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FORMULATION, DEVELOPMENT AND EVALUATION OF FAST DISSOIVING TABLET CONTAINING SOLID DISPERSION OF MOSAPRIDE: A RESEARCH

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ABSTRACT

The dosage form's ability to transport the medication to the site of action at a rate and amount sufficient to produce the desired pharmacological response determines the drug's effectiveness. This dosage form characteristic is known as biologic availability, physiologic availability, or just bioavailability. Thus, the rate and amount of a medicine that remains unchanged from its dosage forms is referred to as its bioavailability. The in-vivo efficacy of medications taken orally is contingent upon their tissue permeability and solubility properties. The concept of solid dispersion was proposed by Sekiguchi and Obi in the early 1960's, who investigated the generation and dissolution performance of eutectic, melts of a sulfonamide and water soluble carrier. Solid dispersion represents a useful pharmaceutical method for increasing the dissolution, absorption and therapeutic efficacy of the drug in the dosage forms. United States Food and Drug Administration (USFDA) defined fast dissolving tablet as "A solid dosage forms containing active ingredient or medical substances which disintegrates rapidly within a matter of seconds when placed upon the tongue." The disintegration time for fast dissolving tablets ranges from few seconds to about a minute.

KEYWORDS: Mosapride; Fast Dissolving Tablet; Solid Dispersion; Formulation Technique; Evaluation Methods; Appication.

INTRODUCTION

United state Pharmacopeia approved this dosage form as orally disintegrating tablet. European pharmacopeia defines a similar terms, Or dispersible tablets, that disperses rapidly within 3 minutes in mouth before swallowing. Over a decade, the demand for development of fast dissolving tablets has tremendously increased as it has impact on the patient's compliance. Fast dissolving tablets are beneficial for various groups of populations particularly who have difficulty in swallowing. Fast dissolving tablet are also appreciated by pediatric, geriatric patients, institutional patients along with mentally disabled patients who enable to take self-medication, and patients who suffering from nausea, vomiting and motion sickness complications. Fast dissolving tablets are also called as orodispersible tablets, orally disintegrating tablets, rapid tablets, quick disintegrating tablets, rapimelt tablets, fast disintegrating tablets. This dosage forms allow high patients compliance, high drug loading, have a good mouth feeling and tastes.

Solid Dispersion

The concept of solid dispersion was proposed by Sekiguchi and Obi in the early 1960's, who investigated the generation and dissolution performance of eutectic, melts of a sulphonamide drug and water soluble carrier. Solid dispersion represents a useful pharmaceutical method for increasing the dissolution, absorption and therapeutic efficacy of the drug in the dosage forms.

The concept of solid dispersion refers to a group of solid products consisting of at least two different components, generally a hydrophilic matrix and a hydrophobic drug.

1.2. Classification of solid dispersion:

a. Simple eutectic mixture
b. Solid solution
c. Glass solution
d. Amorphous precipitation in crystalline carrier
e. Complex formation

a. Simple eutectic mixture

A simple eutectic mixture is an intimately blended physical mixture of two crystalline components which are miscible in the liquid state, but immiscible in solid state. A mixture of components A and B with

composition E is coole then A and B crystallize out simultaneously. Whereas when other composition is cooled, one of the components starts to crystallize out before the other.

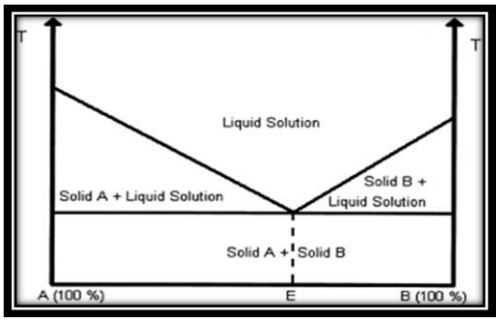


Fig. Phase diagram for simple eutectic mixture.

dispersion represents a useful pharmaceutical method for increasing the dissolution, absorption and therapeutic efficacy of the drug in the dosage forms. United States Food and Drug Administration (USFDA) defined fast dissolving tablet as "A solid dosage forms containing active ingredient or medical substances which disintegrates rapidly within a matter of seconds when placed upon the tongue." The disintegration time for fast dissolving tablets ranges from few seconds to about a minute.

b. Solid solution

A solid solution is made up of solid solvent-dissolved solid solute particles. There is a molecular-level reduction in particle size. The drug's effective surface area increases dramatically when it is disseminated in the carrier matrix, which increases the drug's rate of dissolution.

Because solid solution inhibits drug crystallisation by lowering molecular mobility, it has enhanced the physical stability of amorphous drugs. The following subtypes of solid solutions are categorised: Based on the traits that make them miscible.

i. Constantly stable solution
ii. Solid solution with discontinuities

The distribution of solute/solvent molecules within the lattice depends on.

i. Solid interstitial solution.
ii. Amorphous or substitutional solid solution.

i. Continuous solid solution: All of the components in a continuous solid solution are miscible with one another in both the liquid and solid states. Because a continuous solid solution requires a stronger heteromolecular bond than a homomolecular one, the lattice energy of the continuous solid solution at all compositions is greater than that of the corresponding pure components in the solid state.

