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Original Research Article

Formulation and Evaluation of Mouth Dissolving Tablets of Montelukast sodium

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Abstract:
The present study aims to formulate mouth dissolving tablets of montelukast sodium by direct compression method for the faster action, better absorption and improvement of bioavailability of the drug in management of Asthma. Total six formulations were developed with varying concentrations of combination of Crosspovidone and Sodium starch glycolate as super disintegrating agents. The tablets were prepared by direct compression method. The prepared MDT were evaluated for various parameters i.e. shape and size, weight variation, thickness, hardness, friability, wetting time, disintegration time, drug content, dissolution test, accelerated stability studies etc. After comparing the results (particularly disintegration time and dissolution profile), it was concluded that formulation TF3 was selected as the best formulation among all.
Keywords: Montelukast sodium, Mouth Dissolving Tablets, Direct Compression, in-vitro dissolution.

Introduction

Mouth dissolving tablets (MDT) is a tablet that dissolves within seconds of being placed on the tongue. After breakdown, MDT forms gel-like compounds, which aid patients in easily ingesting their medications. According to the Pharmacopoeia, the disintegration period of MDT ranges from a few seconds and more than a minute. [1-3] MDTs can be prepared by different methods as direct compression, freeze-drying, spray drying, sublimation and wet granulation method.[4] The aim of this study was to formulate MDTs with sufficient mechanical reliability and to achieve faster disintegration in the oral cavity without additional water. Attempts were made to enhance dissolution rate along with faster disintegration using superdisintegrants such as Crosspovidone and sodium starch glycolate (SSG) in the formulation of tablets. [5] Montelukast sodium binds to the CysLT type 1 receptor with high

affinity and selectivity, which therefore helps in preventing any physiological functions of CysLTs like LTC4, LTD4, and LTE4 at the receptor that may impede asthma. Montelukast sodium is rapidly absorbed following oral administration. Mean peak plasma concentration (Cmax) is achieved 3 hours (Tmax) after administration in adults in the fasted state. The mean oral bioavailability is 64%.[6]

Material and Method

Materials

Montelukast sodium was obtained from Accuris Healthcare and Allied Services LLP. Ahmedabad. Sodium Starch Glycolate and Crospovidone were obtained from Global Pharma, Mumbai. All the other ingredients used were of research grade.

Methodology

Physicochemical Characterization of Drug (Preformulation Studies):

Preformulation study is an important study of physical and chemical properties of the drug substance alone and when drug substance combined with excipients. It is the first and foremost step in the rational development of any dosage form. The objective of the preformulation study is to produce useful information on the formulation in developing stable and bioavailable dosage forms. The study of preformulation parameters maximizes the chances of formulating and developing an acceptable, safe, efficacious and stable product.

Physical Appearance

The physical form and color of the drug Montelukast Sodium was observed visually.

Melting Point

The melting point determination of the drug was done by using the melting point apparatus. A small amount of pure drug of Montelukast Sodium was taken in a capillary tube and it was kept in the melting point apparatus. The reading of melting point was taken in triplicate and noted.

Calibration Curve of Montelukast Sodium using UV-Visible Spectroscopy:

Scanning of Montelukast sodium in Distilled water and Phosphate buffer pH 6.8

50 mg of drug was dissolved in the respective solvents in 100 ml volumetric flask, and volume was made to 100 ml with the corresponding solvent. 2 ml of this stock solution was further diluted to 50 ml to get concentration of 20µg/ml. This solution was scanned in UV-spectrophotometer and characteristic peak (λmax) was observed.

Calibration curve of Montelukast sodium in Distilled water and Phosphate buffer pH 6.8

50 mg of Montelukast sodium was dissolved in the respective solvents and volume was made up to 100 ml by same solvent. This gave the concentration of 500 µg/ml (stock solution). 1, 2, 3, 4, 5 and 6 ml of this stock solution was further diluted to 100 ml to get different concentrations of 5, 10, 15, 20, 25 and 30µg/ml. Absorbances were measured at the λmax. The process was performed in triplicate. The standard curve was obtained by plotting concentration (µg/ml) on X-axis and absorbance on Y-axis.

Solubility determination

An excess of the drug was added to conical flask containing each of 10 ml of distilled water and phosphate buffer pH 6.8 respectively. Then conical flasks were shaken manually for some time. After that these conical flasks were kept on a rotary shaker for 24 hours. After 24 hours of shaking, these solutions were filtered using a 0.45µ size filter. Then absorbance of the filtered liquid was taken by using a UV-Visible spectrophotometer at respective λmax. Concentration of dissolved drug was calculated using the standard curve, which is equal to solubility of drug in respective solvent.

