World Journal of Pharmaceutical research

Volume 2, Issue 6, 2301-2316. Research Article ISSN 2277 – 7105

FORMULATION AND EVALUATION OF ORAL DISINTEGRATING TABLETS OF MONTELUKAST SODIUM: EFFECT OF FUNCTIONALITY OF SUPERDISINTEGRANTS

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Article Received on
29 August 2013,

Revised on 26 Sept. 2013,
Accepted on 20 October 2013

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ABSTRACT

Montelukast Sodium is a leukotriene receptor antagonist (LTRA) used for the treatment of asthma and to relieve symptoms of seasonal allergies. Montelukast blocks the action of leukotriene on the cysteinyl leukotriene receptor in the lungs and bronchial tubes by binding to it. In present research work an attempt has been made to prepare fast dissolving tablets of Montelukast sodium were prepared by using direct compression method using superdisintegrants. IR spectral analysis study showed that there was no drug interaction with formulation additives of the tablet. The blend was examined for the pre-compressional parameters results were within prescribed limits and indicated good free flowing property. The prepared tablets formulations were evaluated for post-compressional parameters. All the post-compressional parameter are evaluated were prescribed limits and results were within IP acceptable limits. The *in-vitro* disintegration time of Montelukast sodium fast dissolving tablets were found to be in the range of 11 to 61 sec fulfilling the official requirements. The *in-vitro* disintegration time of Montelukast sodium prepared by direct compression method DC7 formulation containing CP 6 % shows around 11.52 sec. The tablets prepared by direct compression method the $t_{50\%}$ and $t_{90\%}$(time for 50% and 90% of release) values decreased with increase in the level of CP. In all the prepared formulation 50 % and 90 % of drug release ranges between within ranges 0.95 min to 2.91 min and 3.60 min to 8.92 min respectively. Among all formulations DC7 showed 99.85% drug release within 4 min. The stability study conducted as per the ICH guidelines and the formulations were found to be stable. It was concluded that the rapidly disintegrating tablets with proper hardness,

rapid disintegration in the oral cavity with enhanced dissolution rate can be made using super disintegrants.

Keywords: Fast dissolving tablets, Montelukast sodium, sodium starch glycolate, Crosscarmellose sodium, Crospovidone, Kyron-T-315.

INTRODUCTION

Oral delivery is currently the gold standard in the pharmaceutical industry where it is regarded as the safest, most convenient and an economical method of drug delivery having the highest patient compliance.[1] Tablet is most popular among all dosage forms existing today because of convenience of self administration, compactness and easymanufacturing.[2] Many patients express difficulty in swallowing tablets and hard gelatin capsules, resulting in noncompliance and ineffective therapy.[3]

To overcome this weakness, scientists have developed innovative drug delivery systems known as fast dissolving tablets.[4] United States Food and drug administration (FDA) defined fast dissolving tablet (FDT) as "a solid dosage form containing medicinal substance or active ingredient which disintegrate rapidly usually within a matter of seconds when placed up on the tongue".[5] Their characteristic advantages such as administration without water, 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.[6]

Montelukast sodium is chemically designated as [R-(E)]-1-[[[1-[3-[2-(7-chloro-2-quinolinyl) ethenyl] phenyl]-3-[2-(1-hydroxy-1-methylethyl) phenyl] propyl] thio] methyl] cyclopropane acetic acid, monosodium salt, an orally administered drug of choice in the treatment of asthma in adults and children. Other problems like hand tremors, dysphagia in case of geriatric and non co-operative patients and the problem of swallowing is common phenomenon which leads to poor patient compliance. To overcome these drawbacks mouth dissolving tablets or orally disintegrating tablets or fast dissolving tablets has emerged as an alternative oral dosage form.[7]

The pediatric and geriatrics patients are of particular concern. To overcome this, dispersible tablets [8] and fast-disintegrating tablets [9] have been developed. Most commonly used methods to prepare these tablets are; freeze-drying/Lyophilization [10] tablet molding [11] and direct-compression methods [12]. Lyophilized tablets show a very porous structure, which causes quick penetration of saliva into the pores when placed in oral cavity [10, 13]. The main

disadvantages of tablets produced are, in addition to the cost intensive production process, a lack of physical resistance in standard blister packs and their limited ability to incorporate higher concentrations of active drug [8]. Moulded tablets dissolve completely and rapidly. However, lack of strength and taste masking are of great concern[14] . Main advantages of direct compression are low manufacturing cost and high mechanical integrity of the tablets [15]. Therefore, direct-compression appears to be a better option for manufacturing of tablets.

