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FORMULATION AND EVALUATION OF PRESS COATED TABLETS OF MONTELUKAST SODIUM

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ABSTRACT

Montelukast sodium, is an antileukotriene agent for asthma and allergic rhinitis, is a BCS II drug with high permeability and low solubility. This study aims to formulate and assess montelukast sodium tablets using press coating. Tablets were prepared with montelukast sodium as the core in three formulations (CF1, CF2, CF3) by varying diluent (PROSOLV SMCC HD 90) and super disintegrant (AC-Di-Sol) concentrations. Before compression, powder flow characteristics like Repose angle, Bulk density(BD), Tapped density (TD), Hausner's ratio (HR), and Carr's compressibility index (CI) were assessed for CF1 to CF3, followed by optimization. Coating material was created with nine combinations (POF1 to POF9) using gum karaya as a binder and Avicel pH 101 as diluent. Tablets from all batches were analyzed for weight variation, drug content uniformity, hardness, friability, and in vitro disintegration time. POF4 (gum karaya and Avicel pH101 in a 93:40 ratio) had a lag time of 4.5 hours before drug release, making it the optimized formulation. POF4 underwent FTIR, SEM, DSC, and P-XRD studies, showing no reaction between the drug and excipients. Thus, gum karaya is deemed suitable for the development of montelukast sodium tablets. The study successfully developed and evaluated montelukast sodium tablets with desired properties for potential use.

Keywords: Montelukast Sodium, Press coated tablets, Gum karaya, *In-vitro* disintegration time, lag time, characterization studies

INTRODUCTION

Asthma is a chronic inflammatory condition of the airways characterized by increased sensitivity to triggers. A notable issue in asthma management is Nocturnal Asthma (NA), where symptoms worsen at night. An effective strategy would be a drug delivery system that releases medication in the morning. Montelukast sodium, an Antileukotriene agent, helps treat asthma by dilating bronchioles and has high permeability with low solubility **[1, 2]**. To enhance its delivery, core and core-coated tablets of Montelukast sodium were prepared using a press coating technique. This method allows for a programmable lag phase before controlled drug release, offering significant advantages in pharmaceutical applications. Press-coated tablets can protect sensitive drugs, separate incompatible components, and achieve sustained or modified release. By encasing the core in a coating that delays medication release until the coating dissolves, this technique supports the treatment of chronic diseases like asthma, which often present symptoms at night.

MATERIALS AND METHODS

Materials: Montelukast sodium and AC- Di-Sol were supplied by Srivar Pharma Pvt. Ltd, Tirupati, Andhra pradesh, PROSOLV SMCC H D90 and Avidone were obtained from Natco Pharma Ltd, Hyderabad, Gum karaya and Avicel pH 101 were acquired from Merck specialities Pvt ltd, Mumbai,India.The remaining excipients being magnesium stearate and talc were procured from SD Chem Fine, Hyderabad

Method:

Preparation of Standard curve of Montelukast sodium in Phosphate buffer pH 6.8

Buffer preparation: 28.80 grams of Di-sodium hydrogen orthophosphate and 11.45 grams of Potassium di-hydrogen phosphate were accurately weighed in a standard flask and makes the volume up to 1000ml utilizing distilled water **[6]**.

Estimation of λ max: Weigh 50mg of the pure drug and dissolve in a few ml of ethanol in a graduated 50 ml of standard flask and make up the volume to 50ml utilizing phosphate buffer pH 6.8. From this, further dilutions were done to get 10µg/ml. Scanned this solution containing 10µg/ml, with a range of 200 to 400 nanometer by means of UV visible spectrophotometer (SHIMADZU/1800). Based on maximum optical density of the drug, the lambda max was fixed at 267 nm.

Standard graph of Montelukast sodium: Weigh accurately about 50mg of Montelukast sodium and transfer to 50ml standard

volumetric flask, diluted, dissolved first with a small amount of ethanol and make up the volume by utilizing phosphate buffer pH 6.8. From this, take 10ml and dilute to 100ml with phosphate buffer pH 6.8. Additional, dilutions were performed using phosphate buffer pH 6.8 to obtain various concentrations of 1, 2, 4, 6, 8 and 10 micro-grams per milliliter of Montelukast sodium. Each of the solution was analyzed for optical density using a UV-visible spectrophotometer (SHIMADZU) at 267nm**.**

Content uniformity: A group of ten tablets from each one of the formulation was taken and powdered in a motor. Weigh equivalent to 10 milligrams of montelukast sodium and transfer to a volumetric flask of 100 ml with small quantity of ethanol, make up by utilizing phosphate buffer pH 6.8 and sonicated for 1 hour in order to dissolve drug, filter the solution. From this filtered solution, take 10 ml and make up to 100 milliliters by utilizing phosphate buffer pH 6.8. The resulting solution was estimated for its absorbance at a wavelength of 267 nanometers utilizing UV visible spectrophotometer (SHIMADZU/1800) against the phosphate buffer pH 6.8 as a blank**.**

Formulation of montelukast sodium tablet using press coating technique.