Drug-Excipient Compatibility Study (FTIR)

The compatibility studies provide the suitability of the drug's combination with excipients in the fabrication of the dosage form. The compatibility study is carried out to establish

that the drug has not undergone any change(s) after it has been subjected to various processing steps during the formulation. The drug-excipient compatibility study was done by using an FTIR spectrophotometer. The FTIR spectrum of pure drug and excipients alone were recorded. Then, after preparing the tablets, IR spectrum of selected formulations and physical mixture of ingredients corresponding to those formulations were also recorded. The range of scanning was 4000 cm^{-1} - 400 cm^{-1}. The characteristic peaks of Montelukast sodium were compared in these spectra. [5]

Formulation of Mouth Dissolving Tablets (MDTs) containing Montelukast sodium

In the present study, mouth dissolving tablets containing Montelukast sodium were prepared using the direct compression process. All of the ingredients were weighed, passed through sieve no. 60 and mixed in a mortar and pestle. The powder mixture was again passed through sieve no. 60 and used for further processing.

Table 1: Formulation of MDTs containing Montelukast sodium

Ingredients	MDT1	MDT2	MDT3	MDT4	MDT5	MDT6
Montelukast sodium (mg)	5	5	5	5	5	5
Crosspovidone (mg)	8	8	8	8	10	10
Sodium starch glycolate (mg)	7	9	11	13	7	9
Microcrystalline cellulose (mg)	20	20	20	20	20	20
Mannitol (mg)	114	112	110	108	112	110
Magnesium stearate (mg)	3	3	3	3	3	3
Talc (mg)	1	1	1	1	1	1
Aspartame (mg)	2	2	2	2	2	2

Evaluation of Pre-compression parameters

Powder mixture formulated was evaluated for different pre-compression parameters using standard procedures. The evaluation were done in triplicate (n=3) and mean was calculated.

Angle of repose

Angle of repose is used to determine flow property of the powder. It is defined as the maximum angle possible between the surface of a pile of the powder and horizontal plane. It can be measured by the funnel method. In this method, the funnel is placed above graph paper at distance of 6 cm. The powder is kept in the funnel and allowed to flow. The powder forms a pile. The height and diameter of powder pile is measured. The angle of repose is calculated using following formula:

$$\theta = tan^{-1}\left(\frac{h}{r}\right)$$

Where, "θ" is angle of repose, "h" is height of pile and "r" is radius of the base of pile.

Bulk density

The bulk density and tapped density are evaluated to determine filling of powder in the die. To determine bulk density, weighed amount of powder mixtures is filled in a measuring cylinder, and the bulk volume of powder is noted. The following formula is used to determine the bulk density: [7]

$$Bulk\ density = \frac{Weight\ of\ powder}{Bulk\ volume\ of\ powder}$$

Tapped density

To determine tapped density, weighed amount of powder mixtures is filled in a measuring cylinder, tapped for 50 times and the tapped

volume of powder is noted. The following formula is used to determine the tapped density:

$$Tapped\ density = \frac{Weight\ of\ powder}{Tapped\ volume\ of\ powder}$$

Carr's Index

It represents the powder flow properties. It can be computed by the formula:

$$Carr's\ index = \frac{D_t - D_b}{D_t}\ x\ 100$$

Where D_t: tapped density of the powder

D_b: bulk density of the powder

Hausner's ratio

Hausner's ratio is also used to represent flow properties of powder. It is calculated by using following formula and it is expressed in percentage: [8]

$$Hausner's\ ratio = \frac{Tapped\ density}{Bulk\ density}$$

Compression of powders into tablets (MDT)

Mouth dissolving tablets containing Montelukast sodium were prepared by direct compression. Drug and excipients were mixed properly. Lubricant (talc) and glidant (magnesium stearate) were mixed to this prepared powder mixture. This powder blend was used to prepare MDT by direct compression using tablet punching machine. [7]

Evaluation of Prepared Tablets (MDT)

After formulation of tablets, they are evaluated for various parameters. Prepared MDTs were evaluated for following parameters:

Shape and Size

Diameter and thickness of prepared MDTs were determined using Vernier callipers. Three tablets from each formulation were taken and average was calculated.

Weight variation

This test is performed to check the uniformity of weight of the prepared tablets, as drug content is directly related to the weight of tablet. In this process, 20 tablets were weighed individually. The average weight of one tablet was calculated by taking average mean. As per IP, not more than two tablets deviate by more than the limit prescribed and none tablets deviate by more than twice of the limit prescribed in individual monograph.

Thickness variation

Thickness of prepared MDTs were determined using Vernier callipers. Three tablets from each formulation were taken and average was calculated.[10]

Hardness

Hardness of tablets is the amount of force needed to split them. Monsanto's hardness tester, Pfizer's hardness tester, and others are used to determine the tablet hardness. Hardness is measured in kilogrammes or pounds.

