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FORMULATION, DEVELOPMENT AND IN VITRO EVALUATION BEZAFIBRATE FAST DISSOLVING TABLETS

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ABSTRACT

This study aimed to formulate, develop, and evaluate fast-dissolving tablets of bezafibrate using the solid dispersion method. The formulation process focused on enhancing the dissolution rate and bioavailability of bezafibrate, a poorly water-soluble drug. Precompression parameters such as thickness, diameter, hardness, friability, drug content, and weight variation were optimized to ensure the quality and uniformity of the tablets. In vitro evaluation involved assessing dispersion time, wetting time, and dissolution profiles over a three-month period to determine stability under different storage conditions. The findings suggest that the developed bezafibrate fast-dissolving tablets hold promise for improved drug delivery and patient compliance, offering valuable insights into their formulation and performance.

KEYWORDS: Bezafibrate, Fast-dissolving tablets, Solid dispersion and In vitro evaluation.

INTRODUCTION

Drug delivery systems (DDS) are a strategic tool for expanding markets/indications, extending product life cycles and generating opportunities. Oral administration is the most popular route for systemic effects due to its ease of ingestion, pain, avoidance, versatility and most importantly, patient compliance. Also solid oral delivery systems do not require sterile conditions and are therefore less expensive to manufacture. Patient compliance, high-

precision dosing, and manufacturing efficiency make tablets the solid dosage form of choice. The oral route remains the perfect route for the administration of therapeutic agents because the low cost of therapy, manufacturing and ease of administration lead to high levels of patient compliance. Among all other dosage forms, solid dosage forms are widely used. Especially, oral solid formulations hold a high potential as they serve to be most convenient for the administration of drugs because oral dosage forms can be self-administered by the patient, they are obviously more profitable to manufacture than parenteral dosage forms that must be administered, in most cases, by trained personnel.

Over 80% of the drugs that are formulated to produce systemic effects are marketed as oral dosage forms. The most used pharmaceutical solid oral dosage forms today include granules, pellets, tablets and capsules. Compared to other solid oral dosage forms, tablets are the manufacturer's dosage form of choice because of their relatively low cost of manufacture, packaging, and shipment; increased stability. The tablets can be made directly from powders or from granules pellets, or from film-coated multiple units. Tablets are now the most popular dosage form, accounting for some 70% of all ethical pharmaceutical preparations produced. Drug products are currently designed for three groups of individuals: infants, pediatrics and adults. The needs of the infants are obviously different from those of children 2 to 12 years of age and the needs of children are obviously different from those of adults. However, the needs of the elderly population are being overlooked as they have special characteristics that necessitate dosage forms designed especially for them.

Many older patients have difficulty swallowing tablets or capsules and yet most dosage forms administered to the elderly are tablets or capsules. Uncoated tablets are convenient and economical to manufacture but are often difficult to swallow and often cause discomfort by "hanging" in the throat. Coated tablets and capsules are somewhat easier to swallow but with increasing age and the large number of drug products that are administered to a single individual, this is a source of apprehension. Liquid dosage forms are relatively easy to administer but are more costly, easily spilled, often do not taste good, occupy large volumes of space per dosage unit, and possess some inherent stability problems. As is evident, the needs of the elderly differ from those of other populations and deserve special attention in new drug development, product formulation, posology, product packaging, product labelling, patient information, and product marketing and sales. A practical and new dosage form would be of value for these patients.

There currently are several fast-dissolving products on the market. The development of enhanced oral protein delivery technology by Fast dissolving Tablets which may release these drugs in the mouth are very promising for the delivery of high molecular weight protein and peptide.

Fast dissolving tablets are dosage form, which disintegrate in patient's mouth within a few seconds without the need of water, or chewing, providing best remedy for the patient suffering from dysphasia. Some drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down the stomach. In such cases the bioavailability is greater than those observed for conventional dosage form.[1]

Pediatric and geriatric patients may have difficulties in swallowing or chewing pharmaceutical dosage forms for oral administration. Tablets that rapidly dissolve upon contact with saliva in the buccal cavity could present a solution to those problems and so there is an increased interest in fast dissolving dosage forms for buccal, sublingual and oral administration. Fast dissolving/ disintegrating tablet are perfect fit for these patients as these immediately release the active drug when placed on tongue by rapid disintegration/ dispersion, followed by dissolution of drug.

