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Research Article

FORMULATION AND INVITRO EVALUATION OF TENOXICAM ORAL DISPERSIBLE TABLETS

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ABSTARCT

In the present work, an attempt has been made to develop fast disintegrating tablets of Tenoxicam. Novel method of co processed super disintegrates technology was employed to formulate the tablets using co processed polymers like vivasol,polyplasdone. All the formulations were prepared by direct compression method. The blend of all the formulations showed good flow properties such as angle of repose, bulk density, tapped density.then checked for compatability using FTIR and DSC studies. The prepared tablets were shown good post compression parameters and they passed all the quality control evaluation parameters as per I.P limits. Among all the formulations F14 formulation showed maximum drug release i.e., 99.3% in 4 min hence it is considered as optimized formulation. The F14 formulation contains CP5 as super disintegrate in the concentration of 40 mg. (CP 5 contains Vivasole and polyplasdone XL in 3:1 ratio).

KEYWORDS: *Tenoxicam, Co processed super disintegrates, Vivasole and Polyplasdone XL.*

INTRODUCTION

Drug delivery systems (DDS) are a strategic tool for expanding markets/indications, extending product life cycles and generating opportunities. DDS make a significant contribution to global pharmaceutical sales through market segmentation, and are moving rapidly.Drug delivery systems are becoming increasingly sophisticated as pharmaceutical scientists acquire a better understanding of the physicochemical and biochemical parameters pertinent to their performance [1-4].

Despite of tremendous advancements in drug delivery, the oral route remains the perfect route for the administration of therapeutic agents because the low cost of therapy, ease of administration lead to high levels of patient compliance [5, 6].

It is always the aim of a scientist or a dosage form designer to enhance the safety of a drug molecule while maintaining its therapeutic efficacy. Recent advances in NDDS aim for the same by formulating a dosage form, convenient to be administered so as to achieve better patient compliance. Mouth Dissolving Tablet (MDT) is one among such approaches [7-9].

Improved patient compliance has achieved enormous demand. Consequently demand for their technologies is also increasing many folds. To develop a chemical entity, a lot of money, hard work and time are required. So focus is rather being laid on the development of new drug delivery systems for already existing drugs, with enhanced efficacy and bioavailability, thus reducing the dose and dosing frequency to minimize the side effects [10].

The oral route of administration is the most preferred route due to its many advantages like ease of administration, accurate dosage, self-medication, pain avoidance, versatility and patient compliance. Tablets and capsules are the most popular dosage forms [11, 12].

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MATERIALS AND METHODS

Experimental method:

Materials:

Tenoxicam, Microcrystalline cellulose, Vivasole, Polyplasdone XL, Magnesium stearate, Talcall the chemicals used were lab grade.

Formulation of Fast dissolving tablets of Tenoxicam:

Preparation of co processed super disintegrates:

Co processed super disintegrates were prepared by using sodium Vivasole and polyplasdone XL. The super disintegrates were mixed in different concentrations and labeled as CP1, CP2, CP3. The blend of super disintegrates was mixed thoroughly for a period of 15 min, collected and used for preparing formulations in different concentrations table 1.

Preparation of tablets:

Composition of Tenoxicam Fast dissolving Tablet by direct compression is shown in table 2. All the ingredients were weighed. Required quantity of drug and excipient mixed thoroughly in a polybag. The blend is compressed using rotary tablet machine-10 station with 6mm flat punch, B tooling. Each tablet contains 20 mg Tenoxicam and other pharmaceutical ingredients table 2.

RESULTS AND DISCUSSION

Standard Calibration curve of Tenoxicam:

Evaluation Parameters for Fast Dissolving Tablets of Tenoxicam:

Pre-compression parameters: The data's were shown in Table 4. The values for angle of repose were found in the range of 25°-30°. Bulk densities and tapped densities of various formulations were found to be in the range of 0.41 to 0.50 (gm/cc) and 0.50 to 0.58 (gm/cc) respectively. Carr's index of the prepared blends was fall in the range of 13.06% to 18.18%. The Hausner ration was fall in range of 1.14 to 1.22. From the result it was concluded that the powder blends had good flow properties and these can be used for tablet manufacture.

Invitro dissolution studies were carried out by using 500ml of 6.8 pH phosphate buffer in USP dissolution apparatus by using paddle method. The dissolution studies were carried out for about 30 min.The dissolution data for all the formulations were given in the Table 7.

From the tabular column 6 it was evident that the formulations prepared with super disintegrate CP5 showed maximum % drug release in 4 min i.e. 99.3%, 96.3% (F13, F14) formulations and the concentration of super disintegrate is 30mg,45 mg). So the principle of coproceesed super disintegrates was found to be useful to produce oro dispersible tablets. F13 formulation was considered as optimized formulation as it contains less concentration of super disintegrate.

