18.22	Fair
F_3	0.3821	0.6434	21	0.4829	2.5543	26.76	Poor
F_4	0.4064	0.5589	14	0.2965	1.2512	19.50	Fair
F_5	0.4255	0.5263	11	0.1725	1.2364	17.34	Fair
F_6	0.3291	0.5622	19	0.3897	3.0187	29.76	Poor
F_7	0.3025	0.5433	23	0.4024	3.5431	34.87	very poor
F_8	0.3032	0.5498	18	0.3102	2.8765	28.04	poor
F_9	0.2984	0.6100	22	0.4512	3.0124	33.98	very poor
F_{10}	0.2900	0.6210	25	0.4657	3.1546	34.08	very poor
F_{11}	0.2456	0.6342	24	0.4532	3.2143	36.00	very poor
F_{12}	0.4058	0.5343	15	0.2723	1.2465	19.20	Fair
F_{13}	0.3412	0.5628	27	0.4567	3.4010	36.76	very poor
F_{14}	0.2946	0.6110	25	0.4576	3.4122	37.76	very poor
F_{15}	0.2434	0.5789	21	0.4423	3.3532	36.84	very poor

Table - 2: Formulations of Fast Dissolving Tablet (Quantities in mgs)

F.Code	Drug	S_1 (Plantago Ovata)	S_2 (Trigonella Foenum-graceum)	S_3 (Croscarmellose sodium)	MCC	Mannitol	Talc	Mg. Stearate
F_1	60	10	-	-	115	500	600	400
F_2	60	20	-	-	105	500	600	400
F_3	60	30	-	-	95	500	600	400
F_4	60	-	10	-	115	500	600	400
F_5	60	-	20	-	105	500	600	400
F_6	60	-	30	-	95	500	600	400
F_7	60	-	-	10	115	500	600	400
F_8	60	-	-	20	105	500	600	400
F_9	60	-	-	30	95	500	600	400

Table - 3: Evaluation of formulated tablets

F.Code	Thickness	Weight variation (% Deviation)	Hardness test (kg/cm²)	Disintegration time (In Sec)	% Friability	Wetting time (In Sec)	Uniformity Dispersion
F_1	3.44	(-) 2.0816 – 2	8	13	1.547466	10	Pass
F_2	3.42	(-) 2.0816 – 2	7	10	1.045719	8	Pass
F_3	3.44	(-) 0.7875 – 0.7758	7	25	0.492361	15	Pass
F_4	3.52	(-) 0.7875 – 0.7758	9	22	0.470496	12	Pass
F_5	3.74	(-) 1.0452 – 1.0246	7	20	0.176154	14	Pass
F_6	3.53	(-) 1.0452 – 1.0246	9	11	1.045719	9	Pass
F_7	3.62	(-) 2.08163 – 2	7	16	1.307222	6	Pass
F_8	3.45	(-) 0.7875 – 0.7758	9	22	0.110066	11	Pass
F_9	3.52	(-) 0.7875 – 0.7758	7	8	1.212991	8	Pass

Table - 4: Cumulative % drug release for formulations F_1 – F_9

F_1	F_2	F_3	F_4	F_5	F_6	F_7	F_8	F_9
0	0	0	0	0	0	0	0	0
75.84	78.75	79.84	80.39	90.46	84.78	82.59	65.42	66.8
77.8	81.49	82.04	82.31	92.18	86.7	85.06	69.56	72.54
80	82.56	85.06	85.88	95.78	89.17	87.25	73.42	76.98
82.34	84.12	87.48	88.54	97	93.29	90.54	79.32	79.92
84.78	85.18	89.42	90.32	98.98	94.4	95.76	82.84	82.38
89.7	88.32	90.12	93.56	99.54	95.17	96.2	88.7	84.76

2.4. Evaluation of formulated tablets

During evaluation, the hardness of the tablets was determined by hardness tester (Dr.Schleuniger) and friability tests were performed using Roche friabilator. Disintegration test was performed by using Disintegration test apparatus (Electrolab ED – 2 AL-USP).

3. RESULTS AND DISCUSSION

3.1. Evaluation tests for tablets

The physical parameters such as hardness, friability tests related to fast dissolving tablets of Mefenamic acid containing fenugreek, plantago ovate and croscarmellowse sodium are given in table no 3. The Hardness of the tablets was in the range from 7 - 9 kg/cm2 which were within the acceptable range. The % friability test was performed and the loss of weight of the tablets was not more than 1% which was in the USP acceptable friability range.

3.2. In vitro Release study of Formulations

All the nine formulations were subjected for *in vitro* dissolution studies using tablet dissolution tester USP XXIII. The samples were withdrawn at different time intervals and analyzed at 285 nm. Cumulative drug release and cumulative % drug retained were calculated on the basis of mean amount of Mefenamic acid present in respective tablet.

The results obtained for *in vitro* drug release of the formulations F_1 to F_9 are tabulated in table no 4.

In preliminary studies, Disintegration properties of these tablets were dependant on content of superdisintegrating agents. Hence different ratios of drug: superdisintegrants were designed to study tablet drug release retardation. Faster release was obtained from tablets

containing optimum concentration of particular natural superdisintegrant.

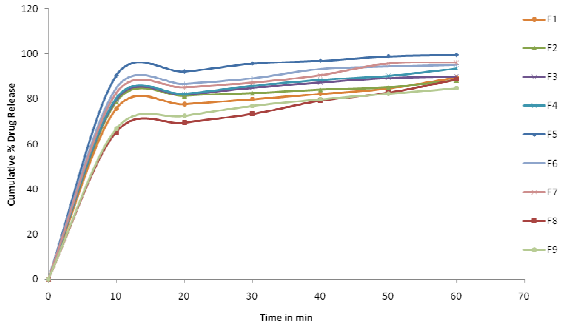

Figure - 1: Cumulative % Drug Release for Formulations F_1 – F_9.

From figure no 1 it can be observed that for all the tablets the rate and extent of drug release decrease with increase in concentration.

The drug release revealed that formulation containing plantago ovate i.e. formulation F_1, F_2 and F_3 showed 89.7 %, 88.32% and 90.12% of drug release after one hour, respectively. Formulation containing Fenugreek reveals that formulations F_4, F_5 and F_6 show 93.56%, 99.54% and 95.17% at the end of one hour respectively. Formulation containing Croscarmellose Sodium reveals that formulations F_7, F_8 and F_9 show 96.2%, 88.7% and 84.76% at the end of one hour respectively.

In all the formulations F_5 shows maximum drug release retardation because of optimum concentration i.e. 99.54%.

3. CONCLUSION

In the present study, the superdisintegrant property of *Fenugreek* seeds has been explored. The tablets disintegrated much faster and consistently when fenugreek was used as a superdisintegrant compared with plantago ovate and crosscarmellose sodium. It can be concluded that *Fenugreek* seeds could be used as a natural superdisintegrant in the formulation of fast dissolving tablets.

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