In the present study an attempt had been made to prepare mouth dissolving tablets of montelukast sodium in the oral cavity with enhanced dissolution rate and hence improved patient compliance. The basic approach used in the development of mouth dissolving tablets is the use of different superdisintegrants like croscarmellose sodium (CCS), sodium starch glycolate (SSG), Kyron T134 and crospovidone (CP), which provide instantaneous disintegration of tablet after putting on tongue, thereby releasing the drug in saliva. These systems may offer superior profile with potential mucosal absorption, thus increase the drug bioavailability. These systems are also called mouth dissolving tablets, melt-in-mouth tablets, Reprimelts, porous tablets, oro dispersible, quick dissolving or rapidly disintegrating tablets.

MATERIAL AND METHODS

Montelukast sodium was procured as a gift sample from Redefining Healthcare, Unimark Remedies Limited, Vapi, Gujarat, India. Superdisintegrants like crospovidone, sodium starch glycolate, croscarmellose, kyron-T. Other excipients like Mannitol, Microcrystalline cellulose, flavor, Sodium lauryl sulphate (SLS), Talc, and Magnesium stearate purchased from S.D. Fine chem., Mumbai. All other materials were of analytical reagent grade.

Preparation of fast dissolving tablets by direct compression method [16, 17]

Montelukast sodium fast dissolving tablets were prepared by direct compression method by using co-processed superdisintegrants like CP, SSG, CCS, Kyron-T. Mannitol, Microcrystalline Cellulose (MCC) as a diluents, Aspartame as a sweetening agent, Mint as a flavor, Magnesium Stearate, Talc used as a lubricant and glidant. All the ingredients (except granular directly compressible excipients) were passed through # 60-mesh separately. Then the ingredients were weighed and mixed in geometrical order after sufficient mixing of drug as well as other components and compressed into tablets of 200mg using 6 mm BB Tooling round flat punches on 12- station rotary tablet machine. Compression force of the machine was adjusted to obtain the hardness of 3-4 kg/cm^2.

Compatibility studies

IR Studies: IR spectra for pure drug Montelukast sodium and DC3, DC7, DC11 and DC15 powdered tablets were recorded in Infrared spectrophotometer with KBr pellets.

Evaluation of fast dissolving tablets of Montelukast sodium

Pre-compression Parameters: The tablet blends were evaluated for their bulk density, tapped density, Carr's index and flow properties.

Post-compression Parameters

Hardness test: The hardness of the tablets was determined using Pfizer hardness tester. It is expressed in kg/cm^2. Six tablets were randomly picked from each formulation and the mean and standard deviation values were calculated.

Friability: A friability test was conducted on the tablets using Friabilator. A friability test was conducted on the tablets using Friabilator. Twenty tablets were selected from each batch and any loose dust was removed with the help of a soft brush. The tablets were initially weighed ($W_{initial}$) and transferred into Friabilator. The drum was rotated at 25 rpm for 4 min after which the mini-tablets were removed. Any loose dust was removed from the tablets as before and the tablets were weighed again (W_{final}). The percentage friability was then calculated by,

$$F = [(W_{initial} - W_{final})/ W_{initial}] \times 100$$

% Friability of tablets less than 1% is considered acceptable.

Weight variation: The weight variation test was conducted by weighing 20 randomly selected tablets individually, calculating the average weight and comparing the individual tablet weights to the average. The specification of weight variation is 10%.

Estimation of drug content [18]: Five tablets weighted and crushed in a mortar then weighed powder contain equivalent to 10 mg of drug transferred in 100ml of 0.5% of SLS solution to give a concentration of 100µg/ml. Take 15ml of this solution and diluted it upto 100ml with 0.5% of SLS solution to give a concentration of 15µg/ml. Absorbance measured at 342nm using UV-Visible Spectrophotometer.

Disintegration time [19]: Tablet disintegration is an important step in drug absorption. The test for disintegration was carried out in Electro lab USP disintegration test apparatus. It consists of 6 glass tubes which are 3 inches long, open at the top, and held against a 10 mesh screen,

at the bottom end of the basket rack assembly. To test the disintegration time of tablets, one tablet was placed in each tube and the basket rack was positioned in a 1 liter beaker containing 0.5% of SLS in water at 37°C ± 1°C such that the tablet remains 2.5 cm below the surface of the liquid. The time taken for the complete disintegration of the tablets was noted.

Wetting time: 10 ml of distilled water containing Eosin, a water-soluble dye was placed in a petri dish of 10 cm diameter. Tablets were carefully placed in the centre of the petri dish and the time required for water to reach the upper surface of the tablet was noted as the wetting time. The test results are presented as mean value of three determinations.

Water absorption ratio [20]: 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 indicated by R, which is calculated by using the below mentioned equation.

