Development and Evaluation of Mouth Dissolving Tablets of Montelukast Sodium Using Co-processed Excipients

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Authors’ contributions

This work was carried out in collaboration among all authors. Author KSK designed the study, wrote the first protocol and wrote the first draft of the manuscript. Authors DMR, YDR, JNG and AB managed the analyses of the study and review literature. All authors read and approved the final manuscript.

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ABSTRACT

Background: The concept of formulating ODT containing montelukast sodium offers an appropriate, practical approach to accomplish fast release of the drug. Absorption of these tablets takes place directly into the systemic circulation which bypass the hepatic first-pass metabolism of montelukast sodium which ultimately results in the improvement in the bioavailability.

Method: In the present study ODT tablets of montelukast sodium were prepared by using different Superdisintegrants like natural and synthetic (tulasi, hibiscus, orange peel powder, Ispaghula, banana peel powder, Crospovidone). Thirteen formulations were designed, using a two level of Superdisintegrants (minimum and maximum concentration) and employing two Superdisintegrants at a time by using the co-processed technique.

Results: No significant drug and excipients interaction was observed. The prepared tablets were evaluated by weight variation, thickness, hardness, friability, drug content uniformity, disintegration

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time, wetting time, in-vitro dissolution studies. A formulation containing 6mg of natural and synthetic Superdisintegrants was offered the relatively rapid release of montelukast sodium when compared with other concentrations employed in this investigation.

**Conclusion:** Montelukast sodium formulation were prepared by Crospovidone and ispaghula combination of Superdisintegrants were releases 98.91% drug in 30 min.

**Keywords:** ODT; montelukast sodium; superdisintegrants; and co-processed techniques.

1. **INTRODUCTION**

Most of the drugs are taken orally, can produced systemic effects. It is the preferred way of administered owing to its various advantages and improve the patient compliance [1]. ODTs have been defined as “A solid dosage form containing medicinal substances which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue” [2]. This type of dosage form is preferable for who are difficulty in swallowing (especially for pediatric, geriatric, bedridden), suffering from dysphagia, motion sickness, mental disorders, repeated emesis etc. [3].

Montelukast sodium is an orally available leukotriene receptor antagonist which is widely used for the prophylaxis and chronic treatment of asthma and has been linked to rare cases of clinically apparent liver injury. Montelukast is a member of quinolines, a monocarboxylic acid and an aliphatic sulfide. It has a role as a leukotriene antagonist, an anti-asthmatic drug and an anti-arrhythmia drug. It is a conjugate acid of a montelukast.

Synthetic Superdisintegrants are frequently used in tablet formulation to improve the rate and extent of tablet disintegration there by increasing the rate of dissolution. Today, we have a number of plant-based pharmaceutical excipients and various researchers have explored the utility of some of these plant-based materials (mucilage acts as a Superdisintegrants) as pharmaceutical Superdisintegrants. Plant products serve as an alternative to synthetic products because of local accessibility, eco-friendly nature, bio-acceptable, renewable source and lower prices compared to important synthetic products [4,5].

Montelukast sodium selectively antagonizes leukotriene D4 (LTD4) at the Cysteinyl leukotriene receptors. It is having low half-life 2.5-5.5hrs. It comes under the BCS classification II i.e., low solubility and high permeability which is suitable for the ODT formulation.

Disintegration time of the dosage form should be reduced by using Superdisintegrants. Montelukast Sodium ODT tablets were prepared by using different super disintegrating agents such as Isapghula, Banana peel, Orange peel, Tulasi, Hibiscus are used as natural Superdisintegrants and Cross povidone used as synthetic Superdisintegrants. Superdisintegrants are used at various concentrations to study the effect on disintegration time, wetting time and dissolution.

2. **MATERIALS AND METHODS**

2.1 Materials

Montelukast Sodium is gift sample from the Hetero labs, Crospovidone, Mannitol, Starch, Saccharin Sodium, Cabosil, Magnesium Stearate, Lactose is purchased from SDFCL, Mumbai, MCC is purchased from Karnataka Fine Chem.