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The advantages of mouth dissolving dosage form are increasingly being recognized in both industry and academia. The basic approach used in the development of the fast-dissolving tablet is the use of super disintegrants. Croscarmellose sodium, sodium starch glycolate, and crospovidone were screened in the present study, and the best one was used for further studies.[2]

Techniques employed in the preparation of mouth dissolving tablets include spray drying, molding, mass extrusion, direct compression, freeze-drying, vacuum-drying and sublimation technique by using sublime agents like camphor, menthol. However, as microcrystalline cellulose (MCC) and low-substituted hydroxyl propyl cellulose (L-HPC) were used as

excipients in these tablets, patients, sometimes feel a rough texture in their mouth due to the incomplete solubilization of this type of tablet in saliva. To eliminate this type of inconvenience in the mouth, we attempted to use a Perlitol SD200 as an excipient instead of crystalline cellulose and L-HPC, in the preparation of this type of tablet. However, use of Perlitol SD200 in tablet as water soluble excipient does not rapidly dissolve in saliva since it is difficult for water to penetrate into the tablets due to its low porosity. Above techniques have been tried by researchers to maximize the pore structure of tablet matrix.[3]

Freeze drying is cumbersome, and it yields a fragile and hygroscopic product. Therefore, it was decided to adopt the vacuum-drying technique in the present investigation. Vacuum drying was adopted after addition of a subliming agent to increase porosity of the tablets. It is likely that a porous hydrophilic matrix will easily pick up the disintegrating medium and break quickly. Using Perlitol SD200 with subliming materials. We chose menthol, camphor, thymol and ammonium bicarbonate as a subliming material.[4]

MATERIALS AND METHODS

MATERIALS

Bezafibrate obtained from (CHEMICO SCIENTIFIC, ERODE); Avicel pH 102, Sodium starch glycolate, Magnesium stearate and Talc obtained from (Cid company, Giza, Egypt); Polyethylene glycol (PEG4000), Poly vinyl pyrrolidine and carboxy methyl cellulose (CMC) obtained from (EL. Nasr pharmaceutical chemicals Co. Egypt); potassium dihydrogen orthophosphate, disodium hydrogen orthophosphate and absolute ethanol obtained from (CHEMICO SCIENTIFIC, ERODE), Commercial haloperidol product purchased from local. All reagents & solvents used were of analytical grade.

METHODS

PREFORMULATION STUDIES[14,15]

Before formulation of drug substances into a dosage form, it is essential that the drug and polymer should be chemically and physically characterized. Preformulation studies give the information needed to define the nature of the drug substance and provide a framework for the drug combination with pharmaceutical excipient in the fabrication of a dosage form.

4.7. Fourier transform infrared (FTIR) spectroscopy

Drug-excipients compatibility were tested, comparisons were made between the spectra of pure haloperidol powder, Avicel pH 102, polymer, SSG, Mg stearate, physical mixture and

selected solid dispersion formula by (Perkin-Elmer 1600 FTIR spectrophotometer) using potassium bromide disk method. The wave number scanning range was 4000–400 cm^{-1} and the resolutions were 1 cm^{-1}.

4.8. Differential scanning calorimetry (DSC)

Analysis was made using (Shimadzu DSC-60). Samples weighing 5 mg of pure fenofibrate powder, excipients, physical mixture and selected solid dispersion formula were heated in hermetically sealed aluminum pans over the temperature range (0–200 °C) at a constant rate of 10 °C /min under a nitrogen purge (30 ml/min).

8.1 Pre formulation Studies

8.1.1 Solubility study

The solubility of pure Bezafibrate and in presence of polymer was determined in distilled water. An excess quantity of the drug and weighted amount of physical mixture (175.28 mg) were added to 10 ml of water in screw-capped bottles. All the bottles were shaken in a shaker water bath at 25°±0.5 °C for 72 h. After attainment of equilibrium, the solutions were filtered, and concentration of drug was determined by spectrophotometer at λ max 243 nm (Huang and Dai, 2014).[42]

Solubility enhancement ratio was calculated using the following equation.

$$\text{Solubility enhancement ratio (SER)} = \frac{\text{Solubility of drug in presence of polymer}}{\text{Solubility of drug in water}}$$

8.2 Preparation of physical mixture

Physical mixture of Bezafibrate with polymer PEG 4000, PVP and CMC at different ratio (1:2, 1:4, 1:6 and 1:8) were prepared by mixing the accurately weighed quantity of drug and polymer in a glass mortar with the help of pestle. This mixture was then subsequently passed through sieve number 60 and stored in a desiccator for 24 h.

8.3 Preparation of solid dispersion of Bezafibrate

Solid dispersions containing Bezafibrate and polymer (PEG4000, PVP and CMC) in the proportion of 1:2, 1:4, 1:6 and 1:8 had been prepared by melting method, and solvent evaporation method.

8.3.1 Melting method

Solid dispersions were prepared by melting each of Bezafibrate alone and polymer in porcelain dish. The fusion temperature was controlled between 60 and 70 °C. The molten mixture was immediately cooled and solidified in an ice bath with vigorous stirring. The solid obtained was scrapped, crushed, pulverized and passed through sieve number 60. The obtained product was stored in a desiccator until used for further studies (Dhote et al., 2014).[43]

8.3.2 Solvent method

In this method, Bezafibrate and polymer was dissolved in 0.38 ml ethanol. The solvent was evaporated until a clear, solvent free film is left. The film was further dried to constant weight. The co-precipitate was crushed and the dried powder passed through sieve number 60.The final product was stored in a desiccator until further use (Adeli, 2016).[44]

Formulation and preparation of tablets

Tablets of pure Bezafibrate, physical mixture and solid dispersion were prepared by direct compression method. The physical mixtures and solid dispersions equivalent to 5 mg of bezafibrate were weight and uniformly mixed with diluents (Avicel), lubricant (Magnesium stearate) and super disintegrants (Sodium starch glycolate) according to Table 1. All the ingredients were passed through sieve number 60 prior to mixing and then directly compressed using compression machine (Single punch tablet machine fitted with10 mm flat faced punches and dies (Korsh Forgeries; type AO, Berlin, Western Germany) (Yasir and Sara, 2014).