***In-vitro* release [21-23] :** The *in-vitro* release pattern of FDT was studied as per method given by Chaudhari *et al*. *In-vitro* dissolution studies of FDT were performed at 37 ± 0.5°C using 0.5% w/v aqueous solution sodium lauryl sulfate in USP II paddle method at 50 rpm. 5 mL of filtered aliquot was manually withdrawn at pre-determined time intervals and replaced with 5 mL of fresh 0.5% sodium lauryl sulfate solution maintained at the same temperature. The samples were analyzed at 342nm using a UV spectrophotometer.

Details of dissolution test:

Dissolution test apparatus	: USP type II
Speed	: 50 rpm
Stirrer	: Paddle type
Volume of medium	: 900 ml
Volume withdrawn	: 5 ml
Medium used	: 0.5% SLS in distilled water
Water Temperature	: 37 ± 0.5ºC

The stability study[24] of the tablets was carried out according to International conference on Harmonization guidelines for zone III and IV. The formulations were stored at 25°C/ 60% and 40°C / 75 % RH for three months by storing the samples in stability chamber (Thermo Lab, Mumbai).

RESULT AND DISCUSSION

In the present study the IR spectra for pure drug Montelukast sodium and its formulations like DC3, DC7, DC11 and DC15 with various polymers and other excipients is taken to establish the physical characterization of drug and its formulations **(Fig 1).** The drug-excipients study was done by Fourier transform infrared (FT-IR) spectroscopy study, the prominent peaks of Montelukast sodium pure drug were shown at absorption peaks for the drug montelukast sodium has got tertiary -OH groups exhibited a broad peak around 3300 cm^{-1} and a -COOH peak which is in the form of a salt has exhibited a strong peak near 1700 cm^{-1}. The aromatic C-H peaks are also observed between 2900-3000 cm^{-1}. In formulations like DC3, DC7, DC11 and DC15 exhibited characteristic absorption peaks in the same range of pure drug peak. Hence, it could be confirmed that there is no chemical interaction between drug and excipients in the formulation.

The values of pre-compression parameters evaluated were within prescribed limits and indicated good free flowing property **(Table 2).** All the post-compression parameters are evaluated were prescribed limits and results were within IP acceptable limits. Results of post-compression parameters were shown in (**Table 3).**

In all the formulations, hardness test indicated good mechanical strength ranges from 2.74 kg/cm^2 to 3.52 kg/cm^2. The friability range is 0.54 to 0.74 % to be well within the approved range (<1%)indicated that tablet had good mechanical resistance. The weight variation was found in all designed formulations in the range 196.81 to 200.44 mg. All the tablets passed weight variation test as the average percentage weight variation was within 7.5% i.e. in the pharmacopoeia limits. The standard deviation values indicated that all the formulations were within the range.

The drug content uniformity was in between 97.26 to 99.91 %, water absorption ration were found between 46.32 to 86.03% and wetting time between 68.31 to 97.48 sec. The results of drug content, water absorption ration and wetting time were tabulated in **Table 3**. Rapid disintegration within several minutes was observed in all the formulations. The *in-vitro* disintegration data is tabulated in the (**Table 3) and Fig 2-3.** The *in-vitro* disintegration time of fast dissolving tablets were found to be 11.52 to 61.44 sec. which is in the range of fulfilling the official requirements. By the addition of superdisintegrants the disintegration time increased significantly ($P<0.05$) tablets prepared.

Table 1: Composition of mouth dissolving tablets of Montelukast Sodium

Ingredients (mg)	DC1	DC2	DC3	DC4	DC5	DC6	DC7	DC8	DC9	DC10	DC11	DC12	DC13	DC14	DC15	DC16
MS	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
SSG	4	8	12	16	-	-	-	-	-	-	-	-	-	-	-	-
CP	-	-	-	-	4	8	12	16	-	-	-	-	-	-	-	-
CCS	-	-	-	-	-	-	-	-	4	8	12	16	-	-	-	-
Kyron-T	-	-	-	-	-	-	-	-	-	-	-	-	4	8	12	16
Talc	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
Mg Stea	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
MCC	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40
Aspartame	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Flavor	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Mannitol	138	134	130	126	138	134	130	126	138	134	130	126	138	134	130	126
Total wt(mg)	200	200	200	200	200	200	200	200	200	200	200	200	200	200	200	200

**** MS=Montelukast sodium, SSG= Sodium starch Glycolate, CP= Crospovidone, CCS= Crosscarmellose sodium, MCC= Microcrystalline cellulose, Mg Stea= Magnesium stearate.***

