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Formulation and Evaluation of Fast Dissolving Tablet of Ibuprofen

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Abstract
The aim of the present investigation was to develop fast dissolving tablets of Ibuprofen, an NSAID drug used for the treatment of arthritis. Due to its low solubility, gastric irritation and its short biological half-life of 2 hours, fast dissolving tablets of Ibuprofen were prepared using superdisintegrants in order to improve the dissolution rate, thereby the absorption and to reduce gastric irritation. The influence of concentration of the sodium starch glycolate was studied by a set of four formulations (F1, F2, F3, F4) with concentrations of sodium starch glycolate viz, 2.5%, 3.75%, 5% & 6.25%w/w respectively. Also the influence of various superdisintegrants was studied by a set of three formulations (F4, F5 and F6) with three superdisintegrants viz, Sodium starch glycolate (6.25%), Croscarmellose sodium (6.25%), Crospovidone (6.25%) respectively. The formulation prepared with 6.25%w/w of sodium starch glycolate was offered relatively rapid release of Ibuprofen when compared with other concentrations of Sodium Starch glycolate. The formulation prepared with Crospovidone was offered relatively rapid release of Ibuprofen when compared with other superdisintegrants. So, we can conclude that nature and concentration of the superdisintegrant showed influence on the rate of dissolution.

Keywords: superdisintegrants, sodium starch glycolate, crospovidone, croscarmellose sodium, NSAID, concentration

Introduction
Fast dissolving tablets are defined as "A solid dosage form containing medicinal substances, which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue" In case of conventional tablets, physical problems with swallowing (dysphagia) can occur at any age but are particularly prevalent in the elderly and those with dementia, whereas refusal to swallow is often encountered in geriatric, pediatric and psychiatric patients. Difficulties and resistance to tablet-taking are common in all patient groups. In recent years, fast dissolving tablets have been developed to overcome problems related to swallowing difficulties. Fast Dissolve, Quick Dissolve, Rapid Melt, Quick Disintegrating, Mouth Dissolving, Orally Disintegrating, Oro Dispersible, Melt-in-Mouth, etc. are terms that represent the same drug delivery systems. The orally disintegrating property of tablet is attributed to a quick ingress of water into the tablet matrix, which creates porous structure and result in rapid disintegration. When put on tongue, these tablets disintegrates instantaneously, releasing the drug which dissolves or disperses in saliva. The drugs may be absorbed from mouth, pharynx or esophagus as the saliva passes down into the stomach. Advantages of the Fast dissolving tablets include ease of swallowing without the aid of water, rapid onset of action, enhanced dissolution rate, increased gastric absorption, improved oral bioavailability, minimized first pass metabolism and improved patient compliance.

Ibuprofen is a non-steroidal anti-inflammatory drug (NSAID) used for relief of signs and symptoms of rheumatoid arthritis, osteoarthritis and is used in chronic and acute conditions of pain and inflammation. As its serum concentrations and analgesic effect are correlated, rapid absorption of ibuprofen could be a prerequisite for the quick onset of its action. The major problems with drug is its very low solubility in biological fluids, gastric irritation and its short biological half-life of 2 h. It is practically insoluble in water and so possesses poor solubility and subsequent poor GI absorption and bioavailability. In order to improve the dissolution rate and thereby the absorption, fast dissolving tablets of Ibuprofen were prepared using superdisintegrants by direct compression. The use of fast dissolving tablets could help to reduce the gastrointestinal side effects of ibuprofen, since the tablet is disintegrated within the mouth.

Criteria for Fast dissolving Drug Delivery System
The tablets should;
- Not require water to swallow, but it should dissolve or disintegrate in the mouth in matter of seconds.
- Be compatible with taste masking.
- Be portable without fragility concern Have pleasant mouths feel. Leave minimum or no residue in the mouth after oral administration.
- Exhibit low sensitive to environmental condition as temperature and humidity.
- Allow the manufacture of the tablet using conventional processing and packaging equipment's at low cost.

