# Comparative evaluation of natural and synthetic superdisintegrants with newer superdisintegrant Kyron T-314

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#### Abstract

The main objective of this study was to formulate and evaluate the orodispersible tablets of ondansetron hydrochloride with synthetic and natural superdisintegrants. Various formulations were prepared by direct compression using different concentrations of natural superdisintegrant *i.e.* isolated mucilage of *Plantago ovata* and synthetic superdisintegrants namely Kyron T-314, crospovidone, and croscarmellose sodium ranging from 0.4% to 2%. The initial compatibility studies between the drug and excipients were carried out using FTIR spectroscopy. The blend was evaluated for additive properties. The tablets were evaluated for physical parameters and *in vitro* drug release. The disintegration time and *in vitro* drug release of optimized formulation (FK5) was compared with that of marketed formulation. The disintegration time was found to be 32 sec as compared to 49 sec for marketed formulation. The dissimilarity (f1) and similarity factors (f2) were calculated for optimized and marketed formulation and values were found to be 9.63 and 52.46, respectively. The optimized formulation was subjected to stability studies for three months. The formulation was found to be stable, with insignificant change in the hardness, disintegration time, drug content and *in vitro* drug release pattern.

**Keywords**: orodispersible tablet, ondansetron hydrochloride, Kyron T-314, crospovidone, croscarmellose sodium, isolated mucilage of *Plantago ovata* 

#### 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 these problems, scientists have developed innovative drug delivery systems known as Orally Disintegrating Tablets (ODT). These are novel types of tablets that disintegrate/disperse/dissolve in saliva (Chang et al. 2000). The target populations for these oral disintegrating dosage forms have generally been pediatric, geriatric, and bedridden or developmentally disabled patients who have difficulty in swallowing (Dysphagia). Patients with persistent nausea, sudden episodes of allergic attacks or coughing, who are traveling, or who have little or no access to water are also good candidates for ODTs. The benefits in terms of

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patient compliance, rapid onset of action, increased bioavailability and good stability make these tablets popular as a dosage form of choice in the current market. Some drugs are in such cases bioavailability of drug is significantly greater than those observed from conventional tablet dosage form (Habib et al. 2000, Dobetti 2001, Prajapati and Ratnakar 2009).

The basic approach used in the development of the ODTs is the use of superdisintegrants. Many approaches have been developed to manufacture ODTs. These include vacuum drying direct compression, lyophilization and molding. The direct compression method is inexpensive and convenient for producing tablets of sufficient mechanical strength.

Antiemetics are the agents which can block nausea and vomiting sensations, which are frequently encountered with chemotherapy, radiation therapy, and post operative inducing nausea and vomiting. Ondansetron hydrochloride is a selective serotonin 5-HT3 receptor antagonist indicated for the prevention of nausea and vomiting and reported to be well absorbed from the gastrointestinal tract.

Kyron T-314 is a very high purity polymer used in pharmaceutical formulations as a tablet superdisintegrants in the oral has a very high swelling tendency on hydration either in contact with water or gastrointestinal fluid (GIF). The present study involved the comparison of properties of synthetic and natural superdisintegrants with newer superdisintegrant Kyron T-314.

## Materials and Methods

#### Materials

Ondansetron hydrochloride, crospovidone, croscarmellose sodium and spray-dried lactose were obtained as a gift sample from Natco Pharma Ltd, India. Kyron T-314 was obtained as a gift sample from Corel Pharma Chem., India. Plantago ovata seeds purchased from Yarrow Chem. Products, India. Aspartame, mannitol, aerosil, magnesium stearate, peppermint flavor purchased from S.D. Fine Chemicals, India.

## Isolation of Mucilage

The seeds of *Plantago ovata* were soaked in distilled water for 48 hrs and then boiled for few minutes for complete release of mucilage into water. The material was squeezed through muslin cloth for filtering and separating out the marc. Then, an equal volume of acetone was added to the filtrate so as to precipitate the mucilage. The separated mucilage was dried in oven at temperature less than 60°C, powdered, sieved (#80) and stored in a desicator until use (Chakraborty et al. 2008)

# Preparation of mixed blend of drug and excipients

All the ingredients were passed through mesh no #80. Required quantity of each ingredient was taken for each specified formulation (Table 1) and all the ingredients were subjected to grinding to a required degree of fineness. The powder blend was evaluated for flow properties.