Formulation of an optimized core tablet *(OCT):* In these formulations PROSOLV SMCC HD90, was used as a diluent in the production of tablets. AC-Di-Sol acting as a super disintegrant that facilitates quick breakdown of the tablet. Avidone is utilized as a binder. Magnesium stearate is acting as a lubricant and talc functions as glidant. Three distinct combinations of tablets (CF1 to CF3) were prepared using three different concentrations of PROSOLV SMCC HD90 approximately between 75% to 82% and AC-Di-Sol approximately between 2% to 9% to meet the core weight as 85.4mg for all three combinations of tablets. Out of these three formulations (CF1 to CF3) from the preliminary studies, CF2 formulation was selected as best core tablet formulation and was used as a tablet core for further making core coated tablet formulation. An accurate amount of montelukast sodium, diluent, super disintegrant and binder were weighed and passed through sieve no 40. The above-weighed ingredients are transferred into a polybag in ascending order of their weights and blended for 5 minutes for homogeneous mixing **[10]**. After blending, weighed quantities of talc and magnesium stearate were added and triturated for 1 minute for lubrication. Then, this blended material was directly press using a 16-station rotatory tablet compression machine with a 6mm punch.

Preparation of core-coated tablet *(CCOT):* The coating material was formulated with nine possible combinations (POF1 to POF9) using Gum Karaya as a binder and Avicel pH 101 as diluent were accurately weighed. The wet granulation technique was performed by using a 5% PVP solution mixed with isopropyl alcohol (IPA) and distilled water in a fraction of 70:30. The wet granulated blend was screened by sieving through the mesh size 25 and kept on drying for 2 hrs at 45°C. To dry blend martial was passed through a sieve no. 40 and then talc and magnesium stearate were weighed, added, and mixed for 2 mins. Out of all the formulations (POF1 to POF9) POF4 formulation is considered as optimized formulation. To make the powder bed, halves a quantity of coated material granules were placed into the die cavity. Core tablet was then placed at the middle of the coated material bed and the die cavity was occupied with the left behind half amount of the coated material granules on the top of the core tablet. The core-coated tablets were then punched using 16 station rotary tablet compression machine of a 9mm punch.

Table 1: Formulation of a Core tablet of Montelukast sodium from (CF1- CF3)

Ingredients (mg)	CF1	CF2	CF3
Montelukast Sodium	10	10	10
PROSOLV SMCC HD90	69.5	67	64.5
AC- Di-Sol	2.5	5	7.5
Avidone	2	2	2
Magnesium Stearate	0.6	0.6	0.6
Talc	0.8	0.8	0.8
Total weight	85.4	85.4	85.4

Table 2: Coat tablet composition of gum karaya (POF1-POF9)

Ingredients (mg)	POF1	POF2	POF3	POF4	POF5	POF6	POF7	POF8	POF9
Gum karaya	133	113	103	93	83	63	53	43	0
Avicel pH 101	0	20	30	40	50	70	80	90	133
Talc	1	1	1	1	1	1	1	1	1
Magnesium Stearate	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6
Total weight	134.6	134.6	134.6	134.6	134.6	134.6	134.6	134.6	134.6

Evaluation of core and press core-coated tablets

Repose Angle: The angle of repose was determined using a fixed-funnel technique. Granules were dispensed through the funnel until they just touched the top of the pile. The powder then flowed onto a level surface, and the diameter of the cone-shaped pile was measured to analyze the angle of repose using a formula.

$$\Theta = \boldsymbol{tan}^{-1}\ \boldsymbol{h}/_{\mathrm{r}}$$

Where,Θ= Repose angle**,** 'h ,'r' represents the height and radius of the cone, respectively **[3]**.

Bulk Density (Db): A glass measuring cylinder was filled with 100 g of granules, and

the volume and mass were recorded to determine the apparent bulk density.

$$D_b = M / V_b$$

Where , M represents to powder mass, V_b represents to volume of the powder within the bulk **[3, 4]**.