Both Monsanto and Pfizer hardness tester were used to determine the hardness of the formulated tablets. The hardness was calculated as kg/cm^2. Three tablets from each formulation were taken and average was calculated.

Friability

The Roche friabilator was used to measure friability of the formulated tablets. Weight of 20 tablets was measured and placed in the friabilator chamber. The friabilator was rotated at speed of 25 rpm for 4 min. After completion of 100 revolutions, the tablets were weighted again and % weight loss is calculated, which corresponds to friability.

$$\%\ Friability = \frac{Initial\ weight - Final\ weight}{Initial\ weight} \times 100$$

Wetting time

The wetting time was calculated by placing the tablets in Petri dish containing wet tissue paper. Wet tissue was placed in a petri dish and the tablet was placed over it. The time required for complete wetting of tablets was noted.

Disintegration time

Disintegration time of mouth dissolving tablets was determined using the disintegration test apparatus. One tablet was kept in each tube of the disintegration test apparatus. Phosphate buffer pH 6.8 was used to determine disintegration time at 37°C. The time taken to disintegrate all six tablets was noted as disintegration time.

Drug content

The drug content was calculated by triturating ten tablets in a mortar with pestle to get fine powder. Powder equivalent to weight of one tablet was taken and was dissolved in distilled water. Measure the absorbance of diluted sample

of MS at 283 nm using UV-Visible Spectrophotometer. The drug content was calculated by using standard calibration curve.[9]

Dissolution Test

Dissolution testing measures the extent and rate of solution formation from a dosage form. The dissolution of a drug is important for its bioavailability and therapeutic effectiveness.

Dissolution of prepared mouth dissolving tablets was determined in phosphate buffer ph 6.8 using paddle apparatus, 50 RPM at 37^0C.[10]

Accelerated Stability Studies

Short term accelerated stability studies of the selected formulations were carried out at 40^0C/75%RH over a period of 3 months. The MDTs were wrapped with aluminium foil, and stored in humidity controlled oven for 3 months. Samples were analysed for residual drug contents at time interval of 15 days.

Result and Discussion

Physicochemical Characterization of Drug (Preformulation Studies):

Physical Appearance

Montelukast Sodium was in the form of white solid powder when observed visually.

Melting Point

The melting point determination of the drug was done by using the melting point apparatus. A small amount of pure drug of Montelukast Sodium was taken in a capillary tube and it was kept in the melting point apparatus. The reading of melting point was taken in triplicate and noted. The melting point of Montelukast sodium was found to be 274^0C - 277^0C, which is same as documented (275.9^0C)

Calibration Curve of Montelukast Sodium using UV-Visible Spectroscopy:

Scanning of Montelukast sodium in Distilled water and Phosphate buffer pH 6.8

50 mg of drug was dissolved in Phosphate buffer pH 6.8 in 100 ml volumetric flask, and volume was made to 100 ml with Phosphate buffer pH 6.8. 2 ml of this stock solution was further diluted to 50 ml to get concentration of 20 µg/ml. This solution was scanned in UV-spectrophotometer and characteristic peak (λmax) was observed at 345nm and 346 nm respectively.