Salient Feature of Fast Dissolving drug delivery system
- Ease of Administration to the patient who cannot swallow, such as the elderly, stroke victims, bedridden patients, patient affected by renal failure and patient who refuse to swallow such as pediatric, geriatric & psychiatric patients.
- No need of water to swallow the dosage form, which is highly convenient feature for patients who are traveling and do not have immediate access to water.
- Rapid dissolution and absorption of the drug, which will produce quick onset of action.
- Some drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach. In such cases bioavailability of drug is increased.

- Pregastric absorption can result in improved bioavailability and as a result of reduced dosage; improve clinical performance through a reduction of unwanted effects.
- Good mouth feel property helps to change the perception of medication as bitter pill particularly in pediatric patient.
- The risk of chocking or suffocation during oral administration of conventional formulation due to physical obstruction is avoided, thus providing improved safety.
- New business opportunity like product differentiation, product promotion, patent extensions and life cycle management.
- Beneficial in cases such as motion sickness, sudden episodes of allergic attack or coughing, where an ultra-rapid onset of action required.
- An increased bioavailability, particularly in cases of insoluble and hydrophobic drugs, due to rapid disintegration and dissolution of these tablets.
- Stability for longer duration of time, since the drug remains in solid dosage form till it is consumed. So, it combines advantage of solid dosage form in terms of stability and liquid dosage form in terms of bioavailability.

Benefits of fast dissolving tablets

- Administered without water, anywhere, any time.
- Suitability for geriatric and pediatric patients, who experience difficulties in Swallowing and for the other groups that may experience problems using Conventional oral dosage form, due to being mentally ill, the developmentally disable and the patients who are un-cooperative, or are on reduced liquid intake plans or are Nauseated.
- Beneficial in cases such as motion sickness, suede episodes of allergic attack or Coughing, where an ultra-rapid onset of action required.
- An increased bioavailability, particularly in cases of insoluble and hydrophobic drugs, due to rapid disintegration and dissolution of these tablets.
- Stability for longer duration of time, since the drug remains in solid dosage form till it is consumed. So, it combines advantage of solid dosage form in terms of stability and Liquid dosage form in terms of bioavailability.

Advantages of FDT'S

- Ease of administration to patients who cannot swallow, such as the elderly, stroke victims and bedridden patients; patients who should not swallow, such as renal failure patients; and who refuse to swallow, such as pediatrics, geriatric and psychiatric patients.
- Patient's compliance for disabled bedridden patients and for travelling and busy people who do not • Good mouth feel property of MDDDS helps to change the basic view of medication as "bitter pill", particularly for pediatric patients due to improved taste of bitter drugs. Convenience of administration and accurate dosing as compared to liquid formulation.
- Benefit of liquid medication in the form of solid preparation.
- More rapid drug absorption from the pre-gastric area i.e. mouth, pharynx and esophagus which may produce rapid onset of action
- Pregastric absorption can result in improved bioavailability, reduced dose and improved clinical performance by reducing side effect.

Limitations of Fast Dissolving Tablets

- The tablets usually have insufficient mechanical strength. Hence, careful handling is required.
- The tablets may leave unpleasant taste and/or grittiness in mouth if not formulated properly.

The need for development of FDT'S

Patient factors

Fast dissolving dosage forms are suitable for those patients (particularly pediatric and geriatric patients) who are not able to swallow traditional tablets and capsules with an 8-oz glass of water. These include the following:

- Patients who have difficulty in swallowing or chewing solid dosage forms.
- Patients incompliance due to fear of choking.
- Very elderly patients of depression who may not be able to swallow the solid dosage forms.
- An eight-year old patient with allergies desires a more convenient dosage form than antihistamine syrup.
- A middle-aged patient undergoing radiation therapy for breast cancer may be too nauseous to swallow her H2-blocker.
- A schizophrenic patient who may try to hide a conventional tablet under his or her tongue to avoid their daily dose of an atypical antipsychotic.
- A patient with persistent nausea, who may be journey, or has little or no access to water

Effectiveness factor

Dispersion in saliva in oral cavity causes pre-gastric absorption of drug which dissolves. Buccal, pharyngeal and gastric regions are all areas of absorption for many drugs. Any pre-gastric absorption avoids first pass hepatic metabolism which increase the bioavailability. Furthermore, safety profiles may be improved for drugs that produce significant amounts of toxic metabolites mediated by first-pass liver metabolism and gastric metabolism and for drugs that have a substantial fraction of absorption in the oral cavity and pre-gastric segments of GIT.