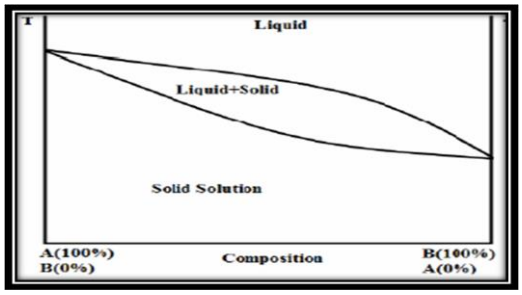


Fig: Phase diagram for Continuous solid solution.

i. Discontinuous solid solution

In this class, the miscibility or solubility of one component in the other is limited. A and β shows the regions of true solid solutions. The region α is a solid solution of B in A that is component A as the solvent and B as the solute. Similarly the region β is a solid solution of A in B. Below a certain temperature, the mutual solubility of the two components start to decrease.

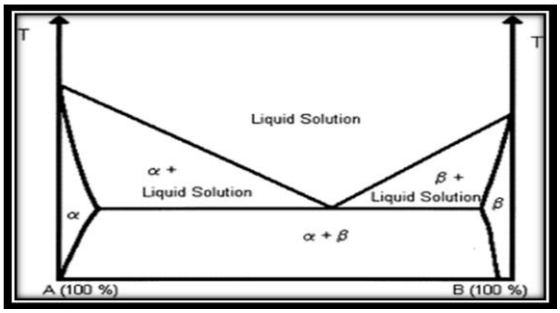


Fig. Phase diagram for Continuous solid solution.

c. Glass solution

A glassy or vitreous form of the carrier solubilizes drug molecules in glass solution, an amorphous, homogenous solution system. Below the glass transition temperature (Tg), the glassy or vitreous state is characterised by transparency and brittleness. Glass solutions have an advantage over solid solutions in that they don't have a strong lattice, which prevents them from acting as a barrier to quick dissolving.

d. Amorphous precipitation in a crystalline carrier

The drug may precipitate in an amorphous form in the crystalline forms of the drug, as an alternative to the drug and carrier crystallising simultaneously.

e. Complex formation: A medication combines with a water-soluble carrier in a solid state to generate a complex. The solubility, absorption rate, and stability constant of the complex all affect the drug's availability. The drug's oral absorption and dissolution rate are improved by the creation of a water soluble complex.

Advantages of solid dispersions

Particles with reduced particle size

In the solid dispersions, drug is dissolved in dissolution medium or inert matrix. A high surface area is formed which gives increased dissolution rate and further enhance the bioavailability of poorly water

soluble drug.

Particle with improved wettability
Solid dispersions improved the wettability of poorly water soluble drug due to this improved in bioavailability of drug.

Particle with higher porosity
Particles in solid dispersion have found to have high porosity. Porous nature of particle results higher dissolution rate. Increase in porosity of particles is depend upon properties of carrier. when the polymer having linear structure are utilized it formed larger and porous particles compared with solid dispersion that prepared with reticular polymer.

Drug in amorphous state
Drug substances in amorphous state shows higher drug release because no energy is required to break up the crystal lattice during dissolution. Therefore, poorly water soluble drug in amorphous state gives high degree of solubility.

Disadvantages of solid dispersion
The main drawback of solid dispersion is instability. A decrease in the rate of dissolution and a reduction in the solubility of the medicine are the results of changes in crystallinity that occur in many solid dispersion systems with ageing, phase separation, moisture absorption, and crystal formation. Temperature and moisture content both exacerbate the degrading effect on solid dispersion. Taciness makes things harder to deal with a lot of the time.

Solid dispersion limitations
Although solid dispersions have attracted a lot of attention in recent decades, there is very little practical use for them. The following are issues or restrictions with solid dispersion: The physical and chemical stability of medications and vehicles.
-The process for making the solid dispersion.
-the reproducibility of its different physicochemical properties.
-the formulation of the solid dispersion into different dosage forms.

Pharmaceutical applications of solid dispersions
-The solid dispersion approach should be investigated further since it may have other.
-uses in addition to improving solubility.
-To achieve a uniform dispersion of extremely small quantities of pharmacological compounds.
-To provide different gaseous or liquid substances in solid dose forms.
-To stabilise a range of unstable medications.
-To create sustained release dosage forms with an immediate release primary dose

Definition of Fast Dissolving Tablet
Fast dissolving tablets
are described as "solid dosage forms containing active ingredient or medical substances which disintegrates rapidly within a matter of seconds when placed upon the tongue" by the United States Food and Drug Administration (USFDA). Fast dissolving pills can dissolve in a matter of seconds to approximately a minute.