## Drug-Excipient interaction studies

The physical mixture of pure drug sample, drug and Kyron T-314 in the ratio 1:1 were subjected to IR spectral studies using FTIR spectrophotometer (FTIR 8400 S, Shimadzu, Japan).

Characterization of powder blends of active pharmaceutical ingredient and excipients (Lachman et al. 1987, Sharma and Gupta 2008)

Angle of Repose: Angle of repose was determined using funnel method. The blend was poured through a funnel that can be raised vertically until a maximum cone height (h) was obtained. Radius of the heap (r) was measured and angle of repose  $(\theta)$  was calculated using the following formula,

$$\theta = \operatorname{Tan}^{-1}(h/r)$$

Where,  $\theta$  = angle of repose, r=radius of the pile, h=height of the pile

Bulk Density: Apparent bulk density (b\*) was determined by pouring the blend into a graduated cylinder. The bulk volume (V\*) and weight of the powder (M) was determined. The bulk density (b\*) was calculated using following formula,

$$b*=M/V*$$

Where, M= weight of the powder, V\*= bulk volume

Tapped Density: The measuring cylinder containing a known mass of blend (M) was tapped for a fixed time (100 tappings). The minimum volume  $(V_i)$  occupied in the cylinder and weight of the blend was measured. The tapped density  $(t^*)$  was calculated using following formula,

$$t*=M/V_t$$

Where, M= weight of the powder,  $V_t$  = tapped volume

Compressibility Index: The simplest method of measurement of free flow of powder is compressibility, an indication of the ease with which material can be induced to flow is given by compressibility index (C.I) which is calculated as follows,

The value below 15% indicates a powder which usually gives rise to excellent flow characteristics, whereas above 25% indicate poor flowability.

Hausner's Ratio (H): This is an indirect index of ease of powder flow. It is calculated by the following formula,

$$H=t*/d*$$

Where,  $t^*$ = tapped density,  $d^*$ = bulk density

Lower Hausner's ratio (<1.25) indicates better flow property.

Compression of tablets

All ingredients were triturated individually in a mortar and passed through #80 sieve (Table 1). Then required quantity of all ingredients were weighed for a batch size of 100 tablets and mixed uniformly in a mortar, except aerosil and magnesium stearate. Finally magnesium stearate and aerosil were added as lubricant. This uniformly mixed blend was compressed in to tablets containing 4 mg drug using 4 mm flat face surface punches on a Rimek-1 rotary tablet machine by direct compression method. Total weight of tablet was kept 50 mg.

Table 1: Tablet formulations of ondansetron hydrochloride containing different superdisintegrants

FK1 4 0.2	32.3 32.1 31.9	Mannitol (mg)	Aspartame (mg)	Mint flavor	O Mg- Stearate (mg)	O.5. Aerosil (mg)	Total (mg)
FKI 4 0.2	32.1 31.9	10				0.5	50
1111	31.9		2				
		4.0		0.5	0.5	0.5	50
		10	2	0.5	0.5	0.5	50
	31.7	10	2	0.5	0.5	0.5	50
	31.5	10	2	0.5	0.5	0.5	50
	32.3	10	2	0.5	0.5	0.5	50
	32.1	10	2	0.5	0.5	0.5	50
	31.9	10	2	0.5	0.5	0.5	50
	31.7	10	2	0.5	0.5	0.5	50
	31.5	10	2	0.5	0.5	0.5	50
FCP1 4 0.2 -	32.3	10	2.	0.5	0.5	0.5	50
FCP2 4 0.4 -	32.1	10	2	0.5	0.5	0.5	50
FCP3 4 0.6	31.9	10	2	0.5	0.5	0.5	50
FCP4 4 0.8	31.7	10	2	0.5	0.5	0.5	50
FCP5 4 1 -	31.5	10	2	0.5	0.5	0.5	50
FCS1 4 0.2	32.3	10	2	0.5	0.5	0.5	50
FCS2 4 0.4	32.1	10	2	0.5	0.5	0.5	50
FCS3 4 0.6	31.9	10	2	0.5	0.5	0.5	50
FCS4 4 0.8	31.7	10	2	0.5	0.5	0.5	50
FCS5 4 1	31.5	10	2	0.5	0.5	0.5	50