Objectives of the study

The objective of present study was;

- Improved functionality can be obtained by combination of superdisintegrants.
- To formulate mouth dissolving Ibuprofen tablet to achieve better compliances, to solve problem of difficulty in swallowing, to enhance on set of action.
- To study the effect of functionality differences of superdisintegrants on disintegration time and dissolution profile of tablet.

Method and Materials

Various techniques for fast dissolving tablets; () m

Dissolving property of the tablet is attributable to a quick ingress of water into the tablet matrix resulting in its rapid disintegration. Hence, the basic approaches to develop mouth dissolving tablets include maximizing the porous structure of the tablet matrix, incorporating the appropriate disintegrating agent, and using highly water soluble

excipients in the formulation.

1) Freeze drying technology
Lyophilization can be used to prepare tablets that have very porous open matrix network into which saliva rapidly moves to disintegrate lyophilized mass after it is placed in mouth. The drug is entrapped in a water soluble matrix which is freeze dried to produce a unit which rapidly disperses when placed in mouth. The preferred drug characteristics for freeze drying formulations are water insoluble, low dose, chemically stable, small particle size and tasteless. Lyophilization is relatively expensive and time consuming manufacturing process.

2) Tablet moulding technology
Molded tablets are designed to facilitate fast absorption of drugs through the mucosal lining of mouth by inclusion of water-soluble ingredients. The advantage of this system is that it has a porous structure which enhances dissolution (thereby enhanced bioavailability) and decreased first pass metabolism of certain drugs. As moulding process is employed usually with soluble ingredient (saccharides) which offers improved mouth feel and disintegration of tablets. However, molded tablets have low mechanical strength, which results in erosion and breakage during handling.

3) Spray drying technology
Spray drying is used in pharmaceutical industries to produce highly porous powders. The processing solvent is evaporated rapidly by spray drying, which renders the product highly porous and thus can be used in manufacturing mouth dissolving tablets. Tablets manufactured from the spray-dried powder have been reported to disintegrate in less than 20 seconds in aqueous medium.

4) Direct compression method
Direct compression is a process by which tablets are compressed directly from mixtures of the drug and excipients, without any preliminary treatment. It offers advantages over the other manufacturing processes for tablets, such as wet granulation and provides high efficiency. The mixture to be compressed must have adequate flow properties and cohere under pressure thus making pretreatment as wet granulation unnecessary. In many cases, the superdisintegrants have a major role in the disintegration and dissolution process of mouth dissolving tablets made by direct compression. The choice of a suitable type and an optimal amount of disintegrates is paramount for ensuring a high disintegration rate. The addition of other formulation components such as water soluble excipients or effervescent agents can further enhance dissolution or disintegration properties18. The disintegrant addition technology (direct compression) is the most preferred technique to manufacture the tablets due to certain tablet size and hardness strongly affect the disintegrates efficacy.

5) Sublimation technology
The key to rapid disintegration for mouth dissolving tablets is the presence of a porous structure in the tablet matrix. Conventional compressed tablets that contain highly water-soluble ingredients often fail to dissolve rapidly because of low porosity of the matrix. Hence, to generate porous matrix, volatile ingredients are used that are later subjected to a process of sublimation. Sublimation is a process in which water passes directly from solid state to vapour state without passing through liquid state. This process involves addition of some inert volatile substances like urea, urethane, naphthalene, camphor, etc. to other excipients and the compression of blend into tablet.

6) Mass-extrusion technology
This technology involves softening the active blend using the solvent mixture of water soluble polyethylene glycol using methanol and expulsion of softened mass through the extruder or syringe to get a cylinder of the product into even segments using heated blade to form tablets. The dried cylinder can also be used to coat granules of bitter tasting drugs and thereby masking their bitter taste.