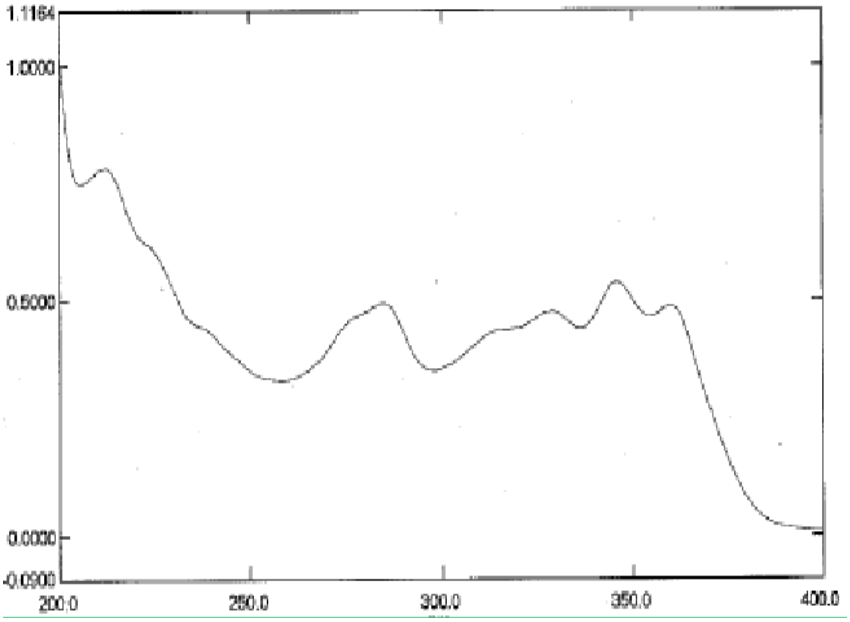

Figure 1: UV spectrum of Montelukast sodium in distilled water

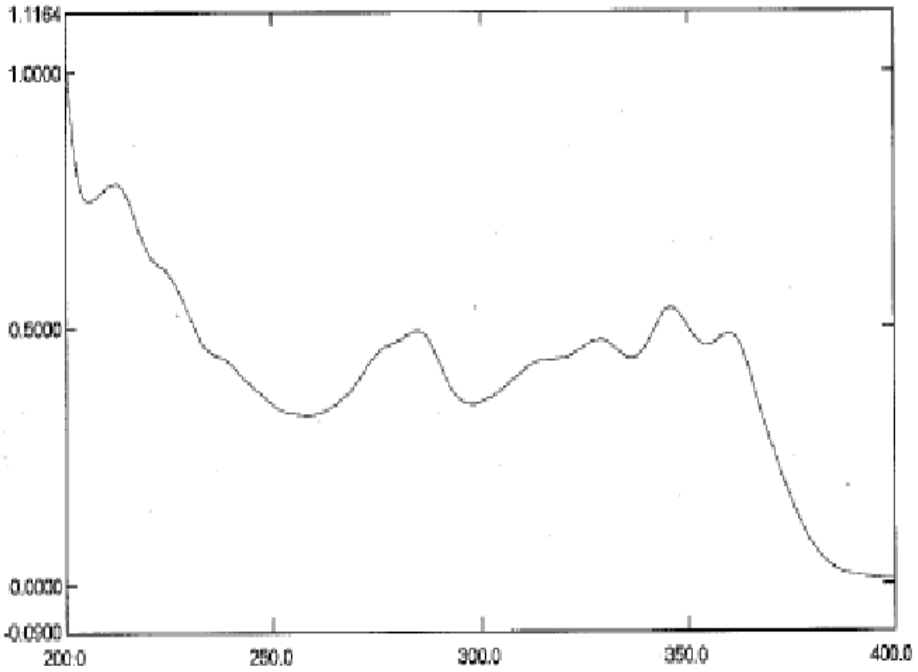

Figure 2: UV spectrum of Montelukast sodium in Phosphate buffer pH 6.8

Calibration curve of Montelukast sodium in Distilled water

The stock solution in concentration of 500 µg/ml was prepared in both the solvents. 1, 2, 3, 4, 5 and 6 ml of this stock solution was further diluted to 100 ml to get different concentrations of 5, 10, 15, 20, 25 and 30 µg/ml. Absorbances were measured at the 345 nm and 346nm for distilled water and phosphate buffer pH6.8 respectively. The process was performed in triplicate. The standard curve was obtained by plotting concentration (µg/ml) on X-axis and absorbance on Y-axis. [11]