Tapped Density: A precise amount of granules (100g) was cautiously transferred into a glass measuring cylinder, and then the cylinder was tapped a fixed number of times (100 taps) till a constant value was found. The tapped density was then analyzed using a particular formula.

$$D_t = M / V_t$$

Where, M represent to powder mass, Vt represent to volume of the powder after tapping.

Hausner's Ratio: The formula can be used to calculate the Hausner's ratio based on the obtain values of both tapped density and bulk density.

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

Carr's Index: This index provides a straightforward assessment of granular material flow ability. It involves measuring both bulk and tapped density. Carr's Index is calculated by using the formula.

$$\text{Carr's Index} = \frac{\text{Trapped density-Bulk Density}}{\text{Tapped density}}$$

Post-compression parameter tests for core and core-coated tablets of montelukast sodium: **[5-7]**

General Appearance: All the prepared Core and Core-coated tablets were assessed for general appearance like shape, size, color, surface, and physical form. The tablets were evaluated for white color, odorless, round, plane surface and having size of 9 mm of solid tablet form **.**

Weight variation: Select and weigh twenty tablets (core and core-coated) using an electronic balance (BL-220H/Shimadzu). Each tablet's mass is compared to the average weight of its type, helping to assess weight consistency essential for quality control.

$$\text{Weight variation percentage} = \frac{\text{Individual tablet weight – Average weight of tablet x 100}}{\text{Average weight of tablet}}$$

Hardness: The core and compression-coated tablets was evaluated using a Monsanto hardness tester. Five tablets from each formulation were tested, and the crushing strength was recorded to calculate the average hardness in kg/cm².

Friability: Ten tablets (core and core coated) were weighed together, then rotated for 4

minutes in a friabilator drum. After removing them, the tablets were reweighed separately, and the weight loss percentage was calculated to assess friability.

$$\text{Friability percent} = \frac{\text{(Initial weight- Final weight)} \times 100}{\text{Initial weight}}$$

***In vitro* disintegration time:** Take 500 mL of phosphate buffer pH 6.8, placed in a beaker of disintegration apparatus and heated to 37±0.5° C. Individually take six tablets of both (core, commercial tablets) placed in the disintegration apparatus (DBK). On top of each tablet perforated discs were placed, and allowed the basket assembly to move up and down at a rate of 28 to 32 cycles per minute. The time taken for each tablet to disintegrate/ break down was noted.

***In vitro* drug release studies:** Core and commercial tablet formulations underwent in vitro dissolution studies using phosphate buffer pH 6.8 for 60 minutes. Core-coated tablets (POF1 to POF9) were tested for 24 hours in suitable media to determine the lag time before drug release. Tablets were placed in 900 ml of 0.1N HCl at 37±0.2°C and 50 rpm for 2 hours, then rinsed with deionized water and transferred to 900 ml of phosphate buffer pH 6.8. Core and commercial tablets were also tested in phosphate buffer pH 6.8 using USP Type II dissolution apparatus at 50 rpm. At intervals of 5, 10, 15, 20, 30, 45, and 60 minutes, 10 ml samples were withdrawn and replaced with fresh buffer to maintain sink conditions. Samples were filtered through a 0.45 µm PVDF filter, and absorbance was measured at 267 nm using a SHIMADZU UV-1800 spectrophotometer, with phosphate buffer as the blank.

Drug content uniformity: Ten tablets were selected and weighed to estimate their average weight. They were crushed in a mortar, and 10 mg of montelukast sodium was dissolved in ethanol, then diluted with phosphate buffer pH 6.8 in a 100 ml flask. After shaking for 30 minutes and filtering, dilutions were made to achieve a concentration of 5 µg/ml of montelukast sodium. The absorbance of the solution was measured at 267 nm using a UV-visible spectrophotometer (SHIMADZU/1800) against the phosphate buffer as a blank.

Characterization of montelukast sodium core-coated tablets:

Fourier Transform Infrared Spectroscopy (FTIR) : Molecular conditions of the drug was assessed by carrying out FTIR study of placebo tablet Montelukast sodium core, Montelukast sodium core-coated tablet and standard montelukast sodium (API) using

FTIR-ATR spectrophotometer (Bruker). The spectra were obtained by scanning between 4000 cm^{-1} to 400 cm^{-1} and by $1cm^{1}$ of resolution **[8]**.

