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RESEARCH ARTICLE

Formulation Development of Orodispersible Tablets of Mosapride citrate using different superdisintegrants and Their Evaluation

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ABSTRACT

Mosapride is novel prokinetic agent which seems to exert its action via a high affinity and specifity for 5-HT_4 receptor. In addition the principal metabolite has high affinity for 5-HT_3 receptors and has proved to be potent 5-HT_3 antagonist. Mosapride has been used to treat gastroesophageal reflux disease, chronic gastritis, nonulcer dyspepsia and diabetic gastropathy. In the present study, an attempt has been made to formulate orodispersible tablets of Mosapride Citrate Dihydrate. The other objective of the study was to evaluate the performance of three different classes of superdisintegrants which are croscarmellose Sodium (Ac-Di-Sol), crospovidone (Polyplasdone XL), sodium starch glycolate (Primojel) in promoting disintegration and dissolution of Mosapride citrate dihydrate orodispersible tablets. At the optimum concentrations of 2% & 4% of selected superdisintegrants, their effect in the orodispersible tablet on the *in vitro* disintegration & in vitro dissolution was evaluated. It was concluded that, the formulation of Mosapride citrate dihydrate orodispersible tablets was made with functionality evaluation of selected superdisintegrants.

Keywords: Mosapride Citrate Dihydrate, Orodispersible tablets, Superdisintegrants, Crospovidone, Prokinetic agent.

1. INTRODUCTION

The tablet is the most widely used dosage form because of its convenience in terms of self-administration, compactness, and ease in manufacturing. However, geriatric and pediatric patients experience difficulty in swallowing conventional tablets, which leads to poor patient compliance. To overcome this weakness, scientists have developed innovative drug delivery systems known as "melt in mouth" or "mouth dissolve (MD)" tablets. Their growing importance was underlined recently when European Pharmacopoeia (European Pharmacopoeia 4.1, 2002) adopted the term “Oro-dispersible tablet” as a tablet to be placed in mouth where it disappears rapidly before swallowing. Ideal orodispersible tablet requires no water for oral administration, yet dissolve / disperse/ disintegrate in mouth in a matter of seconds, have a pleasing mouth feel, have an acceptable taste masking property, be harder and less friable, leave minimal or no residue in mouth after administration, exhibit low sensitivity to environmental conditions (temperature and humidity).[1]

Most elderly patients and children have difficulty swallowing conventional tablets or capsules. The advantages of dispersible tablets are recognized by industry and patients, since there are several products available on the market. These products have a number of drawbacks, including the manufacturing methods used and the mechanical strength. Three techniques are mainly applied to formulate these tablets, namely freeze drying, moulding and direct compression. [2] When the fast disintegrating tablet is orally applied, the drug substance has to be dissolved so that it can be absorbed. Dissolution process consists of various process, e.g. wetting, disintegration and dissolution. Fast disintegrating tablets

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which are generally contains several excipients are involved in a complex series of dissolution process that begin when the solvent contacts the solid and penetrates the tablet matrix. Effects of excipients are assumed to be related to the surface properties of the particles and solid matrix structure. [3]

Mosapride acts selectively on the 5-HT_4 receptor, enhancing gastrointestinal motility. The 5-HT_4 agonist is one of the commonly used agents for the treatment of functional dyspepsia. [4] Mosapride is novel prokinetic agent which seems to exert its action via a high affinity and specificity for 5-HT_4 receptor. In addition the principal metabolite has high affinity for 5-HT_3 receptors and has proved to be potent 5-HT_3 antagonist. [5] Mosapride has been used to treat gastroesophageal reflux disease, chronic gastritis, non-ulcer dyspepsia and diabetic gastropathy. [6]

The objectives of this study were to provide a closer look at the comparative functioning of superdisintegrants in promoting tablet disintegration and to develop a model formulation for discriminating super disintegrant functionality. To those ends, dissolution profiles of Mosapride Citrate Dihydrate were compared for tablets containing different superdisintegrants at different concentration. For many solid dosage forms, disintegration occurs prior to drug dissolution and superdisintegrants such as crospovidone (Polyplasdone XL), croscarmellose sodium (Ac-Di-Sol), sodium starch glycolate (Primojel) are frequently used in tablet formulations to improve the rate and extent of tablet disintegration and thus increase the rate of drug dissolution**.** Also, other objective was to develop orodispersible tablet using polymer (methyl cellulose) so as to mask bitter taste of Mosapride Citrate Dihydrate. [7]