Table 2: Post-compression parameters Montelukast Sodium fast dissolving tablets

FC	Bulk density(g/cc) ± SD, n=3	Tapped density (g/cc) ± SD, n=3	Angle of repose (degree) ± SD, n=3	Carr's index (%) ± SD, n=3	Hausner's Ratio ± SD, n=3
DC1	0.53 ± 0.03	0.63 ± 0.01	28.19 ± 1.20	16.46 ± 0.25	1.22 ± 0.08
DC2	0.52 ± 0.04	0.62 ± 0.02	29.76 ± 0.90	16.24 ± 0.12	1.23 ± 0.10
DC3	0.55 ± 0.08	0.64 ± 0.04	28.44 ± 1.10	20.62 ± 0.32	1.13 ± 0.12
DC4	0.54 ± 0.02	0.54 ± 0.03	28.84 ± 0.80	15.08 ± 0.14	1.15 ± 0.06
DC5	0.51 ± 0.03	0.56 ± 0.02	29.51 ± 0.40	19.73 ± 0.16	1.24 ± 0.06
DC6	0.47 ± 0.06	0.59 ± 0.03	28.16 ± 1.30	16.44 ± 0.18	1.23 ± 0.04
DC7	0.54 ± 0.04	0.63 ± 0.02	29.66 ± 1.40	18.62 ± 0.14	1.16 ± 0.08
DC8	0.45 ± 0.05	0.59 ± 0.03	27.48 ± 0.08	21.48 ± 0.12	1.22 ± 0.02
DC9	0.52 ± 0.06	0.58 ± 0.04	26.74 ± 0.12	20.74 ± 0.14	1.26 ± 0.09
DC10	0.53 ± 0.09	0.65 ± 0.02	27.24 ± 1.20	16.65 ± 0.12	1.19 ± 0.08
DC11	0.54 ± 0.07	0.63 ± 0.05	27.45 ± 0.80	15.44 ± 0.16	1.22 ± 0.14
DC12	0.56 ± 0.09	0.58 ± 0.02	28.46 ± 1.20	22.32 ± 0.20	1.19 ± 0.12
DC13	0.57 ± 0.03	0.62 ± 0.03	28.62 ± 0.72	15.08 ± 0.12	1.17 ± 0.14
DC14	0.51 ± 0.02	0.58 ± 0.06	27.51 ± 0.42	16.44 ± 0.18	1.28 ± 0.06
DC15	0.47 ± 0.05	0.59 ± 0.03	26.19 ± 1.24	18.84 ± 0.12	1.24 ± 0.02
DC16	0.48 ± 0.06	0.61 ± 0.02	28.12 ± 1.36	16.65 ± 0.14	1.16 ± 0.08

* Average of three determinations

Table 3: Post-compression parameters of Montelukast Sodium fast dissolving tablets prepared by direct compression method

FC	Hardness * (Kg/cm^2) ± SD, n=3	Friability (%) ± SD, n=3	Weight variation* (mg) ± SD, n=20	Disintegration time* (sec) ± SD, n=3	Wetting time* (sec) ± SD, n=3	Water absorption ratio* ± SD, n=3	Drug Content* (%) ± SD, n=3
DC1	3.22 ± 0.20	0.59 ± 0.10	199.46 ± 1.2	50.32 ± 1.2	92.12 ± 1.1	52.65 ± 1.1	98.46± 1.4
DC2	3.34 ± 0.06	0.66 ± 0.10	198.26 ± 1.4	31.16 ± 1.4	91.42 ±0.8	58.46 ± 1.6	97.26± 1.2
DC3	3.46 ± 0.12	0.68 ± 0.09	20 0.12 ± 1.0	16.44 ± 1.6	71.22 ±0.2	84.41 ± 1.2	99.48± 0.6
DC4	3.32± 0.14	0.69 ± 0.09	198.68 ± 0.08	22.86 ± 1.2	68.31 ±1.2	86.03 ± 0.8	97.76 ± 1.2
DC5	3.44 ± 0.16	0.74 ± 0.06	200.32 ± 1.4	34.26 ± 1.2	94.42 ± 1.4	72.72 ± 1.8	98.24 ± 0.8
DC6	3.32± 0.14	0.68 ± 1.2	197.42 ± 0.06	21.23 ± 0.6	86.69 ± 1.2	68.62 ± 1.4	96.98 ± 0.6
DC7	3.24± 0.08	0.58 ± 0.10	199.69 ± 1.4	11.52 ± 1.4	71.26 ± 1.6	56.48 ± 1.2	97.68 ± 1.2
DC8	2.98 ± 0.12	0.54 ± 0.04	200.44 ± 0.6	18.56 ± 1.2	50.32 ± 1.0	46.32 ± 1.6	99.25 ± 1.4
DC9	3.32± 0.14	0.58 ± 0.04	200.22 ± 1.4	46.42 ± 1.1	92.32 ± 1.1	86.62 ± 1.2	99.28 ± 1.3
DC10	3.44 ± 0.24	0.56 ± 0.10	200.14 ± 1.2	28.32 ± 1.4	91.26 ± 1.2	79.45 ± 1.6	98.98 ± 1.4
DC11	3.12 ± 0.06	0.68 ± 0.10	198.79 ± 1.4	14.86 ± 1.2	84.32 ±0.7	54.24 ± 0.4	98.64 ± 1.2
DC12	3.52 ± 0.16	0.66 ± 0.09	197.31 ± 1.4	20.16 ± 1.5	50.04 ±0.4	49.20 ± 0.6	98.22 ± 0.6
DC13	2.74 ± 0.18	0.70 ± 0.09	196.81 ± 0.07	61.44 ± 1.4	96.31 ±1.4	54.24 ± 0.6	99.76 ± 1.2
DC14	3.24 ± 0.14	0.72 ± 0.06	199.75 ± 1.3	44.41 ± 1.4	92.23 ± 1.3	61.12 ± 1.2	98.44 ± 0.4
DC15	3.46 ± 0.22	0.68 ± 1.24	199.88 ± 1.2	28.32 ± 1.4	50.02 ± 1.2	67.52 ± 2.2	99.91 ± 0.6
DC16	3.36 ± 0.12	0.62 ± 0.12	199.53 ± 1.4	39.23 ± 0.8	97.48 ± 1.0	76.43 ± 1.9	99.72± 1.4

