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Research Article

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

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ABSTRACT
In this present study the pellets of the Montelukast sodium were prepared in the FBD which were compressed by using the MCC as the diluent. The compressed tablets were than coated with the coating polymer like Eudragit L and Eudragit S in the varying concentration. The dissolution of the tablets was carried out in the USP Basket apparatus and the drug release was studied for all the coated tablets.

KEYWORDS: Montelukast sodium, MCC, Tablet coating.

INTRODUCTION
Pelletization is a technique which is playing a dominant role in last two to three decades in the field of the pharmaceutical. It has been applied for various pharmaceutical functions like taste masking, control release, sustain release and many more. In this particular study sugar beads 20/40 were used for the preparation of pellets. Mini FBD was utilized for carrying out the process of pelletization. The main API was dissolved in the ethanol and it was sprayed on the beads which were loaded in the FBD and maintain in the fluidized state by the bottom spray method. After the pellets were formed assay was carried out and after the assay required amount of the pellets were mixed with MCC and the blend was compressed using 10 station tablet rotary press. For carrying out the coating pan coater was utilize. Eudragit L and Eudragit S was utilize as the coating polymer in the varying concentration.

MATERIALS AND METHODS
Montelukast sodium was obtained from Zydus Cadila Healthcare Ahmadabad. Eudragit L and Eudragit S were obtained as the gift sample from Degussa pharmaceutical Mumbai.

Procedure for the formation of pellets
For the formulation of pellets sugar beads were used.
Montelukast sodium was dissolved in ethanol.
The sugar beads were loaded in the mini FBD and were maintain in the fluidized state.
The solution of the montelukast sodium was sprayed on the fluidized sugar beads.
After the loading of the drug the pellets were dried in the same equipment.

Procedure for compression of tablets
The pellets were mixed with MCC.
Using Mg stearate above blend was lubricated. The lubricated blend was directly compressed on 8 station rotatory machine using 9.5mm round standard concave punches.

Tablet Coating
The compressed tablet was coated with using pan coater.
The coating solution of Eudragit L and Eudragit S were applied in the various concentrations as shown in the above formulation.

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

In the various formulation of the tablet coating various concentration of the coating polymer were employed.

From the drug dissolution profile it was studied that low concentration of the coating polymer where unable to sustain the drug release of the drug from the tablet which was the main aim of these study.. Hence formula 3 and 6 shows that coating polymer employed in this formula was of the optimum concentration.

And shown in the table below formula 3 and 6 have the drug release more than 95%.

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Table 1: Formulation 1 preparation of tablet by compression of pellets

Sr. No	Ingredients	Qty per Tab (mg)	Qty for 50 tablets (mg)
1	Drug loaded pellets	45	2250
2	MCC	205	10250
3	Eudragit L (5%)	50	2500

Table 2: Formulation 2 preparation of tablet by compression of pellets

Sr. No	Ingredients	Qty per Tab (mg)	Qty for 50 tablets (mg)
1	Drug loaded pellets	45	2250
2	MCC	205	10250
3	Eudragit L (10%)	50	2500

Table 3: Formulation 3 preparation of tablet by compression of pellets

Sr. No	Ingredients	Qty per Tab (mg)	Qty for 50 tablets (mg)
1	Drug loaded pellets	45	2250
2	MCC	205	10250
3	Eudragit L (25%)	50	2500

Table 4: Formulation 4 preparation of tablet by compression of pellets

Sr. No	Ingredients	Qty per Tab (mg)	Qty for 50 tablets (mg)
1	Drug loaded pellets	45	2250
2	MCC	205	10250
3	Eudragit S (5%)	50	2500

Table 5: Formulation 5 preparation of tablet by compression of pellets

Sr. No	Ingredients	Qty per Tab (mg)	Qty for 50 tablets (mg)
1	Drug loaded pellets	45	2250
2	MCC	205	10250
3	Eudragit S (10%)	50	2500

Table 6: Formulation 6 preparation of tablet by compression of pellets

Sr. No	Ingredients	Qty per Tab (mg)	Qty for 50 tablets (mg)
1	Drug loaded pellets	45	2250
2	MCC	205	10250
3	Eudragit S (25%)	50	2500

Table 7: Drug release profile for all the formulation

Time	Drug Release					
	Formula 1	Formula 2	Formula 3	Formula 4	Formula 5	Formula 6
0	0	0	0	0	0	0
1	14	14	14	15	14	15
2	15	15	21	56	24	24
3	45	45	28	98	38	38
4	98	54	37	0	58	41
5	0	65	49	0	75	48
6	0	95	55	0	89	56
7	0	0	66	0	95	65
8	0	0	72	0	0	73
9	0	0	79	0	0	82
10	0	0	88	0	0	91
11	0	0	91	0	0	95
12	0	0	96	0	0	98