2. MATERIAL AND METHODS

Materials

Mosapride Citrate Dihydrate was obtained as a gift sample from Dr. Reddy's Holdings Ltd, Hyderabad. Croscarmellose Sodium, Crospovidone, Sodium starch glycolate, Mannitol, Microcrystalline cellulose (Avicel PH 102), Aspartame, Talc, American ice cream flavor and Magnesium stearate were procured as gift samples from Concept Pharmaceuticals Ltd, Aurangabad.

Method

Direct Compression Technique

Formulation development of Oro-dispersible tablet with directly compressible fillers by direct compression technique. Formulation batches from Mosa-1 to Mosa-9 were formulated by direct compression technique.

Blending and Tableting

Mosapride Citrate Dihydrate, aspartame, directly compressible filler {microcrystalline cellulose (PH102)/mannitol (granular)}, superdisintegrant (croscarmellose sodium/ crospovidone/ sodium starch glycolate), talcum and flavor were sifted through the sieve #100 and admixed for about 15 min to make a uniform blend. Magnesium stearate was passed through sieve #100 and mixed with the above blend for approximately 1-2 min. Round flat-faced tablets with diameter of 7 mm were prepared by direct compression to make tablets of said compression specifications as mentioned in Table 04 & Table 5. The tablet press setting was kept constant across all formulations.

Wet Granulation Technique

Formulation development of Oro-dispersible tablet with drug**:** polymer in different concentration by wet granulation technique. Formulation batches from Mosa-10 to Mosa-11 were formulated by wet granulation technique.

Wet Granulation

Active drug, mannitol (10%), & methyl cellulose was subjected to granulation especially wet granulation in order to improve flowability and to uniformly cover the active drug with polymer (methyl cellulose). Methyl cellulose was added in water so as to form thin paste, then active drug was added slowly in the paste and stirred uniformly with glass rod for about 10-15 min or until uniform mixing of the mixture was achieved so as to cover the drug completely with the polymer paste. Then, mannitol (10%) was added into the paste and stirred further for 5 min. This mixture was then allowed to dry (air) or dried in the oven at around 25^0 C for 2 h. This dried mass was passed through sieve #22 to form granules of uniform size.

Blending and Tableting

Superdisintegrant (crospovidone), aspartame, talcum, and flavor were sifted through the sieve #100 and are mixed with drug containing granules & admixed for about 15 min to form uniform blend. Magnesium stearate was passed through sieve #100 and mixed with the above blend for approximately 1-2 min. Round flat-faced tablets with diameter of 7 mm were prepared by to make tablets of said compression specifications as mentioned in Table 5. The tablet press setting was kept constant across all formulations.

Evaluation of Tablets

Evaluation was done on tablets of all formulations batches considering following parameters and results were reported in Table 4 & Table 5.

a) Weight Variation

Twenty tablets were selected at a random and average weight was determined. Then individual tablets were weighed and was compared with average weight.

b) Hardness

Tablet crushing strength (F_c) or hardness, the force required to break a tablet in a diametric compression, was measured using Monsanto tablet hardness tester. [8]

c) Thickness

The thickness of individual tablets was measured using Vernier caliper, which permits accurate measurements and provides information of the variation between tablets.

d) Friability

Friability was measured using Roche Friabilator. Already weighed sample of tablets was placed in the friabilator and subjected to 100 revolutions at 25 rpm. The tablets were de-dusted and reweighed. The friability (f) is given as,

$$f = (1 - \frac{W_o}{W}) \times 100$$

Where, f = Friability

W_o = Weight of the tablets before the test.

