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FORMULATION AND EVALUATION OF ORAL DISINTEGRATING TABLETS OF BEZAFIBRATE

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ABSTRACT

In the present work, an attempt has been made to develop fast disintegrating tablets of Bezafibrate. In the present work Sodium starch glycollate , Cross povidone and Cross carmellose sodium were employed as super disintegrating agents to enhance the solubility and dissolution rate of selected drug molecule. As the numbers of pores were more the body fluid will penetrates more easily. All the formulations were prepared by direct compression method using 6mm punch on 8 station rotary tablet punching machine. The blend of all the formulations showed good 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 F4 formulation showed maximum % drug release i.e., 97.75 % in 25 min hence it is considered as optimized formulation. The F4 formulation contains Cross povidone as super disintegrate in the concentration of 25 mg.

Key Words: Lamivudine, Raltegravir, Chromatography

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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.[1-3 Drug delivery systems are becoming increasingly sophisticated as pharmaceutical scientists acquire a better understanding of the physicochemical and biochemical parameters pertinent to their performance.[4-6]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.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.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.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.[7]

MATERIALS AND METHODS

Formulation of Oro dispersible tablets of Bezafibrate:

Preparation of tablets:

Composition of Bezafibrate oro Dispersible Tablet by direct compression. All the ingredients were weighed. Required quantity of drug and excipients mixed thoroughly in a polybag. The blend is compressed

using rotary tablet machine-8 station with 8mm flat punch, B tooling. Each tablet contains 50 mg Bezafibrate and other pharmaceutical ingredients. Total weight of tablet was found to be 120 mg.

Table 1: List of Materials Used

Name of the material	Source
Bezafibrate	NATCO LABS
Microcrystalline cellulose	Signet Chemical Corporation, Mumbai, India.
Sodium starch glycollate	SD fine chemicals, Mumbai, India.
Cross povidone	Merck Specialities Pvt Ltd, Mumbai, India.
Cross carmellose sodium	Merck Specialities Pvt Ltd, Mumbai, India.
Magnesium stearate	SD fine chemicalss, Mumbai, India
Talc	Merck Specialities Pvt Ltd, Mumbai, India

Table 2: List of Equipment's used

Name of the Equipment	Manufacturer
Weighing Balance	Sartourious
Tablet Compression Machine (Multistation)	Cemach Limited, India.
Hardness tester	Sisco, Mumbai, India.
Vernier callipers	Mitutoyo, Japan.
Roche Friabilator	Labindia, Mumbai, India
DissolutionApparatus	Labindia, Mumbai, India
UV-Visible Spectrophotometer	Labindia, Mumbai, India
pH meter	Labindia, Mumbai, India
FT-IR Spectrophotometer	Per kin Elmer, USA

Table 3: Composition of various tablet formulations

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Bezafibrate (mg)	200	200	200	200	200	200	200	200	200
Sodium Starch Glycollate (mg)	25	50	75	-	-	-	-	-	-
Cross Povidone (mg)	-	-	-	25	50	75	-	-	-
Cross Carmellose Sodium (mg)	-	-	-	-	-	-	25	50	75
Magnesium Stearate(mg)	2	2	2	2	2	2	2	2	2
Talc(mg)	2	2	2	2	2	2	2	2	2
MCC(mg)	Qs	Qs	Qs	Qs	Qs	Qs	Qs	Qs	Qs
Total wt(mg)	400	400	400	400	400	400	400	400	400

RESULTS & DISCUSSION

Standard Calibration curve of Bezafibrate:

Table 4: Concentration and absorbance obtained for calibration curve of Bezafibrate In pH 6.8 Phosphate buffer

S. No.	Concentration (µg/ml)	Absorbance* (at 245 nm)
1	1	0.134
2	2	0.285
3	3	0.465
4	4	0.645
5	5	0.815
6	6	0.955

It was found that the estimation of Bezafibrate by UV spectrophotometric method at λ_{max} 245nm in pH 6.8 Phosphate buffer had good reproducibility and this method was used in the study. The correlation coefficient for the standard curve was found to be closer to 1, at the concentration range, 2- 10µg/ml. The regression equation generated was y = 0.049x + 0.009, R^2 = 0.998.

