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FORMULATION AND EVALUATION OF MONTELUKAST SODIUM FAST DISSOLVING TABLETS

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ABSTRACT

Montelukast sodium is an anti-asthmatic drug mainly prevents leukotriene mediated effect associated with asthma. Mouth dissolving tablets of montelukast sodium was prepared by direct compression method using super disintegrants such as cross carmellose sodium, crosspovidone and sodium starch glycolate. Mouth dissolving tablets (MDTs) disintegrates or dissolves rapidly without water within few seconds in the mouth due to the action of superdisintegrants or maximizing pore structure in the formulation. The tablets were prepared using various diluents like MCC, Lactose and superdisintegrants namely Crosscarmellose sodium, Crosspovidone and Sodium starch glycollate in different concentrations. Pre-compression parameters such as angle of repose, bulk density, tapped density, compressibility index, Hausner's ratio were carried out to study the flow properties of powder to achieve uniformity of tablet weight and the values were within permissible limits. Theprepared tablets were evaluated for hardness, thickness, weight variation, friability, % drug content, wetting time, water absorption ratio, *in vitro* disintegration time, *in vitro* dispersion time and *in vitro* drug release. Theformulation F5 was found to be the best on the basis of wetting time, *in vitro* disintegration time and *in vitro* drug release. Stability studies were carried out at 25^{0}C ± 2^{0}C / 60% ± 5% RH and 40^{0}C ± 2^{0}C / 75% ± 5% RH for a period of 60 days for the selected formulations. The formulation F5 containing Crospovidone (8%) as super disintegrant and microcrystalline cellulose and lactose as diluents was respectively found to be the optimized combination.

Keywords: *Montelukast sodium, Mouth dissolving tablets (MDTs), Direct compression method, Superdisintegrants, Crospovidone, In vitro drug release.*

INTRODUCTION

Oral delivery is currently the gold standard in the pharmaceutical industry because of its convenience in terms of self-administration, compactness, economical and ease in manufacturing having the highest patient compliance[1]. However, geriatric, paediatric and mentally ill patient's experiences difficulty in swallowing conventional tablets, which leads to poor patient's compliance.

United States Food and Drug Administration (US 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".

Montelukast sodium is a selective and orally active leukotriene receptor antagonist that inhibits the cysteinyl leukotriene CysLT1 receptor. Montelukast sodium is an anti-asthmatic, mainly prevents leukotriene mediated effect associated with asthma.

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 super disintegrants like

croscarmellose sodium crosspovidone and sodium starch glycolate 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.

Advantages of Fast Dissolving Tablets (FDTs) of Montelukast sodium

Fast dissolving tablets (also called orally disintegrating tablets) of Montelukast sodium offer several clinical and patient-friendly benefits, especially in asthma and allergic rhinitis management.

1. Improved Patient Compliance
2. Rapid Onset of Action
3. Convenience & Portability
4. Better Bioavailability
5. Improved Palatability
6. Reduced Risk of Choking
7. Enhanced Stability Compared to Liquid Forms
8. Accurate Dosing

Clinical Relevance

Montelukast sodium FDTs are particularly beneficial in:

- Bronchial asthma
- Seasonal allergic rhinitis
- Exercise-induced bronchoconstriction

METHODOLOGY

Preformulation Studies

Organoleptic Properties

- The organoleptic properties like colour, odour and taste of API were evaluated.
- a. Colour: A small amount of Montelukast sodium fast dissolving tablets was taken in a butter paper observed in a well-illuminated place.
- b. Taste and odour: Very less amount of Montelukast sodium fast dissolving tablets was used to assess the taste with help of tongue as well as smelled to get odour.

SOLUBILITY TEST

- Solubility of Montelukast sodium fast dissolving tablets in water, ethanol, methanol was determined by using solicitor at room temperature.

DRUG-EXCIPIENTS COMPATIBILITY STUDIES

Compatibility studies were performed by preparing blend of different excipients with drug and stored at room temperature for one month. The blends were evaluated for every 15 days for changes like caking, liquefaction, discoloration and odour formation. The drug excipients compatibility profiles were shown in Table 1.