Additionally, this dosage form as an oral disintegrating tablet was approved by the United States Pharmacopoeia. Similar terminology, such as dispersible pills, are defined by the European Pharmacopoeia as those that quickly disperse in the mouth for three minutes before being swallowed. Due to its impact on patient compliance, the need for the creation of fast-dissolving tablets has expanded dramatically during the past ten years. Tablets that dissolve quickly are helpful for a variety of demographics, especially those who have trouble swallowing.

Fast-dissolving tablet requirements
- It should have a pleasing texture to the mouth and a passable ability to disguise taste.
- Need no water when taken orally Be firmer and less brittle.
- Less susceptible to environmental factors.

Salient feature of fast dissolving tablet
- Oral administration of fast-dissolving tablets is possible without the need for water.
- Tablets that dissolve quickly and have enough toughness to survive handling during transit and the rigorous production

Advantages of fast dissolving tablets
- Patients who are unable to swallow, such as elderly individuals, stroke victims in bed.
- Patients experiencing renal failure, and psychiatric patients, can benefit from the use of pills.
- Quick medication delivery intervention.
- Easily manageable for administrators.
- Enhanced bioavailability of medications that are poorly soluble in water is achieved by means of Excellent mouth feel quality that increases patients' acceptance.
- It prevents choking or suffocation when taking conventional dosage forms orally.

Limitation of fast dissolving tablets
- Careful handling is required due to insufficient mechanical strength.
- The tablets may leave grittiness in mouth if not formulated properly.

Disadvantages of fast dissolving tablets
- It is hygroscopic in nature so must be store in dry places.

- Fast dissolving tablets also shows the fragile, effervesces granules property.
- It require special packing for stabilization of product.

Patented methods for making tablets that dissolve quickly

i. Zydus Technology

The medicine is physically imprisoned inside the matrix of quickly dissolving carrier material during the freeze-drying or lyophilization process that creates the zydus tablet. The freeze-dried structure of the Zydus tablet dissolves in the mouth in a matter of seconds. The Zydus unit comes in a unique blister pack and is extremely lightweight and delicate.

ii. Durasolv Technology

This is a CIMA Labs-patented technology. This process yields a tablet that contains filler, lubricant, and active pharmaceutical components. The tablet is made using a traditional manufacturing method and is packaged using a traditional method. This technique uses a little quantity of medication.

Mechanism of Action

Mosapride accelerates gastric emptying by acting on 5-hydroxytryptamine type 4 (5 HT4) receptor and is frequently used in the treatment of gastrointestinal (GI) disorders requiring gastroprokinetic efficacy. We tested the effect of mosapride on 5 hydroxytryptamine type 3 (5- HT3) receptor currents because the 5-HT3 receptors are also known to be expressed in the GI system and have an important role in the regulation of GI functions. Using the whole-cell voltage clamp method, we compared the currents of the 5-HT3 receptors when 5-HT was applied alone or was co-applied with mosapride in cultured NCB-20 cells known to express 5-HT3 receptors. The 5-HT3 receptor current amplitudes were inhibited by mosapride in a concentration dependent manner. Mosapride blocked the peak currents evoked by application of 5-HT in a competitive manner because the EC50 shifted to the right without changing the maximal effect.

Pharmacology and Biochemistry

Pharmacology

Mesopride Hydrochloride is the hydrochloride salt form of Mesopride, a prokinetic agent with gastrointestinal (GI) motility-enhancing activity. Although the exact mechanism by which Mesopride exerts its effect has yet to be fully elucidated, this agent appears to inhibit acetylcholinesterase (AchE), an enzyme responsible for the breakdown of acetylcholine (Ach). Increased Ach concentrations lead to an improvement of gastric emptying and GI motility and eventually to a reduction of dyspepsia symptoms.

MeSH Pharmacological Classification

Inhibitors of Cholinesterase medications that cholinesterase inhibitors. Cholinesterases quickly hydrolyze and inactivate the neurotransmitter ACETYLCHOLINE. The activity of endogenously produced acetylcholine at cholinergic synapses is enhanced by the inhibition of cholinesterase. Because cholinesterase inhibitors potentiate cholinergic inputs to the gastrointestinal tract, bladder, eye, and skeletal muscles, as well as having effects on the heart and central nervous system, they are frequently employed in clinical settings.

Gastrointestinal Agents

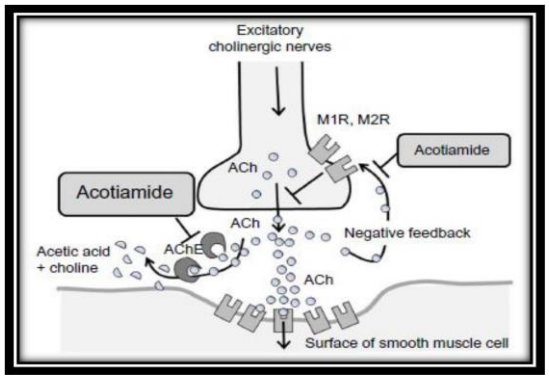
Drugs are used for their effects on the gastrointestinal system, such as to control gastric acidity, regulate gastrointestinal motility and water flow, and improve digestion.

