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FORMULATION AND CHARACTERIZATION OF FAST DISSOLVING TABLETS OF MOSAPRIDE CITRATE BY USING SUBLIMATION TECHNIQUE

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ABSTRACT

Fast dissolving drug delivery is rapidly gaining acceptance as an important new drug delivery technology. The aim the study was to prepare and characterize fast dissolving tablets(FDT) of Mosapride citrate (a water insoluble drug and belongs to BCS class-II) by employing different technologies like liquidsolid by improving wetting, sublimation by creating porous environment, effervescent and super disintegrant by breaking the tablet fast. The FDT of Mosapride citrate was also prepared by adopting direct compression method. Physicochemical properties and *in vitro* release studies were evaluated. The Mosapride citrate FDTs of effervescent technology was showing immediate release with T90 % within 4 min and hence the effervescent technology was proved to be the promising in comparison with other technology types. By using invitro drug release data, it was found that FDTs of Mosapride citrate are following First order kinetics.

KEYWORDS: Mosapride citrate, liquid solid, sublimation, effervescent, super disintegrant. FDT.

INTRODUCTION

Fast dissolving technology is one of the best opportunities to improve bioavailability, immediate relief and patient compliance in comparison to conventional tablets. Fast dissolving drug delivery can be achieved by various conventional methods like direct

compression, wet granulation, moulding, spray drying, freeze drying and sublimation. In order to allow fast dissolving tablets to dissolve in the mouth, they are made of either very porous and soft-moulded matrices or compressed into tablets with very low compression force, which makes the tablets friable or brittle, which are difficult to handle, Often requiring specialized peel off blister packaging. Fast dissolving tablets disintegrate or dissolve rapidly in the saliva without the need for water. They contain agents to enhance the rate of tablet disintegration in the oral cavity, and are more appropriately termed fast-disintegrating tablets, as they may take up to a minute to completely disintegrate. When put on the tongue, this tablet disintegrates instantaneously, releasing the drug, which dissolves or disperses in the saliva. Some drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach.[1,4] Mosapride citrate was used as antihypertensive drug which is a water insoluble drug.[2] By fast releasing and improving the solubility of the drug not only the bioavailability is improved but also immediate relief would be produced.[3]

MATERIALS AND METHODS

Mosapride citrate(Matrix Lab, Hyderabad), Ammonium bicarbonate, Aerosil, Citric acid anhydrous, Camphor, Micro crystalline cellulose, Magnesium stearate, Menthol, Mannitol, Poly ethylene glycol 400, Sodium starch glycolate, Sodium bicarbonate, Sodium saccharine, Cetrimide, methanol(S.D. Fine chem Ltd, Mumbai).

METHODS

Preparation of Mosapride citrate FDT by liquisolid technology[15, 16]

All the ingredients were sifted through sieve number 80. The required quantity of Mosapride citrate was dispersed in the wetting enhancing agent like PEG 400 in the glass mortar. Half of the mannitol was added as a diluent to it and blend was triturated along with SSG, aerosil, menthol, sodium saccharine and magnesium stearate. The remaining mannitol was added and triturated and finally the blend was compressed on 12 station compression machine (CIP Machineries, India) to obtain the tablet weight of 100 mg.

Preparation of Mosapride citrate FDT by sublimation technology[6, 11, 12]

All the ingredients were sifted through sieve number 80. The required quantities of Mosapride citrate, subliming agents, SSG, aerosil, menthol, sodium saccharine magnesium stearate, and mannitol were weighed and the blend was thoroughly mixed in the glass mortar, triturated and finally the blend was compressed on 12 station compression machine (CIP Machineries, India) to obtain the tablet weight of 100 mg. The prepared tablets were heated

in the hot air oven (Biotechnics, Mumbai) at 60 °C until constant weight was obtained.

Preparation of Mosapride citrate FDT by effervescent technology[13, 14]

All the ingredients were sifted through sieve number 80. The required quantities of sodium bicarbonate and citric acid were accurately weighed, preheated at temperature of 80°C to remove absorbed /residual moisture in the oven (Biotechnics, Mumbai) for about 15 minutes. Weigh the required quantities of Mosapride citrate, SSG, aerosil, menthol, sodium saccharine, magnesium stearate, mannitol were added and the blend was then thoroughly mixed in the glass mortar, triturated and finally the blend was compressed on 12 station compression machine (CIP Machineries, India) to obtain the tablet weight of 100 mg.