Table No. 1: Composition of co processed super disintegrates

Ingredients	CP1	CP2	CP3	CP4	CP5
Vivasol (mg)	500	500	500	1500	1000
Polyplasdone XL (mg)	500	1000	1500	500	500

CP = Coprocessed super disintegrate

Table No. 2: Composition of various tablet formulations

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12	F13	F14	F15
Tenoxicam (mg)	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20
CP 1(mg)	20	40	60	-	-	-	-	-	-	-	-	-	-	-	-
CP 2(mg)	-	-	-	20	40	60	-	-	-	-	-	-	-	-	-
CP 3(mg)	-	-	-	-	-	-	20	40	60	-	-	-	-	-	-
CP 4 (mg)	-	-	-	-	-	-	-	-	-	20	40	60	-	-	-
CP 5(mg)	-	-	-	-	-	-	-	-	-	-	-	-	20	40	60
Mg St(mg)	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Talc(mg)	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
MCC(mg)	Qs	Qs	Qs	Qs	Qs	Qs	Qs	Qs	Qs	Qs	Qs	Qs	Qs	Qs	Qs
Total wt(mg)	150	150	150	150	150	150	150	150	150	150	150	150	150	150	150

Table No. 3: Concentration and absorbance obtained for calibration curve of Tenoxicam in 6.8 pH phosphate buffer

S. No.	Concentration (µg/ml)	Absorbance* (at 278 nm)
1	0	0
2	5	0.106
3	10	0.177
4	15	0.265
5	20	0.344
6	25	0.431

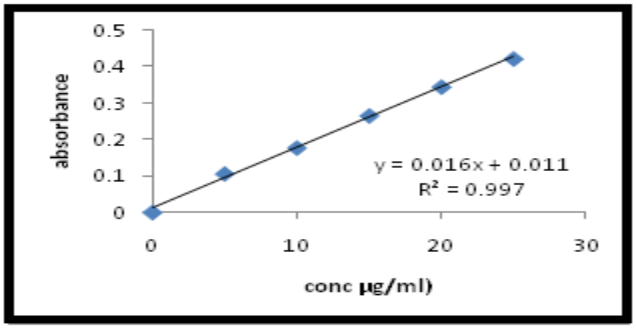

Fig. 1: Standard graph of Tenoxicam 6.8 pH phosphate buffer

Table No. 4: Pre-compression parameters

Formulations	Bulk Density (gm/cm²)	Tap Density (gm/cm²)	Carr's Index(%)	Hausner ratio	Angle Of Repose(θ)
F_1	0.45±0.03	0.55±0.04	18.18±0.01	1.22±0.09	27.91±0.09
F_2	0.47±0.06	0.55±0.03	14.54±0.04	1.17±0.07	28.23±0.06
F_3	0.50±0.04	0.58±0.06	13.79±0.03	1.16±0.06	29.34±0.04
F_4	0.46±0.07	0.55±0.01	16.36±0.06	1.19±0.03	26.71±0.06
F_5	0.50±0.01	0.58±0.06	13.79±0.04	1.16±0.06	29.34±0.03
F_6	0.47±0.06	0.55±0.04	14.54±0.07	1.17±0.03	28.23±0.01
F_7	0.50±0.04	0.58±0.07	13.79±0.03	1.16±0.01	29.34±0.07
F_8	0.41±0.09	0.50±0.03	18.34±0.06	1.21±0.07	26.78±0.09
F_9	0.41±0.03	0.50±0.04	18.02±0.07	1.21±0.06	26.78±0.09
F10	0.45±0.09	0.55±0.03	18.18±0.04	1.22±0.09	25.85±0.06
F11	0.48±0.01	0.57±0.07	15.78±0.03	1.18±0.04	27.45±0.01
F12	0.46±0.07	0.54±0.03	14.81±0.06	1.17±0.03	28.12±0.04
F13	0.49±0.03	0.58±0.06	15.51±0.01	1.18±0.04	27.02±0.03
F14	0.51±0.04	0.59±0.03	13.55±0.04	1.15±0.03	26.36±0.09
F15	0.41±0.09	0.49±0.04	16.32±0.03	1.19±0.09	28.75±0.09