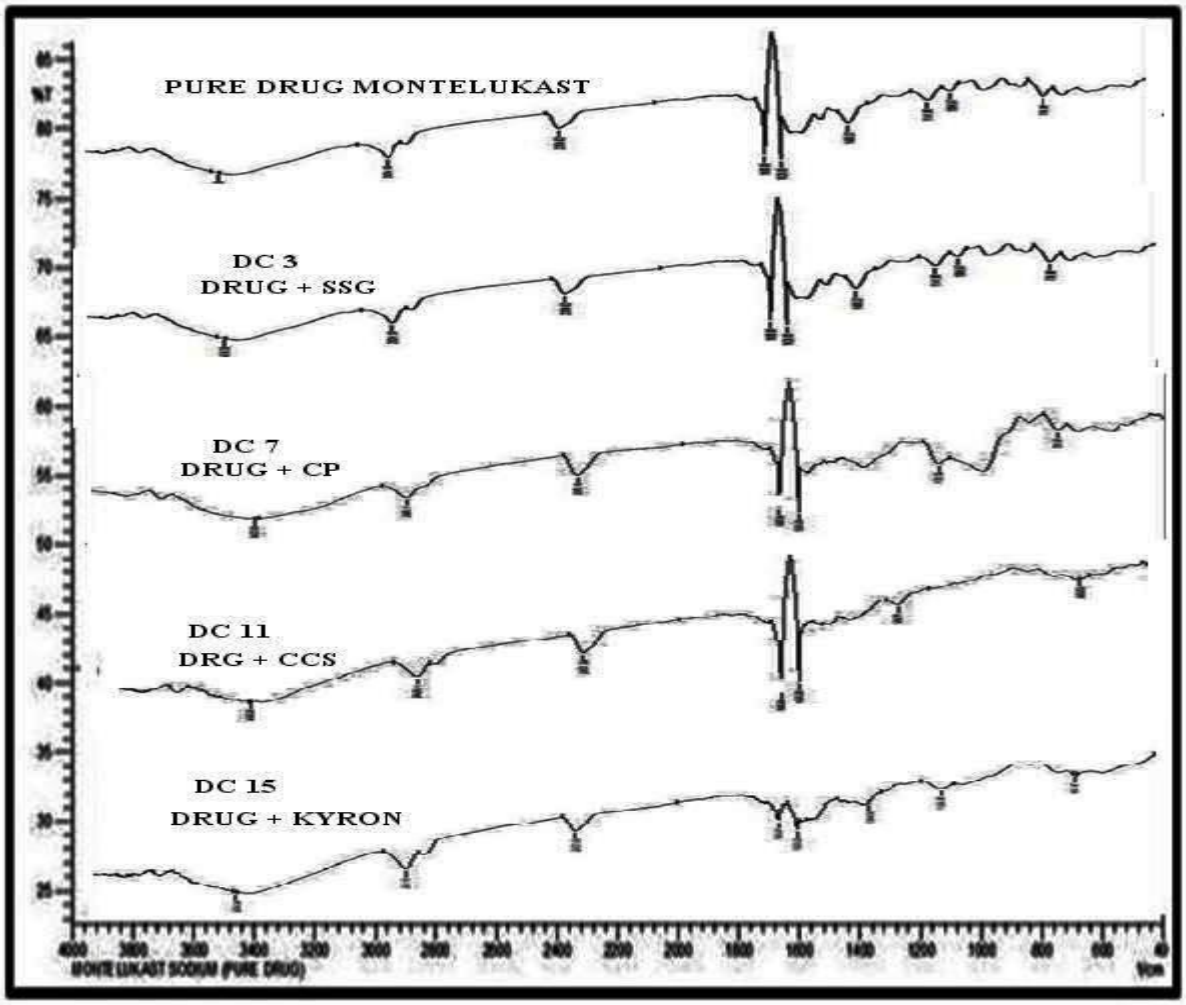

Fig 1: IR Spectra of Pure drug Montelukast sodium, Formulation DC3, DC7, DC11 and DC15.

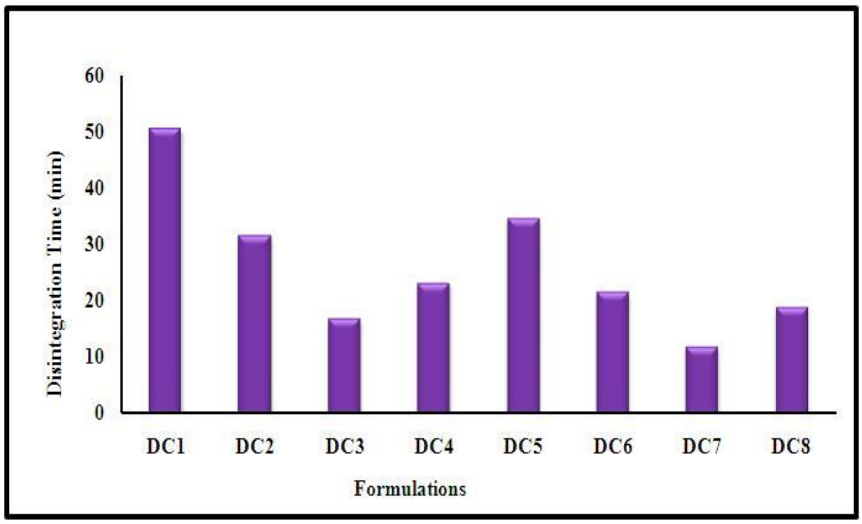

Fig 2: Disintegration time vs Formulation (DC1-DC8)

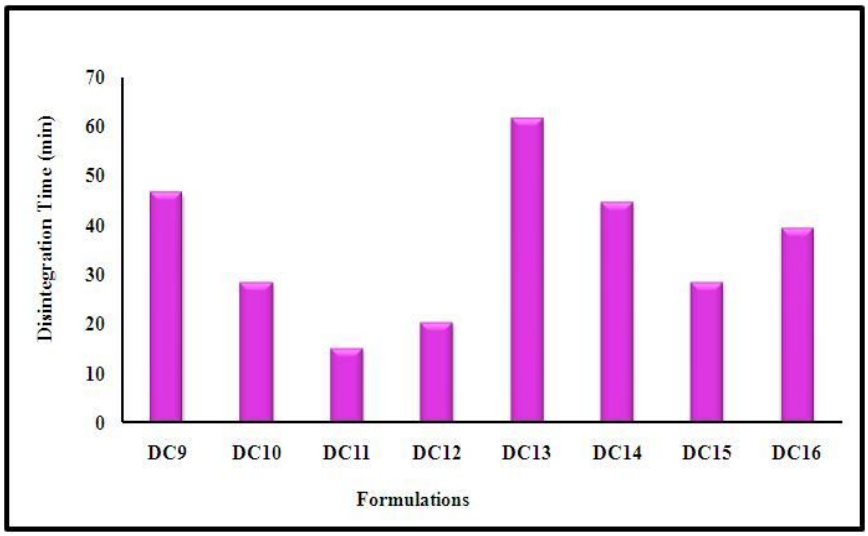

Fig 3: Disintegration time vs Formulation (DC9 - DC16)

Table 4:Release profile of Montelukast sodium fast dissolving tablets prepared by direct compression

Formulation Code	T_{50} (min)	T_{90} (min)
DC1	2.57± 0.20	7.68±0.2
DC2	1.88± 0.16	5.83±0.8
DC3	1.60± 0.12	3.89±0.2
DC4	1.70± 0.14	4.80± 0.4
DC5	1.82± 0.16	5.78±0.4
DC6	1.59± 0.14	4.80±0.6
DC7	0.95± 0.08	3.60±0.6
DC8	1.53± 0.12	3.89± 1.0
DC9	2.94± 0.14	7.83± 1.2
DC10	2.53± 0.24	6.42± 1.2
DC11	0.88± 0.06	2.89±0.7
DC12	0.98± 0.16	3.75±0.4
DC13	2.90± 0.12	8.92±1.2
DC14	2.61± 0.14	7.83± 1.3
DC15	0.97± 0.22	4.76± 1.2
DC16	1.59± 0.12	5.83±0.4