2.2 Methods

2.2.1 Extraction of natural superdisintegrants [6,7,8]

2.2.1.1 Extraction procedure for orange peel powder

Peel was carefully washed and dried under shade for 24 hrs, further dried at 60°C in a hot air oven. Dried fruit peel was cut into pieces and powdered by electric grater. Powdered peel was further passed from sieve no # 20. Peel powder, 200gms of was dissolved in 1 L of water and 1gm of citric acid was added to maintain acidic pH 2. This solution was subjected to reflux condensation at 70°C for 6 h to extract pectin. The extractor thimble was a Whatman cellulose thimble with 33 mm internal and 80 mm external length. Hot acid extract was pressed in a cheese cloth bag and the concentrated juice was cooled to 4ºC. Pectin was precipitated by ethanol: water (2:1 v/v) treatment followed by continuous stirring for 15 min and allowed to stand for 2 h. Pectin coagulate was filtered through cheese cloth, washed with 95% alcohol and pressed. Pressed pectin was further dried to constant weight at 35 – 45°C. Hard pectin cake was ground and

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2.2.1.2 Preparation of ispaghula mucilage

The seeds of Plantago ovata were soaked in distilled water for 48 hours and boiled for few minutes. The collected material was squeezed through muslin cloth to separate them. Then, an equal volume of acetone was added to the filtrate for precipitation of the mucilage. The separated mucilage was dried at 40ºC in a tray dryer. The dried mucilage was powdered and sieved in sieve no # 80. The resultant powder was stored in a desiccator and used for the present study.

2.2.1.3 Extraction procedure for banana powder

Collected fresh whole bananas were cleaned from debris and weighed. Skin peeled bananas were dipped in Ethanol for 5 minutes. Then bananas were weighed and squashed to paste. This paste was added with citric acid (2 to 3%) to remove sticky nature. Then water was separated by Centrifugation and processing. The pressed mass was subjected to drying in Tray dryer. The dried mass was milled and screened to sieve # 80 to get fine powder. The obtained fine powder was ready for use further study.

2.2.1.4 Extraction procedure for Hibiscus rosasinensis mucilage

Hibiscus Leaves were collected carefully and wash with clear water. Leaves were dried under shade for 24 hrs and then further dried in hot air oven at 30 to 40ºC. Leaves were size reduced with the help of grinder to obtain fine powder. Obtain powder was passed through sieve no # 22. Powder was placed in 1000 ml beaker containing distilled water (1:16). Then allow it to boil for at least 3-4hrs with continuous stirring at 60ºC for sufficient mucilage release in water. The solution was filtered through muslin cloth in order to separate marc from the filtrate and refrigerated for cooling (3 to 4ºC). The extract was added to acetone to the quantity (1:3) volume of filtrate to occur precipitation of mucilage.

2.2.1.5 Extraction procedure for tulasi powder

The Tulasi leaves were separated from the stem and washed in clear water. The leaves are dried until they were adequate dry to the ground (Dried upto 7 days). The dried leaves are powdered in an electric grinder until a homogeneous powder was obtained. The obtained Tulasi finely powder was macerated with 100% ethanol for 3 days (1:4). The obtained alcoholic decoction was subjected to filtration with Whatman filter paper to obtain clear filtrate. The obtained filtrate was at low temperature to obtained solid residue. 250gms of Tulasi powder dissolve in 1000ml ethanol.18gms of solid residue obtained. The obtained solid residue was used to super disintegration agent. The ppt mucilage was washed with acetone and filter through muslin cloth. The obtained mucilage dried in hot air oven at a temp of 40ºC. The dried mucilage was grinded and passed through sieve no # 80 and finally storage in a tight Container. The obtained solid product was used to super disintegration agent.

2.2.2 Formulation of montelukast sodium ODT [9,10,11]

Montelukast Sodium Oro dispersible tablets were prepared by simple direct compression method. The API and Excipients such as Superdisintegrants (Natural and Artificial) Binder (starch & MCC), Diluent (Mannitol & Lactose), Glidant (Cabosil), Lubricant (Magnesium stearate), Sweetening agent (Sodium saccharin) are mixed by co-processed technology. In this method, all the excipients and drug were geometrically mixed and that blend was directly used for compression. The mixture was compressed by using an eight-station tablet punching machine (Karnavati Engineering Ltd) with an 8mm standard punch, round concave punch shape and die set at compression force 4-6 ton. Composition of various OD Tablets formulations mention in Table 1.