W = Weight of the tablets after the test.

e) Drug Content

Twenty tablets were weighed and powdered. The blend equivalent to 5 mg of mosapride citrate was weighed and dissolved in sufficient quantity of 0.1N HCl. The solution was filtered through Whatmann filter paper (no.41), suitably diluted with 0.1N HCl and assayed at 272 nm, using a UV-Visible double beam spectrophotometer.

f) Wetting Time

A piece of tissue paper folded twice was placed in a small petri dish (10 cm diameter) containing 10 ml of water. A tablet was put on the tissue paper and allowed to wet completely. The time required for complete wetting of the tablet was then recorded.

g) In vitro Disintegration Time

Disintegration times were measured in 900 ml purified water according to the I.P. method without disc at room temperature (25°C ± 2°C).

h) In vivo Disintegration Time

The time required for the tablets to disperse in mouth cavity was determined by holding the tablets in mouth. The test was performed in 3 healthy human volunteers in the age group of 23 to 28 years. [9]

i) In vitro Dissolution Study

Dissolution of tablets were determined using the USP 24 Method II with paddle speed at 50 rpm. Dissolution was performed in 900 ml 0.1N HCl maintained at 37 ± 0.5°C. Five milliliters of samples were withdrawn at specified time intervals. The volume of dissolution fluid was adjusted to 900 ml, by replacing each 5 ml aliquot withdrawn with 5 ml of 0.1N HCl, pre-warmed at 37 ± 0.5°C. Samples withdrawn were filtered through Whatmann filter paper (no.41), and analyzed at 272 nm, using UV-Visible double beam spectrophotometer (UV-1700 SHIMADZU).

3. RESULTS:

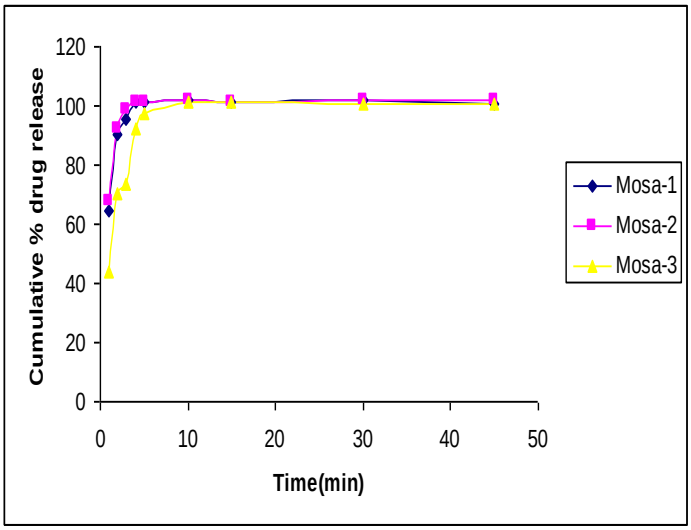

Figure 1: Comparative dissolution profiles of Mosapride Citrate Dihydrate orodispersible tablets in N HCL for formulation batches Mosa-1 to Mosa-3

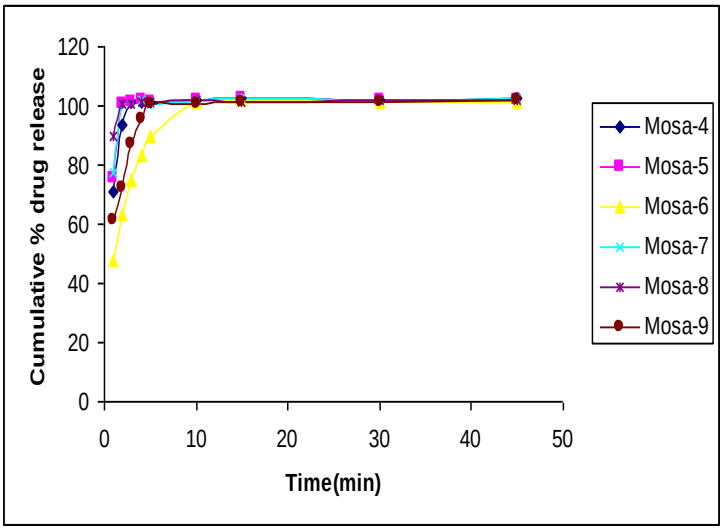

Figure 2: Comparative dissolution profiles of Mosapride Citrate Dihydrate orodispersible tablets in 0.1 N HCL for formulation batches Mosa-4 to Mosa-9