7) Melt granulation technology
Melt granulation technique is a process by which pharmaceutical powders are efficiently agglomerated by a meltable binder. The advantage of this technique compared to a conventional granulation is that no water or organic solvents is needed. Because there is no drying step, the process is less time consuming and uses less energy than wet granulation. It is a useful technique to enhance the dissolution rate of poorly water-soluble drugs, such as griseofulvin. This approach to prepare MDT with sufficient mechanical integrity, involves the use of a hydrophilic waxy binder (Superpolystate, PEG-6-stearate).

8) Phase transition process
MDTs were produced by compressing powder containing erythritol (melting point: 122°C) and xylitol (melting point: 93-95°C), and then heating at about 93°C for 15 min(as shown in Fig.3) After heating, the median pore size of the tablets was increased and tablet hardness was also increased. The increase of tablet hardness with heating and storage did not depend on the crystal state of the lower melting point.

List of Material

Table 2: List of material

Sr No.	Ingredients	Use	Name of Suppliers
1	Ibuprofen	API	Sai Supreme chem, mumbai
2	Sodium starch glycolate	Superdisintegrant	SD Fine, chem, mumbai
3	Croscarmellose sodium	Superdisintegrant	SD Fine, chem, mumbai
4	Crospovidone	Superdisintegrant	SD Fine, chem, mumbai
5	Mannitol	Diluent	SD Fine, chem, mumbai
6	Micro crystalline cellulose	Binder & Diluent	SD Fine, chem, mumbai
7	Avicel pH 102	tablet disintegrant	SD Fine, chem, mumbai
8	Talc	Glidant & Lubricant	SD Fine, chem, mumbai
9	Magnesium stearate	Lubricant	SD Fine, chem, mumbai
10	Vanilla	Flavoring agent	Vast center, India

Preparation of blends and tablets

Fast dissolving tablets of Ibuprofen were prepared by direct compression method as per formulae given in Table. The superdisintegrants (crosscarmellose sodium, sodium starch glycolate, crospovidone) in varying concentration. All the ingredients were passed through # 60. All the ingredients were mixed in a motor and pestle for 5 min. The mixed blend was compressed into tablets on a KBR press tablet compression machine to a weight of 400 mg each, with thickness of 3±0.15 mm and diameter of 13 mm. The prepared tablets were evaluated for the uniformity of weight, drug content, hardness, friability, dispersion time and disintegration time. In solid dosage forms the physiochemical properties of blend rules the tablet quality. The mixing step if not properly optimized can affect the characteristics of blend and thereby tablet produced. The blends were characterized by mass-volume relationship (bulk density, tapped density, Hausner's ratio, compressibility index) and flow properties.

MILLING ⟹ SIEVING ⟹ MIXING ⟹ COMPRESSION

Compression of tablets

Fast dissolving tablets were prepared by a direct compression method involving two steps. In first step, the tablet powder blend (400mg) was compressed using a flat faced single punch (12 mm in diameter) tablet machine (KBr press). In the second step, upper punch was raised and the powder blend of backing layer was placed on the above compact and two layers were then compressed.

Formula

Table 7: Formulations of Fast Dissolving Tablets of Ibuprofen

Sr No.	Ingredients	F1	F2	F3	F4	F5	F6
1	Ibuprofen	100	100	100	100	100	100
2	Sodium starch glycolate	10	15	20	25		
3	Croscarmellose sodium					25	
4	Crospovidone						25
5	Mannitol	107	102	97	92	92	92
6	Micro crystalline cellulose	80	80	80	80	80	80
7	Avicel pH 102	90	90	90	90	90	90
8	Talc	5	5	5	5	5	5
9	Magnesium stearate	5	5	5	5	5	5
10	Flavoring Agent	3	3	3	3	3	3
11	Total weight	400	400	400	400	400	400

POST Formulation Parameters

i) Tablet Hardness

The strength of tablet is expressed as tensile strength (Kg/cm^2). The tablet crushing load, which is the force required to break a tablet into pieces by compression. It was measured using a tablet hardness tester (Monsanto hardness tester).

ii) Thickness and diameter

Tablet thickness should be controlled within 5% or less of a standard value. Mostly tablets have uniform diameter unless they have been prepared by using different dies. Small variation in tablet thickness and diameter significantly affects hardness and dissolution profile of tablet. The thickness and diameter of the tablets were determined using a vernier caliper.