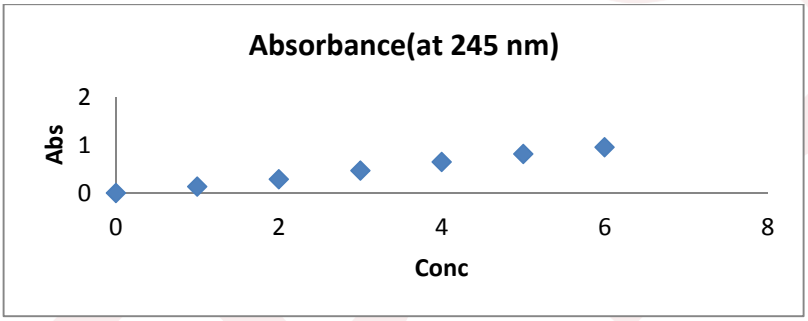

Fig. 1: Standard graph of Bezafibrate in pH 6.8 Phosphate buffer

Evaluation Parameters for Fast Dissolving Tablets of Bezafibrate :

Pre-compression parameters:

The data's were shown in Table 7.2.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 fall in the range of 13.06% to 18.18%. The Hausner ration 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.

Table 5: Pre-compression parameters

Formulations	Bulk Density (gm/cm^2)	Tap Density (gm/cm^2)	Carr's Index (%)	Hausner ratio	Angle Of Repose(Θ)
F_1	0.43	0.58	19.17	1.16	29.34
F_2	0.47	0.55	13.55	1.19	26.71
F_3	0.49	0.58	12.69	1.16	29.34
F_4	0.46	0.55	14.54	1.17	28.23
F_5	0.50	0.58	13.79	1.16	29.34
F_6	0.47	0.52	19	1.16	26.78
F_7	0.47	0.50	19	1.21	26.78
F_8	0.41	0.50	15.31	1.28	28.14
F_9	0.50	0.53	18.14	1.24	26.48

Post compression Parameters:

Assay:

Assay studies were performed for the prepared formulations. From the assay studies it was concluded that all the formulations were showing the %.

Invitro Dissolution studies:

Invitro dissolution studies were carried out by using 500ml of pH 6.8 Phosphate buffer in USP dissolution apparatus by using paddle method. The dissolution studies were carried out for about 30 min.

Table 6: Post compression parameters

	Table 6 Post-Compression parameters:					
Formulation code	**Weight variation (mg)**	**Hardness (kg/cm^2)**	**Thickness (mm)**	**Disintegration Time (sec)**	**Friability (%)**	**Assay (%)**
F1	400	2.4	3.59	30.33	0.49	98.16
F2	404	2.5	3.64	22.66	0.34	98.55
F3	399	2.6	3.59	30.33	0.49	98.16
F4	401	2.3	3.56	17.00	0.34	99.25
F5	402	2.2	3.56	17.00	0.34	99.25
F6	403	2.5	3.56	22.14	0.45	99.21
F7	402	2.9	3.55	23.54	0.44	98.24
F8	400	2.7	3.48	23.14	0.42	99.15
F9	402	2.8	3.44	22.45	0.41	98.55

Table 7: Invitro dissolution studies of all formulations

Time	F1	F2	F3	F4	F5	F6	F7	F8	F9
2	9.77	12.14	10.32	14.21	13	10.32		9.21	18.51
4	17.51	23.16	15.45	21.55	17.5	15.45	20.15	21.8	22.15
6	35.64	38.46	32.15	37.64	32.11	32.15	36.97	33.87	35.23
8	47.21	55.31	50.11	53.74	48.79	50.11	63.17	68.82	68.14
10	56.74	63.84	66.47	61.47	55.94	66.47	68.14	72.64	71.24
15	72.54	75.32	88.41	79.64	75.21	88.41	72.11	89.54	82.14
20	80.21	85.11	90.21	85.21	82.1	92.11	78.45	93.11	86.14
25	85.22	95.21	92.14	97.75	88.34	94.54	88.54	94.22	90.14