2.2.3 Drug-excipient compatibility study by FTIR [12]

The physico-chemical compatibility between Montelukast sodium and the excipients used in the research was tested by IR spectroscopy using Perkin Fourier Transform Infrared Radiation Spectrophotometer (Smilax Laboratories LTD, Hyderabad). The samples were scanned under diffuse reflectance mold and graph was plotted by KBr pellet technique. The spectra were recorded in the wave number region between 3800cm⁻¹ to 800cm⁻¹. The individual spectra obtained for Montelukast sodium and excipients were compared with the spectra of the physical mixture of Montelukast sodium and excipients.
| Ingredients              | TMF1 | TMF2  | HM1 | HMF2 | OMF1 | OMF2 | BMF1 | BMF2 | IMF1 | IMF2 | CPMF1 | CPMF2 | CP&IMF2 |
|--------------------------|------|-------|-----|------|------|------|------|------|------|------|-------|-------|---------|
| Montelukast sodium       | 10   | 10    | 10  | 10   | 10   | 10   | 10   | 10   | 10   | 10   | 10    | 10    | 10      |
| MCC                      | 14   | 14    | 14  | 14   | 14   | 14   | 14   | 14   | 14   | 14   | 14    | 14    | 14      |
| Starch                   | 20   | 20    | 20  | 20   | 20   | 20   | 20   | 20   | 20   | 20   | 20    | 20    | 20      |
| Mannitol                 | 90.62| 90.62 | 90.62| 90.62| 90.62| 90.62| 90.62| 90.62| 90.62| 90.62| 90.62 | 90.62 | 90.62   |
| Sod.Saccharin            | 4.6  | 4.6   | 4.6 | 4.6  | 4.6  | 4.6  | 4.6  | 4.6  | 4.6  | 4.6  | 4.6   | 4.6   | 4.6     |
| Cabosil                  | 1    | 1     | 1   | 1    | 1    | 1    | 1    | 1    | 1    | 1    | 1     | 1     | 1       |
| Mg.sterate               | 4    | 4     | 4   | 4    | 4    | 4    | 4    | 4    | 4    | 4    | 4     | 4     | 4       |
| Lactose                  | 51.24| 49.24 | 51.24| 49.24| 51.24| 49.24| 51.24| 49.24| 51.24| 49.24| 51.24 | 49.24 | 49.24   |
| Superdisintegrants       | 4    | 6     | 4   | 6    | 4    | 6    | 4    | 6    | 4    | 6    | 4     | 6     | 6       |
| Flavor                   | 0.54 | 0.54  | 0.54| 0.54 | 0.54 | 0.54 | 0.54 | 0.54 | 0.54 | 0.54 | 0.54  | 0.54  | 0.54    |
| Total                    | 200  | 200   | 200 | 200  | 200  | 200  | 200  | 200  | 200  | 200  | 200   | 200   | 200     |

All quantities in mg (TMF - Tulasi montelukast sodium formulation, HMF - Hibiscus montelukast sodium formulation, OMF - Orange montelukast sodium formulation, BMF - Banana montelukast sodium formulation, IMF - Ispaghula montelukast sodium formulation, CPMF - Crospovidone montelukast sodium formulation, CP&IMF - Crospovidone and Ispaghula montelukast sodium formulation)
2.2.4 Preformulation studies [13]

2.2.4.1 Bulk density

It is the ratio of mass of the powder to the bulk volume of the powder and is expressed as gm/cc. It is expressed in gm/ml and is given by \( \text{Pb} = \frac{M}{V_p} \)

2.2.4.2 Tapped density

It is the ratio of total mass of the powder to the tapped volume of the powder. Volume was measured by tapping the powder for 750 times and the tapped volume was noted if the difference between these two volumes is less than 2%. \( \text{Dt} = \frac{M}{V_t} \)