Table 5: Composition of tablets containing bezafibrate solid dispersion.

Code	Formulation	Type of polymer and Method	Drug (mg)	Polymer (mg)	Ethanol solvent (mg)	Avicel (mg)	Sodium starch glycolate (mg)	Mg. stearate (mg)	Total weight (mg)
FP	Pure drug	-	5	-------	-------	160	8.25	1.73	75.28
FPM	Physical mixture	-	5	40	------	120	8.25	1.73	75.28
F 1	SD1	PEG / solvent evaporation	5	40	0.3	120	8.25	1.73	75.28
F 2	SD2	PEG / melting	5	40	------	120	8.25	1.73	74.98

F 3	SD3	PVP / solvent evaporation	5	40	0.3	120	8.25	1.73	75.28
F 4	SD4	PVP /melting	5	40	------	120	8.25	1.73	74.98
F 5	SD5	CMC / solvent evaporation	5	40	0.3	120	8.25	1.73	75.28
F 6	SD6	CMC / melting	5	40	-------	120	8.25	1.73	74.98

FP: Tablet containing pure drug.

FPM: Tablet containing physical mixture.

F1: Tablet containing PEG solid dispersion prepared by solvent evaporation method.

F2: Tablet containing PEG solid dispersion prepared by melting method.

F3: Tablet containing PVP solid dispersion prepared by solvent evaporation method.

F4: Tablet containing PVP solid dispersion prepared by melting method.

F5: Tablet containing CMC solid dispersion prepared by solvent evaporation method.

F6: Tablet containing CMC solid dispersion prepared by melting method.

8.8 Dissolution studies

The *in-vitro* dissolution study of Bezafibrate alone or from solid dispersions and physical mixtures was determined using Dissolution Pharma Tester type II (pharma test sp6400, Mph, Germany). The dissolution test was performed using 900 ml of phosphate buffer (pH = 6.8), at 37 °C ± 0.5 °C and 50 rpm. Weight amount equivalent to 5 mg of Bezafibrate were added to dissolution medium. A sample (5 ml) of the solution was withdrawn from the dissolution apparatus at 5, 10, 20, 30, 40, 50 and 60 min. The sample was replaced with fresh dissolution medium of the same quantity. The removed samples were filtered through Whatman filter paper and assayed for bezafibrate content at λ max 243 nm after dilution. Each run was performed in triplicate. The amount of drug dissolved was calculated using the standard curve (Yasir and Sara, 2014).[45]

RESULTS AND DISCUSSION

Many patients, especially elderly find it in swallowing tablets, capsules, fluids and thus do not comply with prescription, which results in high incidence of non-compliance-oriented research has resulted in bringing out many safer and newer drug delivery systems. Rapidly

disintegrating/dissolving tablet is one of such examples, for the reason of rapid disintegration or even with saliva.

Significance of this drug delivery system includes administration without water, accuracy of dosage, ease of portability, alternative to liquid dosage forms, ideal for paediatric and geriatric patients and rapid onset of action. The fast-dissolving tablets are synonymous with Fast dissolving tablets, Melt in mouth tablets, Rapi-melts, Quick dissolving tablets, Rapidly disintegrating tablets, Porous tablets, Oro-dispersible tablets and Fast disintegrating tablets. Their characteristic benefits in terms of patient compliance, rapid on-set of action, increased bioavailability, (sometimes bi-pass first pass effect) and good stability make these tablets popular as a dosage form of choice.

Water insoluble diluents such as microcrystalline cellulose and dicalcium phosphate and L-HPC were omitted from the study as they are expected to cause an unacceptable feeling of grittiness in the mouth. Among the soluble diluents, mannitol was selected as a model soluble diluent considering its advantages in terms of easy availability, cost effectiveness, negative heat of dissolution and relative moisture insensitivity. Mouth dissolving tablets of bezafibrate were prepared by sublimation technique, with four subliming agents like menthol, thymol, camphor and ammonium bicarbonate.

Evaluation of precompression properties

For each designed formulation, blend of drug and excipients was prepared and evaluated for pre compression properties shown in **table 2**. Bulk density was found to be between 0.52±0.04 to 0.58±0.01gm/cm^3 and tapped density between 0.67±0.01 to 0.730±0.03 gm/cm3 for all formulations. From density data % compressibility was calculated and was found to be between 16.1±0.03% to 25.8±0.04 percent. Angle of repose was found to be in the range of 25.1±0.03 to 29.7±0.02. Hausner ratio was found below 1.22±0.02 to 0.35±0.05. Bulkiness was found to be in the range of 1.74±0.02 to 1.89±0.05. All the formulation shows the fair to good flow properties for direct compression and hence tablets were prepared by using direct compression technology.