Table: 1 Drug-Excipients Compatibility Protocol

S. No	Drug And Excipients	Ratio (Drug: Excipients)
1	Montelukast sodium	1
2	Montelukast sodium + Strach	1:1
3	Montelukast sodium + Pregelatinizedstarch	1:1
4	Montelukast sodium + sodium starch glycolate	1:1
5	Montelukast sodium + Croscarmellose sodium	1:1
6	Montelukast sodium + Crospovidone	1:1
7	Montelukast sodium + Magnesium stearate	1:1
8	Montelukast sodium + Lactose	1:1
9	Montelukast sodium + Talc	1:1
10	Montelukast sodium + Propylparaben	1:1

MATERIAL AND METHODS

Materials

Montelukast sodium was obtained as a gift sample from Matrix India (P) Ltd, Hyderabad. Microcrystalline cellulose, Croscarmellose sodium (Ac-di-sol), Sodium starch glycolate and Crospovidone were obtained as a gift sample from Zydus research center, Ahmedabad. All other chemicals and solvents used were of analytical reagent grade.

Methods

Drug- polymer interaction studies

Fourier Transform Infra-Red (FT-IR) spectral analysis

Fourier–Transform Infrared (FT–IR) spectrums of pure Montelukast sodium and combination of drug and excipients were obtained by a Fourier-Transform Infrared spectrophotometer, (FTIR-8300, Shimadzu, Japan) using the KBr disk method. The scanning range was 400 to 4000 cm^{-1} and the resolution was $1cm^{-1}$. This spectral analysis was employed to check the compatibility of drugs with the excipients used.

Preparation of Montelukast sodium by direct compression method

Mouth dissolving tablets of montelukast sodium were prepared by direct compression method using croscarmellose sodium, crospovidone and sodium starch glycolate as super disintegrants and mannitol and lactose as diluents. The composition of formulation is shown in the table 1 and table 2. The drug, diluents, super disintegrants and sweetener were screened through 40 mesh and properly mixed together. Talc and magnesium stearate were screened through 80 mesh and blended with initial mixture. Powder thus obtained was compressed into tablets on a 10-station single punch rotary tablet compression machine (Rimek). A biconvex punch 8 mm in diameter was used for tableting. Compression force of the machine was adjusted to obtain the hardness of 3-4 kg/cm^2.

Table 2: Composition of Montelukast sodium fast dissolving Tablets

Ingredients	F-I (mg)	F-II	F-III	F-IV	F-V
Montelukast	5.00	5.0	5.00	5.00	5.00

sodium		0			
Lactose	126.90	126.90	126.90	126.90	126.90
Maize Strach	15.00	_	_	_	_
Pregelatinized starch	_	15.00	_	_	_
Sodium starch glycolate	_	_	15.00	_	_
Croscarmellose sodium	_	_	_	15.00	_
Crospovidone	_	_	_	_	15.00
Propylparaben	0.30	0.30	0.30	0.30	0.30
Magnesium stearate	1.50	1.50	1.50	1.50	1.50
Talc	1	1	1	1	1
Weight of each tablet (mg)	150.00	150.00	150.00	150.00	150.00

Quantity per Tablet (mg)

EVALUATION OF MOUTH DISSOLVING TABLETS

PRE-COMPRESSIONAL STUDIES

i) Angle of Repose (Θ):

The frictional force in powder can be measured by the angle of repose. It is the maximum angle possible between the surface of pile of powder and the horizontal plane.

The angle of repose was determined using following equation,

$\tan \theta = h/r$

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

Where, h = height of pile (cm)

r = radius of the base of pile (cm)

ii) Bulk Density:

Bulk density = weight of sample taken / volume noted

A sample of about 2.5 gm was poured into 10ml-graduated cylinder. The cylinder was dropped at 2-second intervals onto a hard wooden surface three times, from a height of one inch. The volume was recorded and the bulk density was calculated.

iii) Tapped density:

The tapped density was calculated by using the following formula

td = M/Vt

Vt =minimum volume (cm3)

M= the weight of blend(gm)

td=tapped density

iv) Carr's Index

The formula for Carr's Index is as below,

v) Hausner ratio:

The Hausner ratio of the powder was determined by the following equation:

Hausner ratio = TBD / LBD

POST-COMPRESSIONAL STUDIES

i)General appearance:

size, shape, colour, presence or absence of odour, taste surface texture was determined.

ii) Thickness and diameter

The tablet thickness and diameter was measured using vernier calliper.

iii) Hardness

The hardness of the tablets was determined using Monsanto hardness tester. (kg/cm^2)

iv)Friability test:

