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Research Article

DESIGN DEVELOPMENT AND EVALUATION OF MODIFIED RELEASE TABLET OF MONTELUKAST SODIUM BY DRY COMPRESSION AND TABLET COATING

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ABSTRACT
In this particular study tablets were prepared by the dry compression method using roller compactor. The compressed tablets were then coated with the HP 55 and HP 50 coating polymer in the various concentration. The dissolution was carried out in the USP Basket apparatus. The drug release profile was very different for all the formulation as the concentration of the coating polymer varied in all the formulation.

KEYWORDS: Montelukast sodium, Roller compactor, tablet coating.

INTRODUCTION
The cysteinyl leukotrienes (LTC4, LTD4, LTE4) are the products of aracidonic acid metabolism and are released from various cells, including mast cells and eosinophils. This eicsanoids bind to cysteinyl leukotriene (CysLT) receptors. The CysLT (CysLT1) receptors is found in human airway (including airway of smooth muscles and airway macrophages) and on other pro inflammatory cells (including eosinophils and certain myeloid stem cells). CysLT have been co related with pathophysiology of asthma and allergic rhinitis. In the present study the tablets were prepared by the dry compression method using the mini Roller compactor. The slugs obtain were pass through the oscillating granulator on which the sieve no 40 was attach. For the tablet coating HP 50 and HP 55 was utilize in various concentration. The main of applying the coating polymer in various concentration was to see that how optimum concentration of the coating polymer is required to get the sustain release for upto 12 hr. The main aim of designing this particular dosage was that it should release the drug more than 95%.

MATERIALS AND METHODS
Montelukast sodium was obtained from Zydus Cadila Healtcare Ahmedabad. HP 50, HP 55 was obtained as a gift sample from Strides Arco Lab Bangalore.

Procedure for dry granulation
All the ingredient mention in the above formula other than coating material were mixed properly.
The blend was passed in the mini roller compactor.
The slug were obtain as the thin long rod.
The slug was pass in the oscillating granulator having the sieve no 40 beneath it.
The desired shape granules were obtain.

Procedure for preparation of tablets
Mg stearate was weighed and passed through mesh no 60
Using Mg stearate above blend was lubricated.
The lubricated blend was directly compressed on 10 station rotatory machine using 9.5mm round standard concave punches.

Procedure for the tablet coating

The compressed tablets were coated with the different concentration of the coating polymer mention in the formula.

Pan coater was utilized to perform the coating.

Along with the tablet dummy tablets were also placed so that uniform coating is applied to the tablets.

Dissolution Studies

The dissolution of coated tablet was carried out for 12 hrs, for first two hr it was carried out in pH 1.2 buffer solution and for the next 10 hr it was carried out in pH 7.2 buffer solution. The dissolution was carried out using USP basket app. After every 1 hr 5 ml sample was withdrawn and was analyzed using UV spectrophotometer at max absorbance at 350 nm.

RESULT AND DISCUSSION

From the dissolution studies it was seen that formula no 1, 2, 4 and 5 were unable to give the sustain release of the drug from the tablet, the simple reason for this must be that the coating polymer which was used for this formula were of the low concentration.

In the formula no 3 and 6 the drug release was more than 95%.

So it can be concluded that in the formula no 3 and 6 the coating polymer utilize were of the optimum concentration.

ACKNOWLEDGEMENT

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Table 1: Formulation 1 preparation of tablet by dry compression

Sr. No	Ingredients	Qty per Tab (mg)	Qty for 50 tablets (mg)
1	Montelukast Sodium	10	500
2	Microcrystalline cellulose	170	8500
3	Croscarmellose sodium	50	2500
4	HP 50 (10 %)	70	3500

Table 2: Formulation 2 preparation of tablet by dry compression

Sr. No	Ingredients	Qty per Tab (mg)	Qty for 50 tablets (mg)
1	Montelukast Sodium	10	500
2	Microcrystalline cellulose	170	8500
3	Croscarmellose sodium	50	2500
4	HP 50 (20 %)	70	3500

Table 3: Formulation 3 preparation of tablet by dry compression

Sr. No	Ingredients	Qty per Tab (mg)	Qty for 50 tablets (mg)
1	Montelukast Sodium	10	500
2	Microcrystalline cellulose	170	8500
3	Croscarmellose sodium	50	2500
4	HP 50 (40 %)	70	3500

Table 4: Formulation 4 preparation of tablet by dry compression

Sr. No	Ingredients	Qty per Tab (mg)	Qty for 50 tablets (mg)
1	Montelukast Sodium	10	500
2	Microcrystalline cellulose	170	8500
3	Croscarmellose sodium	50	2500
4	HP 55 (10 %)	70	3500