2.2.4.3 Carr’s index

A material having values less than 20 to 30% is defined as the free-flowing material, based on the apparent bulk density and tapped density, the percentage compressibility of the bulk drug was determined by using the following formula.

\[ \text{CI} = \frac{\text{TD} - \text{BD}}{\text{TD}} \times 100 \]

2.2.4.4 Hausner’s ratio

It indicates the flow properties of the powder and the ratio of Tapped density to bulk density of the powder or granules is called Hausner’s ratio. It is measurement of frictional resistance of the drug. The Ideal range should be 1.2 – 1.5.

\[ \text{HR} = \frac{\text{TD}}{\text{BD}} \]

2.2.4.5 Angle of repose

It is defined as maximum angle possible between the surface of the pile of powder and the horizontal plane. The angle of repose was determined by the funnel method suggested by Newman. Angle of repose is determined by the following formula

\[ \tan \theta = \frac{h}{r} \]

2.2.5 Characterization of prepared ODT: [14,15,16]

2.2.5.1 Weight variation test

For weight variation test IP procedure was followed. Twenty tablets were taken and their weight was determined individually and collectively using single pan electronic balance (AR 0640, Ohaus Corp. USA). The average weight of the tablets was determined from collective weight. From the individual tablets weight, the range and percentage standard deviation were calculated. Not more than 2 tablets should deviate from the average weight of tablets and the maximum percentage ± 10mg deviation allowed according to IP.

2.2.5.2 Thickness

Thickness is an important characteristic in reproducing appearance and also in counting by using filling equipment. Take 20 tablets and their thickness was recorded using digital vernier callipers.

2.2.5.3 Hardness

The hardness of tablet depends on the weight of material used, space between the upper and lower punches at the time of compression and pressure applied during compression. The hardness of the tablet was determined using a Monsanto hardness tester. It is expressed in kg/cm.

2.2.5.4 Friability test

Friability test indicates physical strength of compressed tablets. Test for tablet Friability was carried out according to I.P 2007, according to which friability below 1% passes the test. Twenty tablets were weighed initially and transferred to the Friabilator. The instrument was operated at 25 rpm for 4 minutes. The tablets were reweighed and percentage loss was calculated using formula.

\[ \% \text{Friability} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100 \]

2.2.5.5 Drug content uniformity

Three tablets of Montelukast sodium containing the equivalent of 10mg of drug were collected randomly and powdered. The powder equivalent to 10mg of drug was weighed accurately, dissolved in 100mL of water. The solution was filtered and an aliquot corresponding to 100μg / ml was analyzed at 287.3 nm by using UV spectrophotometer.

2.2.6 Disintegration test

It is the time necessary for the FDT to completely disintegrate until no solid residue remains. The time for disintegration of ODTs was generally less than 1min and actual disintegration time that patient can experience ranges from 5-30 seconds.
2.2.6.1 Wetting time

A tissue paper folded twice was placed in a petridish containing 6ml of water in which amaranth dye was dissolved. The time required for red colored solution to reach the upper surface of the tablet and to completely wet it was noted as the wetting time.

2.2.6.2 Dissolution test

It is defined as the process of transfer of molecules or ions from the solid state into solution. In-vitro dissolution study was performed by using USP dissolution apparatus type-II (paddle) at 50rpm. Phosphate buffer (pH 6.8) was used as dissolution medium and temperature was maintained at 37±0.5°C. 5 mL of dissolution media is withdrawn from the bowel at different time intervals i.e., 5, 10, 15, 20, 25, 30, min and sample were replaced by the fresh phosphate buffer. The collected samples were used to determine the amount of drug content present in the samples by using UV spectrophotometer and absorbance was measured at 287.3nm. Triplicate replications in the dissolution test.

\[
\text{% drug released} = \frac{\text{concentration} \times \text{dilution factor}}{100}
\]

3. RESULTS AND DISCUSSION

3.1 Evaluation Results of Drug-Excipient Compatibility Study by FTIR

The ODT of Montelukast sodium were successfully prepared by direct compression method using natural Superdisintegrants like natural and synthetic like tulasi, hibiscus, orange peel powder, Ispaghula, banana peel powder, Crospovidone at varying concentrations and an optimized formula was selected.