Preparation of Mosapride citrate FDT by using all technology types

All the ingredients were sifted through sieve number 80. The required quantities of Mosapride citrate, PEG 400, sodium bicarbonate, citric acid, ammonium bicarbonate, SSG, aerosil, menthol, sodium saccharine, magnesium stearate, mannitol were added and the blend was thoroughly mixed in the glass mortar, triturated and finally the blend was compressed on 12 station compression machine (CIP Machineries, India) to obtain the tablet weight of 100 mg. The prepared tablets were heated in the hot air oven at 60 °C until constant weight was obtained.

EVALUATION OF FORMULATIONS OF MOSAPRIDE CITRATE FDT

The Mosapride citrate formulations were evaluated for the following physicochemical parameters.

General appearance

The general appearance of tablets, its visual identity and overall elegance is essential for consumer acceptance. The control of genera appearance of tablets involves measurement of number of attributes such as tablet size, color and surface texture and hence the parameters were evaluated.

Weight variation[5]

Ten tablets were selected at randomly from each formulations and average weight was determined (Digital balance, AUX 220, Shimadzu). Then individual tablets were weighed and compared with the average weight.

Thickness[7]

The thickness of diclofenac sodium tablets was measured using a screw gauge (Dwarakamai, Hyderabad). The average values and the standard deviations were calculated.

Hardness[7]

Hardness of tablet is defined as the force applied across the diameter of the tablet in order to break the tablet. The resistance of the tablet to chipping, abrasion or breakage under condition of storage, transformation and handling before usage depends on its hardness. Hardness of the tablet of each formulation was determined using Monsanto hardness tester (E 30, Dwarakamai, Hyderabad). The average values, and the standard deviations were calculated.

Friability[5]

The friability test was performed using a Roche friabilator (PSM-02, Electro lab, Mumbai). Six pre weighed tablets were rotated at 25 rpm for 4 minutes. The dedusted tablets were then reweighed and the percentage of weight loss was calculated. The percentage friability of the tablets was measured as per the following formula.

$$\% \text{ Friability} = (\text{Initial weight} - \text{Loss in weight}) / \text{Initial weight} * 100$$

Friability below 1% was considered as acceptable.

Wetting time and water absorption ratio (R)[5]

Five circular tissue papers were placed in a petridish with a 10-cm diameter. Ten ml of water containing methyl red was added to the petridish. The methyl red solution is used to identify the complete wetting of the tablet surface. A tablet was carefully placed on the surface of tissue paper in the petridish at room temperature. The time required for water containing methyl red solution to reach the upper surface and wet the tablets completely was noted as the wetting time. The weight of the tablet prior to placement in the petridish was noted as Wb utilizing (Digital balance, Aux 220, Shimadzu). The wetted tablet was then removed and reweighed as Wa. Water absorption ratio R, was then determined according to the following equation.

$$R = 100 (Wa - Wb) / Wb$$

Where Wb and Wa are the weight before and after water absorption, respectively.

***In vitro* disintegration test**[5]

Six tablets without the disc were introduced in each tube of the basket of the disintegration test apparatus (TGR56, Electro Lab, Mumbai). The basket was positioned into a beaker containing 900 ml of distilled water and operated at 37 ± 0.5 °C. The stop watch was started and the tablets were observed for disintegration. The stopwatch was stopped when the tablets got disintegrated with no palpable mass remaining in the apparatus and the time was noted as the disintegration time.

Content uniformity of the Mosapride citrate tablets in SSF pH 6.75 containing 0.2 % cetrimide[8, 9]

One tablet was taken in 10 ml volumetric flask; 1 ml of water was added to disintegrate the tablet. Then 9 ml of methanol was added and agitated in the cyclomixer (CM 101, Remi Ltd, Mumbai) for 15 min. The volume was made up to mark with methanol. The solutions were filtered, suitably diluted with and suitably diluted prior to spectrophotometric analysis. The medium was replenished with an equal amount 5 ml of dissolution medium. The absorbance of these solutions was analyzed at 326 nm by UV spectroscopy (UV 1700, Shimadzu).

***In vitro* drug release of Mosapride citrate in SSF pH 6.75 containing 0.2% cetrimide**[8, 9]

In vitro drug release studies were carried out using Type II apparatus (VDA-D, Veego, India) at 50 rpm. 500 ml of SSF pH 6.75 containing 0.2 % cetrimide was used as the dissolution medium. The temperature of the dissolution medium was maintained at 37 ± 0.5 °C. An aliquot 5 ml of dissolution medium was withdrawn at specific time intervals, filtered and suitably diluted prior to spectrophotometric analysis. The medium was replenished with an equal amount 5 ml of dissolution medium. The absorbance of these solutions was analyzed at 326 nm by UV spectroscopy (UV 1700, Shimadzu).

