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Research Article

DESIGN DEVELOPMENT AND EVALUATION OF MODIFIED RELEASE TABLET OF MONTELUKAST SODIUM USING ETHYL CELLULOSE AND TRAGACANTH

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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. The drug was mixed with Ethyl Cellulose and Tragacanth as a dry binder and ethanol was used as solvent to perform the granulation in FBD by the bottom spray method. The granules obtain were mixed with the other ingredients and were compressed using 10 station tablet rotary press. The dissolution was carried out using USP paddle apparatus.

KEYWORDS: FBD, Montelukast sodium, Ethyl Cellulose.Introduction:

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 tablets were prepared by using the ethyl cellulose and tragacanth as a binder. The method adopted was dry binder method as the binder was directly added to prepare the blend with the drug. The ethanol acts as the solvent which was sprayed on the blend using in the FBD by bottom spray method. The granules obtain were dried in the same FBD in which the actual granulation was carried out. The tablets were compressed using the 10 station tablet rotary press.

MATERIALS AND METHODS

Montelukast sodium was obtained from Zydus Cadila Healtcare Ahmedabad. Ethyl Cellulose and Tragacnth was obtained as a gift sample from Oral Laboratories Daman.

The granules were formulated by mixing all the material shown in the table below. The blend was loaded in the FBD. The blend was maintained in the fluidized state. The ethanol which acts as the solvent was sprayed on the blend by the bottom spray method. The granules formed were dried in the same instrument and were compressed using 10 station rotary press.

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 analysed using UV spectrophotometer at max absorbance at 350 nm.

RESULT AND DISCUSSION

As seen from the table given below drug release profile there was no satisfactory drug release from formula 1, 2 and 3.

In the formula no 4, 5 and 6 there was satisfactory drug release.

As the tablets was required to sustain the drug release for 12 hr formula 1,2 and 3 was unable to do that as the tablet totally disintegrated at 9^{th} hr.

In the formula 4,5 and 6 the drug release was up to 96 % and it was able to release the drug up to 12 hr.

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Table 1

Sr.no	Material	Qty Per Tab	Qty Per 50 Tab
1	Montelukast Sodium	10	500
2	MCC	210	10500
3	Croscarmellose sodium	50	2500
4	Ethyl Cellulose	10	500
5	Tragacanth	20	1000

Table 2

Sr.no	Material	Qty Per Tab	Qty Per 50 Tab
1	Montelukast Sodium	10	500
2	MCC	200	10000
3	Croscarmellose sodium	50	2500
4	Ethyl Cellulose	10	500
5	Tragacanth	20	1500

Table 3

Sr.no	Material	Qty Per Tab	Qty Per 50 Tab
1	Montelukast Sodium	10	500
2	MCC	190	9500
3	Croscarmellose sodium	50	2500
4	Ethyl Cellulose	20	1000
5	Tragacanth	30	1500

Table 4

Sr.no	Material	Qty Per Tab	Qty Per 50 Tab
1	Montelukast Sodium	10	500
2	MCC	140	7000
3	Croscarmellose sodium	50	2500
4	Ethyl Cellulose	50	2500
5	Tragacanth	50	2500

Table 5

Sr.no	Material	Qty Per Tab	Qty Per 50 Tab
1	Montelukast Sodium	10	500
2	MCC	170	8500
3	Croscarmellose sodium	50	2500
4	Ethyl Cellulose	20	1000
5	Tragacanth	50	2500

Table 6

Sr.no	Material	Qty Per Tab	Qty Per 50 Tab
1	Montelukast Sodium	10	500
2	MCC	180	9000
3	Croscarmellose sodium	50	2500
4	Ethyl Cellulose	30	1500
5	Tragacanth	30	1500

Table 7: Dissolution Release profile of all formula

Time	Drug Release					
	Formula 1	Formula 2	Formula 3	Formula 4	Formula 5	Formula 6
1	12	12	22	10	10	10
2	17	17	25	15	15	15
3	25	25	28	25	25	25
4	36	36	32	38	38	38
5	38	38	45	49	42	42
6	40	40	49	55	52	52
7	43	43	56	68	67	67
8	0	55	62	71	75	75
9	0	60	65	78	85	85
10	0	0	0	88	92	92
11	0	0	0	92	96	96
12	0	0	0	98	96	98