Table 6: Results of precompression properties.

Formulation	Angle of repose (^{0}) *	Bulk density (gm/cm^3) *	Tapped density (gm/cm^3) *	Carr's index (%) *	Hausner ratio (HR)*	Bulkiness (cc/g) *
F1	28.0±0.01	0.57±0.01	0.69±0.01	17.6±0.05	1.24±0.041	1.74±0.02

F2	29.7±0.02	0.55±0.02	0.73±0.02	24.7±0.04	1.22±0.05	1.80±0.04
F3	25.1±0.03	0.56±0.03	0.71±0.02	21.1±0.04	1.27±0.04	1.76±0.04
F4	26.1±0.01	0.53±0.02	0.72±0.02	25.8±0.04	1.35±0.05	1.85±0.04
F5	27.5±0.02	0.57±0.02	0.67±0.02	20.8±0.03	1.26±0.04	1.89±0.05
F6	25.1±0.03	0.52±0.04	0.68±0.01	16.1±0.03	1.29±0.04	1.75±0.04

*All values are expressed as mean ± SD, n=3

CRYSTAL PROPERTIES

When the bezafibrate subjected to three cycles process results in decrease in particle size from 14µm to 7µm and also increases in surface area after three cycling processes. There is no change in melting point of bezafibrate after micronization.

Table 8: Particle Size Parameters.

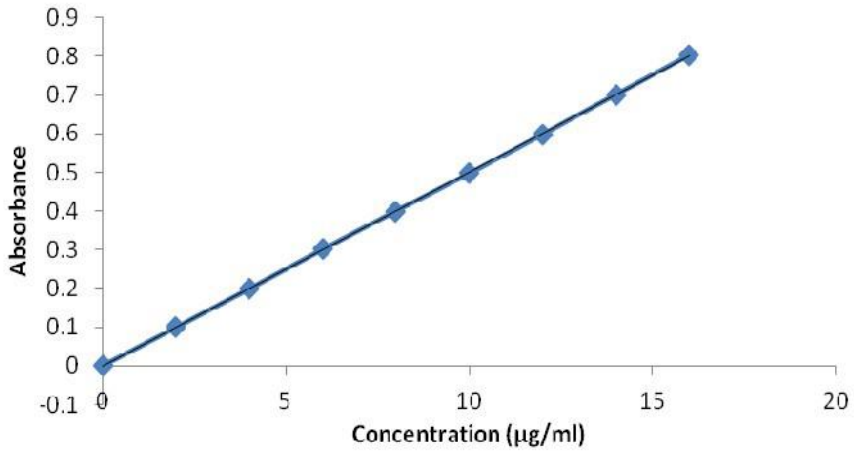
Particle Parameters		Non-micronized	After Ist cycle	After2ndcycle	After3rdcycle
Particle size(µm)	D (0.10)	1.323	0.946	0.871	0.800
	D (0.50)	7.004	5.141	4.451	3.925
	D (0.90)	13.713	10.362	9.517	7.832
Surface area (m^2/g)		0.76	1.12	1.48	1.94
Melting point		80	79	81	80

ANALYTICAL PROPERTIES

From the standard calibration curve of drug, it was concluded that drug obeys Beer Lambert's law in concentration range of 2-16mcg/ml. Standard calibration graph and table were given below.

Table 7: Standard calibration curve data for Bezafibrate API.

Concentration (µg/ml)	Absorbance
2	0.099
4	0.199
6	0.301
8	0.400
10	0.497
12	0.598
14	0.701
16	0.803



The linear equation was obtained as Y=0.0501X - 0.0011, R^2=0.9995 Correlation coefficient values indicated the linear correlation between concentration and absorbance.

Evaluation of post compression properties of fast disintegrating tablet

Tablets were prepared using direct compression technique. Since the powder material was free flowing, Tablets were obtained of uniform weight due to uniform die fill, tablets were obtained of uniform weight variations as per Pharmacopeial specifications. All the tablets were exhibit in white colour, odourless, convex in shape with smooth surface with zero defects. The drug content was found in the range of 97.15 – 100.21% (acceptable limit) and the hardness of the tablets between 3.8 – 4.0 kg/cm^2. Friability of the tablets was found below 1 % indicating a good mechanical resistance of tablets. Thickness of the formulations were varied from 2.8±0.02 to 3.2±0.02 mm, diameter of the formulations was varied from 9.7±0.01 to 10.2±0.01 mm. All the parameters were found well within the specified limit **(table 10).**

Table 10: Results of Post Compression Properties of Bezafibrate Tablets.

