WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.084
Volume 9, Issue 14, 1014-1026. Research Article ISSN 2277– 7105

FORMULATION AND EVALUATION OF MOUTH DISSOLVING TABLETS OF MONTELUKAST SODIUM" MONTELUKAST SODIUM

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Article Received on
16 Sept. 2020,

Revised on 06 Oct. 2020,
Accepted on 27 Oct. 2020

DOI: 10.20959/wjpr202014-19154

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ABSTRACT

The aim of the present research work, to select the best possible diluent - disintegrant combination to formulate mouth dissolving tablets of montelukast sodium, which disintegrates in matter of seconds in the oral cavity, thereby reducing the time of onset of pharmacological action. Lycoat, ludiflash, sodium starch glycolate and Mannitol, were used as disintigrant. In all the formulations, Magnesium stearate and talc were used as lubricant and glidant respectively. The results of the drug – excipient compatibility studies revealed that there was no chemical interaction between the pure drug and excipients. Direct compression method was employed to formulate the tablets, because of its cost effectiveness and due to reduced number of manufacturing steps. The pre-compression parameters like bulk density, tapped density, Carr's 'index and angle of repose were determined. All the formulations showed acceptable flow properties. The post compression parameters like the hardness, thickness, friability and weight variation, disintegration time, disintegration time in oral cavity and In-vitro release were carried out and the values were found to be within IP limits. The percentage drug content of all the tablets was found to be between 96.24 % and 99.46 % of Montelukast sodium, which was within the acceptable limits. Among all the formulations F6 shows 99.82% drug release. F6 contains ludiflash (15mg), it shows better % drug release compared to other formulations.

KEYWORDS: montelukast sodium, ludiflash, Lycoat, Direct compression, sodium starch glycolate.

INTRODUCTION

Drug Delivery Systems (DDS) are a strategic tool for expanding markets /indications, extending product life cycles and generating opportunities. DDS make a significant contribution to global pharmaceutical sales through market segmentation, and are moving rapidly.

Drug delivery systems are becoming increasingly sophisticated as pharmaceutical scientists acquire a better understanding of the physicochemical and biochemical parameter pertinent to their performance. Despite of tremendous advancements in drug delivery, the oral route remains the perfect route for the administration of therapeutic agents because of low cost of therapy, ease of administration, accurate dosage, self-medication, pain avoidance, versatility, leading to high levels of patient compliance. Tablets and capsules are the most popular dosage forms.[1] But one important drawback of such dosage forms is 'Dysphagia' or difficulty in swallowing. This is seen to afflict nearly 35% of the general population. This disorder is also associated with a number of conditions like.

1. Parkinsonism
2. Motion sickness
3. Unconsciousness
4. Elderly patients
5. Children
6. Mentally disabled persons
7. Unavailability of water.[2]

Improved patient compliance has achieved enormous demand.

Consequently demand for their technologies is also increasing many folds. To develop a chemical entity, a lot of money, hard work and time are required. So focus is rather being laid on the development of new drug delivery systems for already existing drugs, with enhanced efficacy and bioavailability, thus reducing the dose and dosing frequency to minimize the side effects.[3] It is always the aim of a scientist or a dosage form designer to enhance the safety of a drug molecule while maintaining its therapeutic efficacy. Recent advances in Novel Drug Delivery Systems (NDDS) aim for the same by formulating a dosage form, convenient to be administered so as to achieve better patient compliance. Pharmaceutical technologists have put in their best efforts to develop a Fast Dissolving Drug Delivery System[4], i.e Mouth Dissolving Tablet.

Mouth dissolving tablet (MDT)

It is a tablet that disintegrates and dissolves rapidly in the saliva, within a few seconds without the need of drinking water or chewing. A mouth dissolving tablet usually dissolves in the oral cavity within 15 s to 3 min. Most of the MDTs include certain super disintegrants and taste masking agents.