Pharmacodynamics

Mesopride is a novel gastroprokinetic medication that works by inhibiting the activity of the stomach enzyme acetylcholinesterase (AChE) and by inhibiting muscarinic receptors, which leads to increased acetylcholine release. Through antagonism of the inhibitory presynaptic M1 and perhaps M2 receptors as well as reversible inhibition of AChE, mesopride amplifies the effects of ACh release from enteric nervous system nerve terminals. As a result, it makes more ACh available on postsynaptic receptors in the neuromuscular junction and enteric nervous system.

Pharmacologically effective site of Mesopride.

- ✓ ACh- Acetylcholine
- ✓ AChE- Acetylcholinesterase
- ✓ MIR- Muscarinic acetylcholine receptor ml
- ✓ M2R- Muscarinic acetylcholine receptor m2



In addition, Mesopride itself may act on postsynaptic M5-like accentuating rhythmic smooth muscle contractions through an agonistic effect. Furthermore, enhanced gastric accommodation to meal ingestion has been shown after Mesopride treatment. Mesopride may also modify brain-gut interactions via its effects on the afferent vagus nerve, modifying sensory input from the GI tract to the CNS or modulating vago-vagal reflex pathways. All of these effects on gastrointestinal motility provide the drug with an attractive pharmacodynamic profile for the

treatment of FD with PDS which is at least in part associated with delayed gastric emptying, impaired gastric accommodation, and susceptibility to anxiety and stress.3 The gastroprokinetic activity of Mesopride does not appear to be associated with prolongation of the QT interval, based on animal studies. In this study, unlike cisapride, Mesopride had no effects on myocardial monophasic action potential duration, QT interval or corrected QT interval.4

Chemical kinetics

Mosapride's maximal plasma levels are attained 1-1.5 hours after oral consumption. The medication's half-life in plasma is 7–10 hours. The average amount of mosapride eliminated in stool is 45%. Cytochrome P450 is not significantly inhibited by mosapride.

Safe handling precautions

Steer clear of the eyes and skin. Prevent the production of aerosols and dust. Wherever there is a dust accumulation, provide suitable exhaust ventilation. Refer to section 2.2 for precautions.

Safe storage requirements, including any incompatibilities

Store the container in a dry, well-ventilated area with the lid securely closed. For short term storage (weeks to 3 months), 2 to 8 °C is recommended; for long term storage (months to years), use -20 °C. Store in a dry area.

METHOD OF PREPARATION OF SOLID DISPERSION

Various preparation methods of solid dispersions are as follows.

1:6:1 Fusion Method

The fusion method also called as the melt method. In this method, the melting phase is consists of suspended active drug ia a previously melted carrier mass, instead of using both drug and carrier in the melted state, therefore reducing the process time and temperature. After cooling, the obtained mixture must be pulverized regarding further use. This method is less difficult technically. However, the use of high temperature, several drugs can be degraded during melting process can be a limitation of this method. Another limitation of method is incomplete miscibility of drug and carrier. To avoid this limitation several modification were introduced to the original method like hot stagiest rusion method, melt agglomeration method.

EVALUATION PARAMETER

1) Evaluation of solid dispersions

- Physical appearance
- Drug content uniformity
- % practical yield
- Solubility study
- In-vitro dissolution study
- Differential scanning calorimetry (DSC)
- Fourier Transform Infra-Red (FTIR) Spectroscopy

2) Evaluation of fast-dissolving tablets and conventional tablets of Mosapride

❑ **Pre-compression parameters**

- Angle of repose
- Bulk density
- Tapped density
- Hausner Ratio
- Carr's index

❑ **Post-compression parameters**

- Hardness
- Friability
- Weight variation
- Uniformity of thickness
- Drug Content Uniformity
- Wetting time
- In-Vitro disintegration time
- In- vitro dissolution study
- Differential scanning calorimetry (DSC)
- Fourier Transform Infra-Red (FTIR) Spectroscopy

DIRECT COMPRESSION PROCESS FOR MAKING MOSAPRIDE-FAST DISSOLVING TABLETS

Mosapride fast-dissolving tablets were made using the direct compression method using the formula. Each component was put through a 40 mesh sieve in isolation. After combining a small amount of the solid dispersion containing 25 mg of Mosapride and diluents each time to create a homogenous mixture, the other ingredients were combined in a geometric order. The prepared mixture was compressed (10 mm Punch) with a tablet press equipment that has many stations.

Evaluation of Fast Dissolving Tablets

Pre-compression parameters

1) Angle of repose
2) Bulk Density
3) Tapped Density
4) Hausner‟s Ratio
5) Compressibility Index (Carr‟s Index)

Determination of angle of repose, Carr‟s index and Hausner‟s ratio were used to characterize flow properties of the solid dispersion systems. The flow ability of a powder is a critical importance in the production of pharmaceutical dosage forms in order to get a uniform feed as well as reproducible filling of tablet dies, otherwise, high dose variation will occur.