Scanning Electron Microscopy (SEM) : The surface features of montelukast sodium press-coated tablets, core tablets, and standard montelukast sodium (API) were examined using Scanning Electron Microscopy (SEM, HITACHI). Samples were fixed on aluminum stubs with double-sided adhesive tape and made electrically conductive by sputter coating with a thin layer of gold or platinum. The thickness was set to 600°A for effective electron penetration, and SEM images were captured at 5-15 Kv **[9]**.

Differential Scanning Calorimetry (DSC): The nature of montelukast sodium in the core tablet was assessed against the standard montelukast sodium. The samples were wrapped in aluminum foils and placed in the Diffraction Scanning Calorimetric (DSC: TADSC 2500), the test conditions include a temperature range of 25℃ to 300℃ continues rate of 10.00 ℃ per minute under a nitrogen purge rate of 20 milliliter per minute **[10]**.

Powder X-ray Diffractometry (PXRD): The montelukast sodium press-coated tablets and montelukast sodium core tablets were measured using an X-ray powder diffractometer (PXRD: Empyrean-Series 3 Malvern pananalytical). The diffraction pattern was noted using Ni filtered Cu K-α1 (45kV/30mA) radiation. The samples were analyzed among the angular range of starting position 3 to end position 40 (2Θ) using steps size of 0.0330 and 34.9250 counting time per each step **[11].**

RESULTS AND DISCUSSION

Standard graph of Montelukast sodium in phosphate buffer pH 6.8 : Montelukast sodium working standard should be taken and weighed carefully at 50 mg, taken into a 50 ml standard flask, and then it is dissolved in ethanol in small quantity and diluted with phosphate buffer pH 6.8. From this take 5ml and, dilute to 50ml by utilizing phosphate buffer pH 6.8 to get 100µg/ml. From this, the necessary dilutions were done to get 1,2,4,5,6,8, and 10 µg/ml using the same phosphate buffer pH 6.8. The optical density of each solution was assessed at 267nm by means of a UV-visible spectrophotometer (SHIMADZU/1800). The standard graph of montelukast sodium in phosphate buffer pH 6.8 was drawn by taking the concentration range from 1 to 10 microgram per milliliter. The calibration curve for montelukast sodium in pH 6.8 phosphate buffer was linear from 1 -10µg/ml with R2>0.99. Shown in **Figure 1** and **Table 3**.

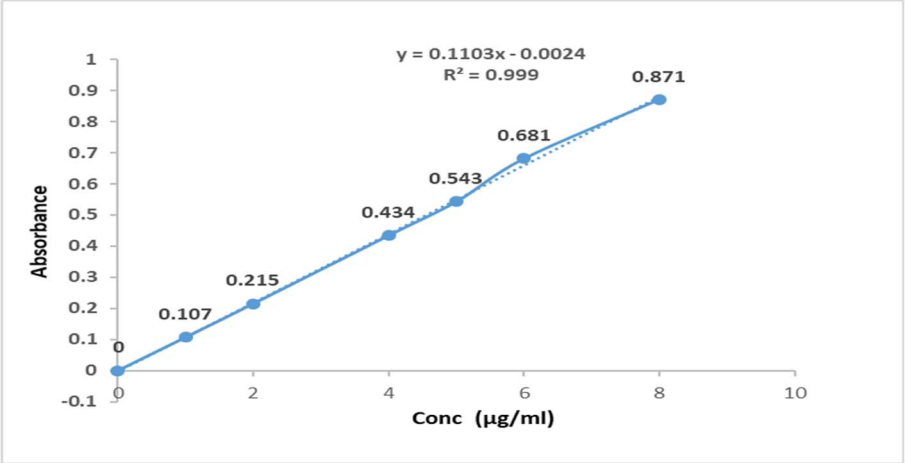

Figure 1: Standard graph of Montelukast sodium in Phosphate buffer pH 6.8 at 267nm

Table 3: Standard graph of Montelukast sodium in Phosphate buffer pH 6.8

Concentration (µg/ml)	Absorbance
0	0
1	0.107
2	0.215
4	0.434
5	0.543
6	0.681
8	0.871
10	1.074

Evaluation of pre-compression parameters for core powder formulations: Powder flow characteristics of montelukast sodium formulation are very important in processing operations and formulating procedures, as these flow properties of powders were determined by dose uniformity and ease of filling in a container. Powder flow characteristics are assessed in all formulations CF1 to CF3. The flow properties of all formulations were represented in **Table 4**. Results indicated that the angle of repose ranged from 32.06±0.11to 33.12±0.03 degrees, Carr's compressibility index ranging from 11±0.01 to 14±0.02 percent and Hausner's ratio from 1.11±0.04 to 1.15±0.02. The results showed that the angle of repose was < 35° showing good flow properties for all formulated powders (CF1 to CF3), confirming all powder formulations (CF1 to CF3) resulted in good compressible characteristics and flow ability.