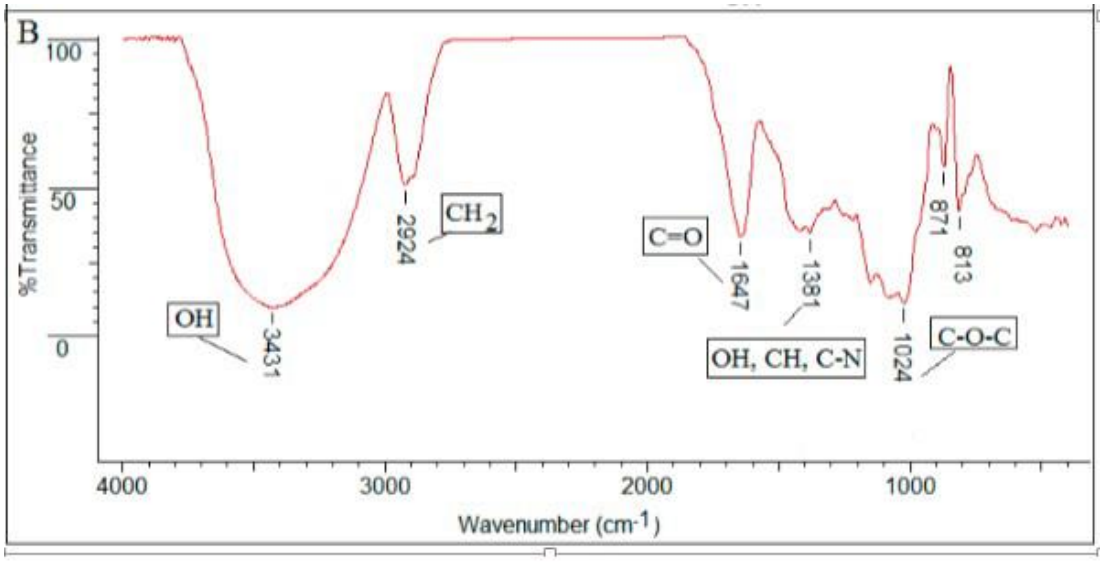
Formulation code	Diameter (mm)*	Thickness (mm)*	Hardness (kg/cm2) *	Friability (%)***	Drug content (%) **	Weight variation (mg)**
F1	10.1±0.02	3.0±0.01	4.0±0.1	0.32±0.01	98.12±0.04	199±0.01
F2	9.8±0.01	3.1±0.02	3.9±0.12	0.45±0.02	98.35±0.05	200±0.01
F3	9.7±0.01	3.2±0.02	4.0±0.05	0.45±0.01	97.15±0.05	198±0.01
F4	10.2±0.01	2.8±0.02	3.9±0.09	0.55±0.04	99.15±0.02	197±0.02
F5	10.1±0.02	2.9±0.02	4.0±0.08	0.61±0.03	100.12±0.03	202±0.02
F6	10.2±0.01	3.0±0.01	3.8±0.01	0.71±0.03	98.45±0.02	201±0.02

*All values are expressed as mean ± SE, n=5; **All values are expressed as mean ± SE, n=20; ***All values are expressed as mean ± SE, n=10.

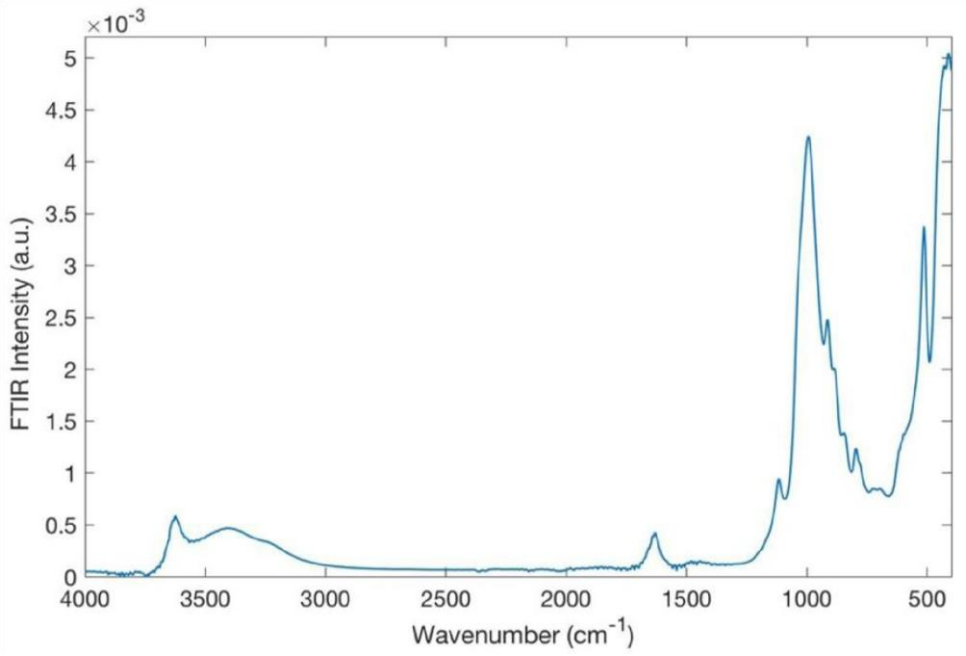
Compatibility Studies

Fourier transform infra-red spectroscopy (FTIR)