Angle of Repose

Angle of repose has been used as indirect methods of quantifying powder flow ability. Angle of repose is defined as the maximum angle possible between the surface of pile of the powder and horizontal surface the frictional force in a loose powder or granules can be determined by angle of repose. Angle of repose for blend of each formulation was determined by fixed funnel method. The funnel is secured with its tip with height h, above a plane of paper kept on a flat

horizontal plane. The powders were poured through the funnel until the apex of the conical pile so formed just reaches the tip of funnel. The angle of repose was determined by substituting the values of the base radius „r ‟and height of the pile „h‟ in the formula given below,

Tan = h / r

=is the angle of repose,

h =is the height in cm and r =is the radius.

Bulk density

Bulk density was determined by pouring pre-sieved drug and excipients blend into a graduated cylinder and measuring the volume and weight "as it is". It is expressed in g/ml and is given by

Db = M / V0

Where,

M is the mass of powder

Tapped density

It was determined by placing a graduated cylinder, containing a known mass of drug- excipient blend, on mechanical tapping apparatus. The tapped volume was measured by tapping the powder to constant volume. It is expressed in g/ml and is given by

Dt = M / Vt

Where,

M is the mass of powder

Table: Relation between angle of reposeand flow properties.

Angle of repose (degrees)	Flow
<25	Excellent
25-30	Good
30-40	Passable
>40	Very poor

Carr's Index (%Compressibility)

The compressibility index and Hausner ratio are measures of the property of powder to be compressed. The packing ability of drug was evaluated from change in volume, which is due to rearrangement of packing occurring during tapping. It was indicated as Carr‟s compressibility index was calculated as follows.

Carr's index% = [Tapped density - Bulk density/Tapped density] X 100

Table: Grading of powders for their flow properties.

Consolidation index (Carr's %)	Flow
5-15	Excellent
12-16	Good
18-21	Fair to passable
23-35	Poor
33-38	Very poor
40	Very very poor

Hausner Ratio

It is measurement of frictional resistance of the drug. He showed that the powder with low inter particle friction had ratio of approximately 1.2, whereas more cohesive less free flowing powder have Hausner‟s ratio greater than 1.6. Hausner‟s ratio less than 1.25 indicate good flow properties. It was determined by the ratio of tapped density and bulk density

Hausner Ratio = Tapped density / Bulk density

Post compression Parameters

Prepared tablets were subjected to evaluation of different properties including tablet hardness, friability, uniformity of thickness, In vitro disintegration time, In vitro dissolution test etc.

1) Hardness
2) Friability
3) Weight Variation
4) Uniformity of thickness
5) Drug content uniformity
6) Wetting time
7) In -vitro disintegration time
8) In- vitro dissolution study
9) Differential scanning calorimetry (DSC)
10) Fourier Transform Infra-Red (FTIR) Spectroscopy

Hardness

Hardness indicates the ability of a tablet to withstand mechanical shocks while handling. The hardness of the tablets was determined using Monsanto hardness tester. It is expressed in Kg/cm2. Three tablets were randomly picked and mean hardness of the tablets formulation was determined.

Friability

Tablet hardness is not an absolute indicator of strength, since some formulations compressed into very hard tablet tend to cap on attrition losing their crown potions. Therefore another measure of tablet strengths, its friability is often measured. The friability of tablets was determined using Roche friabilator.

It is expressed in percentage (%). Twenty tablets were initially weighed and transferred into friabilator. The friabilator was operated at 25rpm for 4 minutes or run up to 100 revolutions. The tablets were weighed again. The % friability was then calculated by Percentage friability of tablets less than 1% is considered acceptable.

Weight Variation Test

The weight of tablets is measured to ensure that a tablet contain the proper amount of drug. Twenty tablets were selected at random and the average weight was determined.

USP official limits of percentage deviation of tablet are presented in the table no. 13 Average weight of tablet Percent deviation

130 mg or less 10

More than 130 mg or less than 324 mg 7.5

More than 324 mg or more 5 100 Initial weight of the tablets

Initial weight of the tablets – Final weight of the tablets

% Friability X
In all the formulations the tablet weight was 400 mg, hence 5% maximum difference allowed.

Uniformity of Thickness
The thickness of the tablets was determined using a vernier caliper. Three tablets from each type of formulation were used and average values were calculated. It is expressed in mm.

Uniformity of Drug Content
Five tablets of each type of formulation were weighed and crushed in mortar and powder equivalent to 25 mg of drug transferred in conical flask containing 25 ml phosphate buffer 6.8. Its concentration 1000mcg/ml.10 ml from this stock solution was taken and diluted to 100 ml phosphate buffer 6.8.; it makes 100 g/ml. Then 25 g/ml solution prepared by taking 2.5 ml from this stock solution and diluted up to 10 ml. Absorbance measured at 319 nm.