Kinetic analysis of dissolution data[10]

To study the mechanism of drug release from the matrix tablets, the dissolution data were fitted into Zero order, First order, Higuchi and Hixson's crowell cube root equation.

Table-1 Master formula of Mosapride citrate tablets, % (To find effect of technology types)

Ingredients (%)	FL	FS	FE	FA
Technology type	Liquisolid	Sublimation	Effervescent	All
Mosapride citrate	5	5	5	5
Ammonium bicarbonate	-	25	-	25
PEG 400	1	-	-	1
Sodium bicarbonate	-	-	20	20
Citric acid	-	-	15.25	15.25
SSG	2	2	2	2
Aerosil	0.5	0.5	0.5	0.5
Menthol	0.5	0.5	0.5	0.5
Sodium saccharine	1	1	1	1
Magnesium stearate	1	1	1	1
Mannitol	89	65	54.75	28.75
Total weight of tablet in %	100	100	100	100

FL -Formulation of liquisolid technology **FS** -Formulation of Sublimation technology **FE** -Formulation of Effervescent technology.

RESULTS & DISCUSSION

Standard Calibration curve of Mosapride citrate

Table 7.1: Concentration and absorbance obtained for calibration curve of Mosapride citrate Using 0.1 N HCl

S. No.	Concentration (µg/ml)	Absorbance* (at 240 nm)
1	0	0
2	10	0.119
3	20	0.236
4	30	0.358
5	40	0.476
6	50	0.590
Correlation Coefficient R^2 = 0.999 Absorbance y = 0.11x +0.001		

It was found that the estimation of mosapride citrate by UV spectrophotometric method at λ_{max} 274 nm in 0.1 N HCl had good reproducibility and this method was used in the study. The correlation coefficient for the standard curve was found to be closer to 1, at the concentration range, 10-50 µg/ml. The regression equation generated was y = 0.11x +0.001.

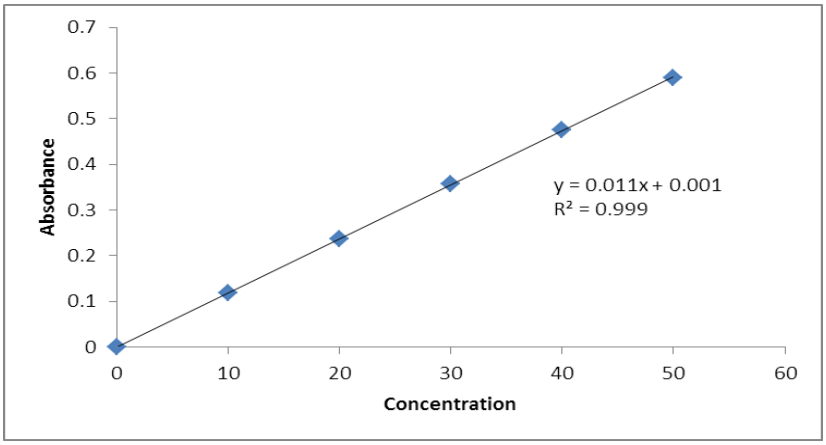

Fig 3: standard graph of Mosapride citrate in 0.1 N HCl

7.2 Evaluation Parameters for fast Dissolving Tablets of Mosapride citrate

7.2.1 Pre-compression parameters

The data were shown in Table 7.2.The values for angle of repose were found in the range of 25°-30°. Bulk density and tapped density of various formulations were found to be in the range of 0.43 to 0.51 (gm/cc) and 0.51 to 0.58 (gm/cc) respectively. Carr's index of the prepared blends was fall in the range of 10.90% to 15.78%. The Hausners ratio was fall in range of 1.12 to 1.18. From the result it was concluded that the powder blends had good flow properties and these can be used for tablet manufacture.