Table 4: Pre compression parameters of Montelukast sodium powder formulations

Formulation code	Angle of repose (°)	Bulk density (gm/cm3)	Tapped density (gm/cm3)	Compressibility index (%)	Hausner's ratio
CF1	32.06±0.11	0.29 ±0.05	0.27±0.04	12±0.08	1.13±0.05
CF2	32.68±0.06	0.26±0.08	0.37±0.05	14±0.02	1.11±0.04
CF3	33.12±0.03	0.34±0.06	0.21±0.03	11±0.01	1.15±0.02

Data are expressed as Mean ± SD; n=3.

EVALUATION OF FORMULATED MONTELUKAST SODIUM CORE TABLETS AND COMMERCIAL TABLETS

Post compression parameters evaluation of core tablet and commercial tablets of montelukast sodium (MONTAIR-10)

Drug content uniformity, hardness, friability, and *in vitro* disintegration time: Drug content uniformity, hardness, friability, and in vitro disintegration time for core tablet and commercial tablets of montelukast sodium are depicted in **Table 5**. Drug content uniformity for both core and commercial tablets was observed to be >99%. The hardness values for core as well as commercial tablets were found to be 4.5±0.05 and 4.2±0.08 Kg per cm^2. Percent friability was performed to determine the capability of tablet to survive abrasion during, handling and transport. For core and commercial tablets were found to be 0.48±0.12% and 0.42±0.06 %, respectively. The *in vitro* disintegration time for core tablets were 18±0.12 seconds and for commercial tablets it was found as 80±0.09 seconds.

Table 5: Post-compression parameters of core tablets and commercial tablets

S. No.	Formulations	Optimized core tablet	Commercial tablet
1	Drug content uniformity (%)	99.36±0.21	99.24±0.44
2	Hardness (Kg/cm^2)	4.5±0.05	4.2±0.08
3	Friability (%)	0.48±0.12	0.42±0.06
4	*In vitro* disintegration time (sec)	18±0.12	80±0.09

1)mean± SD; n=10, 2) mean± SD; n=5, 3) mean± SD; n=10, 4) mean± SD; n=6.

Drug content uniformity, hardness, Friability, and *lag time. :* Table 6 represents the drug content uniformity, hardness, friability, and lag time values for the entire core coated tablet formulations (POF1 to POF9). The results indicated that the drug content values were ranged from 99.5±0.12 to 100.6±0.05. The hardness values ranged from 4.2±0.02 to 4.4±0.17 and friability values ranged from 0.59±0.04 to 0.64±0.05. The formulations POF1 to POF9 exhibited varying lag times followed by rapid release of montelukast sodium from the formulations. It was detected that with the, rise in the concentration of karaya gum, the lag time for the release of the drug from the formulations rise. A ratio of Gum karaya: Avicel pH 101 were present for the formulations (POF1) 133:0, (POF2)113:20, (POF3)103:30, (POF4)93:40, (POF5)83:50, (POF6)63:70, (POF7)53:80, (POF8)43:90 and (POF9)0:113. The corresponding lag time values were found to be 15±0.02, 9.5±0.13, 7.5±0.04, 4.5±0.01, 2.5±0.16, 2.0 ±0.15, 1.5±0.06,1.0±0.05 and 0.5±0.01 respectively for POF1 to POF9 formulations.

Table 6: Post-compression parameters of core-coated tablets

Formulation	POF 1	POF2	POF3	POF4	POF5	POF6	POF7	POF8	POF9
Drug content uniformity (%)	99.8 ±0.06	99.5 ± 0.12	100.6 ± 0.05	100.2 ± 0.02	99.7 ±0.14	99.9± 0.12	100.3 ± 0.02	99.9 ± 0.05	100.1 ± 0.04
Hardness (kg/cm^2)	4.2 ±0.02	4.5 ±0.01	4.5 ± 0.12	4.4 ±0.03	4.4 ± 0.11	4.5 ±0.05	4.4 ± 0.17	4.5 ± 0.01	4.3 ± 0.04
Friability (%)	0.62 ±0.14	0.61 ± 0.13	0.59 ± 0.04	0.63 ± 0.02	0.64 ± 0.05	0.60 ±0.15	0.63 ± 0.03	0.61 ± 0.12	0.62 ± 0.01
Lag time (hr.)	15 ± 0.02	9.5 ± 0.13	7.5 ± 0.04	4.5 ± 0.01	2.5 ± 0.16	2.0 ±0.15	1.5 ±0.06	1.0 ± 0.05	0.5 ± 0.01

1)mean± SD, n=10; 2) mean± SD, n=5; 3) mean± SD, n=10; 4) mean± SD, n=3.