Sr. no	Concentration	Absorbance
1	0	0
2	5	0.0084
3	10	0.0164
4	15	0.2637
5	20	0.3545
6	25	0.4573
7	30	0.5574
8	35	0.6325
9	40	0.7184
10	45	0.8147
11	50	0.9158

Wetting Time
A piece of tissue paper folded twice containing was placed in a small Petri dish (ID =6.5 cm) containing 10 ml of phosphate buffer 6.8, a tablet was put on the paper and the time required for complete wetting was measured as wetting time. The study was performed in triplicate.

1) In -vitro disintegration time
Generally accepted maxima is that for a drug to be readily available to the body, it must be in solution form. For most of the tablets the first important step toward solution is breakdown of the tablet into smaller particles, a process known as disintegration. In vitro disintegration time is measure using is integration test apparatus as per I.P. specifications. I.P. specifications: Place one tablet in each of the 6 tubes of the basket. Add a disc to each tube and run the apparatus using phosphate buffer 6.8 maintained at 370±2°C as the immersion liquid. The assembly should be raised and lowered between 30 cycles per minute in the pH 6.8 maintained at 370±2°C. The time in seconds taken for complete disintegration of tablet with no palpable mass remaining in the apparatus was measured and recorded. The assembly was removed from liquid. The tablets pass the test if all of them have disintegrated. If 1 or 2 tablets fail to disintegrate repeat the test for 12 additional tablets; not less than 16 of the total of 18 tablets tested disintegrate, finally observe the disintegration time of the tablets.

In-vitro dissolution study
The release rate of Mosapride- from fast dissolving tablets was determined using United State Pharmacopoeia (USP) dissolution testing apparatus II (paddle method). The dissolution test was performed using 900 ml of phosphate buffer 6.8 dissolution medium, at 37±0.5°C and 50 rpm. Sample volume of 5 ml was withdrawn at every 1 minute time interval and filtered. The volume withdrawn was replaced by fresh volume of dissolution medium to maintain constant volume of medium. The filtered samples were analyzed spectrophotometrically at 319 nm using phosphate buffer 6.8 as a blank. Drug content in dissolution sample was determined by calibration curve. The study was carried out in triplicate.

Differential scanning calorimetry (DSC) of fast dissolving tablets
DSC was performed in order to assess the thermotropic properties and thermal behavior of oral fast dissolving tablets prepared. Differential scanning calorimetry thermograms of optimize formulation were recorded on a thermal analyzer. The samples were heated from 25 to 500 °C at a heating rate of 10 °C/min in an inert nitrogen atmosphere.

Fourier Transform Infra-Red (FTIR) Spectroscopy of fast dissolving tablets
IR spectroscopy is one of the qualitative analytical techniques, which offers the possibility of detecting chemical interaction. Infrared spectra of optimized formulations were determined. on Fourier Transform Infrared Spectrophotometer using KBr dispersion method. The base line correction was done using dried potassium bromide. Then the spectrum of physical mixture of drug and potassium bromide was recorded. TS5 –Tablets prepared by using solid dispersion product prepared by solvent evaporation method. [Containing 2.5 % croscarmellose sodium+2.5 % crospovidone]

RESULTS AND DISCUSSION

Preformulation Study of Drug

Melting Point
The melting point of Mesopride- was found to be 161^0c which complies with a range that is given in the literature i.e. 158-162^0c.

Determination of λ max of the Mosapride
The standard solution of Mesopride- shows maximum absorbance at 319 nm wavelength in spectroscopy.