Table 7.2: Pre-compression parameters

Formulations	Bulk Density (gm/cm^2)	Tap Density (gm/cm^2)	Carr's Index (%)	Hausner ratio	Angle Of Repose(Θ)
F_1	0.46 ± 0.06	0.54 ± 0.05	14.81 ± 0.06	1.17 ± 0.05	25.91 ± 0.04
F_2	0.48 ± 0.04	0.56 ± 0.03	14.28 ± 0.05	1.16 ± 0.06	27.23 ± 0.06
F_3	0.51 ± 0.05	0.58 ± 0.06	12.0 ± 0.08	1.13 ± 0.05	29.12 ± 0.03
F_4	0.48 ± 0.05	0.57 ± 0.08	15.78 ± 0.04	1.18 ±0.04	25.71 ± 0.05
F_5	0.50 ± 0.07	0.58 ± 0.04	13.79 ± 0.07	1.16 ± 0.08	27.44 ± 0.09
F_6	0.48 ± 0.06	0.56 ± 0.05	14.28 ± 0.02	1.17 ± 0.07	26.13 ± 0.04
F_7	0.49 ± 0.04	0.55 ± 0.06	10.90 ± 0.05	1.12 ± 0.03	27.34 ± 0.07
F_8	0.45 ± 0.03	0.52 ± 0.08	13.46 ± 0.03	1.15 ± 0.04	25.78 ± 0.04
F_9	0.43 ± 0.08	0.51 ± 0.07	15.68 ± 0.04	1.18 ± 0.06	26.14 ± 0.02

Weight variation test

Tablets of each batch were subjected to weight variation test, difference in weight and percent deviation was calculated for each tablet and was shown in the Table 7.3. The average weight of the tablet is approximately in range of 99.24 to 102.35mg. The permissible limit is

±10%. The results of the test showed that, the tablet weights were within the pharmacopoeia limit.

Hardness test

Hardness of the three tablets of each batch was checked by using Pfizer hardness tester and the data were shown in Table 7.3. The results showed that the hardness of the tablets is in range of 2.3 to 2.7 kg/cm^2, which was within IP limits.

Thickness

Thickness of three tablets of each batch was checked by using Vernier Caliper and data shown in Table-7.3. The result showed that thickness of the tablet is raging from 2.18 to 2.64.

Friability

Tablets of each batch were evaluated for percentage friability and the data were shown in the Table 7.3. The average friability of all the formulations lies in the range of 0.34 to 0.49% which was less than 1% as per official requirement of IP indicating a good mechanical resistance of tablets.

Drug content

Drug content studies were performed for the prepared formulations. From these studies, it was concluded that all the formulations were showing the % drug content values within 96.25- 99.25 %.

Table 7.3 Post compression parameters

Formulation	Weight variation (mg)	Hardness (kg/cm^2)	Thickness (mm)	Friability (%)	Drug content (%)
F_1	101.2 ± 0.14	2.5 ± 0.03	2.59 ± 0.06	0.43 ± 0.08	99.23
F_2	100.9 ± 0.39	2.6 ± 0.05	2.64 ± 0.04	0.34 ± 0.06	98.55
F_3	99.86 ± 0.87	2.5 ± 0.04	2.59 ± 0.05	0.49 ± 0.05	98.16
F_4	102.35 ± 0.16	2.6 ± 0.06	2.18 ± 0.06	0.47 ± 0.04	99.34
F_5	98.24 ± 0.79	2.3 ± 0.07	2.59 ± 0.03	0.49 ± 0.06	97.46
F_6	100.75 ± 0.63	2.7 ± 0.05	2.43 ± 0.08	0.34 ± 0.04	98.55
F_7	99..37 ± 0.74	2.5 ± 0.08	2.29 ± 0.07	0.49 ± 0.05	98.16
F_8	100.69 ± 0.02	2.6 ± 0.06	2.46 ± 0.02	0.34 ± 0.07	99.25
F_9	99.74 ± 0.17	2.5 ± 0.04	2.55 ± 0.06	0.34 ± 0.03	96.25

In vitro disintegration time: Tablets of each batch were evaluated for in vitro disintegration time and the data were shown in the Table 7.4. The results showed that the disintegration time of prepared tablets were in the range 19 to 48 seconds.

Wetting time

Wetting time to the time required to wet completely when kept motionless on the tissue paper in a petridish.

- All the FDT formulations were evaluated for their wetting time as per the procedure described in the methodology section, and the results are shown in table 7.4
- The average wetting time for all the formulations was in the range of (17 to 38) seconds.
- It was also observed that formula F1 which had the least wetting time also had the minimum disintegration time showing a strong correlation between disintegration time and wetting time.