Percent drug release of drug core (10mg), press coated tablet and commercial tablets (MONTAIR-10): The percent drug release of montelukast sodium form optimized core tablets and commercial tablets in pH 6.8 phosphate buffer is represented in **Table 7** and **Figure 2**. It was apparent from the table and figure that the optimized core tablet of montelukast sodium showed a little higher rate of in *vitro* drug release rates compared with commercial tablets of montelukast sodium.

Table 7: Percent drug release of drug core (10mg), press coated tablet and commercial tablets (MONTAIR-10)

Time (min)	Percent drug release Drug core(10m g)	Press coated tablet (10mg)	Percent drug release of commercial tablets (MONTAIR- 10)
0	0	0	0
5	25.27	27.56	24.61
10	60.36	61.46	59.88
15	85.42	87.5	70.19
20	89.96	91.75	82.75
30	90.55	92.9	80.05
45	90.99	92.95	80.34
60	91.43	93.36	81.4

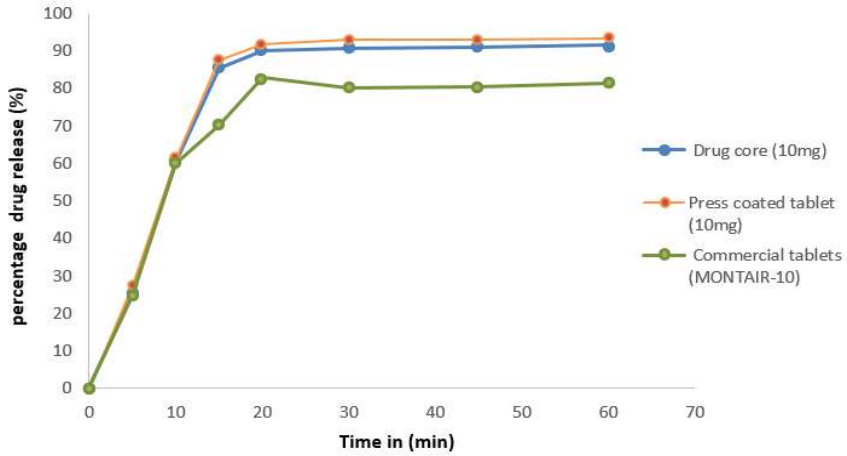

Figure 2: Percent drug release of drug core (10mg), press coated tablet and commercial tablets (MONTAIR-10)

CHARACTERIZATION OF PRESS COATED TABLETS OF MONTELUKAST SODIUM

Fourier Transform Infrared Spectroscopy (FTIR): The spectra of placebo, Montelukast sodium core, Core coated and Standard Montelukast sodium (API) were taken **Figures 3, 4, 5, 6, and Table 8.** The pure Montelukast sodium exhibits representative peaks at 3257.92 cm^{-1} (N-H stretch) ,1702.79 cm^{-1} (C-O stretch),1583.23 cm^{-1} (C=C) and 1488.43 cm^{-1} (C-N Aromatic). All these peaks have appeared in Montelukast sodium press coated tablets (POF4) at 3257.44 cm^{-1}(N-H stretch),1721.81 cm^{-1} (C-N stretch),1599.27 cm^{-1} (C=C) and 1507.36 cm^{-1} (C-N Aromatic), indicating no interactions between Montelukast sodium and excipients in press coated tablets formulation

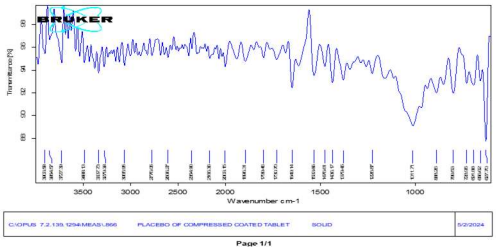

Figure 3: FTIR of placebo of press coated tablet

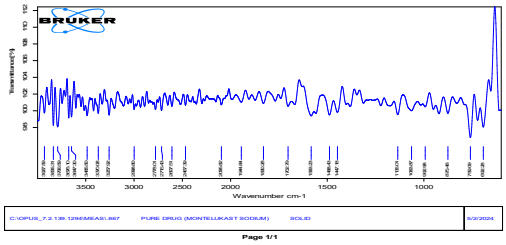

Figure 4: FTIR of pure drug (Montelukast sodium)