Ideal properties of MDT[5-7]

A Mouth Dissolving Tablet should

a. Not require water or other liquid to swallow.
b. Easily dissolve or disintegrate in saliva within a few seconds.
c. Have a pleasing taste.
d. Leave negligible or no residue in the mouth when administered.
e. Be portable and easy to transport.
f. Be able to be manufactured in a simple conventional manner within low cost.
g. Be less sensitive to environmental conditions like temperature, humidity etc.,

Advantages of MDT[8-13]

h. No need of water to swallow the tablet.
i. Can be easily administered to pediatric, elderly and mentally disabled patients.
j. Accurate dosing as compared to liquids.
k. Dissolution and absorption of drug is fast, offering rapid onset of action.
l. Bioavailability of drugs is increased as some drugs are absorbed from mouth, pharynx and esophagus through saliva passing down into the stomach
m. Advantageous over liquid medication in terms of administration as well as
n. transportation
o. First pass metabolism is reduced, thus offering improved bioavailability and thus reduced dose and side effects.
p. Free of risk of suffocation due to physical obstruction when swallowed
q. offering improved safety.

MATERIALS AND METHODS

Table 5.1: Materials Used.

Sr. No	Materials	Company
1.	Montelukast	Ajanta Pharma Ltd. Aurangabad
2.	LYCOAT	Signet Chemical Corp., Mumbai
3.	LUDIFLASH	Signet Chemical Corp., Mumbai
4.	SSG	Dipa Chemical Industries A'bad
5.	PVP K-30	Dipa Chemical Industries A'bad
6.	Mannitol	Dipa Chemical Industries A'bad
7.	Magnesium Stearate	Dipa Chemical Industries A'bad

Table 5.2: Instruments &Equipments Used.

Sr. No	Instruments/Equipments	Company
1.	Digital balance	Citizon Electronic Balance
2.	Hardness tester	Pfizer Tester
3.	Friability test apparatus	Roche Friabilator Electrolab
4.	Tablet disitigration Test Apparatus	Electrolab
5.	Vernier caliper	Dolphin
6.	Tablet dissolutionn tester	Lab india DS-8000
7.	Tablet Compression Machine	Karanavati Engg. Ltd. Mini Press
8.	UV Spectrophotometer	Lab India UV 3200
9.	FTIR Spectrophotometer	Shimadzu -8400 S
10.	DSC	DSC-60 Shimadzu, Japan

EXPERIMENTAL METHODOLOGY

Calibration Curve For Montelukast Sodium In 0.1nhcl

Procedure

Preparation of Standard Stock Solution

10 mg of Montelukast sodium was accurately weighed into 10 ml volumetric flask and dissolved in small quantity of 0.1N HCL. The volume was made up to 10 ml with the 0.1N HCL to get a concentration of (1000µg/ml) SS-I. From this, 1 ml was withdrawn and diluted to 10 ml with distilled water to get a concentration of (100 µg/ml) SS-II.

Scanning of Drug

From stock solution (SS-II), 1ml was withdrawn and the volume was made upto 10ml with 0.1N HCL to get a concentration of 10 µg/ml. UV scan range was taken between the wavelengths 200-400nm. It gave a peak at 292nm and the same was selected as λ_{max} for Montelukast sodium.

Calibration Curve in 0.1NHCL

From the standard stock solution (SS-II), 0.5, 1.0, 1.5, 2.0 and 2.5ml were with drawn and volume was made upto10 ml with 0.1 NHCL to give a concentration of 5, 10, 15, 20 and 25µg/ml. Absorbance of the sesolutions was measured against a blank of 0.1N HCL at 260nm for Montelukast sodium and the absorbance values are summarized in Table Calibration curve was plotted, drug concentrations versus absorbance was given in the Figure.

Table 6.1: Formulations.