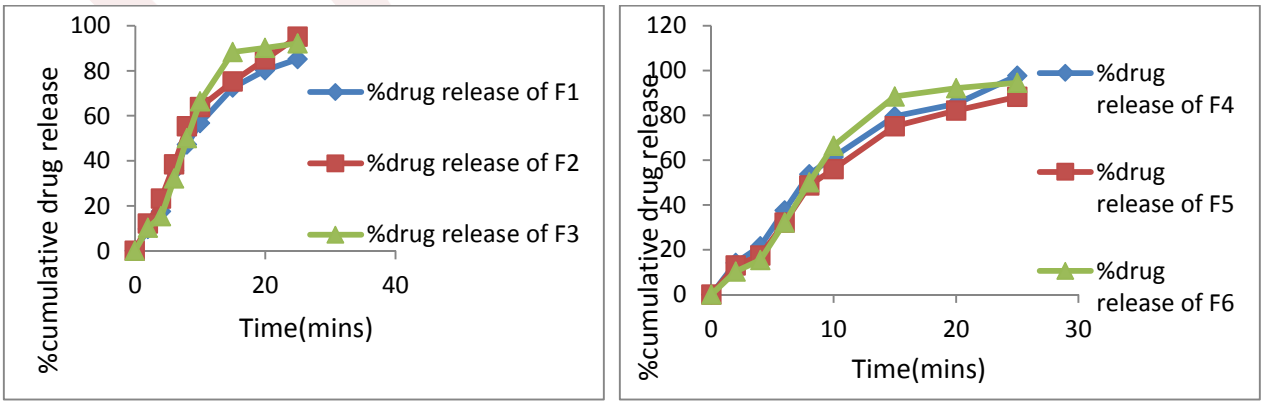

Fig. 2& 3: Dissolution profile of formulations F1 to F6

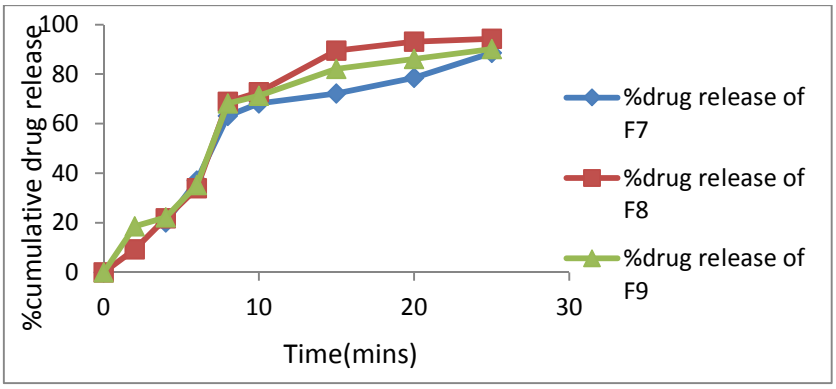

Fig 4: Dissolution profile of formulations F6 to F9

From the tabular column 7.4 it was evident that the formulations prepared with super disintegrate Cross carmellose sodium showed maximum % drug release in 25 min i.e.97.75% (F4 formulations and the concentration of super disintegrate was 25 mg). So the principle of super disintegrates was found to be useful to produce oro dispersible tablets. F4 formulation was considered as optimized formulation.

CONCLUSION

An attempt has been made to develop fast disintegrating tablets of Bezafibrate. In the present work Sodium starch glycolate, Cross povidone and Cross carmellose sodium were employed as super disintegrating agents to enhance the solubility and dissolution rate of selected drug molecule. As the numbers of pores were more the body fluid will penetrates more easily. All the formulations were prepared by direct compression method using 6mm punch on 8 station rotary tablet punching machine. The blend of all the formulations showed good 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 F4 formulation showed maximum % drug release i.e., 97.75 % in 25 min hence it is considered as optimized formulation. The F4 formulation contains Cross povidone as super disintegrate in the concentration of 25 mg.

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