3.2 Compatibility Studies

FTIR spectrum of pure drug and physical mixture of drug and excipients were studied. In the present study, it was observed that, there were no shifts in individual main peaks of pure drug substance. So, this indicates that there were no incompatibility issues of drug with formulation excipients used. It is evident that, the absorption bands at 2916.405 \( \text{cm}^{-1} \), 3741.199 \( \text{cm}^{-1} \), 1159.975 \( \text{cm}^{-1} \), 1316.124 \( \text{cm}^{-1} \) indicate the presence of C – H (Alkanes), O – H (Alcohol), C – O (Aliphatic Ether) and O – H (Phenol) correspond to the montelukast sodium pure drug.

3.2.1 Preformulation studies

Preformulation were carried out for the powder blend. The results are within the limit and showed good flow property, it shown in Table 2.

3.2.2 Tablet evaluation studies

The values of weight variation and friability were found to be within the limits of ODTs stated in the Indian Pharmacopoeia. Thickness of the tablets varied from 2.80 mm to 3.03 mm. Hardness of the tablets varied from 4.02-4.88 kg/cm which are within the limits only. The % friability and disintegration time values also within the limits of ODTs. Results were shown in Table 3. And wetting process were completed at 35 seconds. It shown in Fig. 2.

3.2.3 In-vitro dissolution studies:

Formulations TMF1 and TMF2 showed 80.55 & 83.65% of drug release in 30 min respectively. As the concentration of reached maximum level in TMF2 could not be increased further, to achieve 100% drug release, various other Superdisintegrants were employed in different concentrations.

The tablets of HMF1, HMF2, OMF1, OMF2 & BMF1, BMF2 showed 82.43, 85.89, 75.89, 77.87, 79.61 and 86.71% of drug release in 30min. Drug release profile of all these formulations did not show 100% drug release within much less time. However, Crospovidone used alone in the above formulations unable to release the drug within much less time and the aim was not achieved.

Drug release profile of IMF1 & IMF2 formulations mentioned above closure to the 100% drug release. As both showed 94.25% and 97.74% in 30 min. compare to other formulations as ispaghula acts by the swelling action which helps in release of the drug.

In Co processed formulation of CPIMF showed slow drug release due to presence of Superdisintegrants s in maximum concentration which could hinder drug release due to swelling action. CPIMF showed maximum drug release (98.91%) due to presence of highest concentrations of Crospovidone and Ispaghula which could facilitate drug release by disintegration and rapid capillary action. The results shown in Fig. 2.
Table 2. Pre formulation parameters

| Sl.No | Formulation code | Bulk density (gm/cc) | Tapped density (gm/cc) | Carr’s Index(%) | Hausner’s ratio | Angle of repose(°) |
|-------|------------------|----------------------|------------------------|-----------------|----------------|-------------------|
| 1     | TMF 1            | 0.65±0.05            | 0.74±0.10              | 9.72±3.01       | 1.14±0.072     | 27.5±1.50         |
| 2     | TMF 2            | 0.65±0.04            | 0.77±0.10              | 10.51±2.01      | 1.15±0.071     | 27.7±1.59         |
| 3     | HMF 1            | 0.67±0.05            | 0.72±0.09              | 10.36±2.85      | 1.18±0.046     | 28.2±1.20         |
| 4     | HMF 2            | 0.65±0.04            | 0.71±0.09              | 9.23±2.06       | 1.18±0.047     | 27.4±1.02         |
| 5     | OMF 1            | 0.63±0.06            | 0.71±0.09              | 10.52±2.49      | 1.17±0.045     | 26.9±1.34         |
| 6     | OMF 2            | 0.73±0.02            | 0.78±0.11              | 10.83±3.01      | 1.14±0.080     | 27.3±1.43         |
| 7     | BMF 1            | 0.65±0.02            | 0.75±0.13              | 8.41±3.24       | 1.18±0.045     | 26.9±1.31         |
| 8     | BMF 2            | 0.62±0.08            | 0.75±0.10              | 10.42±2.75      | 1.13±0.070     | 27.6±1.21         |
| 9     | IMF 1            | 0.66±0.06            | 0.73±0.11              | 12.12±2.58      | 1.06±0.018     | 27.8±1.89         |
| 10    | IMF 2            | 0.63±0.06            | 0.78±0.11              | 10.42±3.11      | 1.09±0.03      | 26.3±0.79         |
| 11    | CPMF 1           | 0.67±0.04            | 0.77±0.12              | 10.42±2.45      | 1.11±0.07      | 26.7±1.20         |
| 12    | CPMF 2           | 0.66±0.06            | 0.75±0.10              | 12.12±2.41      | 1.10±0.32      | 26.4±1.19         |
| 13    | CP & IMF         | 0.67±0.05            | 0.77±0.12              | 10.45±2.41      | 1.08±0.05      | 26.9±2.7          |