- **In vitro dispersion time:** Mosapride citrate FDTs F1 containing Polyplastone XL dispersed time is 21.41 seconds. The dispersion time of formulations (F1) containing Polyplastone XL was lower than those containing Explotab and Solutab, which might be attributed due to its rapid water absorbing nature and delayed dispersion time.
- The *in vitro* dispersion time for all formulation was found to be in a range of 21.41 to 53.98 seconds

Water Absorption ratio: All the formulations were evaluated for water absorption ratio according to the procedure described in methodology section and the results are shown in table 7.4.

- The maximum water absorption ratio was shown by formulation F1 and F7 i.e., 98%.
- Water absorption ratio is proportional to dissolution rate profile as higher the water absorption ratio faster the dissolution.

Table 7.4: In vitro disintegration time, Wetting time, dispersion time, % water absorption ratio

Formulation	Disintegration Time(sec)	Wetting time (sec)	In vitro dispersion time*(sec)	%Water absorption ratio*
F1	19.33 ± 0.14	17.32 ± 0.16	21.41 ± 0.17	98
F2	36.33 ± 0.12	34.22 ±0.14	39.12 ± 0.15	95
F3	46.66 ± 0.17	44.12 ± 0.15	48.15 ± 0.28	97
F4	22.00 ± 0.28	20.12 ± 0.23	24.03 ± 0.28	98
F5	40.33 ± 0.25	38.32 ± 0.21	44.01 ± 0.24	97
F6	48.66 ± 0.21	46.29 ± 0.19	53.98 ± 0.14	96
F7	21.33 ± 0.13	19.13 ± 0.22	23.15 ± 0.16	98
F8	38.23 ± 0.19	36.57 ± 0.16	41.08 ± 0.25	97
F9	44.00 ± 0.16	42.89 ± 0.24	46.85 ± 0.18	95

In vitro Dissolution studies: In vitro dissolution studies were carried out by using 900ml of 0.1 N HCl in USP dissolution apparatus by using paddle method. The dissolution studies were carried out for about 30 min. The dissolution data for all the formulations were given in the Table 7.5.

Table 1: Invitro dissolution data

Time(Min)	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
2	31.97	14.48	12.36	28.14	12.47	10.36	30.65	13.57	11.68
4	64.44	26.03	24.32	46.37	24.98	19.57	51.35	26.86	21.65
6	95.12	37.42	31.61	60.78	35.36	28.74	63.98	38.65	32.25
8		48.39	49.31	78.34	46.32	37.12	82.23	51.35	44.48
10		59.54	58.39	94.36	58.58	49.32	96.14	57.98	53.87
15		70.22	74.34		67.34	58.14		69.23	64.23
20		82.48	88.17		78.25	69.74		80.36	76.36
25		94.36	94.66		88.65	79.86		93.42	85.36
30			98.17		99.41	88.19			97.14
35						99.74			