iii) Weight Variation Test

Randomly selected 20 tablets were weighed individually and together in a single pan balance. The average weight was noted and standard deviation was calculated. IP limit for weight variation in case of tablets weighting up to 120 mg is ± 10%, 120 mg to 300 mg is ± 7.5% and more than 300 mg is ± 5%.

$$PD= (W_{avg}) – (W_{initial}) / (W_{avg}) \times 100$$

Where
PD= Percentage deviation,
W_{avg} = Average weight of tablet,
$W_{initial}$ = Individual weight of tablet.

iv) Friability

Roche friabilator was used to determine the friability. Pre weighed tablets were placed in friabilator and rotated at a speed of 25 rpm for 4 minutes or up to 100 revolutions. The tablets are dropped from a distance of 6 inches in each revolution. The tablets were then reweighed after removal of fines and the percentage of weight loss was calculated.

% Friability = initial weight – final weight/initial weight *100

v) Content uniformity

Twenty tablets were powdered, and powder equivalent to 100 mg of Ibuprofen was accurately weighed and transferred into a 100 ml volumetric flask. Initially, 5 ml methanol was added and shaken for 10 min. Then, the volume was made up to 100 ml with 7.2 phosphate buffer. The solution was filtered, diluted suitably and analyzed spectrophotometrically at 221 nm.

vi) Wetting time and water absorption ratio

A piece of paper folded twice was kept in a Petri dish containing 6 ml of purified water containing amaranth dye. A tablet was placed on the tissue paper. The time required to develop a color on the upper surface of the tablet was recorded as the wetting time. The same procedure was followed for determining the water absorption ratio(R) and was determined according to the following equation.

$$R = [(Wa – Wb)/Wb] \times 100$$

Where, Wb and Wa were the weights of the tablet before and after water absorption.

vii) In vitro dispersion time

Tablet was added to 10 ml of phosphate buffer solution pH 6.8 (pH of saliva) at 37+ 0.5°C. Time required for complete dispersion of tablet was measured.

viii) Disintegration test

The disintegration time for all formulations was carried out using tablet disintegration test apparatus. Six tablets were placed individually in each tube of disintegration test apparatus. The water was maintained at a temperature of 37°±2°C and time taken for the entire tablet to disintegrate completely was noted.

ix) Fineness of dispersion
This test is performed by placing two tablets in 100 ml of water and stirring it gently, till the tablets get completely disintegrated. The formulation is considered to form a smooth dispersion if the complete dispersion passes through a sieve screen with a nominal mesh aperture of 710 µm without leaving a residue on the mesh.

x) In vitro dissolution studies
In vitro dissolution studies are performed by using USP dissolution test apparatus using 7.2 phosphate buffer as dissolution medium. The paddles are allowed to rotate at speed of 100 rpm. The dissolution medium was maintained at a temperature of 37+0.5 OC and samples are withdrawn at an interval of every 5 min. The volume of the withdrawn samples is replaced by fresh dissolution medium in order to keep the volume of the dissolution medium as constant. The withdrawn samples were filtered and absorbance was measured at absorption maxima of 221nm using UV-visible spectrophotometer.

Results and Discussion

Characterization of Ibuprofen

Table 8: Characterization of Ibuprofen

Properties	Results
Description	Crystalline
Solubility	Soluble in Ethanol, Methanol, Acetone, Dichloromethane
Taste	Slightly bitter
Odor	Odorless
Color	White
Melting Point	75-80^{0}C

Characterization of Ibuprofen-
1] Description: Ibuprofen was found to be white, crystalline powder.
2] Solubility: The Ibuprofen was found to be soluble in ethanol and methanol Acetone, Dichloromethane.
3] Melting point of drug: The melting point of Ibuprofen was found to be in the range of 75-80^{0}C.

Thin layer chromatography (TLC)

Table 9: Parameters of thin layer chromatography of Ibuprofen

Sr. No.	Parameters	Magnitudes
1.	Distance traveled by solvent front	4.9 cm
2.	Distance traveled by solute	2.7 cm
3.	Stationary phase used	silica gel G
4.	Mobile phase used	Chloroform(9): Methanol(1)
5.	Rf value calculated	0.55
6.	Rf value reference	0.60

Calculated R_f value was found to be close to reference R_f value, hence Ibuprofen sample passes the test of purity.