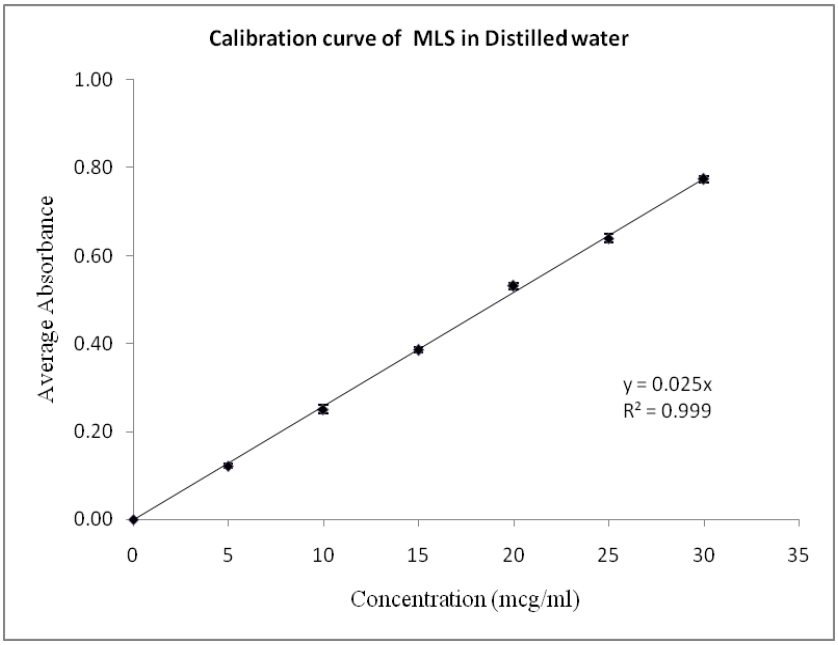

Figure 3: Calibration curve of Montelukast sodium in distilled water, n=3

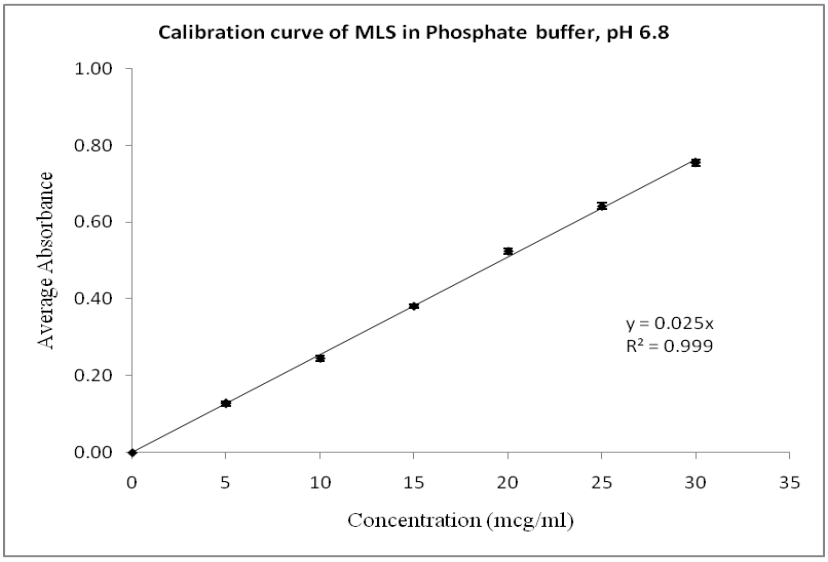

Figure 4: Calibration curve of Montelukast sodium in Phosphate buffer pH 6.8, n=3

Solubility determination

Table 2: Solubility of Montelukast sodium in various solvents

S. No.	Solvent	Solubility of MLS (mg/ml)
	Distilled water	31.5 mg/ml
	Phosphate buffer, pH 6.8	18.6 mg/ml

It can be observed that the drug Montelukast sodium is freely soluble in distilled water and Phosphate buffer pH 6.8.

Drug-Excipient Compatibility Study (FTIR)

The drug-excipient compatibility study was done by using an FTIR spectrophotometer. The FTIR spectrum of pure drug and physical mixture of ingredients corresponding to the formulations were also recorded. The range of scanning was 4000 cm^{-1} - 400 cm^{-1}. The characteristic peaks of Montelukast sodium were compared in these spectra.