Roche Friabilator was used for the purpose

Percentage friability = (Initial weight - Final weight /Initial weight) × 100

vi) Weight variation

20 tablets were selected randomly from each formulation and weighed individually to check for weight variation. The US Pharmacopoeia allows a little variation in the weight of a tablet.

vii) Drug content uniformity

The tablets were tested for their drug content uniformity randomly for 20 tablets.

viii)Wetting time and water absorption ratio:

The water absorption ratio, R, was determined using the following equation,

$$R = Wa - Wb / Wb \times 100$$

Where,

1. Wb is the weight of the tablet before water absorption and
2. Wa is the weight of the tablet after water absorption.

ix) In vitro disintegration time

The disintegration time was performed by apparatus specified in USP at 50 rpm. 900 ml of 0.5%SLS was used as disintegration medium and the temperature of 37± 0.5°C and time in second taken for complete disintegration of the tablet.

x) In vitro drug release studies

In vitro release of montelukast sodium from tablets was determined by using USP XXIV paddle dissolution apparatus (Electrolab TDT-06P) at 50 rpm using 900 ml of 0.5%SLS and temperature was maintained at 37±0.5° C throughout the study. 5 ml sample was collected at regular intervals for 30 min and the same volume of fresh medium was replaced. The samples withdrawn were filtered and drug content in each sample was analysed after suitable dilution by Shimadzu 1700 UV-Visible spectrophotometer at 342 nm.

xi) Stability Studies

Long term testing

25°C ± 2°C / 60% ± 5% RH for 12 months

Accelerated testing

40°C ± 2°C / 75% ± 5% RH for 12 months

In present study, stability studies were carried out at 25°C ± 2°C / 60% ± 5% RH and 40°C ± 2°C / 75% ± 5% RH for a period of 60 days for the selected formulations. The formulations were then evaluated for changes in the physicochemical properties, wetting time, *in vitro* disintegration time and *in vitro* drug release.

RESULTS AND DISCUSSION:

Drug-excipients compatibility studies:

Fourier Transform Infrared (FTIR) Spectroscopy

The FTIR spectra showed similar characteristic peaks at their respective wavelengths with minor differences. The similarity in the peaks indicated the compatibility of drug with formulation excipients.

EVALUATION OF PRECOMPRESSION PARAMETERS

The precompression blends were evaluated for the following parameters such as angle of repose, bulk density, tapped density, compressibility index and Hausner ratio.

Angle of repose (θ)

The data obtained from angle of repose for montelukast sodium was found to be 23.93 to28.68. All the formulations showed the angle of repose less than 31, which reveals good flow property.

Bulk density:

Bulk density for the blend was performed. The bulk densities of montelukast sodium were ranges from 0.43gm/ccto0.58gm/cc.

Tapped density:

Tapped bulk density (TBD) for the blend was performed. The tapped bulk density of montelukast sodium rangesfrom0.49gm/ccto0.78 gm/cc respectively.

Carr's consolidation index

The results of Carr's consolidation index or compressibility index (%) of montelukast sodium were ranges from 11.53%to25.64%.

Hausner ratio:

Hausner ratio of montelukast sodium showed between 1.13 to 1.31 indicates better flow properties.

Table No:3Precompression Parameters

Formulation Code	Angle of Repose (θ)	Bulk Density (g/cm³)	Tapped Density (g/cm³)	Compressibility Index (%)	Hausner's Ratio
F1	29.3 ± 0.1	0.305 ± 0.2	0.361 ± 0.2	16.2 ± 0.2	1.18 ± 0.2
F2	27.8 ± 0.4	0.300 ± 0.6	0.357 ± 0.3	16.0 ± 0.9	1.18 ± 0.7
F3	28.2 ± 0.1	0.305 ± 0.5	0.354 ± 0.1	15.5 ± 0.4	1.19 ± 0.5
F4	26.9 ± 0.9	0.292 ± 0.7	0.367 ± 0.8	16.3 ± 0.7	1.17 ± 0.2
F5	27.7 ±	0.304 ±	0.342 ±	15.4 ± 0.2	1.17 ± 0.3
	0.8	0.4	0.5		

All the values are expressed as mean ± SD, n = 3

POST-COMPRESSION PARAMETERS

a) General appearance

There was no change in the colour and odour of the tablets from all the batches.