FK= Formulations of Kyron, FM= formulations of Mucilage, FCP= formulations of crospovidone, FCS= formulations of croscarmellose sodium; 0.5mg of aerosil, magnesium stearate and mint flavor were used in all formulations.

#### Evaluation of tablets

Weight variation: Twenty tablets were randomly selected and average weight was determined. Then individual tablets were weighed and percent deviation from the average was calculated.

Hardness: The strength of tablet is expressed as tensile strength (kg/cm²). 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). Three tablets from each formulation batch were tested randomly and the average reading noted.

Friability. Friability of the tablets was determined using Roche Friabilator (Electrolab, India). This device consists of a plastic chamber that is set to revolve around 25 rpm for 4 min dropping the tablets at a distance of 6 inches with each revolution. Preweighed sample of 20 tablets was placed in the friabilator and were subjected to 100 revolutions. Tablets were dusted using a soft muslin cloth and reweighed. The friability (F %) is given by the formula

$$F(\%) = (1 - W_0 / W) \times 100$$

Where, Wo is weight of the tablets before the test and W is the weight of the tablets after test

Wetting time: Five circular tissue papers of 10-cm diameter were placed in a petri dish with a 10 cm diameter. Ten mL of water at 37±0.5°C containing eosin, a water-soluble dye, was added to the petri dish. A tablet was carefully placed on the surface of tissue paper. The time required for water to reach the upper surface of the tablets was noted as the wetting time. (Gohel et al. 2004, Park et al. 2008).

Water absorption ratio: A piece of tissue paper folded twice was placed in a small petri dish containing 6 mL of water. A tablet was put on the paper and the time required for complete wetting was measured. The wetted tablet was then weighed. Water absorption ratio R, was determined using following equation (Park 2008)

$$\mathbb{R}=\mathbb{W}_a-\mathbb{W}_b/\mathbb{W}_b\times 100$$

Where, Wa= weight of tablet after absorption, Wb= Initial weight of the tablet

Disintegration time: Disintegration time was measured using a modified disintegration method. For this purpose, a petri dish was filled with 10 mL of water at 37±0.5°C. The tablet was carefully put in the centre of the petridish and the time for the tablet to completely disintegrate into fine particles was noted. (Gohel et al. 2004)

Content uniformity: 20 Tablets were randomly selected and average weight was calculated. Tablets were powdered in a glass mortar. Powder equivalent to 4 mg was weighed and dissolved in 100 mL of 0.1N hydrochloric acid, filtered and drug content was analyzed spectrophotometrically at 310 nm.

#### In vitro release studies

In vitro drug release of ondansetron hydrochloride orodispersible tablets was determined using USP Dissolution Apparatus II (Paddle type) (Electrolab TDT-08L, India). The dissolution test was performed using 500 mL 0.1N hydrochloric acid at  $37\pm0.5^{\circ}$ C. The speed of rotation of paddle was set at 50 rpm. 5 mL samples were withdrawn at time points of 5, 10, 15, 20, 25, and 30 min and same volume was replaced with fresh media. Absorbance of solution was checked by UV spectrophotometer (ELICO- 164 double beam spectrophotometer, India) at a wavelength of 310 nm and drug release was determined from standard curve ( $\mathbb{R}^2$ =0.996).

#### Accelerated stability studies

Stability studies were carried out on optimized formulation. The tablets were stored at 40°C and 75% RH for duration of three months. After for every one month samples were withdrawn and tested for various parameters like hardness, drug content and *in vitro* drug release.