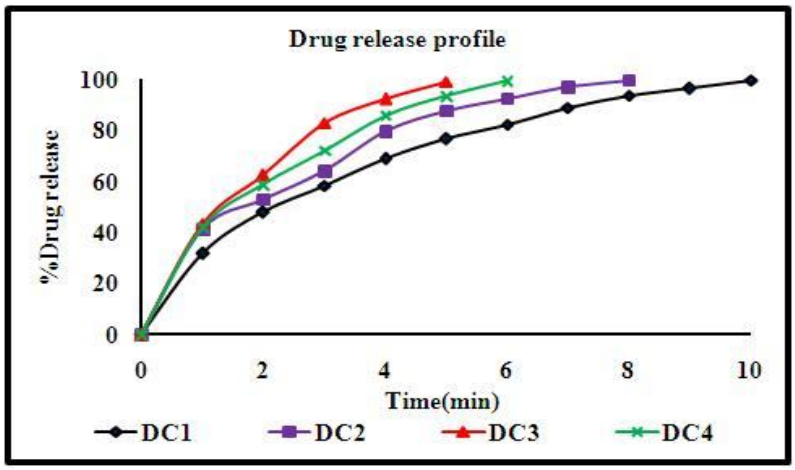

Fig 4: Release profile of formulation containing SSG (DC1-DC4)

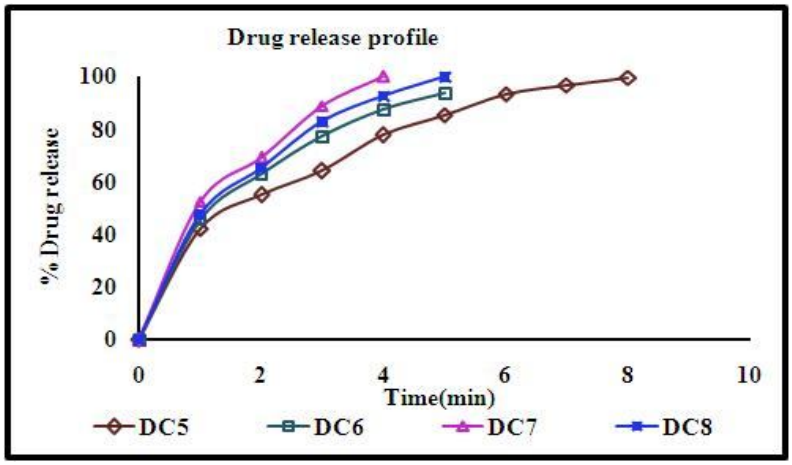

Fig 5: Release profile of formulation containing CP (DC5-DC8)

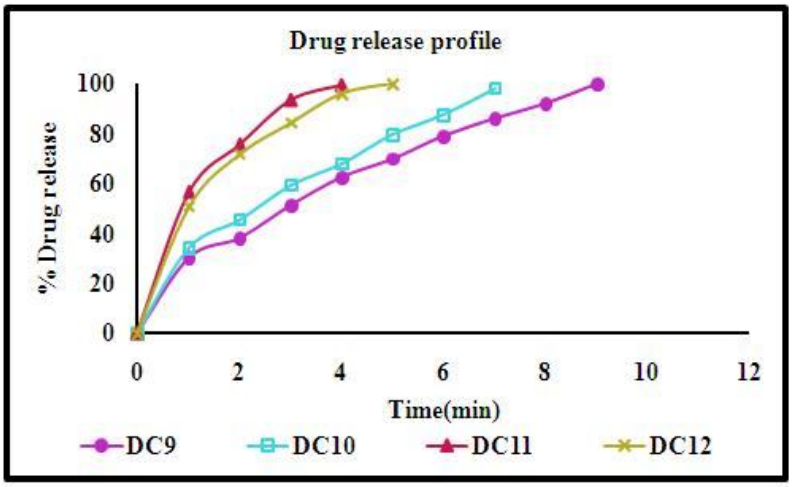

Fig 6: Release profile of formulation containing CCS (DC9-DC12)

