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Research Article

DESIGN DEVELOPMENT AND EVALUATION OF MODIFIED RELEASE TABLET OF MONTELUKAST SODIUM

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ABSTRACT
The purpose of this research was to prepare a modified release tablet of montelukast sodium. Montelukast sodium is Leukotriene antagonist which is rapidly absorbed after the oral administration. At first the drug was spray dried, the complex obtained was mixed with the other excipient and tablets were compressed using 10 station tablet rotary press. The compressed tablets were coated with different coating polymer like HP 50, HP 55 and Eudragit S. The tablets were evaluated for drug release by carrying out the dissolution and UV spectroscopy.

KEYWORDS: Spray drying, Montelukast sodium, Tablet coating.Montelukast sodium

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 are 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. The poor solubility and wet ability of Montelukast sodium leads to poor dissolution and hence variation in bioavailability. Thus increasing the dissolution is of therapeutic importance. A large number of researches had been carried out to improve the dissolution rate. Various techniques like spray drying, solid dispersion, use of polymer like cyclodextrin had been employed to enhanced the dissolution. HPMC 8cps, 5cps and 3cps one of the promising polymer both at research level as well commercial level was used for this particular study in order to improve its dissolution rate. The tablet coating was applied using various polymers like HP 50, HP55 and Eudragit S in various coating proportion.

MATERIALS AND METHODS
Montelukast sodium was obtained from Zydus Cadila Healtcare Ahmedabad. HPMC 8 cps, 5 cps and 3 cps, HP 50, HP 55 and Eudargit S was obtain as a gift sample from Strides Arco Lab Bangalore.

The spray drying was performed by dissolving the drug in ethanol in which various grade of HPMC were dissolved. The table 1 to 3 show how the spray drying was carried out, as shown in the table in each formula the polymer used were of various grade and as the low viscosity polymer were utilized the assay was improved and % yield of the obtain complex was also better compare to the formula no 1 to 9. The complex was weighed according to the assay and was utilized for the compression of the tablets. As seen in the table 4, 5 and 6 the tablets were compressed using 10 station rotary press, the tablet were coated with the various polymer in varying proportion. For formula 1 the tablet were coated with HP 50 10 %, in formula 2 the tablets were coated with HP 55 10 %, and in formula 3 tablets were coated with Eudragit S 10 %. For the formula 5 the tablets were coated with HP 50 30 %, in formula 5 the tablets were coated with HP 55 % 30 %, and in formula 6 the tablets were coated with Eudragit S 30 %. For

formula 7 the tablets were coated with the HP 50 50 %, for formula 8 tablets were coated with HP 55 50 % and for formula 9 tablets were coated with Eudragit S 50 %.

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 solutions 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 analysed using UV spectrophotometer at max absorbance at 350 nm.

RESULT AND DISCUSSION

From the spray drying method and dissolution release viscosity play an important role in the drug release. The polymer concentration also plays an important role in release of the drug from the tablets.
Hence it can be concluded that formula no 4, and 6 gave the satisfactory drug release.

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Table 1

Material	Formula 1	Formula 2	Formula 3
API(gm)	20	20	20
HPMC 8 Cps (gm)	10	15	30
Water (ml)	150	150	100
Ethanol (ml)	..	50	100
Assay	85	85	85

Table 2

Material	Formula 7	Formula 8	Formula 9
API(gm)	20	20	20
HPMC 3 Cps (gm)	10	15	30
Water (ml)	150	150	100
Ethanol (ml)	..	50	100
Assay	98	98	98

Table 3

Material	Formula 4	Formula 5	Formula 6
API(gm)	20	20	20
HPMC 5 Cps (gm)	10	15	30
Water (ml)	150	150	100
Ethanol (ml)	..	50	100
Assay	94	93	98

Table 4: Tablet compression of spray dried complex

Material	Formula 1	Formula 2	Formula 3
Spray dried complex	17.64	17.64	17.64
Mannitol	204.16	204.16	204.16
MCC	60.00	60.00	60.00
Red ferric oxide	0.2	0.2	0.2
Croscarmellose sodium	9.00	9.00	9.00
Aspartame	3.00	3.00	3.00
Vanilin flavor	3.00	3.00	3.00
Mg Stearate	3.00	3.00	3.00
tablet wt	300.0	300.0	300.0

Table 5: Tablet compression of spray dried complex

Material	Formula 4	Formula 5	Formula 6
Spray dried complex	11.00	10	10
Mannitol	239	230	230
MCC	60.00	60.00	60.00
Red ferric oxide	0.2	0.2	0.2
Croscarmellose sodium	9.00	9.00	9.00
Aspartame	3.00	3.00	3.00
Vanilin flavor	3.00	3.00	3.00
Mg Stearate	3.00	3.00	3.00
tablet wt	300.0	300.0	300.0