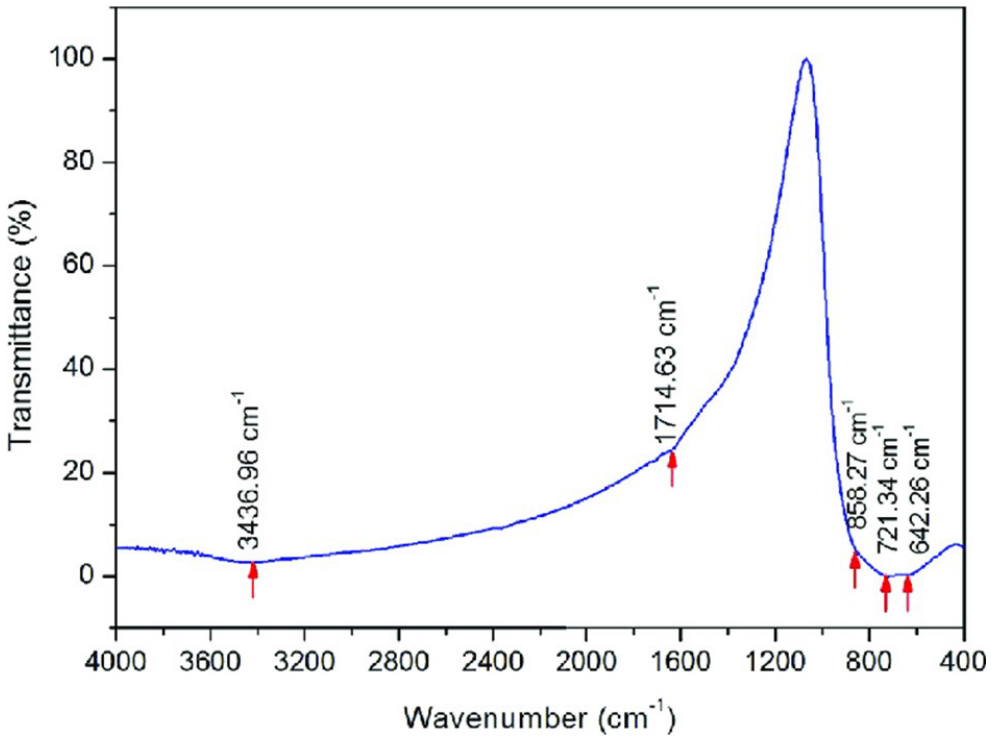
IR spectra of bezafibrate and its physical mixture with formulation excipients were determined using FT-IR. and are presented in Figure2. Pure bezafibrate spectra showed sharp characteristic peaks at 3431, 2924, 1647, 1381, 1024, 871 and 813cm−1. FTIR-spectra of bezafibrate and its physical mixture with excipients are exactly same, and there is no shift of peaks or disappearance of principle peaks or modification of the principle peaks indicating that there is no interaction between the drug and excipients.