b) Thickness and diameter

The range for tablets of montelukast sodium ranged from 3.12 ± 0.01 to 3.16 ± 0.03mm respectively

c)Hardness

The hardness was maintained within the range of 3.3 ± 0.23 to 3.9 ± 0.23 kg/cm^2.

d)Friability

The friability was found for montelukast sodium in the range 0.23 to 0.38% within the approved range (<1%) which indicates the tablets had good mechanical resistance.

e) Weight variation

The weight variation was found in the range of 149.83±0.36 to 150.92±0.41 was less than ±7.5% i.e. in the Pharmacopoeial, limits which provide good uniformity in all formulations.

f) Drug content:

The percentage drug content was found to be in the range of 98.3 ± 0.50to 99.85 ± 0.62%.

g) Wetting time

Water absorption ratio for these formulation batches varied in the following decreasing order:

Crosspovidone > Crosscarmellose sodium > Sodium starch glycollate

Formulation batches of F1-F5 wetting time was found between 26 to 47seconds and for F1-F5wetting time was found to be 30-50 sec.

h) Water Absorption Ratio

The water absorption ratio increased with increase in the concentration of super disintegrant from 2-8 %. The water absorption ratio found in the range between 54.21 ± 0.87to 79.83 ± 0.91% as MCC as diluent and 57.21 ± 0.87 to 73.83 ± 0.91% as lactose as diluent.

i) In vitro Disintegration Time

In vitro disintegration time was found to be 32-53 sec as MCC as diluent and 37-58sec.

j) In vitro dissolution studies:

Theformulation batches F1toF5 comprises threedifferent types of super disintegrants, *in vitro* drug release at 25 minutes between 89.2 to 98.9% and for F1 to F5 found to be 87.2 to 97%.

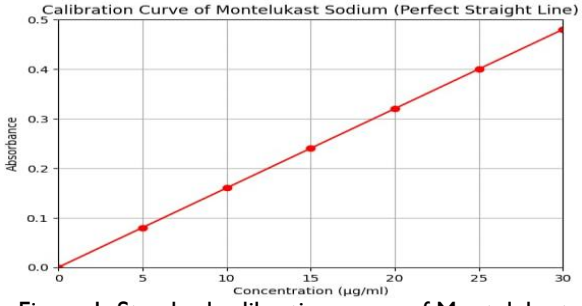

Fig no 1: Standard calibration curve of Montelukast sodium

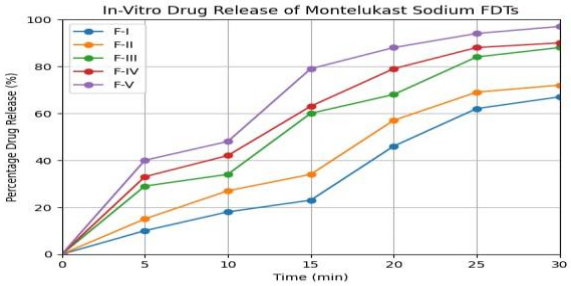

Fig no 2: Dissolution rate projects of different formulations (F1-F5)

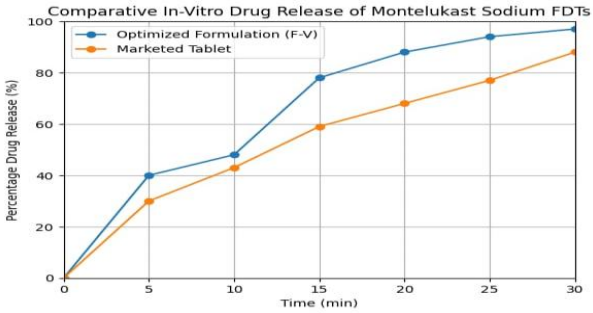

Fig no 3: Comparative of optimized best formulation & marketed product

Table No 4: Evaluation of Montelukast sodium Tablets

Formulation Code	Disintegration Test (sec)	Wetting Time (sec)	Water Absorption Ratio (%)	Taste
F-I	5.21 ± 0.015	73 ± 0.57	70.18 ± 0.57	Sweet
F-II	5.07 ± 0.064	70 ± 0.57	86.88 ± 0.56	Sweet
F-III	4.50 ± 0.057	64 ± 0.53	90.80 ± 0.59	Sweet
F-IV	3.23 ± 0.057	40 ± 0.54	93.80 ± 0.58	Sweet
F-V	1.10 ± 0.01	30 ± 0.54	96.80 ± 0.58	Sweet
Marketed Sample	2.42 ± 0.025	39 ± 0.43	92.14 ± 0.57	Sweet