Tablet Ingredients (mg) / Batch No.	Mosa-1	Mosa-2	Mosa-3	Mosa-4	Mosa-5	Mosa-6	Mosa-7	Mosa-8	Mosa-9
Mosapride Citrate Dihydrate eq to Mosapride Citrate Anhydrous	5.3	5.3	5.3	5.3	5.3	5.3	5.3	5.3	5.3
Aspartame	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3
Microcrystalline Cellulose (PH102)	117.42	117.42	117.42						
Mannitol (Granular)	-	-	-	117.42	117.42	117.42	114.82	114.82	114.82
Croscarmellose Sodium	2.6	-	-	2.6	-	-	5.2		
Crospovidone	-	2.6	-	-	2.6	-		5.2	
Sodium Starch Glycolate	-	-	2.6	-	-	2.6			5.2
Talcum	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3
American Ice cream flavor	0.65	0.65	0.65	0.65	0.65	0.65	0.65	0.65	0.65
Magnesium Stearate	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3
Menthol	0.130	0.130	0.130	0.130	0.130	0.130	0.130	0.130	0.130
Total weight (mg)	**130**	**130**	**130**	**130**	**130**	**130**	**130**	**130**	**130**

Table 1: Formulation Design of Orodispersible tablets by direct compression technique

Tablet Ingredients (mg) / Batch No.	Mosa - 10	Mosa – 11
Mosapride Citrate Dihydrate eq to Mosapride Citrate Anhydrous	5.3	5.3
Methyl cellulose	2.5	5
Mannitol	17.5	15
Drugs containing Granules	**25.30**	**25.30**

Table 2 A: Formulation Design of Drug containing granules

Tablet Ingredients(mg)/Batch No.	Mosa - 10	Mosa – 11
Drugs containing Granules	25.30	25.30
Aspartame	1.5	1.5
Mannitol (Granular)	113.3	113.3
Crospovidone	6	6
Talcum	1.5	1.5
Magnesium Stearate	1.5	1.5
American Ice cream flavor	0.75	0.75
Menthol	0.150	0.150
Total Weight (mg)	**150**	**150**

Table 2-B: Formulation Design of Orodispersible tablets by Wet granulation technique

Batch No	Evaluation Parameters				
	Angle of Repose(^{0})	Bulk Density (g/cm^3)	Tapped Density (g/cm^3)	Compressibility Index (%)	Hausner's Ratio
Mosa-1	36.09 ± 0.784	0.343±0.002	0.378±0.002	9.817±0.400	1.103±0.016
Mosa-2	36.19 ± 0.695	0.342±0.002	0.379±0.003	9.375±1.351	1.108±0.004
Mosa-3	35.18 ± 1.088	0.340±0.003	0.378±0.002	9.995±0.967	1.111±0.011
Mosa-4	26.46 ± 0.348	0.530±0.006	0.619±0.008	14.48±1.140	1.169±0.015
Mosa-5	26.01 ± 0.451	0.531±0.005	0.617±0.007	13.82±0.994	1.160±0.013
Mosa-6	25.83 ± 0.521	0.526±0.005	0.614±0.004	14.38±0.485	1.168±0.006
Mosa-7	24.74 ± 0.285	0.520±0.005	0.609±0.007	14.91±0.943	1.175±0.012
Mosa-8	26.74 ± 0.637	0.520±0.009	0.612±0.004	14.56±1.931	1.170±0.026
Mosa-9	25.84 ± 0.467	0.524±0.006	0.614±0.008	14.67±1.951	1.172±0.026
Mosa-10	28.10 ± 0.470	0.511±0.006	0.602±0.007	15.00±1.434	1.176±0.019
Mosa-11	31.03 ± 0.803	0.517±0.003	0.614±0.004	15.86±0.554	1.188±0.007