## Similarity and dissimilarity factors

A model independent approach was used to estimate the dissimilarity factor  $(f_1)$  and similarity factor  $(f_2)$  to compare the dissolution profile of optimized formulation (FK5) with marketed formulation. The difference factor  $(f_1)$  calculates the percent difference between the reference and test curve at each time point and is a measurement of the relative error between two curves. The following equations were used for calculating  $f_1$  and  $f_2$ .

$$f_1 = \{ [\sum_{t=1}^{n} |R_t - T_t|] / [\sum_{t=1}^{n} R_t] \} \times 100$$

The similarity factor (f<sub>2</sub>) is given by the fallowing equation:

$$f_2 = 50 \times \log \{ [1 + (1/n) \sum_{t=1}^{n} (R_t - T_t)^2]^{-0.5} \times 100 \}$$

Where, n= number of time points,  $R_t=$  dissolution value of the reference batch at time t,  $T_t=$  dissolution value of the test batch at same time point.

For *in vitro* dissolution curves to be considered similar  $f_1$  values should be in the range of 0-15 while values of  $f_2$  should lie within 50-100.

# Results and Discussion

In the present study, ondansetron hydrochloride orally dispersible tablets were prepared by using synthetic superdisintegrants namely, Kyron T-314, crospovidone, croscarmellose sodium and natural superdisintegrant such as isolated mucilage of *Plantago ovata*. IR spectroscopic studies revealed that drug was compatible with all the excipients (Fig 1a and 1b).

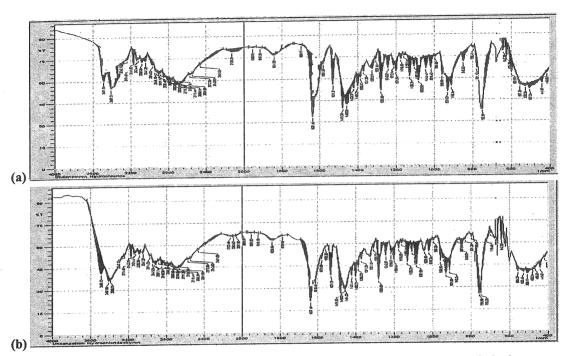


Figure 1. IR spectra of a) Ondansetron hydrochloride, b) physical mixture of Ondansetron hydrochloride and Kyron T-314

The blend of all the batches were evaluated for parameters like angle of repose was found to be between 22.47±0.84 and 27±0.81. Bulk density was found to be between 0.606±0.005 and 0.722±0.003 g/cm³ and tapped density between 0.661±0.001 and 0.791±0.001 g/cm³. Hausner's ratio was found 1.17. All the formulations showed good blend properties for direct compression and hence tablets were prepared by direct compression technology (Table 2).

The hardness of the tablets was found to be  $2.9\pm0.22$  to  $3.2\pm0.32$  kg/cm<sup>2</sup> and friability was found to be below 1% indicating good mechanical resistance. The drug content was found to be 99.1 to 101.13% (Table 3).

The most important parameter that needs to be optimized in the development of orodispersible tablets is the disintegration time of tablets. In the present study disintegration time of all batches were found in the range of  $32\pm1.18$  to  $101\pm1.28$  sec fulfilling the official requirements (3 min) for dispersible tablets.