All the values are expressed as mean ± SD, n = 3

k) Stability Studies:

Stability studies of formulation F1-F5was performed at 25°C ±2°C /60% ± 5% RH and 40°C ± 2°C /75% ± 5% RH for a period up to 60 days. There was no change in colour and shape of the tablets when stored at 25°C ± 2°C /60% ± 5% RH and 40°C ±2°C /75% ±5% RH and observed every 20 days interval up to 60 days. Formulations F1-F5showed not much variation in any parameter and were stable and retained its original properties.

CONCLUSION

From the study conducted and from the observations and the results obtained thereof, following conclusions were drawn:

1. The fast-dissolving tablets of Montelukast sodium was successfully developed and evaluated. FTIR studies concluded that drug and excipients were compatible with each other.
2. The formulated tablets were satisfactory in terms of hardness, thickness, friability, weight variation, drug content, wetting time, water absorption ratio, *in vitro* disintegration time, *in vitro* dispersion time and *in vitro* drug release.
3. Formulation containing super disintegrant Crosspovidone showed least wetting time and *in vitro* disintegration time.
4. As the super disintegrant concentration increases, the wetting time and *in vitro* disintegration time on tablets decreases.
5. The formulation F5 was found to be the best on the basis of wetting time, *in vitro* disintegration time and *in vitro* drug release.
6. The formulation F1-F5containing Crospovidone (8%) as super disintegrant and microcrystalline cellulose and lactose as diluents was respectively found to be the optimized combination.

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NIL

CONFLICT OF INTEREST

Not declared

AUTHOR CONTRIBUTION

All authors are contributed equally.

INFORM CONSENT AND ETHICAL CONSIDERATIONS

Not applicable

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REFERENCES

1. Rajkumar G, Satyendra SB, Ashish P, Kshamashil S, Gourav T and Rituraj S. A Review on Formulation & Evaluation of or dispersible Tablets. WJPR 2012; 1(3): 576-590.
2. Dinesh Mohan S, Vanitha K, Ramesh A, Srikanth G, Akila S. Formulation and Evaluation of Salbutamol Sulphate Fast Dissolving Tablet. IJRPBS 2010; 1(2): 105-108.
3. Jeevan Adham S, Dhachinamoorthy D, Chandrashekar KB, Muthukumaran M, Sriram N, Joyasaruby J. Formulation and evaluation of naproxen sodium or dispersible tablets-A sublimation technique. Asian Journal of Biomedical and Pharmaceutical Sciences 2010;4 (1): 48-51.
4. Chang RK, Guo X, Burnside B, Couch R. Fast-dissolving tablets. Pharm Technol 2000; 24(6):52–58.
5. Bi Y, Sunada H, Yonezawa Y, Dayo K, Otsuka A, Iida K. Preparation and evaluation of compressed

tablet rapidly disintegrating in oral cavity. Chem Pharm Bull (Tokyo) 1996; 44:2121-2127.
6. Praveen K, Kamlesh D. A Review: Fast Dissolving Drug Delivery System: Current Developments in Novel System Design and Technology. IJBAR 2012; 03(02): 82-98.
7. Indian Pharmacopoeia. The Controller of Publications, Ministry of Health and Family Welfare. New Delhi 1996: A-572-598.
8. Parodi B, RussoE, Caviglioli G,Caffagi G, Bignardi G. Development and characterization dosage form of oxycolon HCl. Drug Development Ind Pharm 1996: 22, 445-450.
9. Wang L, Tang S. A novel ketoconazole effervescent tablet for vaginal delivery. Int J Pharm 2008: 350,181-187.
10. John R, Dyer. Application of absorption spectroscopy of organic compounds. Indian edition. 2003: 33-38.
11. Nandgude T, Bhise K, Shinde V, Sharma D. Mouth dissolving tablet: geriatrics and paediatrics friendly drug delivery. Indian Drugs 2007; 4: 271-302.
12. United States Pharmacoepia. Asian Ed Convention Inc.2005: 233-45.
13. Gore S, Devarajan P. Mouth dissolving tablets Design of *in vitro* disintegration test. Ind J Pharm Sci 2000; 62(6): 508