All values are mean ± SD, n=3

Table 3: Evaluation of Powder Blends of formulation batches

Batch No	Evaluation Parameters				
	Angle of Repose(^{0})	Bulk Density (g/cm^3)	Tapped Density (g/cm^3)	Compressibility Index (%)	Hausner's Ratio
Mosa-1	36.09 ± 0.784	0.343±0.002	0.378±0.002	9.817±0.400	1.103±0.016
Mosa-2	36.19 ± 0.695	0.342±0.002	0.379±0.003	9.375±1.351	1.108±0.004
Mosa-3	35.18 ± 1.088	0.340±0.003	0.378±0.002	9.995±0.967	1.111±0.011
Mosa-4	26.46 ± 0.348	0.530±0.006	0.619±0.008	14.48±1.140	1.169±0.015
Mosa-5	26.01 ± 0.451	0.531±0.005	0.617±0.007	13.82±0.994	1.160±0.013
Mosa-6	25.83 ± 0.521	0.526±0.005	0.614±0.004	14.38±0.485	1.168±0.006
Mosa-7	24.74 ± 0.285	0.520±0.005	0.609±0.007	14.91±0.943	1.175±0.012
Mosa-8	26.74 ± 0.637	0.520±0.009	0.612±0.004	14.56±1.931	1.170±0.026
Mosa-9	25.84 ± 0.467	0.524±0.006	0.614±0.008	14.67±1.951	1.172±0.026
Mosa-10	28.10 ± 0.470	0.511±0.006	0.602±0.007	15.00±1.434	1.176±0.019
Mosa-11	31.03 ± 0.803	0.517±0.003	0.614±0.004	15.86±0.554	1.188±0.007

All values are mean ± SD, n=3, DP_{60} =Drug percent dissolved in 60 sec.

Table 4: Evaluation of Compressed Tablets for Formulation Batches

Evaluation Parameters*	Mosa-7	Mosa-8	Mosa-9	Mosa - 10	Mosa – 11
Weight. Variation (± %)	1.247±0.942	0.816±0.707	2.449±1.414	1.527±1.178	1.527±1.885
Hardness (Kg/cm^2)	3.95±0.050	4.01±0.076	4.03±0.0577	3.81±0.0288	3.93±0.144
Thickness (mm)	2.88±0.0288	2.81±0.0288	2.85±0.00	2.96±0.028	2.95±0.00
Friability (%)	0.716±0.040	0.706±0.015	0.703±0.032	0.663±0.037	0.556±0.030
Drug Content (%)	101.37±0.248	100.08±0.723	101.23±0.430	99.65±0.248	99.50±0.448
Wetting Time (Sec)	14.33±0.0208	11.16±0.115	18.20±0.200	15.03±0.152	16±0.1
***In vitro* DT(Sec)**	17.43±0.152	14.26±0.208	23.70±0.100	17.53±0.472	18.43±0.115
***In vivo* DT (Sec)**	25.26±0.251	22.10±0.173	32.03±0.208	28.53±0.251	30.03±0.152
DP_{60} (%)	77.61±1.330	89.81±1.431	61.36±1.005	-	52.36±1.812

All values are mean ± SD, n=3, DP_{60} =Drug percent dissolved in 60 sec.

Table 5: Evaluation of Compressed Tablets for Formulation Batches

4. DISCUSSION

In the present investigation, Mosapride Citrate Dihydrate orodispersible tablets were prepared with different concentrations of three selected superdisintegrants microcrystalline cellulose (Avicel PH 102) & mannitol (Granular) were used as diluents along with selected superdisintegrants in different concentrations: croscarmellose sodium (Ac-Di-Sol), crospovidone (Polyplasdone XL), sodium starch glycolate (Primojel). Formulation batches of Mosa-1 to Mosa-3 were comprised of microcrystalline cellulose (Avicel PH 102) as filler along with three different superdisintegrants with 2% concentration. Formulation batches of Mosa-4 to Mosa-6 were comprised of mannitol (Granular) as filler along with three different superdisintegrants with 2% concentration while formulation batches of Mosa-7 to Mosa-9 were comprised of mannitol (Granular) as filler along with three different superdisintegrants with 4% concentration. However, formulation batches Mosa-10 to Mosa-11 comprised of mannitol (Granular) along with different concentration of polymer (methyl cellulose) and 4% optimum concentration of crospovidone as superdisintegrant which was selected from earlier trials of direct compression technique. As shown earlier in Table 03, blends of active drug and excipients were prepared and evaluated for various parameters. Angle of repose of all formulation batches from Mosa-1 to Mosa-11 was found in the range of 24.74 to 36.19º.