Calibration of ibuprofen

Standard curve of Ibuprofen in phosphate buffer pH 7.2 at 221nm was plotted using various concentrations against the absorbance values found at respective concentrations. The standard curve of Ibuprofen was found to be linear in the range of 5-30 µg/ml, which means that present drug sample was obeying Beers- Lamberts range and coefficient of correlation was found to be 0.9895. The observations of calibration curve are shown in table 11, the plot of calibration curve and the statistical parameters from the calibration curve.

Table 10: Calibration of Ibuprofen

Concentration(µ/ml)	Absorbance (nm)
5	0.153
10	0.288
15	0.351
20	0.457
25	0.529
30	0.605

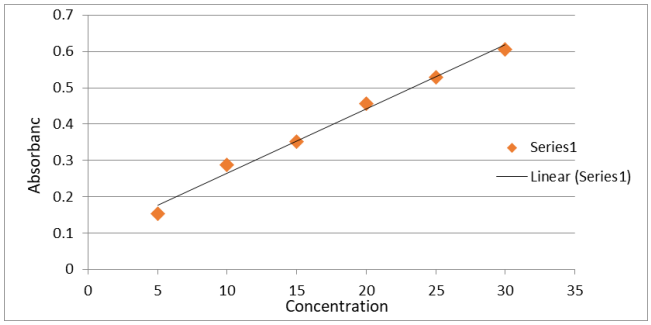

Fig 1: Calibration curve of Ibuprofen in phosphate buffer pH 7.2

The calibration curve exhibited good coefficient of correlation as shown in table 11.

Table 11: Parameters of calibration

Sr.No	Parameters	Observations
1	λ max	221nm
2	Slope	0.017
3	Intercept	0.088
4	Coefficient of correlation (R^2)	0.995

For determination of unknown concentration of Ibuprofen following equation of straight line was used,

$$Y= mX+C$$

Where,
Y= absorbance, m= slope,
X= concentration, C = Intercept,
So from the calibration curve, the following equation was obtained:

$$Y= 0.017\ X+ 0.088$$

Preformulation of Ibuprofen Blend

The angle of repose of all formulations was found to be in the range of 25.17 to 27.74 which indicates that they possess good flow properties. The values of Carr's index and Hausner's ratio were within the limit indicating good compressibility. All these parameters showed good flow property coupled with uniform die fill and thus ensured uniformity of weight of tablets. Therefore direct compression method was used for preparing the tablets.

Table 14: Preformulation of Ibuprofen Blend

Formulation code	Angle of repose	Bulk density (gm/cc)	Tapped density (gm/cc)	Compressibility Index (%)	Hausner ratio
F1	29.03±0.11	0.368±0.008	0.453±0.012	18.76±0.745	1.23±0.017
F2	26.47±0.18	0.368±0.004	0.492±0.007	25.20±0.785	1.33±0.018
F3	25.17±0.14	0.347±0.007	0.453±0.009	23.39±0.872	1.30±0.011
F4	27.74±0.09	0.368±0.009	0.492±0.019	25.20±0.687	1.33±0.027
F5	25.96±0.20	0.347±0.005	0.472±0.022	26.48±0.697	1.36±0.024
F6	27.42±0.14	0.393±0.008	0.491±0.014	19.95±0.875	1.25±0.021

Evaluation of prepared Ibuprofen FDT Tablet

Table 15: Evaluation of Ibuprofen FDT Tablet

Formulation code	Hardness (Kg/cm2)	Uniformity of weight(mg)	Friability (%)	Wetting Time (sec)	Water Absorption Ratio (%)
F1	3.8±0.015	394±0.77	0.77±0.13	44±0.22	46.32±0.12
F2	3.6±0.02	393±0.64	0.73±0.19	50±0.31	51.10±0.09
F3	4.2±0.017	397±0.81	0.87±0.09	52±0.35	57.37±0.17
F4	4.0±0.015	397±0.73	0.83±0.10	42±0.27	78.87±0.22
F5	3.6±0.017	399±0.69	0.75±0.19	35±0.37	87.29±0.14
F6	4.2±0.010	399±0.61	0.88±0.11	26±0.41	92.54±0.16