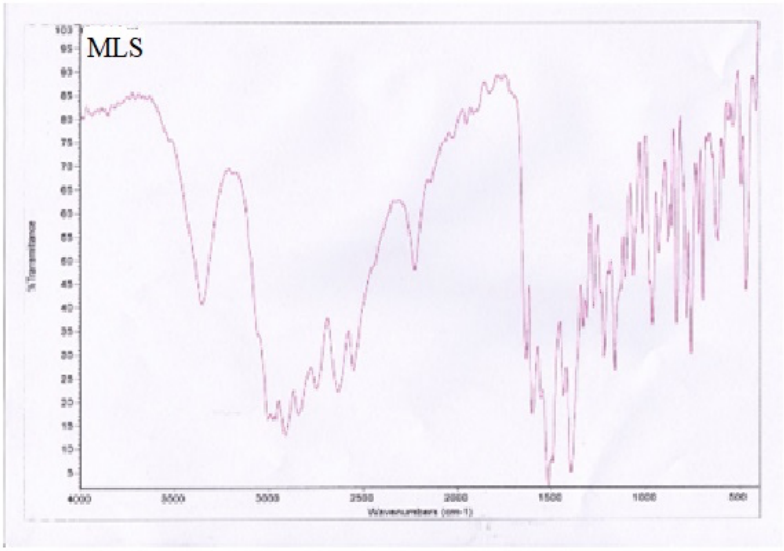

Figure 5: FTIR spectrum of Montelukast sodium

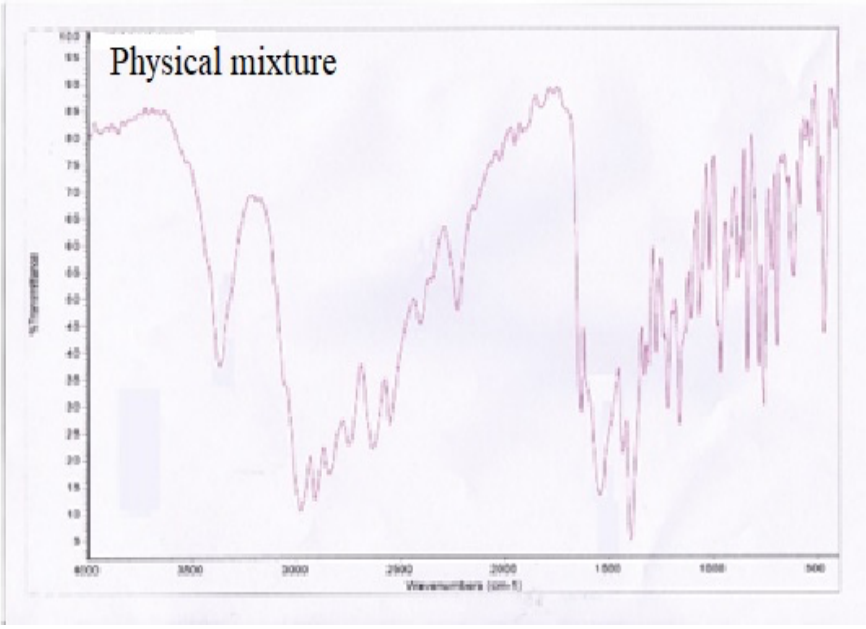

Figure 6: FTIR spectrum of Physical mixture corresponding to MT3

The FTIR spectra of pure drug (Montelukast sodium) showed all the characteristic peaks, which confirm the identification of drug. FTIR spectra of the physical mixture of drug and excipients corresponding to the formulation were also recorded. The spectra showed that all the characteristic peaks were intact. It showed that that the drug has not undergone any change(s) after it has been subjected to various processing steps during the formulation. Therefore the method can be used to prepare mouth dissolving tablet using the drug and excipients.[12]

Formulation of Mouth Dissolving Tablets (MDTs) containing Montelukast sodium

In the present study, mouth dissolving tablets containing Montelukast sodium were prepared using the direct compression process. All of the ingredients were weighed, passed through sieve no. 60 and mixed in a mortar and pestle. The powder mixture was again passed through sieve no. 60 and used for further processing.

Evaluation of Pre-compression parameters

Powder mixture formulated was evaluated for different pre-compression parameters using standard procedures. The evaluation were done in triplicate (n=3) and mean was calculated.

Angle of repose

Angle of all the powder mix was determined by the funnel method. Angle of repose was found to be between 29.26^0 - 32.41^0 for all the powder blends which are within the standard limits. It is evident from the results, that the powder blends of all the formulations possess good flow properties.

Bulk density

Bulk density of all the powder mix was determined by the measuring cylinder method. Results are tabulated below (along with tapped density).

Tapped density

Tapped density of all the powder mix was determined by the measuring cylinder method using tapped density apparatus. Bulk density and Tapped density were found to be between 0.368 - 0.398 gm/cm^3 and 0.461 - 0.487 gm/cm^3 respectively for all the powder blends. It may be concluded that the powder blends of all the formulations possess good flow properties.

Carr's Index

Carr's compressibility index represents the powder flow properties. Carr's Compressibility Index was found to be between 16.21 - 21.87 for

all the powder blends which are within the standard limits. It may be concluded that the powder blends of all the formulations possess good flow properties.

Hausner's ratio

Hausner's ratio was found to be between 1.19 - 1.28 for all the powder blends which are within the standard limits. It may be concluded that the powder blends of all the formulations possess good flow properties.

Based upon various pre-compression parameters, it was concluded that the powder blends are suitable for compression into tablet. (13)

Compression of powders into tablets (MDT)

Mouth dissolving tablets containing Montelukast sodium were prepared by direct compression. Drug and excipients were mixed properly. Lubricant (talc) and glidant (magnesium stearate) were mixed to this prepared powder mixture. This powder blend was used to prepare MDT by direct compression using tablet punching machine.

Evaluation of Prepared Tablets (MDT)

After formulation of tablets, they were evaluated for various parameters. Prepared MDTs were evaluated for following parameters:

Shape and Size

Diameter and thickness of prepared MDTs were determined using Vernier callipers. Three tablets from each formulation were taken and average was calculated. All the tablets prepared were round in shape. Diameter was found to be 8 mm and thickness was found to be 3 mm for all the formulations.

Weight variation

This test is performed to check the uniformity of weight of the prepared tablets, as drug content is directly related to the weight of tablet. In this process, 20 tablets were weighed individually. The average weight of one tablet was calculated by taking average mean. As per IP, not more than two tablets deviate by more than the limit prescribed and none tablets deviate by more than twice of the limit prescribed in individual monograph.

None of the tablet deviated by the limit prescribed (5%). Therefore, the prepared tablets pass the test for weight variation.

Thickness variation

Thickness of prepared MDTs were determined using Vernier callipers. Three tablets from each formulation were taken and average was calculated. All the tablets prepared were round in shape. Diameter was found to be 8 mm and thickness was found to be 3 mm for all the formulations.

Hardness

Both Monsanto and Pfizer hardness tester were used to determine the hardness of the formulated tablets. The hardness was calculated as kg/cm^2. Three tablets from each formulation were taken and average was calculated.