Bulk density of formulation batches Mosa-1 to Mosa-9 was found in the range of 0.340 to 0.531 g/cm^3 while Tapped density was found in the range of 0.378 to 0.619. However, Bulk density of formulation batches Mosa-10 to Mosa-11 was found in the range of 0.511 to 0.517 g/cm^3 while Tapped density was found in the range of 0.602 to 0.614. From the data of bulk and tapped density, Compressibility index and Hausner's ratio were calculated and for formulation batches Mosa-1 to Mosa-9 compressibility index was found in the range of 9.37 to 14.91%. However, for formulation batches Mosa-10 to Mosa-11 compressibility index was found in the range of 15.00 to 15.86. Hausner's ratio of all formulation batches from Mosa-1 to Mosa-11 was found between >1.25. The data of compressibility index and hausner's ratio of all formulation batches indicate better flow properties of powder blends of drug and excipients.

As shown in Table 1 to Table 2-B, Tablets of all formulation batches from Mosa-1 to Mosa-9 were prepared by direct compression technique while formulation batches from Mosa-10 to Mosa-11 were prepared by wet granulation technique. Due to the better flow properties of all formulation batches, all tablets obtained were of uniform weight with acceptable variation. As shown in Table 4 and Table 5, Hardness of all formulation batches were found in the range of 3.81 to 4.06 Kg/cm^2. Friability of all formulation batches were found between 0.55 to 0.71 % indicating good mechanical resistance of tablets. Drug content of all formulation batches of Mosa-1 to Mosa-9 was found between 100.08 to 101.66% while that of formulation batches of Mosa-10 to Mosa-11 was found between 99.50 to 99.65. Wetting time of all formulation batches were found in the range of 11.16 to 24.43 seconds which predicts rapid disintegration time of orodispersible tablets of all formulation batches. Relatively faster in vivo & in vitro disintegration time was of all formulation batches at different concentrations of three superdisintegrants while there was better in vivo & in vitro disintegration time was found with crospovidone as superdisintegrant at 2 and 4 %. In this study, it was found that, microcrystalline cellulose exhibited gritty feeling in the mouth after disintegration. By itself it has no taste and conventional sweeteners or flavors could be required in higher proportions to mask unpleasant taste of drug. However, with the use of mannitol suggested that there was improvement not only in mouth feel but also *in vitro* disintegration time (DT) and dissolution profile of the drug. However, drug containing granules prepared by using polymer (methyl cellulose) was tasteless in ratio of 1:1 (drug: polymer) for about 2 min when placed in oral cavity of healthy human volunteers, as we know that disintegration time of orodispersible tablets in oral cavity is only 1 min or less.

Tablets of all formulation batches with optimum concentration of superdisintegrants disintegrate rapidly without disc in the IP test. Croscarmellose sodium (Ac-Di-Sol) may be used at concentration upto 5% w/w as tablet disintegrant, although 2% w/w is used at tablets prepared by direct compression and 3% w/w in tablets prepared by wet granulation process[9]. Crospovidone (Polyplasdone XL) may be used at concentration range between 2%- 5% in tablets prepared by direct compression or wet granulation process[9] while sodium starch glycolate (Primojel) may be used at concentration range of 2% -8% in formulation trials, with optimum concentration of 4%, although in many cases 2% is sufficient. [10] All tablets disintegrated rapidly without disc in the IP test especially when used at optimum concentrations of selected superdisintegrants. Basically both Sodium starch glycolate & Croscarmellose sodium give approximately the same disintegration times at 2 and 3% levels, so that using these at a 2% level generally suffices to obtain maximum disintegration efficiency. [11]