FTIR of Bezafibrate



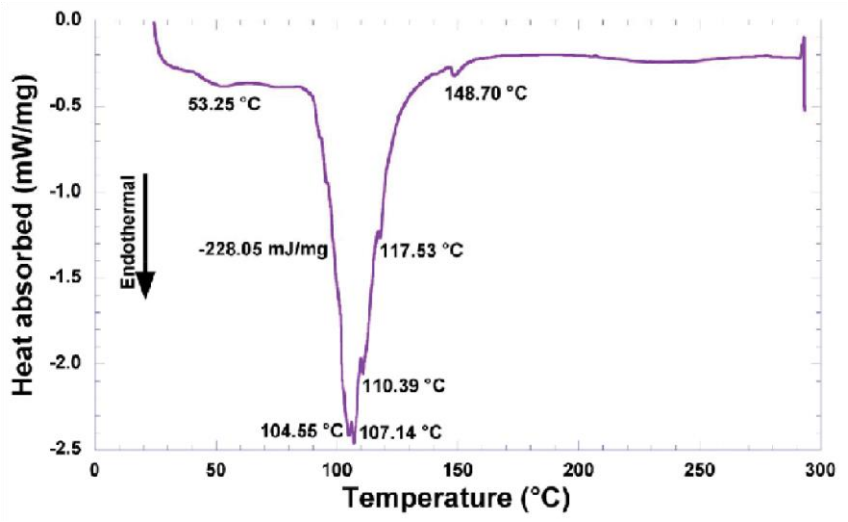
FTIR of Carboxy Methyl Cellulose



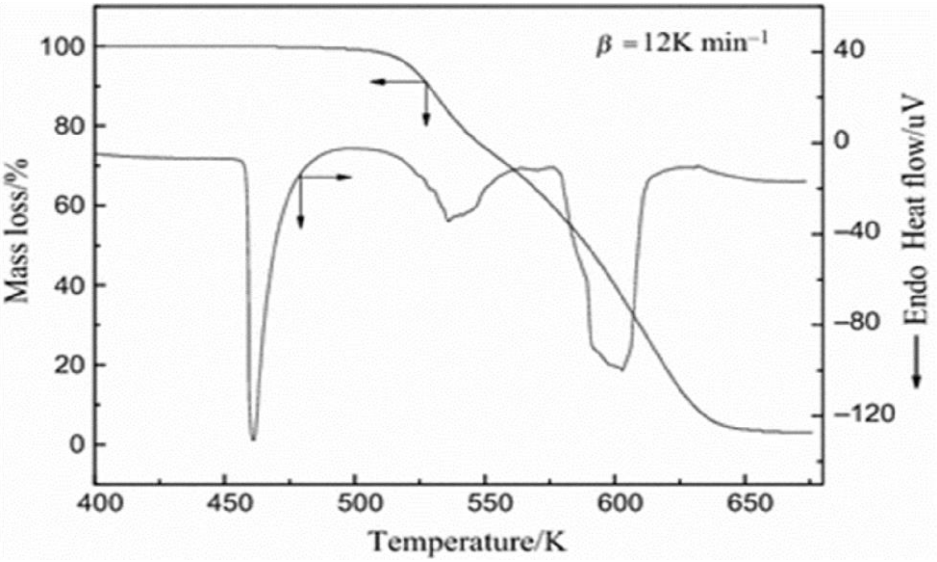
FTIR of Poly Vinyl Pyrrolidone

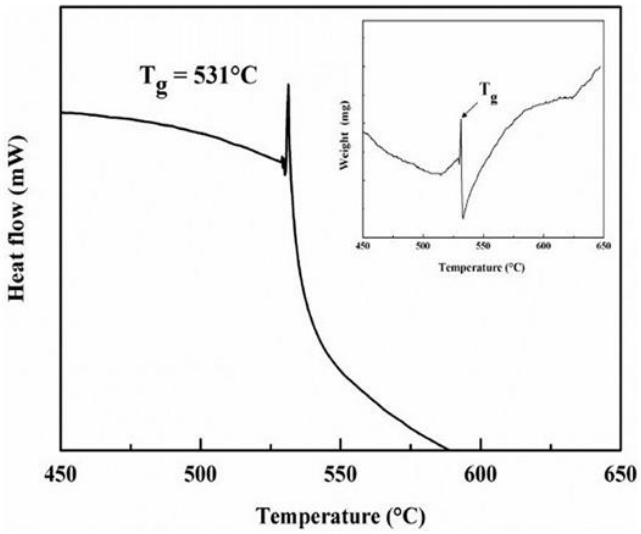
Differential Scanning Calorimetry (DSC)

The DSC analysis (Figure 3) of pure Bezafibrate showed a characteristic, sharp endotherm peak at 104.55°C corresponding to its melting point and indicates the crystalline nature of the drug. The DSC analysis of physical mixture of drug and excipients revealed negligible change in the melting point of bezafibrate in the presence excipients, indicating no modification or interaction between the drug and excipients. On the basis of the results obtained in the preliminary screening studies, the batch containing crospovidone showed the fastest disintegration. Hence, it was selected for further studies. Polyvinylpyrrolidone was used as a binder at a concentration of 10% wt/vol, considering its widespread applicability in the industry. Subliming agents such as menthol, camphor, thymol and ammonium bicarbonate were used to increase porosity of the tablets in the preliminary tablet formulations. Menthol containing tablets exhibited faster disintegration as compared with tablets containing camphor, thymol and ammonium bicarbonate. The batches F3 to F6 were prepared using menthol at different concentrations to study its effect on disintegration time. The sublimation time (6-12 hours).