Table 2: Evaluation of mixed blend of drug and excipients

Formulation	Angle of repose $(\theta)^*$	Bulk density (g/cm <sup>3</sup> )*	Tapped density (g/cm <sup>3</sup> )*	Hausner's ratio*	Compressibility index (%)*
FK1	25.26±1.03	0.642±0.014	0.735±0.004	1.144±0.019	12.58±1.520
FK2	23.52±0.98	0.646±0.006	0.735±0.009	1.137±0.003	12.09±0.233
FK3	24.78±0.82	0.617±0.004	0.722±0.003	1.170±0.013	14.53±0.926
FK4	24.89±0.80	0.634±0.005	0.720±0.008	1.136±0.022	11.99±1.739
FK5	24.21±0.72	0.645±0.005	0.742±0.005	1.150±0.001	13.24±0.169
FM1	24.47±0.92	0.641±0.004	0.727±0.002	1.134±0.004	11.88±0.332
FM2	24.97±0.86	0.630±0.005	0.710±0.006	1.126±0.019	11.24±1.491
FM3	24.78±0.78	0.642±0.007	0.712±0.009	1.108±0.007	9.82±0.070
FM4	22.58±0.94	0.654±0.011	0.728±0.003	1.130±0.009	10.16±1.202
FM5	24.62±0.90	0.658±0.003	0.749±0.002	1.138±0.002	12.20±0.127
FCP1	25.76±0.83	0.613±0.007	0.682±0.003	1.112±0.017	10.11±1.414
FCP2	26.28±0.90	0.606±0.005	0.661±0.001	1.088±0.012	8.24±0.947
FCP3	26.32±0.69	0.660±0.010	0.750±0.011	1.135±0.001	11.93±0.084
FCP4	24.79±0.72	0.650±0.002	0.738±0.009	1.135±0.010	11.90±0.813
FCP5	26.26±1.01	0.644±0.006	0.732±0.013	1.137±0.011	12.06±0.841
FCS1	27.54±0.81	0.646±0.005	0.728±0.003	1.126±0.004	11.19±0.339
FCS2	22.47±0.84	0.722±0.003	0.791±0.001	1.095±0.006	8.72±0.523
FCS3	26.62±0.97	0.673±0.004	0.752±0.004	1.116±0.013	10.49±1.067
FCS4	26.38±1.05	0.623±0.004	0.701±0.012	1.125±0.028	11.10±2.220
FCS5	24.21±0.68	0.615±0.005	0.694±0.006	1.129±0.018	11.44±1.435

Values are expressed as Mean ±SD, \*n=3, FK= Formulations of Kyron, FM= Formulations of Mucilage, FCP=Formulations of crospovidone, FCS= Formulations of cros

Table 3. Evaluation of Tablets

Formulati on	Weight variation (mg)***	Hardness (kg/cm²)*	Friability (% w/w)*	Wetting time (sec)**	Water absorption ratio (%)**	DT (sec) **	Content uniformity (%)	t <sub>30</sub> (%)**
FK1	50±1.19	3.1±0.64	0.27±0.12	62±1.21	110±1.23	83±1.21	101.13	95.96±1.46
FK2	52±1.12	3.0±0.62	0.23±0.18	56±1.92	118±1.29	76±1.96	99.98	96.00±1.28
FK3	52±0.99	3.1±0.53	0.21±0.12	44±1.08	121±1.30	62±1.23	99.80	96.45±1.23
FK4	51±1.05	3.0±0.39	0.22±0.15	32±1.29	132±1.42	53±1.28	99.32	98.79±2.23
FK5	49±1.10	3.1±0.32	0.25±0.24	29±1.02	135±1.46	32±1.18	100.82	99.79±2.57
FM1	49±0.98	3.1±0.12	0.28±0.21	78±1.76	113±1.81	99±1.34	99.24	95.26±2.59
FM2	50±1.11	2.9±0.57	0.24±0.16	67±1.91	123±1.43	79±1.29	99.85	96.78±3.12
FM3	50±1.86	3.0±0.53	0.19±0.13	54±1.41	129±1.45	72±1.31	99.62	98.25±3.56
FM4	50±0.98	2.9±0.22	0.27±0.16	49±1.96	132±1.39	68±1.20	99.45	98.56±1.26
FM5	52±0.87	3.0±0.49	0.47±0.11	39±1.03	139±1.46	52±1.24	99.62	98.52±2.34
FCP1	52±1.23	3.2±0.36	0.37±0.12	79±1.36	106±1.28	92±1.78	99.42	95.48±3.46
FCP2	52±1.76	3.0±0.62	0.33±0.61	69±1.26	114±1.89	87±1.24	99.36	95.96±1.57
FCP3	50±1.24	2.9±0.60	0.31±0.64	52±1.10	120±1.65	72±1.10	99.52	96.24±1.39
FCP4	51±0.99	3.1±0.43	0.39±0.25	44±1.14	123±1.97	67±2.42	99.23	97.25±2.27
FCP5	51±1.10	3.0±0.26	0.30±0.31	36±1.19	136±1.32	52±1.35	99.11	97.96±1.29
FCS1	52±1.32	2.9±0.36	0.20±0.23	82±1.18	102±1.49	101±1.28	99.89	95.96±1.16
FCS2	50±1.12	3.0±0.52	0.22±0.14	67±1.92	109±1.39	96±1.32	100.19	96.01±1.28
FCS3	49±1.75	2.9±0.62	0.29±0.12	72±1.87	112±1.45	85±1.41	99.52	96.28±1.32
FCS4	48±1.13	3.0±0.65	0.30±0.21	59±1.34	120±1.69	78±1.25	99.49	96.89±1.21
FCS5	49±1.18	3.2±0.32	0.46±0.13	41±1.20	129±1.58	69±1.36	99.21	96.92±1.28