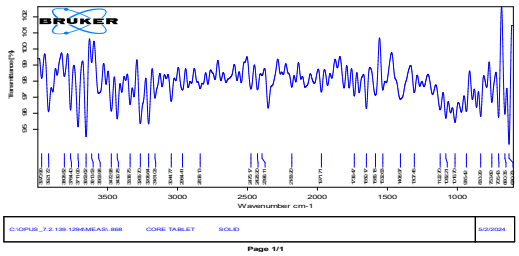

Figure 5: FTIR of coated tablet

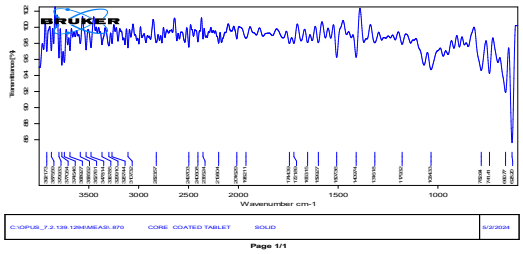

Figure 6: FTIR of press coated tablet

Table 8: Characeristic peaks of Montelukast sodium and Montelukast sodium press coated tablets

Functional group	Drug Range (Peak) cm^{-1}	Montelukast sodium Pure drug cm^{-1}	Montelukast sodium press coated tablet cm^{-1}
N-H	3000-3318	3257.92	3257.44
C-O	1670-1735	1702.79	1721.81
C=C	1496-1685	1583.23	1599.27
C-N (Aromatic)	1452-1496	1488.43	1507.36

Scanning electron microscopy (SEM): The surface morphology of montelukast sodium press-coated tablet, montelukast sodium core tablet, and standard montelukast sodium (API) were examined by scanning electron microscopy (Model: SEM S3400N, Make: HITACHI) **Figure 7**. The SEM images indicate that there was no deposition or aggregation of particles on the surface of press coated tablets.

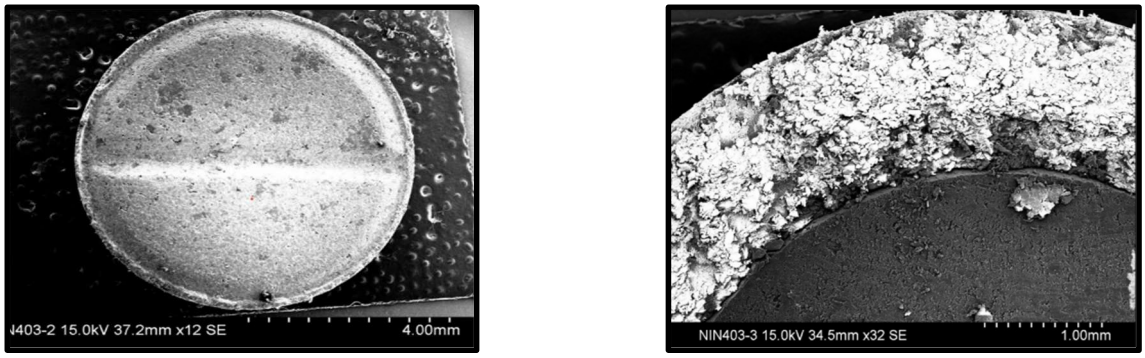

Figure 7: Scanning electron microscopy (SEM) image of a)press coated tablet, b) core and press coated tablet

Differential Scanning Calorimetry (DSC): The physical states along with the thermal behaviour of the drug in montelukast sodium core tablets and standard montelukast sodium (API), were discovered from thermo gram of DSC, using differential scanning calorimeter (DSC: TADSC 2500). It is shown from **Figure 8** that the peak temperature was found at 76.64°C and 72.98°C for core tablets and pure drug respectively. This demonstrates that there was no evidence polymorphic change happening in these two samples.