Table 16: Evaluation of Ibuprofen FDT Tablet

Formulations Code	Disintegration Time(sec)	Dispersion Time(sec)	Drug Content (%)
F1	90±0.31	122±0.71	91±0.18
F2	85±0.34	98±0.84	93±0.21
F3	78±0.46	77±0.67	92±0.14
F4	65±0.35	84±0.59	87±0.34
F5	49±0.47	107±0.62	93±0.42

Tablet thickness and Diameter

Thickness of tablets was determined by using micrometer screw gauge. The thickness of the prepared tablets was found to be between 2.8 to 3 mm and diameter of tablets was found in the range of 1.2 mm.

There was no marked variation in the thickness of tablet within each formulation indicating uniform behavior of powder throughout the compression process. The result of measured thickness and diameter of each formulation was as shown in the table no. 17.

Table 17: Thickness and Diameter of Tablet

Formulations	Thickness (mm)	Diameter(mm)
F1	2.8±0.014	1.2±0.0011
F2	2.8±0.018	1.2±0.0017
F3	3.0±0.015	1.2±0.0022
F4	3.0±0.012	1.2±0.0019
F5	3.0±0.013	1.2±0.0021
F6	3.0±0.012	1.2±0.0021

Hardness

Tablet hardness was determined by using Monsanto hardness tester. A hardness value of the formulation was ranged from 3.6 to 4.2 kg/cm2, which indicated good strength of tablet. The measured hardness of each formulation was as shown in the table no.15.

Friability

Tablet friability was determined by Roche friabilator and weight loss was calculated and represented in the terms of percent friability. Friability values of all the formulation were less than 1%, indicating good strength of tablets that can withstand the pressure exerted during handling and transportation or shifting.

Weight variation test

The weight variation test carried out showed that all the formulations passed the weight variation test. The average weight of tablet within each formulation was found to be uniform. This indicated uniform filling of the die cavity during tablet compression. The prepared tablet of all formulations exhibited weight in the range of 394 to 399 mg (table no. 15). This indicated that the tablets of all the formulations passed the weight variation test.

Wetting time and water absorption ratio study:

An objective behind formulation of FDT was to improve disintegration time and to serve that purpose, water absorption by FDT should be appropriate. So for evaluation of water uptake by FDT wetting time and water absorption ratio of Ibuprofen FDT was carried out, observations obtained are enlisted in table.15

Determination of drug content:

The drug content was found to be uniform among all formulations and was ranged from 87 to 95% which complied with the official standards for Ibuprofen. The content of active ingredient in each formulation was as shown in the table no. 16.

Dissolution Study

Table 18: Percent cumulative Drug Release of Ibuprofen

Time (min)	F1	F2	F3	F4	F5	F6
0	0.00	0.00	0.00	0.00	0.00	0.00
5	23.15±0.33	32.02±0.23	37.32±0.47	42.58±0.21	47.73±0.72	49.44±0.63
10	31.65±0.41	41.67±0.18	49.45±0.48	55.91±0.65	59.52±0.57	62.42±0.45
15	42.11±0.16	53.66±0.21	61.56±0.28	67.12±0.32	72.17±0.24	77.18±0.17

The above formulations shows drug release in percent.