Values are expressed as Mean ±SD, \*n=3, \*\*n = 6, \*\*\*n= 20, DT= Disintegration time

Fig. 2 depicts the disintegration behavior of the tablets in water. This rapid disintegration of the oral dispersible tablets were due to penetration of saliva into the pores of the tablets, which leads to the swelling of super disintegrants to create enough hydrodynamic pressure for quick and complete disintegration of the tablet. Batch FK5 was selected as optimized batch containing

Kyron T-314 as superdisintegrant in 2% concentration. It showed less disintegration time of 32 sec. It was observed that less disintegration time was observed when Kyron T-314 was used as superdisintegrant, may be due to swelling at faster rate upon contact with water and elimination of lump formation after disintegration when compared with mucilage of *Plantago ovata*, crospovidone and croscarmellose sodium. Mucilage of *Plantago ovata* showed more disintegration time than Kyron T-314 but less disintegration time was observed with mostly used superdisintegrants crospovidone and croscarmellose sodium. Kyron T-314 was effective at concentration i.e. 2% and next best disintegration was shown by mucilage of *Plantago ovata* at a concentration of 2%, indicating that it is also a good disintegrant having the additional advantage of being natural. Finally the disintegration time of optimized formulation was compared with marketed formulation the results showed that formulated tablet disintegrated in 32 sec as compared to 49 sec for marketed ondansetron tablet (ZOFER MD). The formulation FK5 was found to be the best, as this formulation showed less disintegration time and possessing good tabletting properties.

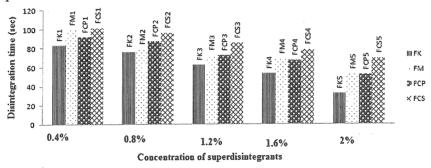


Figure 2. Disintegration time of different superdisintegrants with different concentrations

Fig. 3 depicts the relation between the concentration of superdisintegrants and wetting time. Wetting time was used as a parameter to correlate with disintegration time in oral cavity. This is an important criterion for understanding the capacity of disintegrants to swell in the presence of little amount of water.

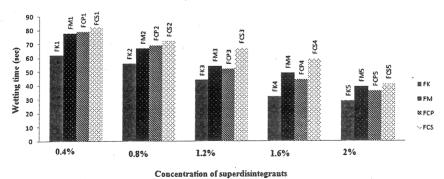


Figure 3. Wetting time of different superdisintegrants with different concentration

Since the dissolution process of a tablet depends upon the wetting followed by disintegration of the tablet, it could be assumed that wetting was the only cause of disintegration. This indicates that that aqueous medium penetrates into the tablet and replaces the air adsorbed on the particles, which weakens the intermolecular bonds and breaks the tablet into fine particles. The wetting time of the formulated tablets were found in the range of  $29\pm1.02$  to  $82\pm1.18$  sec.

Water absorption ratio was performed to know the moisture sorption and water uptake properties of superdisintegrants. Water absorption ratio was increased and disintegration time and wetting time was decreased with an increase in concentration of superdisintegrants. The water absorption ratios of the formulated tablets were found in the range of  $102\pm1.49$  to  $139\pm1.46$ .