The average hardness of prepared tablets was found to be 3.1 - 3.7 kg/cm^3, which are within the standard limits. It may be inferred that hardness is optimum for mouth dissolving tablets.

Friability

The friability of prepared tablets was found to be 0.45 - 0.74%, which are less than the standard limits (1%). It may be concluded that the prepared mouth dissolving tablets pass the friability test.

Wetting time

The wetting time of prepared tablets was found to be 56 - 88 second, which are optimum for mouth dissolving tablets. Formulation MT3 showed minimum wetting time among all the formulations.

Disintegration time

The Disintegration time of prepared tablets was found to be 2.3 - 5.5 minute, which is optimum for mouth dissolving tablets. Formulation MT3 showed minimum Disintegration time among all the formulations. (14)

Drug content

The drug content was calculated by triturating ten tablets in a mortar with pestle to get fine powder. Powder equivalent to weight of one tablet was taken and was dissolved in distilled water. The absorbance of diluted sample was measured at 345 nm using UV-Visible Spectrophotometer. The drug content was calculated by using standard calibration curve. The percent drug content of prepared tablets was found to be 95.60 - 97.80%, which is within the prescribed limits. Therefore, the prepared mouth dissolving tablets pass the test for drug content (content uniformity).

Dissolution Test

Dissolution testing measures the extent and rate of solution formation from a dosage form. The dissolution of a drug is important for its bioavailability and therapeutic effectiveness. Dissolution of prepared mouth dissolving tablets was determined in phosphate buffer ph 6.8 using paddle apparatus, 50 RPM at 37^0C.

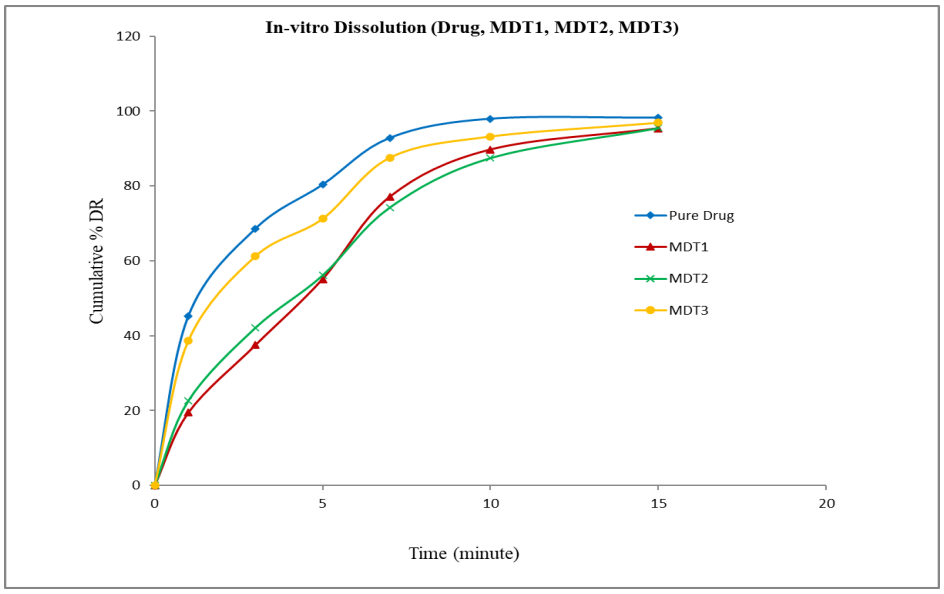

Fig.-5.18(i): In-vitro dissolution of Pure drug, MDT1, MDT2 and MDT3

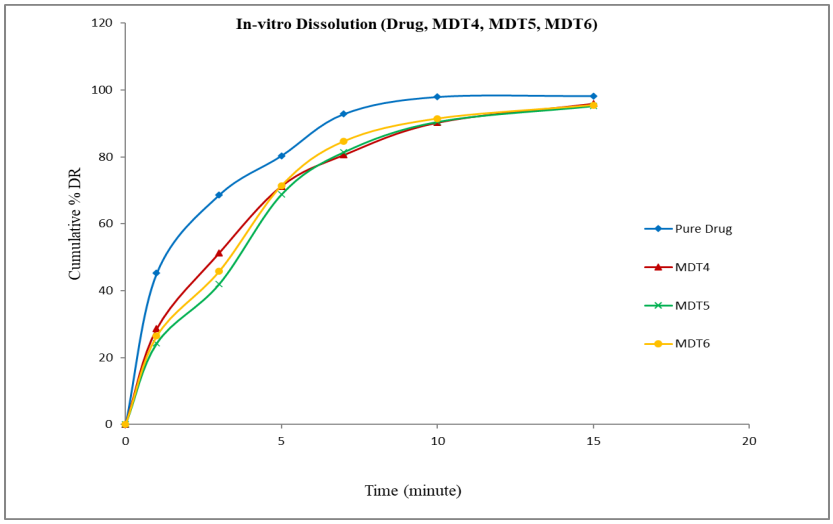

Fig.-5.18(i): In-vitro dissolution of Pure drug, MDT4, MDT5 and MDT6

All the prepared MDT showed fast dissolution profile. Dissolution of Montelukast sodium starts immediately when the tablet is added to the dissolution media. It was observed that for all the films, 90% drug was dissolved within 10 minutes. It can be concluded that mouth dissolving tablets can be prepared using above drug, excipients and procedure, that release the drug rapidly.[15]