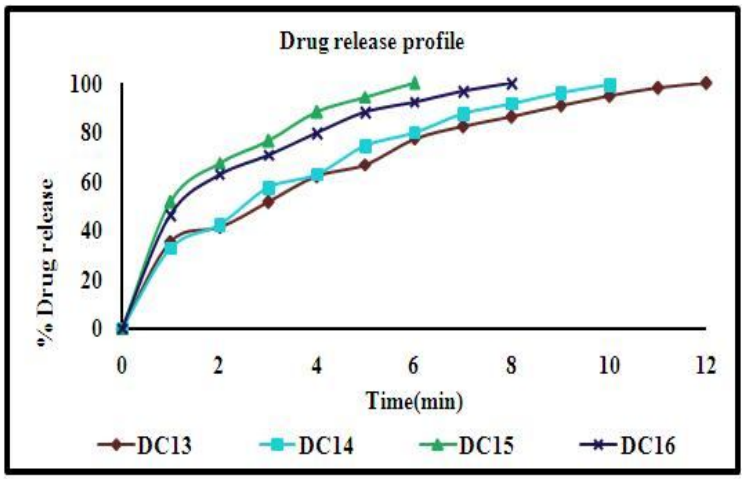

Fig 7: Release profile of formulation containing Kyron T (DC13-DC16)

Table 5: Result for stability study at different temperatures for 3 months

Sl. No.	Formulation code	Month	Hardness Kg/cm²	Percentage Friability	Dispersion time (sec)
25°C/60% RH					
1	**DC3**	**1st**	3.46	0.68	16.44
		2nd	3.49	0.68	17.12
		3rd	3.52	0.67	17.82
2	**DC7**	**1st**	3.24	0.58	11.52
		2nd	3.28	0.59	12.12
		3rd	3.32	0.61	12.48
3	**DC11**	**1st**	3.12	0.68	14.86
		2nd	3.14	0.68	15.14
		3rd	3.13	0.69	15.36
40°C/75% RH					
4	**DC3**	**1st**	3.46	0.68	16.44
		2nd	3.48	0.69	16.58
		3rd	3.52	0.67	17.12
5	**DC7**	**1st**	3.24	0.58	11.52
		2nd	3.26	0.60	11.84
		3rd	3.28	0.59	12.08
6	**DC11**	**1st**	3.12	0.68	14.86
		2nd	3.18	0.67	15.14

		3rd	3.24	0.66	15.36

Based on the *in-vitro* disintegration time, formulation DC7 (8 % CP) were found to be promising and showed a disintegration time of 11.52 sec **(shown in Fig 2).** These results suggest that the disintegration times can be decreased by using wicking type superdisintegrants (CP). Wetting time is closely related to the inner structure of the tablet. *In-vitro* dissolution studies **(Shown in Fig 4-7)** of all the formulations were carried out in pH 1.2 buffer as dissolution medium. The release study results $t_{50\%}$ and $t_{90\%}$ are shown in **Table 4**. The $t_{50\%}$ and $t_{90\%}$ values decreased with increase in the concentration of SSG, CCS and CP. Among all the formulation BD9 (9 % CP) were found to be promising and showed a disintegration time of 12 sec, 50 % of drug released in 1.02 min, and 90 % of drug released in 5.72 min.

The promising formulations were subjected to short term stability study by storing the formulations at 25°C/65% and 40°C/75% RH up to three month. The optimized formulations DC3, DC7 and DC11 were selected. After three month the tablets were again analyzed for the hardness, friability, drug content uniformity and disintegration time. The increase in the disintegration time was observed in case of tablets prepared with direct compression method No change was observed in the hardness, friability and disintegration time of tablets prepared by direct compression, co-processed and solid dispersion method technique. No significant change was observed in the of all formulation. The results were shown in **Table 5.**

CONCLUSION

In the present research work fast dissolving tablets of Montelukast Sodium were prepared by direct compression method. All the tablets of Montelukast Sodium were subjected to weight variation, hardness, friability, *in-vitro* disintegration time, drug polymer interaction, drug content uniformity, water absorption ratio, wetting time, and *in- vitro* drug release. The tablets prepared by direct compression method the $t_{50\%}$ and $t_{90\%}$ (time for 50% and 90% of release) values decreased with increase in the level of CP. In all the prepared formulation by direct compression method 50 % and 90 % of drug release ranges between within ranges 0.95 min to 2.91 min and 3.60 min to 8.92 min respectively. Among all formulations DC7 showed 99.85% drug release within 4 min. The stability study conducted as per the ICH guidelines and the formulations were found to be stable. It was concluded that the rapidly

disintegrating tablets with proper hardness, rapid disintegration in the oral cavity with enhanced dissolution rate can be made using super disintegrants.

ACKNOWLEDGEMENTS

The authors are thankful Redefining Healthcare, Unimark Remedies Limited, Vapi, Gujarat, India for providing Montelukast Soduim as a Gift sample. The authors are also thankful to Sri. Juvadi Sagar Rao Garu, Chairman and Sri. K. Venkat Rao Garu, Director, Jyothishmathi Institute of Pharmaceutical Science, Karimnagar, provide the facilities to carrying out this research work.

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