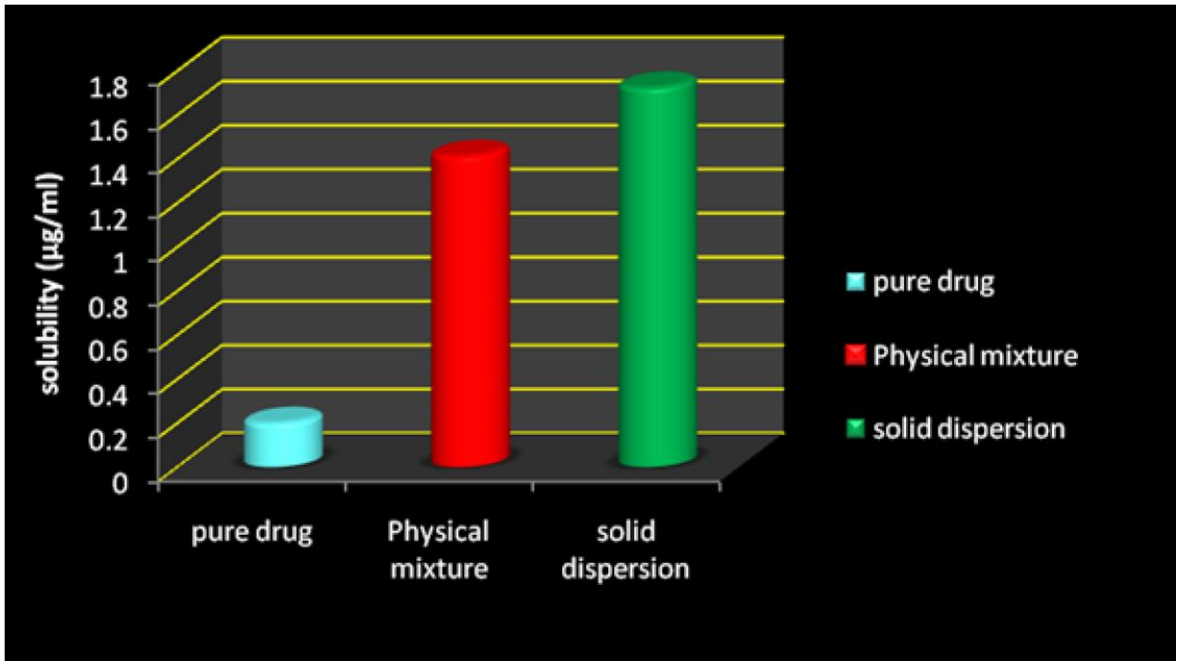
DSC of Bezafibrate





DSC of Carboxy Methyl Cellulose

6.3.3 Stability study



Stability Studies of Bezafibrate, pre formulation and formulations

The optimized formulation F6 were charged on accelerated stability and monitored for appearance, hardness, friability, drug content, *in-vitro* dispersion time, wetting time and dissolution profile study at 1,2 and 3 month.

The stability study reveals no significant variation in appearance, colour, Odor, taste, hardness, friability, drug content, *in-vitro* dispersion time, wetting time and *in-vitro* dissolution study up to three months stability studies for F10 formulations at different temperatures. The formulation was stable under accelerated conditions of temperature and humidity (figure 9).

The different stages of swelling of fast dissolving tablets are shown in

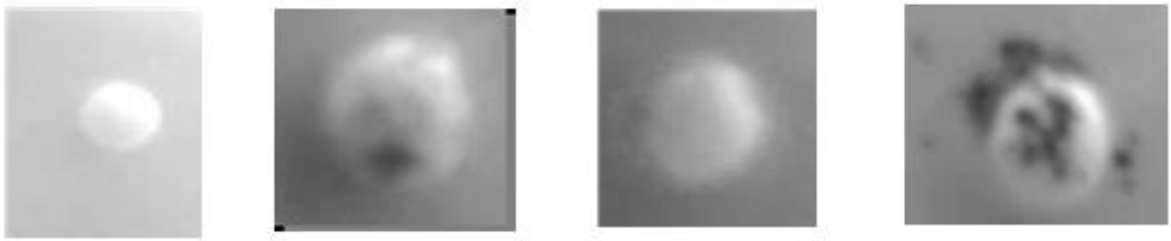


Figure 18: Different stages of Swelling of Fast Dissolving Tablets.

IN-VITRO RELEASE OF BEZAFIBRATE TABLETS

In formulation F_1, F_2, F_3 formulations Poly Vinyl Pyrrolidine (K-25) was used in concentration of 4%, 6%, 8% and surfactant 4.5gm added in dry mix, the release was found to be 83.72%, 86.41% and 84.95% respectively. Hence, to improve release rate it was decided to alter the formulation further.

In F_4 formulation PVP K-25 - 6% and surfactant 4.5gm in binder solution was added and release was found to be 89.41%. In F_5, F_6 formulations only surfactant in different concentrations in dry mix: binder solution as 1:2, 2:1 were used and release was found to be 96.34%, 95.44%.

The percentage of drug release increased with addition of surfactant in 1:2 concentrations and also for further improvement, optimized quantity of granulation fluid to be added. Higher dissolution profile also due to key role of addition of super disintegrant like croscarmellose sodium has strong swelling property and highly porous structure of PVP K25.

SUMMARY AND CONCLUSION

FDTs main requirements to make the faster dissolution of tablets; this can be made by selecting the super disintegrant in optimized concentration. In the present investigation we developed mouth dissolving tablets of Bezafibrate by using sublimation technique using menthol, camphor, ammonium bicarbonate and thymol as sublimating agent.

Sublimation technique using vacuum oven would be an effective alternative approach to use of more expensive adjuvant and sophisticated instruments in the formulation of mouth dissolving tablets. The wetting time or simulated saliva penetration was observed to be very fast with batch F6 tablets.

The total drug from the optimized batch was found to be released within the first ten minutes of dissolution study. **These tablets rapidly dissolved (within 10-20 sec) in saliva.** The prepared tablet gives benefit in terms of patient compliance, low dosing, rapid onset of action, increased bio-availability, low side effect and good stability which make these tablets popular as a dosage form for the treatment of hyperlipidaemia.

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