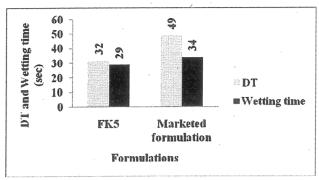


Figure 4. Disintegration time and wetting time of optimized formulation (FK5) and marketed formulation

In vitro drug release of all formulations showed above 90% within 30 min. In vitro dissolution of an optimized formulation FK5 and marketed formulation release was found to be 99.79% and 96.64%, respectively, in 30 min. The optimized formulation was compared with that of marketed formulation and f1 and f2 values were calculated and were found to be 9.62 and 52.46 respectively. For in vitro dissolution curves to be considered similar, f1 values should be in the range of 0-15 while values of f2 should lie within 50-100, ensure similarity or equivalence of the two curves and thus the performance of the test and reference products.

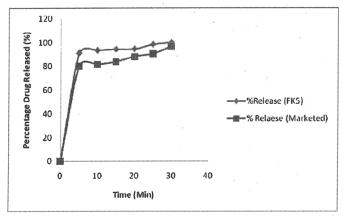


Figure 5. Comparison of in vitro drug release of optimized formulation (FK5) with marketed formulation

The stability of this optimized formulation was known by performing stability studies for three months at accelerated conditions of 40°C±75 % RH on optimized formulation. The formulation was found to be stable, with insignificant change in the hardness, disintegration time, and *in vitro* drug release pattern (Table 4).

Table 4. Stability data of optimized formulation FK5

Parameters	Time in months						
	0 (Initial)	1st month	2 <sup>nd</sup> month	3 <sup>rd</sup> month			
Hardness (kg/cm <sup>2</sup> )	3.1±0.32	2.9±0.11	3.0±0.13	3.0±0.15			
Disintegration time (sec)	32±0.808	30±0.673	28±0.710	29±0.639			
Drug content (%)	100.21	100.14	99.97	100.20			
In vitro drug release (%)	99.79±0.17	99.82±0.32	99.63±0.28	99.98±0.13			

#### Conclusion

From the above data, it can be concluded that Kyron T-314 is having better disintegrant property than other disintegrants namely, mucilage of *Plantago ovata*, crospovidone and croscarmellose sodium. The naturally available *Plantago ovata* also showed good disintegration than other most widely used synthetic superdisintegrants such as crospovidone, croscarmellose sodium.

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#### References

Chakraborthy, S., Khandai, M., Singh, S. P. and Patra, N. (2008) Comparative study on effect of natural and synthetic superdisintegrants in the formulation of fast dissolving tablets. *Int J Green Pharm.* 2: 22-25.

Chang, R., Guo, X., Burnside, B. and Couch, R. (2000). A review of fast dissolving tablets. Pharm Tech. 24: 52-58.

Dobetti, L. (2001). Fast-melting tablets: Developments and Technologies. Pharm. Tech. (Suppl.): 44-50.

Gohel, M., Patel, M., Amin, A., Agarwal, R., Dave, R. and Bariya, N. (2004). Formulation design and optimization of mouth dissolve tablets of nimesulide using vacuum drying technique, AAPS Pharm. Sci. Tech. 5: E36.

Habib, W., Khankari, R. and Hontz, J. (2000). Fast-dissolving drug delivery systems, critical review in therapeutics. Drug Carrier Systems. 17: 61-72.

Lachman, L., Lieberman, H.A. and Kanig, J.L. (1987). The theory and practice of industrial pharmacy, Varghese Publishing House. Mumbai, pp. 182-203.

Park, J. H., Holman, K. M., Bish, G. A., Krieger, D. G., Ramlose, D. S., Herman, C. J. and Wu, S. H. (2008). An alternative to the USP disintegration for orally dissolving tablet. *Pharm. Tech.* 32: 1-3.

Prajapati, B. G. and Ratnakar, N. (2009). A review on recent patents on fast dissolving drug delivery system. *Pharm Tech.* 1: 790-798.

Sharma, S. and Gupta, G.D. (2008). Formulation and characterization of fast dissolving tablet of promethazine theoclate. *Asian J Pharm.* 2:70-2.

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