INGREDIENTS	F1	F2	F3	F4	F5	F6	F7	F8	F9
Montelukast	10	10	10	10	10	10	10	10	10
LYCOAT	5	10	15	-	-	-	-	-	-
LUDIFLASH	-	-	-	5	10	15	-	-	-
SSG	-	-	-	-	-	-	5	10	15
PVP K-30	30	30	30	30	30	30	30	30	30
Mannitol	149	144	139	149	144	139	149	144	139
Magnesium Stearate	4	4	4	4	4	4	4	4	4
Talc	2	2	2	2	2	2	2	2	2
TOTAL(mg)	200	200	200	200	200	200	200	200	200

EVALUATION PARAMETERS

FT-Infrared spectroscopy to find out the compatibility of drug with polymers

This was carried out to find out the compatibility between the drug Montelukast sodium and the disintegrants lycoat, Ludiflash and SSG. 10 mg of the sample and 400 mg of KBr were taken in a mortar and triturated. A small amount of the triturated sample was taken into a pellet maker and was compressed at 10 kg/cm2 using a hydraulic press. The pellet was kept onto the sample holder and scanned from 4000 cm-1 to 400 cm-1 in Shimadzu FT-IR spectrophotometer. Samples were prepared for drug Montelukast sodium, with lycoat, Ludiflash and SSG and physical mixture of drug and polymer. The spectra obtained were compared and interpreted for the functional group peaks.

RESULTS AND DISCUSSION

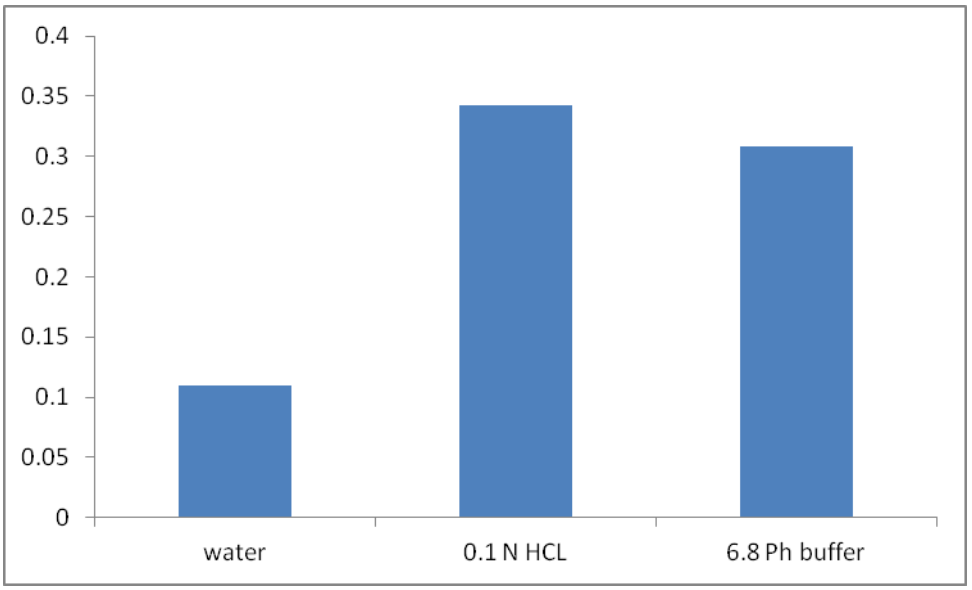
Determination of melting point

The melting point of Montelukast sodium was found to be 134°C which was determined by capillary method. Fine powder of Montelukast sodium was filled in glass capillary tube (previously sealed on one end). The capillary tubeistiedto thermometer and the thermometer was placed in fire. The powder at what temperature it will melt was noticed.

Solubility

Solubility of Montelukast sodium was carried out at 25^0C using 0.1 N HCL, 6.8 phosphate buffer, and purified water.