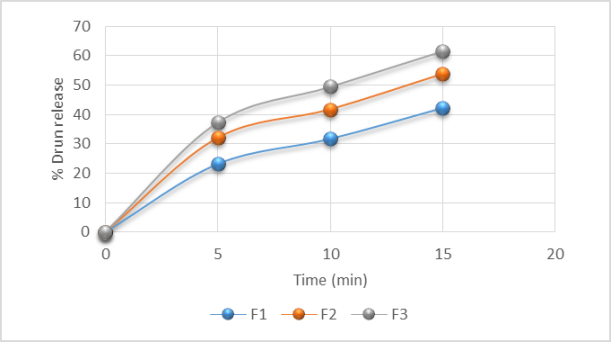

Fig 4: Drug release of F1, F2, F3

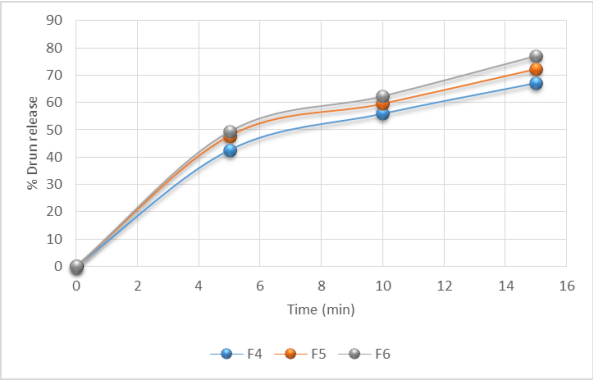

Fig 5: Drug release of F4, F5, F6

By observation of table no.18. It can be concluded that all formulations showed maximum percent drug release within 15 minutes, meanwhile formulation F6 showed maximum drug release (77.18%) within 15 min. While formulation F5 showed maximum drug release (72.17%) within 15 minutes. It means that the prepared fast dissolving tablets of ibuprofen shows desirable drug release.

Disintegration Time

As the concentration of superdisintegrant increase in formulation the disintegration time decreases.

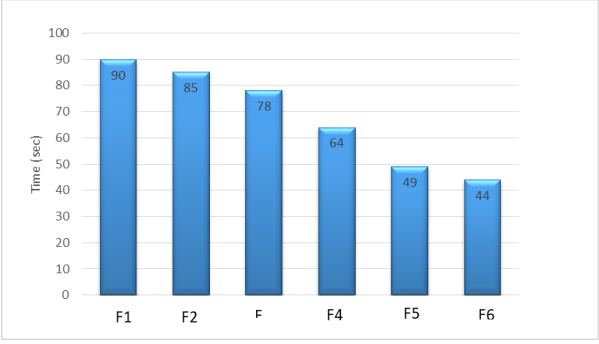

Fig 6: Disintegration Study of all Formulations.

Conclusion

From the results it was found that all the blends exhibited good flow properties and suited for direct compression. The formulation prepared with 6.25%w/w of sodium starch glycolate was offered relatively rapid release of Ibuprofen when compared with other concentrations employed in this investigation. Statistically significant difference between dissolution efficiencies (DE) of Ibuprofen tablets formulated with different concentrations of sodium starch glycolate was observed. The formulation prepared with Crospovidone was offered relatively rapid release of Ibuprofen when compared with other superdisintegrants used in this investigation. Statistically significant difference between dissolution efficiencies (DE) of Ibuprofen tablets formulated with different superdisintegrants was observed. So, we can conclude that nature and concentration of the superdisintegrant showed influence on the rate of dissolution. The rate of drug release was found to be increased by increasing the concentration of the superdisintegrant and found to be highest for tablets formulated with 6.25%w/w of crosspovidone.

Future Perspectives

Fast dissolving drug delivery system in most cases, is a tablet that dissolves or disintegrates in oral cavity without the need of water or chewing. Rapidly dissolving or disintegrating tablets are not only indicated for people who have swallowing difficulties, but also are ideal for active people. Fast dissolving dosage forms have been extensively used to improve therapy with several important drugs. Diabetic is defined high blood sugar level characterize by overacting of exercise missed insulin..

Despite the existence of many binders and disintegrants, there still remains a need in the industry for pharmaceutical superdisintegrants which is highly compatible and multifunctional (thereby allowing for its use in high-dose formulations, etc.). Tablets to be developed in the present study could open avenues in the field of augmented or processed excipients. Moreover, processes of augmentation to be used in this study are simple, ecological, economical and less time consuming.

The obvious advantages of solid dosage forms and changing technological requirements will keep alive the search for newer excipients. The newer excipients are required to be compatible not only with the latest technologies and production machineries, but also with the innovative active principles such as those originating from biotechnology. Developments in the field of excipients and manufacturing machinery have helped in establishing traditional inert excipients as function.

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