In the present study, disintegration ability and thus dissolution behavior were evaluated for three different

classes of superdisintegrants for all formulation batches. Croscarmellose sodium and crospovidone disintegrated tablets more rapidly. Tablets formulated with 2% of those two disintegrants disintegrated nearly immediately, even when tested at room temperature. Tablets formulated with croscarmellose sodium can be seen to rapidly disintegrate into more or less uniform fine particles, while tablets formulated with sodium starch glycolate appeared to disintegrate much more slowly into more or less uniform coarser particles. Tablets containing crospovidone seemed to swell immediately despite the limited swelling capacity of this class of superdisintegrants. Crospovidone was reported to exhibit a high capacity to retain deformation during post compression. [12] Recovery of deformation was partly attributed by the rapid swelling of these tablets upon wetting. Tablets with this class of superdisintegrant disintegrated further into large irregularly shaped fragments when used at 2% concentration. When measured by the IP disintegration apparatus, short disintegration time of these tablets must be due to weakly held particle association under the condition of test. Croscarmellose Sodium disintegrated tablets into rapidly into relatively fine particles. Tablets containing Sodium starch glycolate (primojel) upon disintegration, relatively larger fragments were generated which were not small enough to pass through screen of disintegration vessel. Sodium starch glycolate at lower concentration of 2 %, disintegration time was quite longer and also large variations were observed. Large fragments were observed upon disintegration of tablets containing sodium starch glycolate (Primojel). Croscarmellose Sodium (Ac-Di-Sol) disintegrated tablets into relatively fine particles. Crospovidone (Polyplasdone XL) containing tablets were disintegrated into larger fragments with loosely associated particles, which under the movement of IP disintegration apparatus dispersed easily.

Disintegration test was not very efficient to compare the functionality evaluation of these three different classes of superdisintegrants. In the disintegration test carried out by IP disintegration test apparatus, all the three superdisintegrants appeared highly efficient when used at 2% concentration showing disintegration time as short as 30 seconds. However as discussed above, there was difference in the particle size generated in the disintegrated tablets in the disintegration test. This difference in the generated particle size could affect the drug dissolution since breaking tablets into finer fragments may promote drug dissolution by providing larger total surface area for drug dissolution to take place. Observed results suggested that the disintegrants added into tablet formulations might cause the penetration behavior of water in the tablet, and penetration rate of water would be altered. So, rapid is the penetration rate of water, the shorter is the disintegration time and faster is the dissolution rate. To shorten disintegration times in the oral cavity for the tablet the addition of the disintegrant having a property of quick water uptake in the formulation would be preferable. The disintegration times and dissolution profiles of Mosapride Citrate Dihydrate orodispersible tablets formulated with 2% and 4% concentration of croscarmellose, crospovidone and sodium starch glycolate are given in Table 4-5 & figure 1-2. In this study, it was found that, the tablets formulated with Crospovidone disintegrates nearly at the same time as that of tablets formulated with Croscarmellose Sodium in the same concentration, However, they disintegrate at faster rate than Sodium starch glycolate. In other words, Tablets formulated with 2% of Croscarmellose and 2% of Crospovidone disintegrates nearly at the same rate as that of tablets formulated with 4% of Sodium starch glycolate. Inspite of similarity in the disintegration profiles of these three superdisintegrants, it was found that, they differ in the dissolution behavior (in 0.1 N HCL) of Mosapride Citrate Dihydrate orodispersible tablets. Their dissolution varied in the decreasing order as Polyplasdone XL > Ac-Di-Sol > Primojel. The data obtained from dissolution study were correlated with the apparent differences in particle size generated in the disintegrated tablets. This data obtained from the above study concluded that Polyplasdone XL was the superior disintegrant than the other two and was used in the formulation trials with polymer (methyl cellulose) in the same concentration of 4%.

Thus, it can be concluded that, when used at same w/w percentage concentration, these three disintegrants representing three main classes of superdisintegrants vary in their ability to disintegrate Mosapride Citrate Dihydrate orodispersible tablets into their primary particles. Such difference can potentially affect drug disintegration and subsequently dissolution behavior. Thus, the Mosapride Citrate Dihydrate orodispersible tablets appeared to successfully discriminate the ability of these superdisintegrants to promote drug dissolution and is proposed as model formulation for disintegrants performance testing. Also, with the use of polymer (methyl cellulose), there was no bitter taste was felt while *in vivo* testing.

5. ACKNOWLEDGEMENT

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Pharmaceuticals Ltd, Aurangabad for providing excipients and facilities for conducting research work.

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