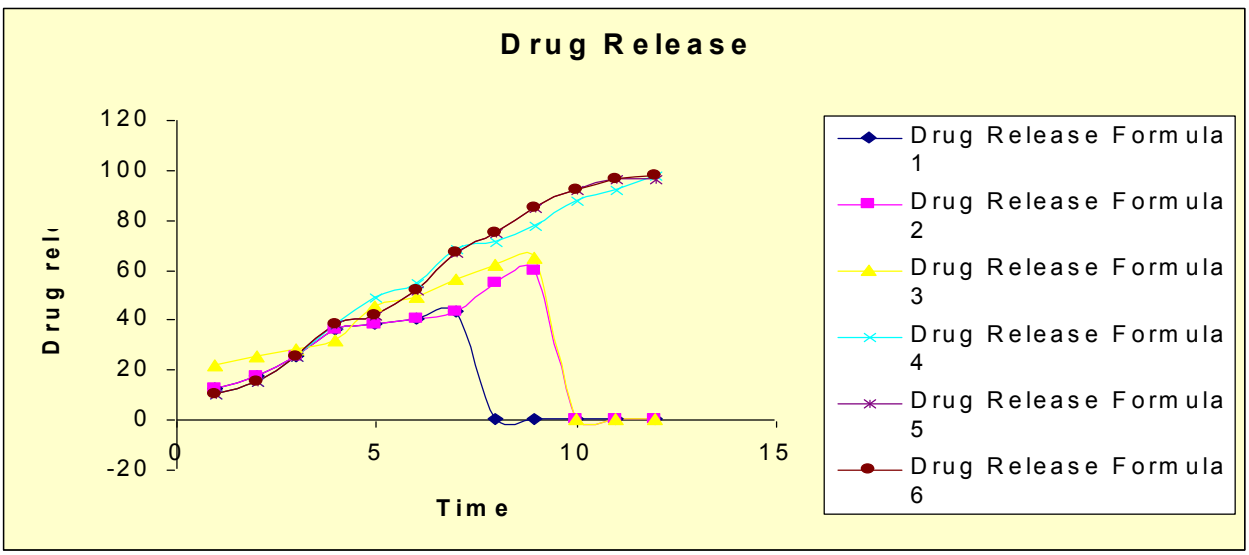

Fig 1: Cumulative percent drug release for all formula

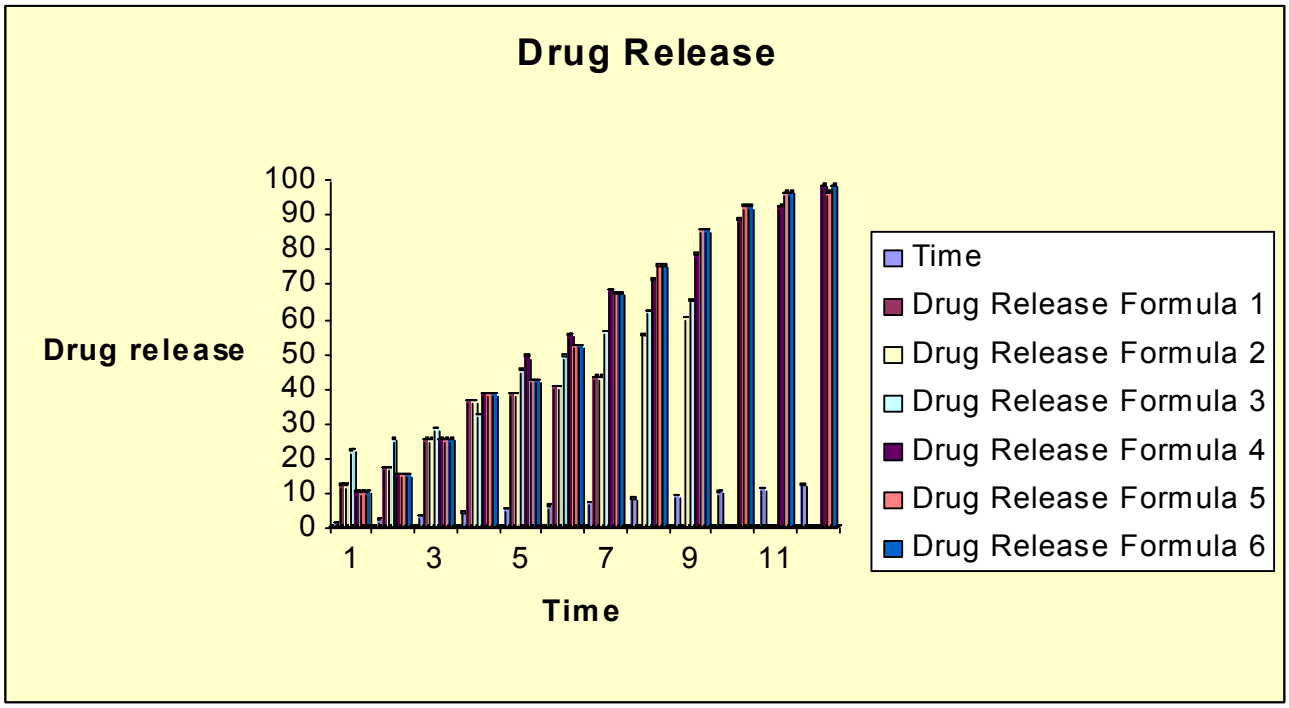

Fig 2: Comparison of drug release for all formula

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