Table No. 5: Post-Compression parameters

Formulation code	Weight variation (mg)	Hardness (kg/cm²)	Thickness (mm)	Disintegration Time (sec)	Friability (%)	Assay (%)
F1	155.9±0.23	2.5±0.26	4.59±0.21	20.33±0.29	0.43±0.29	97.23±0.21
F2	154.4±0.26	2.3±.23	4.64±0.26	23.66±0.21	0.34±0.28	98.55±0.29
F3	160.7±0.24	2.5±0.29	4.59±.23	25.33±0.26	0.49±0.21	98.16 ±0.28
F4	159.2±0.21	2.4±0.24	4.58±0.22	19.00±.23	0.47±0.26	99.34±0.21
F5	149.4±0.28	2.3±0.28	4.59±0.24	20.33±0.28	0.49±.23	98.16 ±0.26
F6	152.4±0.29	2.6±0.22	4.64±0.28	22.66±0.24	0.34±0.26	98.55±.23
F7	151.3±0.22	2.5±0.22	4.59±0.24	20.33±0.26	0.49±.23	98.16 ±0.29
F8	157.3±0.22	2.3±0.24	4.56±0.26	17.00±.23	0.34±0.24	99.25±0.21
F9	152.32±0.24	2.3±0.26	4.56±.23	19.45±0.22	0.34±0.28	100.26±0.29
F10	148.36±0.26	2.5±.23	4.98±0.22	24.36±0.22	0.43±0.21	98.45±0.24
F11	145.34±.23	2.4±0.26	4.73±.23	23.72±0.28	0.52±0.28	99.36±0.28
F12	150.2±0.21	2.4±.23	4.82±0.26	20.63±.23	0.35±0.24	100.02±0.21
F13	151.3±0.28	2.2±0.21	5.03±.23	18.34±0.26	0.64±.23	97.34±0.22
F14	147.6±0.29	2.3±0.28	5.13±0.24	17.47±.23	0.53±0.26	99.36±.23
F15	149.4±0.22	2.5±0.22	5.32±0.21	19.35±0.24	0.48±.23	98.63±0.26

Invitro Dissolution studies:

Table No. 6: Invitro dissolution data (F1 - F7)

Time (Min)	F1	F2	F3	F4	F5	F6	F7
2	25.4±0.3	31.7±0.05	40.8±0.9	24.3±0.9	39.5±0.6	44.9±0.3	35.2±0.7
4	39.6±0.05	40.5±0.3	56.72±0.05	31.6±0.6	56.3±0.3	58.4±0.6	50.2±0.3
6	48.6±0.6	51.9±0.9	76.16±0.3	49.3±0.05	76.2±0.9	63.1±0.3	62.1±0.6
8	54.3±0.9	62.4±0.6	87.4±0.7	58.3±0.3	89.7±0.3	79.7±0.6	73.5±0.3
10	66.4±0.7	79.1±0.3	98.5±0.6	74.3±0.7	97.8±0.3	89.3±0.05	80.4±0.9
15	73.1±0.3	85.5±0.7		88.1±0.6		98.9±0.3	89.3±0.05
20	80.6±0.7	95.2±0.6		97.6±0.7			94.2±0.3
25	91.5±0.6						100.2±0.7
30	97.86±0.9						

Table No. 7: Invitro dissolution data (F8 – F15)

Time (Min)	F8	F9	F10	F11	F12	F13	F14	F15
2	44.2±0.7	53.2±0.4	43.7±0.9	54.2±0.4	75.2±0.9	53.2±0.4	79.3±0.7	83.1±0.4
4	52.1±0.4	66.2±0.7	55.2±0.4	70.3±0.6	85.3±0.4	60.2±0.7	99.3±0.4	96.3±0.7
6	64.9±0.2	79.3±0.6	74.2±0.7	86.3±0.6	99.3±0.7	75.3±0.9		
8	75.3±0.6	85.2±0.2	89.3±0.6	97.3±0.7		94.3±0.2		
10	87.3±0.9	98.2±0.9	95.3±0.9					
15	96.2±0.2							
20								
25								
30								

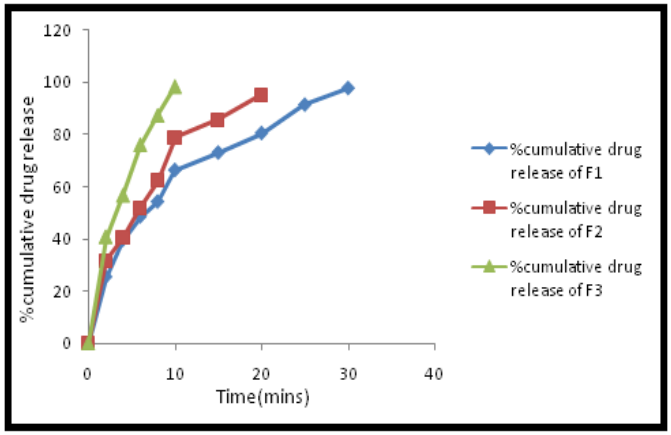

Fig. 2: Dissolution profile of formulations prepared with CP1 as super disintegrate