Table 5: Formulation 5 for preparation of tablet by dry compression

Sr. No	Ingredients	Qty per Tab (mg)	Qty for 50 tablets (mg)
1	Montelukast Sodium	10	500
2	Microcrystalline cellulose	170	8500
3	Croscarmellose sodium	50	2500
4	HP 55 (20%)	70	3500

Table 6: Formulation 6 for preparation of tablet by dry compression

Sr. No	Ingredients	Qty per Tab (mg)	Qty for 50 tablets (mg)
1	Montelukast Sodium	10	500
2	Microcrystalline cellulose	170	8500
3	Croscarmellose sodium	50	2500
4	HP 55(40 %)	70	3500

Time	Drug Release					
	Formula 1	Formula 2	Formula 3	Formula 4	Formula 5	Formula 6
1	0	0	0	0	0	0
2	12	25	10	10	10	10
3	18	38	15	15	15	15
4	23	57	25	36	36	36
5	38	67	38	85	85	47
6	45	77	42	97	97	55
7	98	84	52	0	0	65
8	0	94	67	0	0	72
9	0	0	75	0	0	81
10	0	0	85	0	0	88
11	0	0	92	0	0	94
12	0	0	96	0	0	95

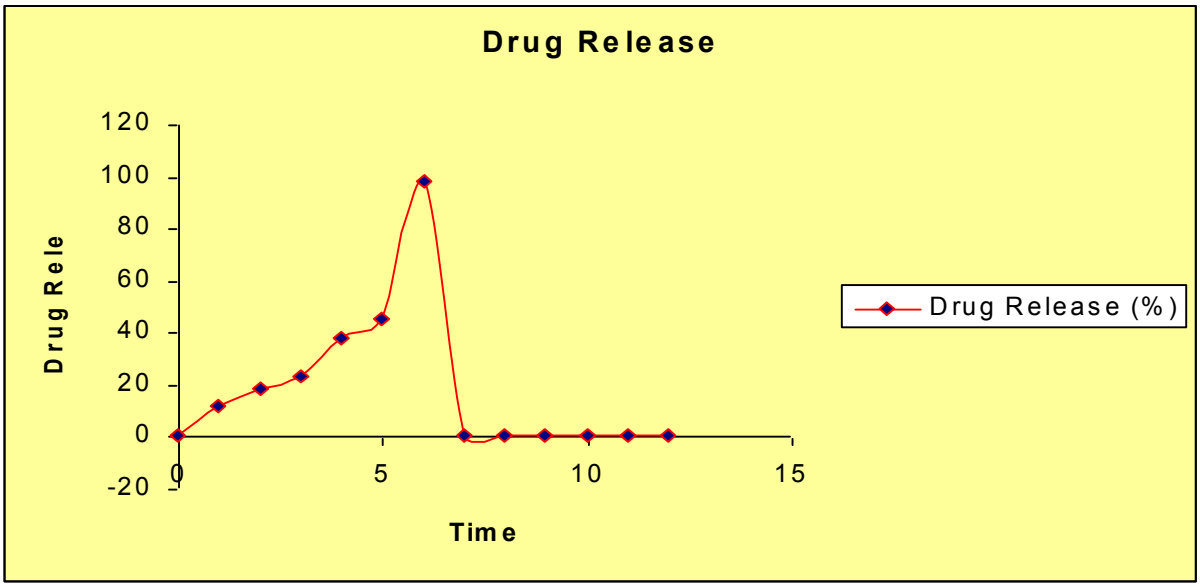

Fig 1: Cumulative percent drug release for formulation 1

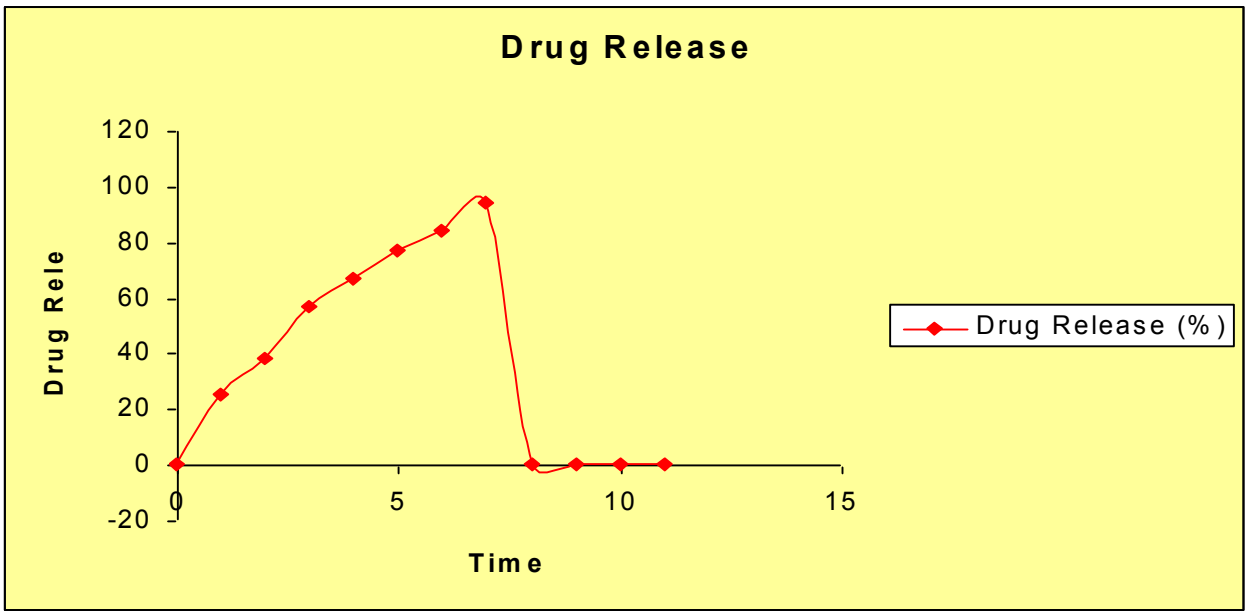