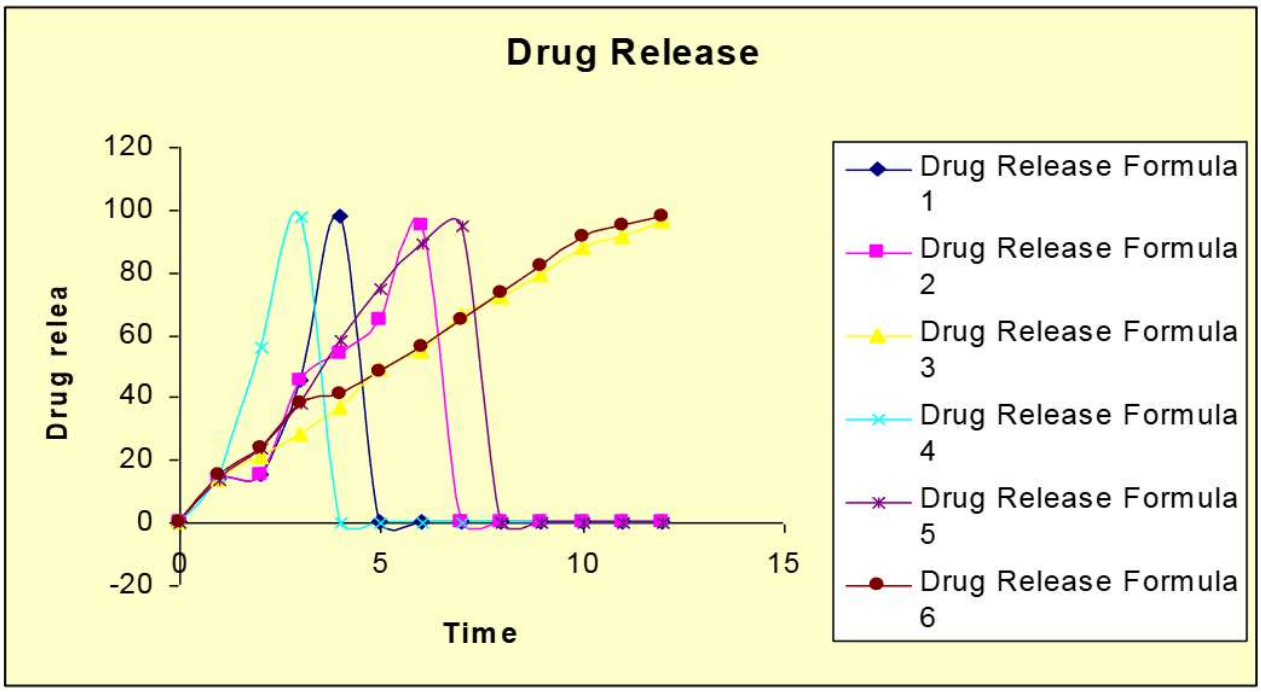


Fig 1: Drug release pattern for all the formulation

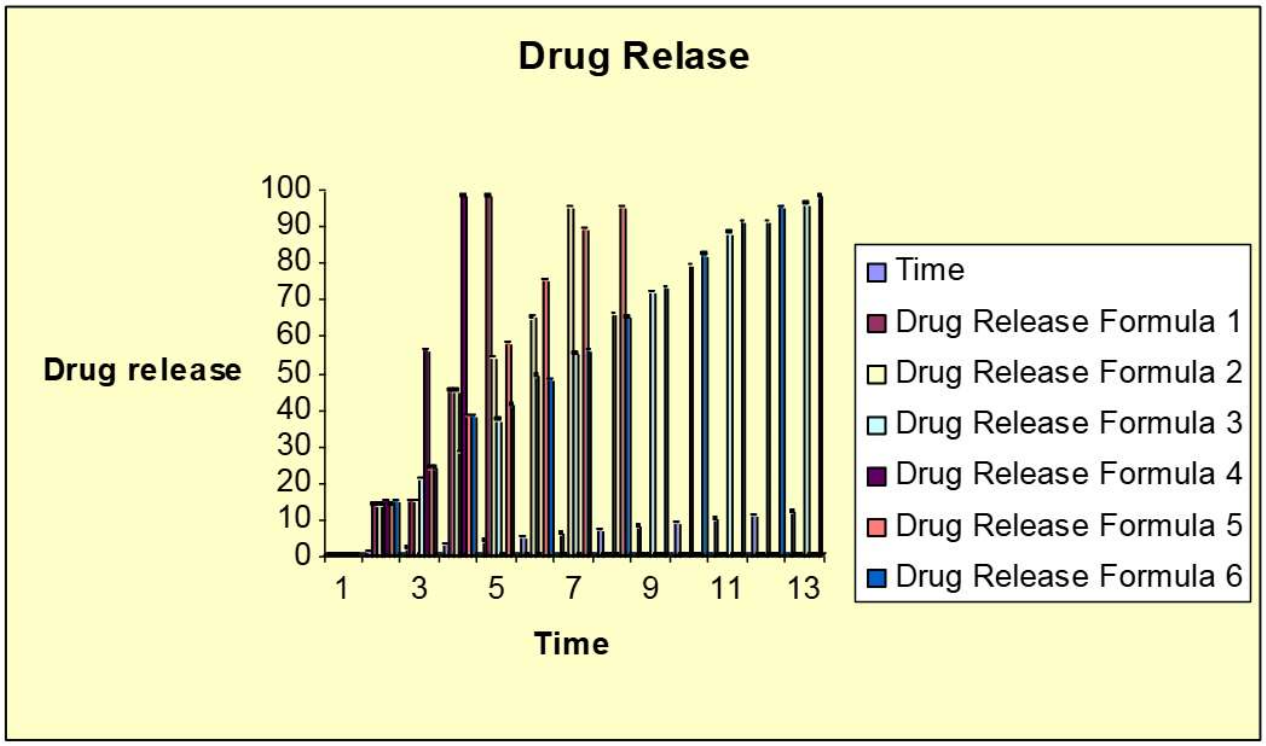


Fig 2: Drug Release Comparison

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