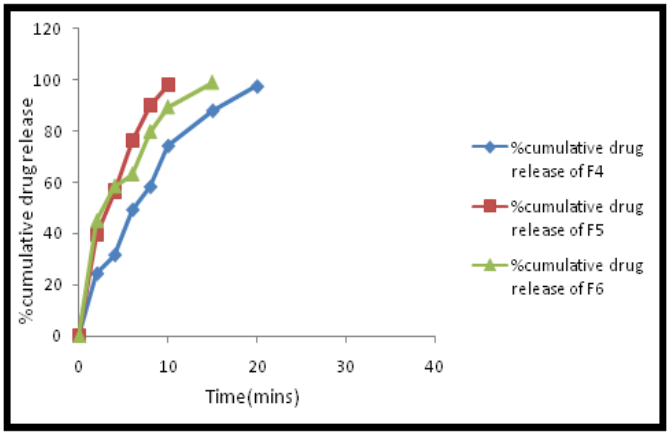

Fig. 3: Dissolution profile of formulations prepared with CP2 as super disintegrate

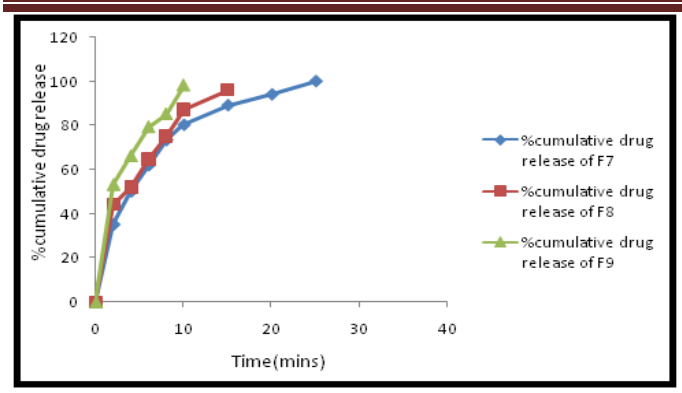

Fig. 4: Dissolution profile of formulations prepared with CP3 as super disinteg

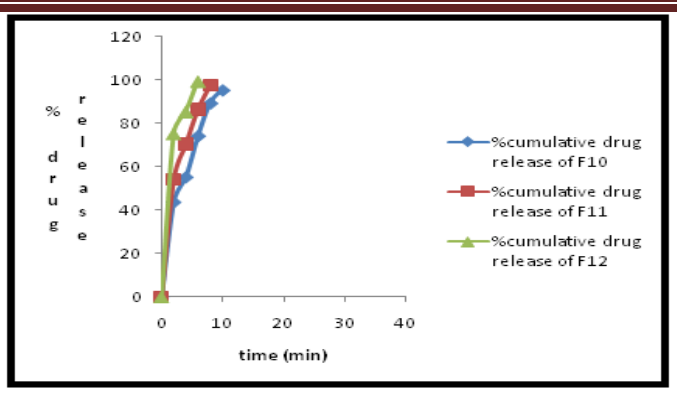

Fig. 5: Dissolution profile of formulations prepared with CP4 as super disintegrate

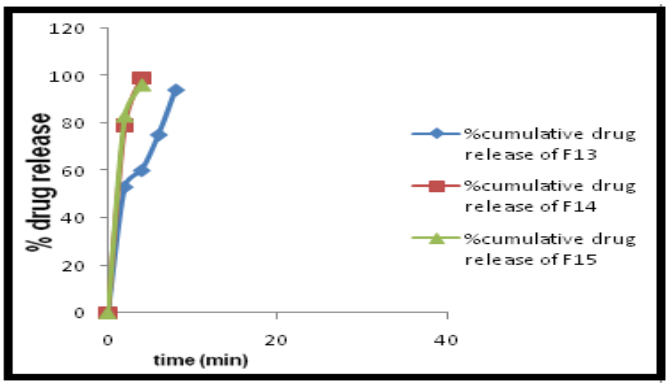

Fig. 6: Dissolution profile of formulations prepared with CP5 as super disintegrate

CONCLUSION

In the present work, an attempt has been made to develop fast disintegrating tablets ofTenoxicam. Novel method of co processed super disintegrates technology was employed to formulate the tablets. All the formulations were prepared by direct compression method. The blend of all the formulations showed god flow properties such as angle of repose, bulk density, tapped density. The prepared tablets were shown good post compression parameters and they passed all the quality control evaluation parameters as per I.P limits. Among all the formulations F14 formulation showed maximum drug release i.e., 99.3% in 4 min hence it is considered as optimized formulation. The F14 formulation contains CP5 as super disintegrate in the concentration of 30 mg. (CP 5 contains Vivasole and polyplasdone XL in 3:1 ratio).

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