Fig. 1. Wetting time of Montelukast sodium tablet
Table 3. Tablet evaluation results

| Formulation code | Weight variation (mg) | Thickness (mm) | Hardness (kg/cm) | Friability (%) | Disintegration (sec) | Wetting time (sec) |
|------------------|-----------------------|----------------|------------------|----------------|---------------------|--------------------|
| TMF 1            | 198.5±1.45            | 4.25±0.1       | 4.08±0.32        | 0.897±0.09     | 89.5±9.1            | 82±3.46            |
| TMF 2            | 197.1±1.95            | 4.28±0.1       | 4.13±0.37        | 0.898±0.06     | 90.7±6.7            | 76±2.8             |
| HMF 1            | 198.1±2.18            | 4.25±0.9       | 4.02±0.03        | 0.874±0.10     | 111.5±5.2           | 85±3.9             |
| HMF 2            | 198.4±1.71            | 4.28±0.08      | 4.1±0.3          | 0.665±0.14     | 110±4.7             | 94±2.7             |
| OMF 1            | 198.2±2.14            | 4.24±0.12      | 4.22±0.4         | 0.587±0.58     | 89.3±6.8            | 91±4.5             |
| OMF 2            | 197.7±2.16            | 4.25±0.09      | 4.12±0.4         | 0.703±0.04     | 84.7±5.8            | 87±4.2             |
| BMF 1            | 197.1±2.28            | 4.27±0.08      | 4.17±0.43        | 0.883±0.05     | 106.4±5.5           | 90±4.8             |
| BMF 2            | 197.1±1.66            | 4.25±0.07      | 4.18±0.3         | 0.69±0.058     | 111.1±3.5           | 94±3.6             |
| IMF 1            | 198.9±1.10            | 4.25±0.08      | 4.1±0.39         | 0.521±0.05     | 67.4±3.5            | 39±3.7             |
| IMF 2            | 198.9±1.63            | 4.27±0.09      | 4.1±0.36         | 0.889±0.05     | 59.7±4.2            | 37±1.6             |
| CPMF 1           | 198.1±1.15            | 4.21±0.09      | 4.1±0.43         | 0.798±0.03     | 53±3.5              | 40±2.4             |
| CPMF 2           | 197.7±1.26            | 4.28±0.09      | 4.23±0.33        | 0.83±0.091     | 49.6±1.7            | 38±2.8             |
| CP&IMF           | 198.5±1.15            | 4.24±0.11      | 4.12±0.36        | 0.865±0.14     | 58.2±4.6            | 35±3.2             |

Fig. 2. Cumulative percentage drug release of Montelukast sodium

4. CONCLUSION

In the present study ODT tablets of Montelukast sodium were prepared by using different Superdisintegrants as Cross povidone, Ispaghula, Tulasi, Hibiscus, Banana peel, Orange peel. Thirteen formulations were designed, using higher and lower level of Superdisintegrants and employing two Superdisintegrants at a time. In the FTIR studies, it was concluded that there was no interaction between drug and Superdisintegrants used in formulation. Formulation of CPIMF showed better taste masking property with immediate disintegration and drug release fulfilling the objective of the study.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.
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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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