F1, F2 and F3 – Containing Polyplastone XL

F4, F5 and F6 – Containing Sodium starch glycolate

F7, F8 and F9 – Containing Cross carmellose

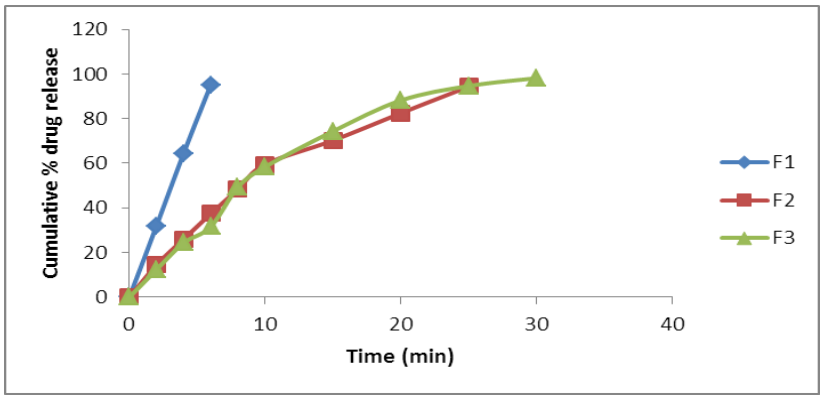

Fig 3: Dissolution profile of formulations prepared with Polyplastone XL

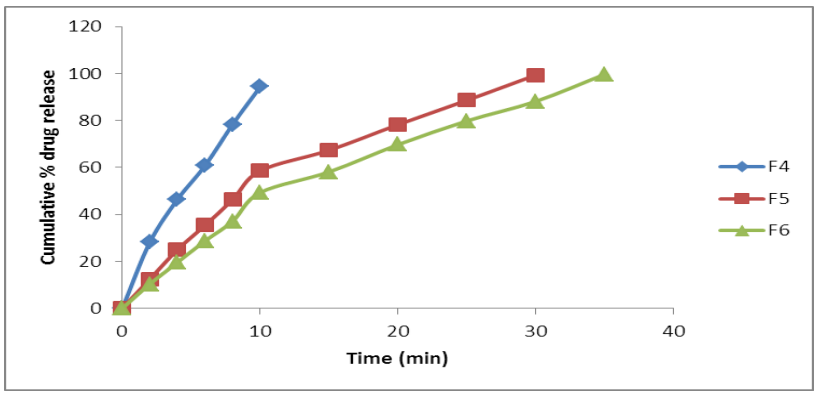

Fig 4: Dissolution profile of formulations prepared with Explotab

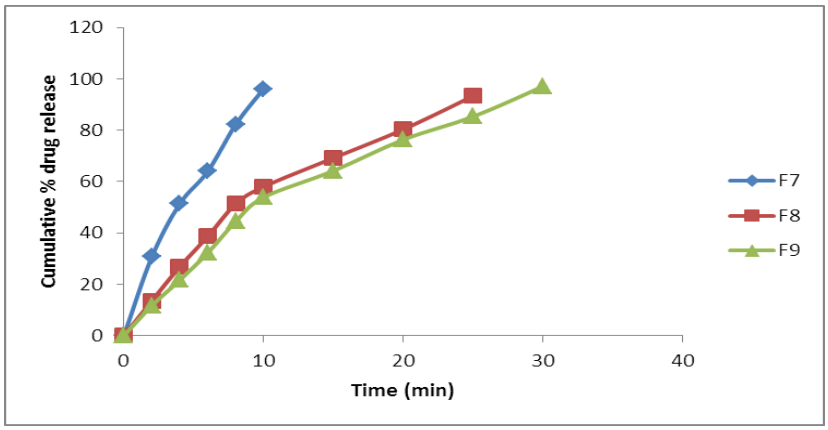

Fig 5: Dissolution profile of formulations prepared with Cross povidone

From the tabular column 7.4 it was evident that the formulations prepared with polyplastone XL (F1) showed maximum % drug release in 6 min i.e.95.12%.

F4 and F7 formulations were also shown good release in 10 min i.e., 94.36 and 96.14. but optimized formulation was F1 which was shown better results in 6 min.

From the dissolution data, drug release was optimized in F1, F4 and F7. While increasing the percentage of super disintegrant, those super disintegrants retards the release of drug. Hence, concluded that optimized percentage (%) of super disintegrant was 10%.

Fourier Transform-Infrared Spectroscopy.

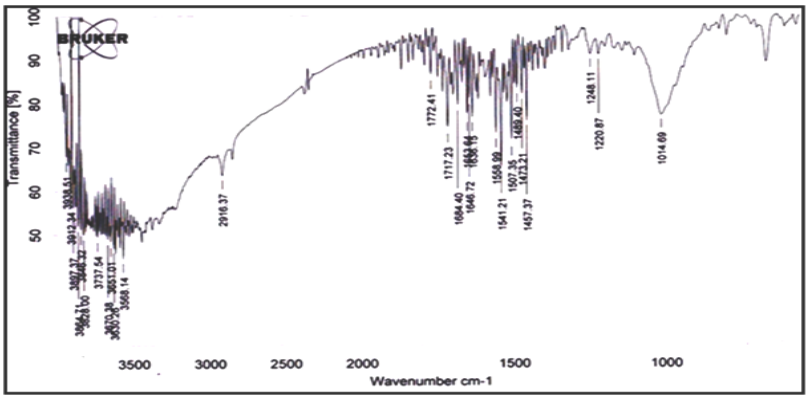

Figure 1: FT-TR Spectrum of Mosapride citrate pure drug.

CONCLUSION

In the present work, an attempt has been made to develop Fast dissolving tablets of Mosapride citrate. Polyplastone XL, Explotab and solutab were used as super disintegrants. All the formulations were prepared by direct compression method using 6mm punch on 10 station rotary tablet punching machine. The blend of all the formulations showed god flow

properties such as angle of repose, bulk density, tapped density. The prepared tablets were shown good post compression parameters and they passed all the quality control evaluation parameters as per I.P limits. Among all the formulations F1 formulation showed maximum % drug release i.e., 95.41% in 6 min. From the dissolution data, concluded that, super disintegrants have shown good drug release in the 10% concentration. If increase in the concentration those formulations have shown retard in drug release.

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