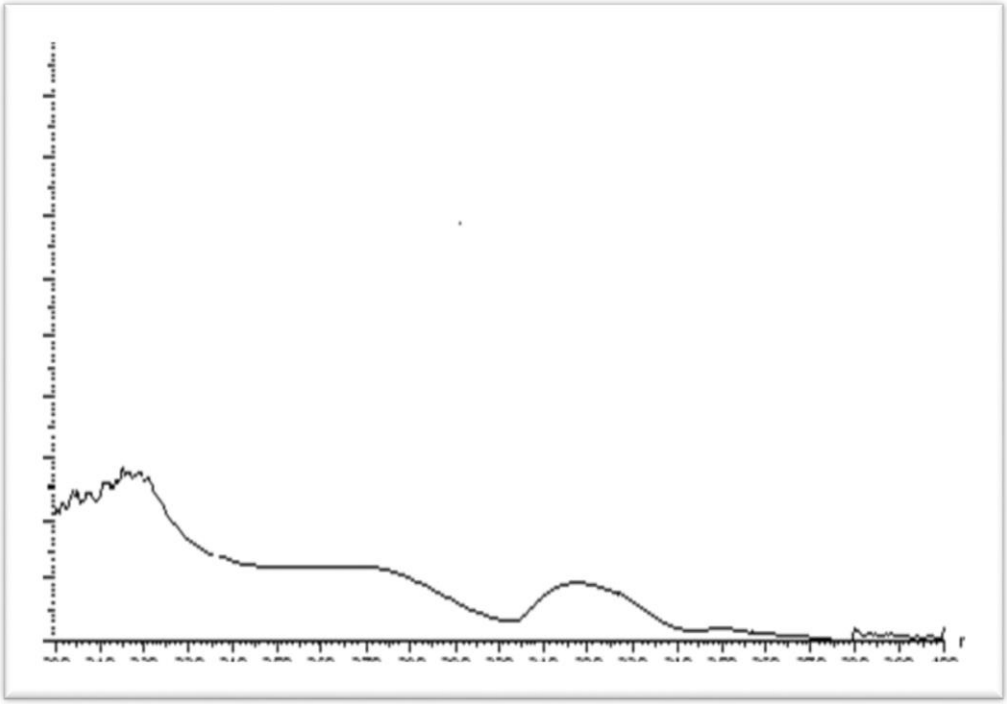


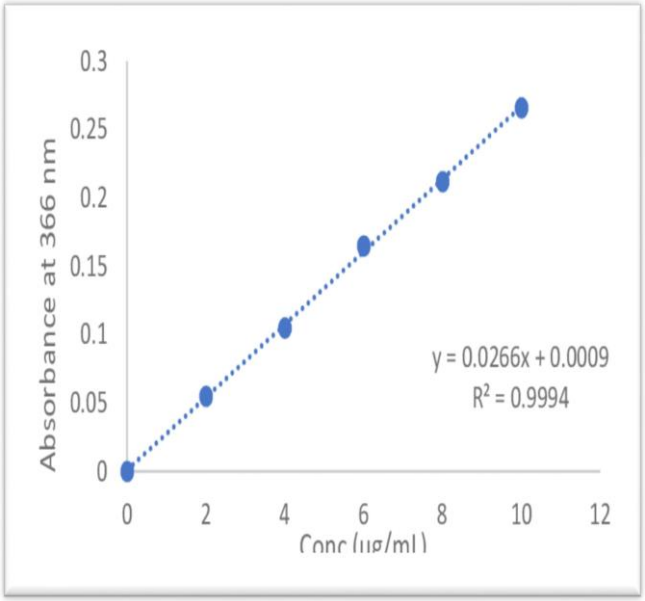
Fig. No. 15: UV spectrum of Mesopride.

Preparation of standard calibration curve of Mosapride

The standard calibration curve of Mosapride- in phosphate buffer pH 6.8 at 319 nm was plotted using various concentrations ranging from 2-50 g/ml, the absorption values are shown in Table no 12, and calibration curve is shown in fig. no 13 Table Observations for standard calibration curve of Mosapride- in pH 6.8phosphate buffer at 319 nm.

Table: Standard curve statistics.

Functional group	Observed wave number (cm_{-1})
C=O in ketone	1688.56
OH in –COOH group	1477.13
C=O in COOH group	1307.06
C=C in aromatic alkene	1145.19



Standard calibration curve of Mosapride.

Differential scanning calorimetry (DSC)

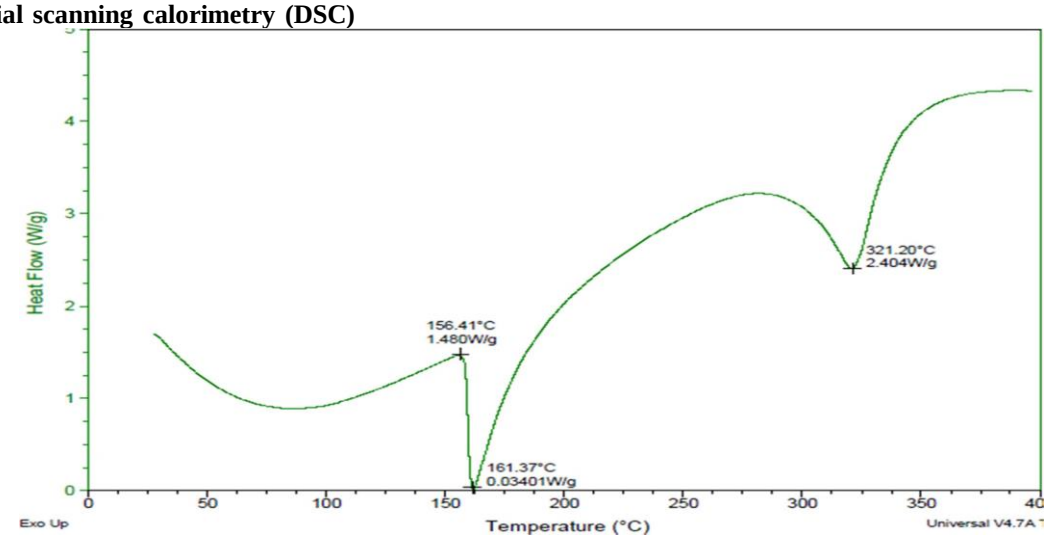
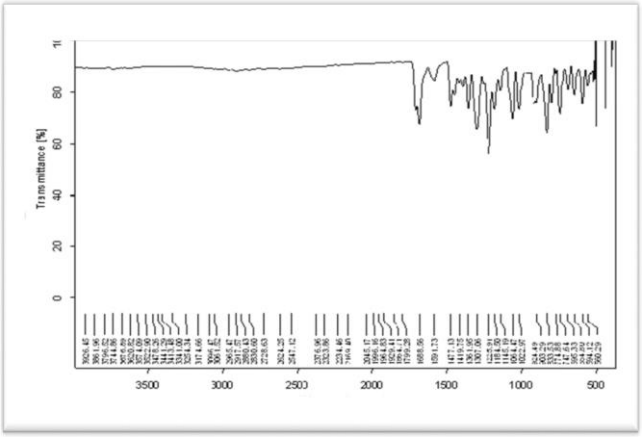