Table 6: Tablet compression of spray dried complex

Material	Formula 7	Formula 8	Formula 9
Spray dried complex	10.61	10.61	10.61
Mannitol	211.19	211.19	211.19
MCC	60.00	60.00	60.00
Red ferric oxide	0.2	0.2	0.2
Croscarmellose sodium	9.00	9.00	9.00
Aspartame	3.00	3.00	3.00
Vanilin flavor	3.00	3.00	3.00
Mg Stearate	3.00	3.00	3.00
tablet wt	300.0	300.0	300.0

Table 7: Dissolution profile

Time (hr)	Formula 1	Formula 2	Formula 3
0	0	0	0
1	43	43	40
2	52	52	57
3	54	54	64
4	55	55	65
5	57	57	66
6	59	59	68
7	60	60	70
8	98	98	95
9	0	0	0
10	0	0	0
11	0	0	0
12	0	0	0

Table 8: Dissolution profile

Time (hr)	Formula 4	Formula 5	Formula 6
0	0	0	0
1	15	21	21
2	25	36	34
3	36	45	43
4	48	47	45
5	52	56	58
6	59	67	65
7	65	71	72
8	72	78	76
9	79	79	82
10	85	88	89
11	88	92	91
12	94	97	97

Table 9: Dissolution profile

Time (hr)	Formula 7	Formula 8	Formula 9
0	0	0	0
1	12	14	16
2	15	17	21
3	19	23	34
4	21	28	38
5	34	34	44
6	42	39	48
7	48	41	51
8	51	48	57
9	55	52	65
10	61	55	74
11	70	60	75
12	71	64	80