Fig 2: Cumulative percent drug release for formulation 2

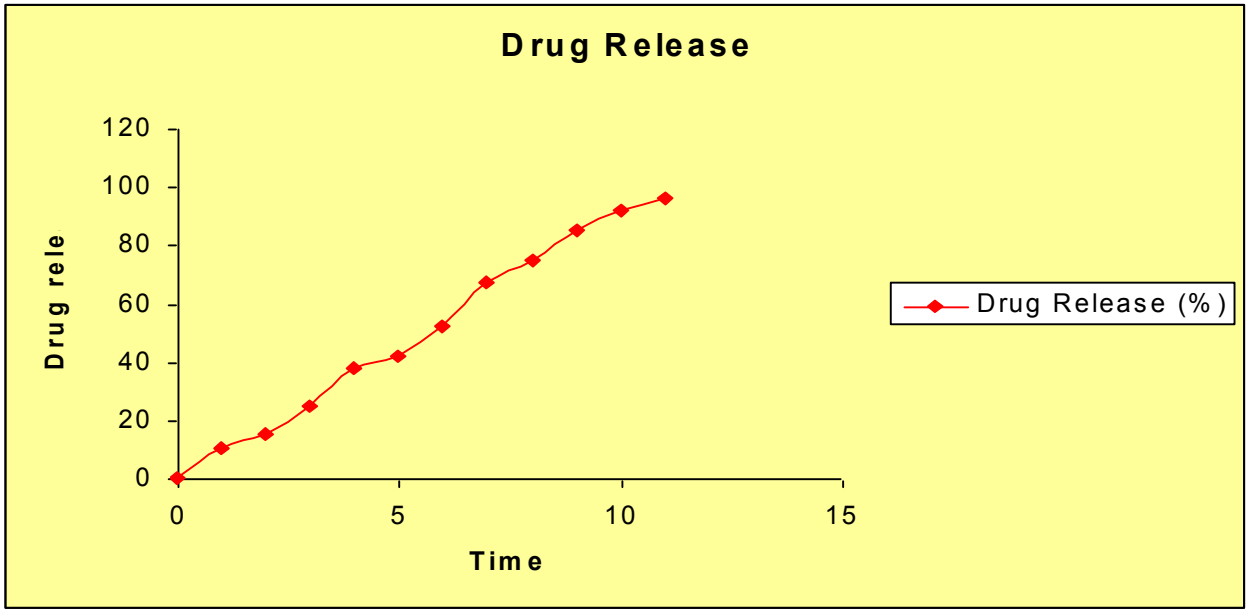

Fig 3: Cumulative percent drug release for formulation 3

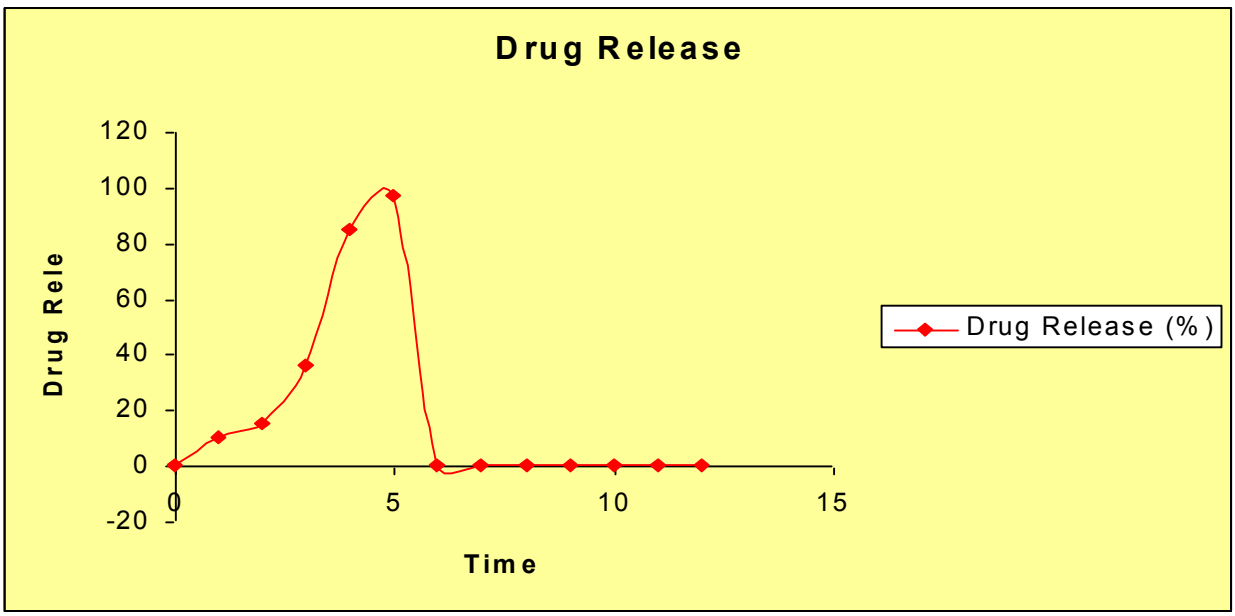

Fig 4: Cumulative percent drug release for formulation 4

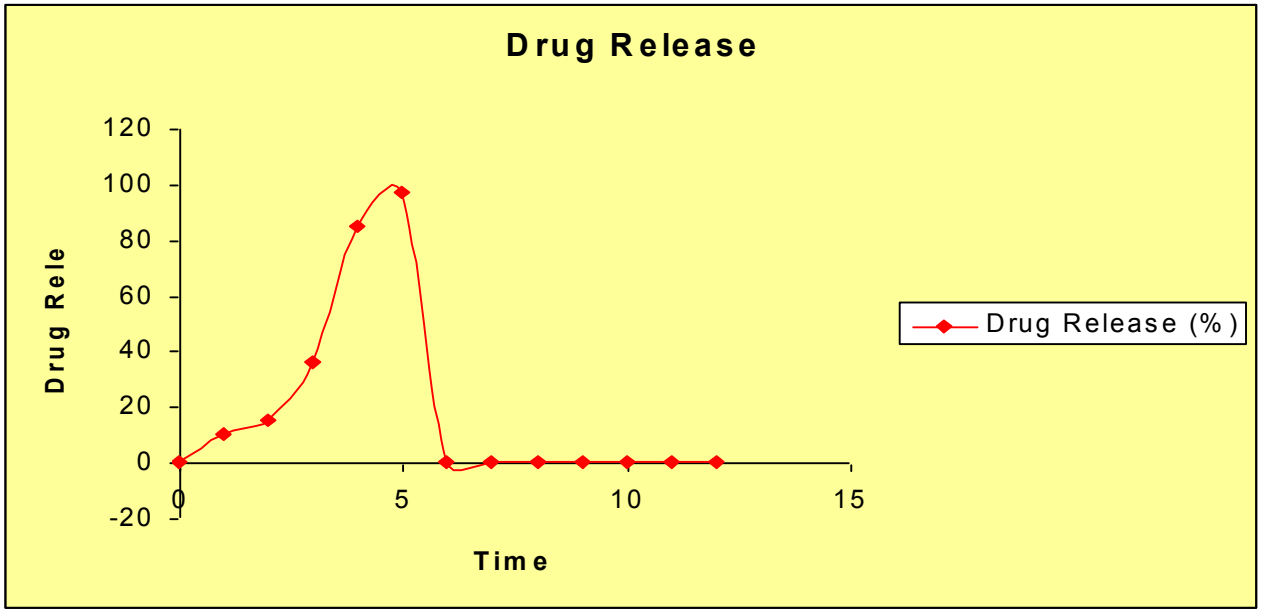

Fig 5: Cumulative percent drug release for formulation 5

Fig 6: Cumulative percent drug release for formulation 6

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