Accelerated Stability Studies

Short term accelerated stability studies of the selected formulations were carried out at 40^0C/75% RH over a period of 3 months. The MDTs were wrapped with aluminium foil, and stored in humidity controlled oven for 3 months. Samples were analysed for residual drug contents at time interval of 15 days.

Table 3: Drug content of prepared MDT at accelerated conditions (AST)

S. No	Formulation Code	% Drug content of films at various time interval (AST) (Mean± S.D.*)						
		Initial	15 days	30 days	45 days	60 days	75 days	90 days
1.	**MDT1**	97.50±1.51	97.35±1.34	97.10±1.18	96.85±1.78	96.35±0.95	96.10±1.35	95.80±1.46
2.	**MDT2**	96.35±1.25	96.20±1.34	96.05±1.64	95.80±1.84	95.55±0.95	95.25±0.98	95.10±1.84
3.	**MDT3**	97.90±1.32	97.65±1.64	97.45±1.82	97.10±1.08	96.85±0.98	96.60±1.47	96.40±1.38
4.	**MDT4**	97.50±1.84	97.30±1.85	97.15±1.62	96.95±1.06	96.80±1.18	96.60±1.83	96.30±1.64
5.	**MDT5**	97.10±1.84	96.95±1.26	96.75±1.65	96.50±0.86	96.20±1.04	95.95±0.95	95.65±1.48
6.	**MDT6**	96.45±1.64	96.30±1.59	96.10±0.91	95.95±1.84	95.70±1.46	95.50±1.08	95.20±1.89

* Standard deviation, n=3

All the formulations showed good stability at accelerated conditions. When content of Montelukast sodium were analysed at various time interval, it was found to be more than 95.10% in all the formulations after 3 month. It can be concluded that mouth dissolving tablets can be prepared using above drug, excipients and procedure, which show good stability.

Summary and Conclusion

In management of Asthma, one of the major challenges is that the patient is not able to swallow tablet. Moreover, immediate onset of action is required. Mouth dissolving tablets provide patient convenience as it does not require water as well as offer faster onset of action as compared to conventional oral tablets.

The objective of the present study is to formulate mouth dissolving tablet of Montelukast sodium for improved patient compliance, faster onset of action and better management of Asthma.

Preformulation studies of drug were performed which included Physical appearance, determination of Melting point which confirmed the identity of the drug. Scanning of Montelukast sodium was done in distilled water and phosphate buffer pH 6.8 and peak (λmax) was observed at 345 nm and 346 nm respectively using UV-spectrophotometer. Subsequently, calibration curve of Montelukast sodium was prepared in distilled water and phosphate buffer pH 6.8. Linearity was observed with R^2 values more than 0.999. Solubility of pure drug was also determined in distilled water and phosphate buffer pH 6.8, which was 31.5 mg/ml and 18.6 mg/ml respectively. Drug- excipient compatibility study was performed using FTIR. The FTIR spectrum of pure drug was recorded. Then, IR spectrum of physical mixture of ingredients corresponding to that formulation were also recorded. The range of scanning was 4000 cm^{-1} - 400 cm^{-1}. The characteristic peaks of Montelukast sodium were compared in these spectra. The spectra showed that all the characteristic peaks were intact. It showed that no interaction occurred between the drug and excipients during formulation. After preformulation studies, Mouth dissolving tablets of Montelukast sodium were prepared using varying amount of excipients. Total 6 formulations (TF1-TF6) were prepared. Initially the powder blends were evaluated for various pre-compression parameters. All the parameters were found optimum for the suitability of

powder blends for compression into tablets. The prepared MDT were evaluated for various parameters i.e. shape and size, weight variation, thickness, hardness, friability, wetting time, disintegration time, drug content, dissolution test, accelerated stability studies etc. The prepared tablet passed all the evaluation tests. All the prepared tablets were found suitable for various evaluation parameters of mouth dissolving tables. After comparing the results (particularly disintegration time and dissolution profile), it was concluded that formulation TF3 was selected as the best formulation among all.

Finally, it can be concluded that mouth dissolving tablet of Montelukast sodium can be formulated using above excipients and method that disintegrate rapidly for improved patient compliance, faster onset of action and better management of Asthma.

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