Fig. DSC of Pure Mosapride

The DSC thermogram of Mesopride- has presented in Fig. no.17 The DSC thermogram of Mesopride- depicts a sharp endothermic peak at 161.370c. Such a sharp endothermic peak signifies that Mesopride- used was in a pure state.

Fourier Transform Infra-Red (FTIR) Spectroscopy



FTIR Spectrum of Pure Mosapride

Table: Observed peaks of FTIR spectra of Mosapride.

code	Hardness Kg/cm$_2$	Friability %	Weight Variation mg	Uniformity of thickness
CT	3.2 ± 0.2	0.51	396 ± 0.62	3.2 ± 0.15
TP1	3.2 ± 0.2	0.64	397 ± 0.48	3.3 ± 0.20
TP2	3.2 ± 0.2	0.47	397 ± 0.90	3.2 ± 0.11
TP3	3.2 ±0.31	0.66	396 ± 0.90	3.1 ± 0.17
TP4	3.1 ±0.11	0.40	395 ± 0.55	3.2 ± 0.1
TP5	2.9 ±0.23	0.52	396 ± 0.7	3.2 ± 0.15
TS1	3.1 ±0.05	0.68	397 ± 1.06	3.2 ± 0.11
TS2	3.1 ±0.11	0.54	397 ± 1.22	3.4 ± 0.41
TS3	3.0 ± 0.2	0.32	396 ± 0.85	3.1 ± 0.15
TS4	3.0 ±0.23	0.41	396 ± 0.80	3.2 ± 0.11
TS5	3.0 ±0.30	0.32	395 ± 0.99	3.2 ± 0.15

Physical parameters of Mosapride- solid dispersionj

Formulation Code	Physical Appearance	
	Color	Appearance
PM1	White	Fine powder
PM2	White	Fine powder
PM3	White	Fine powder
SE1	Light yellow	Fine powder
SE2	Light yellow	Fine powder
SE3	Light yellow	Fine powder

EVALUATION OF SOLID DISPERSION
Incorporated Mosapride
Fast Dissolving Tablet and Conventional Tablet
Results of Pre-compression Parameters

Pre-compression parameters play an important role in improving the flow properties of pharmaceuticals, especially in tablet formulations. These include angle of repose, bulk density tapped density, Hausner's ratio, and Carr's index. Mesopride- fast-dissolving tablets i.e. TP1 to TP5 tablets formulations prepared by using PM3 solid dispersion whereas TS1 to TS5 tablet formulations are prepared by SE3. Optimized batches of solid dispersion of Mesopride- i.e PM3 and SE3 along with various excipients like super disintegrants, diluents, sweeteners, glidants, and lubricants were subjected to precompression parameters to study flow properties**d** powder.

Result of Post -Compression Parameters

blend and to achieve uniformity in tablet weight. The angle of repose of formulations was found to be in the range of 160.18 to 220.45, bulk density was found to be0.418 g/cc to 0.814 g/cc, tapped density was in between0.444 g/cc - 0.665 g/cc Carr's index was found to be within 8.18 %-16.51 %. Hausner's ratio was found to be within 1.08 -1.15 indicating good flow properties as reported in table.

In the current investigation, crospovidone and croscarmellose sodium were used as super disintegrants, and PVP K30 was used as a carrier.

CONCLUSION

an attempt to create fast-dissolving tablets with NSAID solid dispersion. The following findings were drawn from information gathered during the dissolving tablet's formulation and assessment: Using PVP K 30 as a carrier and a physical mixing and solvent evaporation technique, the solid dispersions of mesopride were created at the following weight ratios: 1:3, 1:5, and 1:7. In the presence of PVP K 30, the solubility and dissolving rate of pure mesopride-drug from solid dispersion (SE3) were enhanced. The solvent evaporation approach outperforms the physical mixture method of the two.

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Using PVP K 30 as a carrier and a physical mixing and solvent evaporation technique, the solid dispersions of mesopride.

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