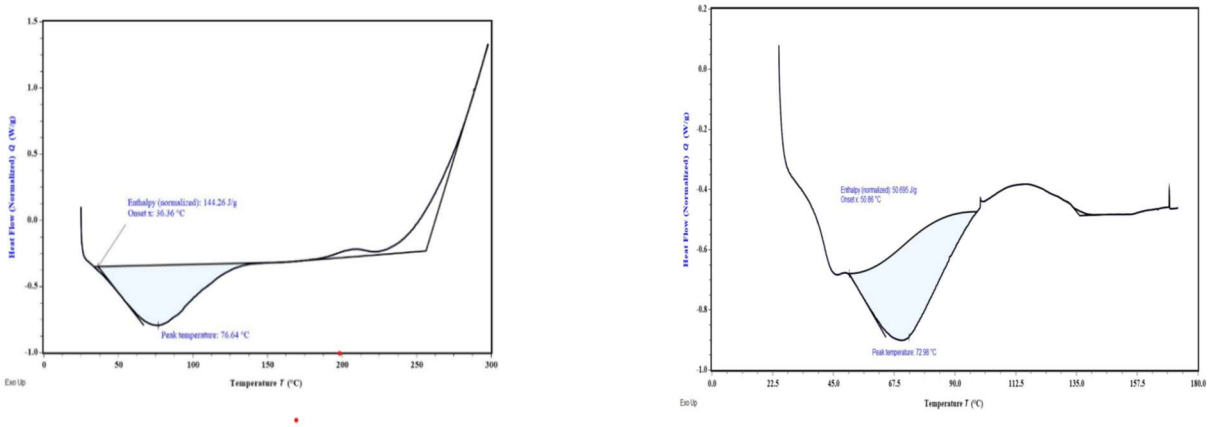

Figure 8: DSC thermo grams of a) montelukast sodium core tablets b) standard montelukast sodium (API)

Powdered X-Ray diffraction study(P-XRD): The pure drug exhibited many representative high-intensity diffraction peaks demonstrating the crystalline character of montelukast sodium **Figure 9**. The peak at around 22.42(2Θ) agrees to the main peak in the montelukast sodium press coated tablet. The same peak also found in the core tablet with the drug at 22.48(2Θ). Indicating the crystalline nature of montelukast sodium in both the press coated and core tablets.

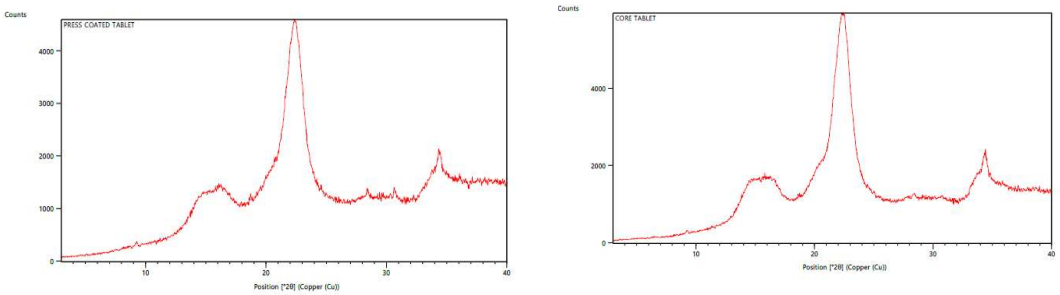

Figure 9: P-XRD of montelukast sodium press coated tablet and core tablet

CONCLUSION

This study was focused on the development and evaluation of montelukast sodium core and coated tablets by using the press coating technique. Varying the proportions of PROSOLV SMCC HD90 and AC-Di-Sol in core tablet formulations (CF1 to CF3). CF2 core formulation was optimized based on preliminary studies mainly disintegration time and friability. Nine possible combinations of Gum karaya and Avicel pH 101 were formulated (POF 1 to POF9). These formulated tablets of all batches (POF 1 to POF9) were subjected to post compression parameters and POF4 Formulation (Gum karaya and Avicel pH101 in the ratio 93:40) with a lag (delay) time of 4.5 hours before the burst (sudden) release of the drug was observed. Hence POF4 formulation was measured as optimized formulation. This POF4 formulation was subjected to dissolution studies along with core, press coated tablet and commercial tablets (Montair-10). The optimized POF4 optimized formulation was subjected to FTIR, SEM, DSC and P-XRD characterization studies. The studies from FTIR, SEM, DSC and P-XRD shown that there was not detected any interactions among the drug (API) and excipients of the formulation. Therefore, from the overhead study it was concluded that gum karaya is appropriate for the development of press coated tablets with montelukast sodium. Overall, the study successfully developed and evaluated montelukast sodium .

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