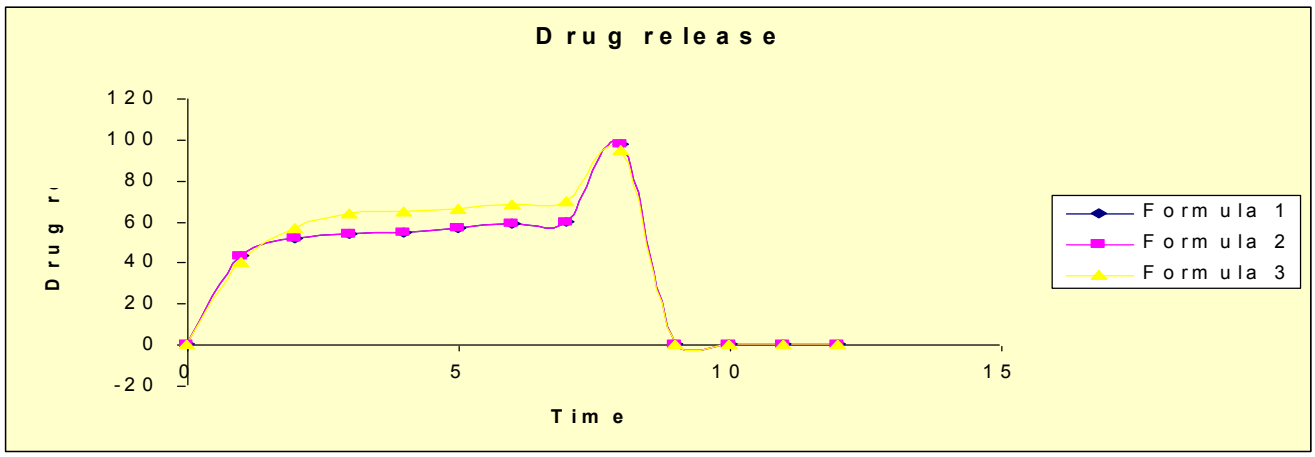

Fig 1: Dissolution release pattern

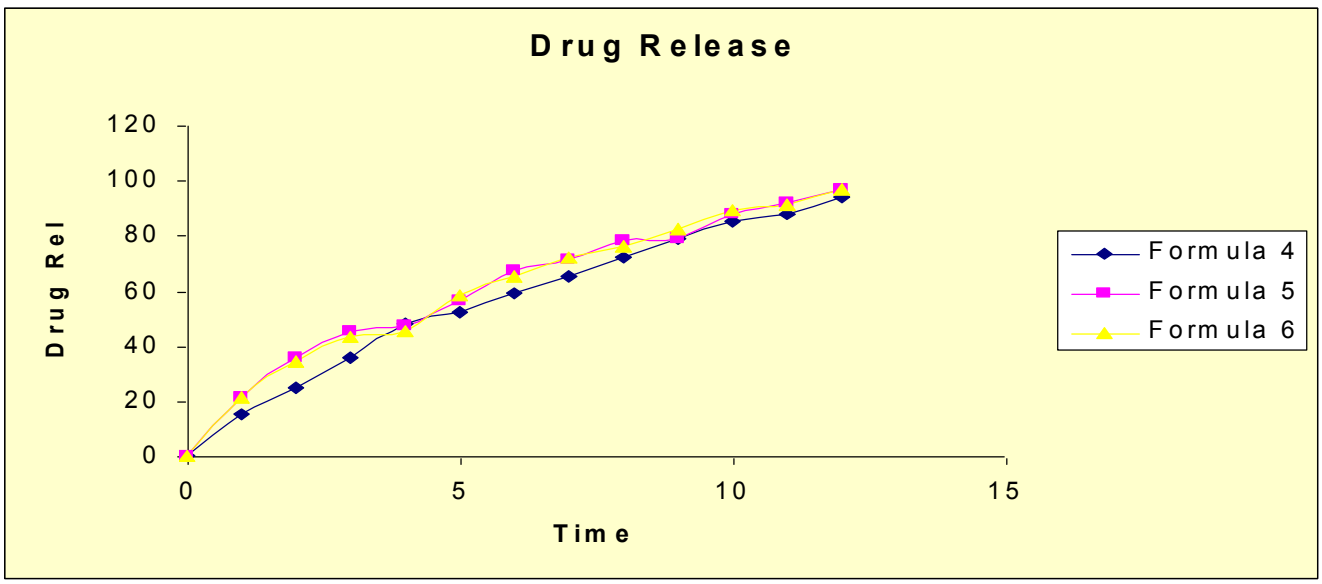

Fig 2: Dissolution release pattern

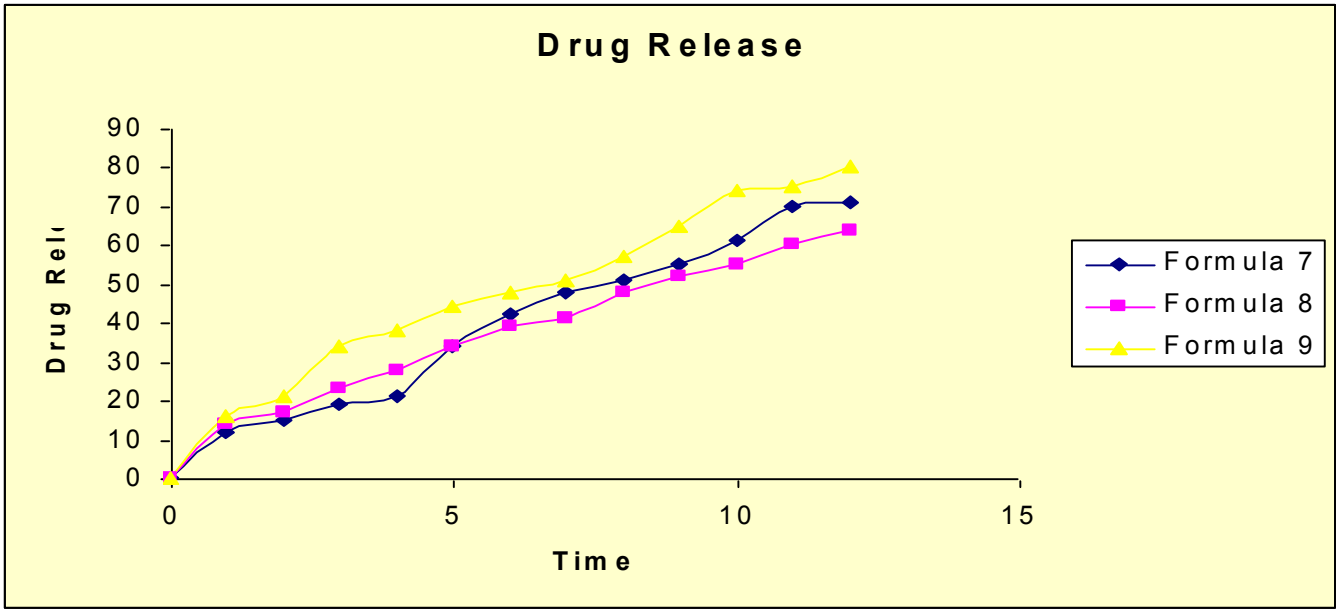

Fig 3: Dissolution release pattern

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