S.NO	MEDIUM	SOLUBILITY(mg/ml)
01	water	0.110
02	0.1 N HCL	0.342
03	6.8 Ph buffer	0.308



DISCUSSIONS

The present study was carried out to develop mouth dissolving tablets of Montelukast sodium by direct compression method. Hence it was necessary to find suitable excipients with good compactability and disintegrating ability.

Preformulation

In the preformulation study, it was found that the estimation of Montelukast sodium by UV spectrophotometric method at λmax292 nm in 0.1N Hydrochloric acid had good reproducibility and this method was used in the study.

Physical properties of tablets

a. Hardness

The hardness was determined for all the formulations and the results were as follows. The hardness of all the formulations was kept at 3.72to 4.20 kg / cm^2 to compare the disintegration time between the formulations.

b. Friability

The percentage friability of all the formulations were found to be within the 1% limit. The results of friability indicated that the tablets were mechanically stable.

c. Weight variation

The weights of the tablets were between 198.2 mg to 202.46 mg. As the weight of tablets was 200 mg, this acceptable weight variation range Hence all the tablet formulations were within the pharmacoepial limits.

d. Assay

The percentage drug content of all the tablets was found to be between 96.42 % and 99.46 % of Montelukast sodium, which was within the acceptable limits. Disintegration time as per IP, Wetting time and Disintegration time in Oral cavity was determined for all the formulations.

e. Disintegration Time as per IP

Disintegration time as per IP, for all the formulations was found to be within 36 seconds, which was well within IP limit. Formulations with Montelukast sodium, ludiflash and mannitol, asdisintegrants exhibited quicker disintegration of tablets. It indicated that amongst the disintegrants used ludiflash, Mannitol, were better disintegrants to formulate rapidly disintegrating tablets by direct compression method.

f. Dissolution rate study

The dissolution study was carried out using 900 ml of simulated gastric fluid as dissolution medium at 50 rpm at 37^0C ± 0.50C in USP Type II apparatus. All the formulations showed rapid dissolution rate and the percentage cumulative drug release (%CDR) after 5 minutes was more than 35% and complete dissolution was achieved within 25 minutes.F6 shows 99.82% of drug release.

g. Drug release kinetics studies

The drug release from the oral disintegrating tablets was explained by the using mathematical model equations such as zero order, first order, Higuchi and peppas equation methods. Based on the regression values it was concluded that the optimized formulation F6 follows higuchi order kinetics.

Order of kinetics	Zero	First
Regression values	0.9491	0.9429

SUMMARY AND CONCLUSION

Summary

The present study is an attempt to select the best possible diluent - disintegrant combination to formulate mouth dissolving tablets of montelukast sodium, which disintegrates in matter of seconds in the oral cavity, thereby reducing the time of onset of pharmacological action.

Lycoat, ludiflash, and sodium starch glycolate, Mannitol, were used as disintegrants. In all the formulations, Magnesium stearate and talc were used as lubricant and glidant respectively.

The results of the drug – excipient compatibility studies revealed that there was no chemical interaction between the pure drug and excipients.

Direct compression method was employed to formulate the tablets, because of its cost effectiveness and due to reduced number of manufacturing steps.

The precompression parameters like bulk density, tapped density, Carr's 'index and angle of repose were determined. All the formulations showed acceptable flow properties.

The post compression parameters like the hardness, thickness, friability and weight variation, disintegration time, disintegration time in oral cavity and Invitro release were carried out and the values were found to be within IP limits.

The percentage drug content of all the tablets was found to be between 96.24 % and 99.46 % of Montelukast sodium, which was within the acceptable limits.

Among all the formulations F6 shows 99.82% drug release.F6 contains ludiflash(15mg), it shows better % drug release compared to other formulations.

CONCLUSION

In the present work, an attempt was made to develop mouth dissolving tablets of montelukast sodium.

From the study conducted, the following conclusions are drawn

Amongst the various combinations of diluents and disintegrants used in the study, tablets that were formulated (direct compression) using ludiflash (15mg), mannitol, exhibited quicker disintegration of tablets.

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