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FORMULATION AND EVALUATION OF DELAYED RELEASE TABLETS OF RABEPRAZOLE

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ABSTRACT

The Rabeprazole sodium is a proton pump inhibitor which is used in the treatment of peptic ulcer. In this study Rabeprazole compression coated tablets were prepared by using HPMCK4M as a compression coating polymer. Nine formulations of compression coated tablets of Rabeprazole were developed by preparing core tablets using microcrystalline cellulose as diluent as in different proportions and varying the composition of compression coating using HPMCK4M, HPMCK15M and ethyl cellulose. The core tablets were prepared by direct compression method. Among all the formulations, F1 was found to be best of all the formulations showing drug release matching the innovator product so to that formulation all the quality control tests were done for conformation. Stability study is carried out at 25°C; 60% RH and 40 °C; 75% RH according to ICH guidelines. The tablets were tested for acid release during the stability period and conformed that results were found within the limits.

KEYWORDS: Rabeprazole sodium, microcrystalline cellulose, peptic ulcer, ethyl cellulose and ICH guidelines.

INTRODUCTION

The oral administration of drugs represents the most common way of drug application due to its high patient acceptance. The major portion of the oral drug delivery comprises of tablets, solid unit dosage forms, having higher patient acceptance. There is a revolutionary improvement in the technology of both in conventional as well as controlled drug delivery systems.[1,2]

The immediate release drug delivery systems are particularly used to produce fast therapeutic drug plasma levels. This results in reduction or loss in drug effectiveness or also increased incidence of side effects. Modified release drug delivery systems include the systems with pH dependent, extended, delayed or pulsed drug release. Sustained, extended or prolonged release drug delivery devices, by contrast, are delayed release dosage forms have to be distinguished from the ones mentioned as they exhibit a more or less pronounced lag time before drug release.[3,4,5]

A delayed release dosage form is designed to release the drug at a time other than promptly after administration. Dosage forms can be designed to modify the release of the drug over a given time or after the dosage form reaches the required location.[6,7]

Delayed release oral dosage forms can control where the drug is released, e.g. when the dosage form reaches the small intestine (enteric-coated dosage forms) or the colon (colon-specific dosage forms). Delayed Release systems release a bolus of the drug after a predetermined time in a predetermined location, i.e. they do not release the drug immediately after ingestion, for example enteric-coated tablets, pulsatile-release capsules.[8,9]

Delayed release dosage forms are designed to provide spatial placement or temporal targeted delivery of a drug to the distal human gut. Spatial placement relates to targeting a drug to a specific organ or tissue, while temporal delivery refers to desired rate of drug release to target tissue over a specified period of time. The primary aim of using delayed release products is to protect the drug from gastric fluids, to reduce gastric distress caused by drugs particularly irritating to the stomach or to facilitate gastrointestinal transit for drugs that are better absorbed from intestine. Delayed Release products are typically enteric-coated or targeted to the colon.[10,11]

MATERIALS AND METHODS

Table 1: List of Instruments.

S. No.	INSTRUMENT	MODEL
1	Electronic balance	Sartorius, India
2	Bulk density apparatus	Electro lab USP, Bangalore
3	Digital pH meter	Serve well Pvt. Ltd, Bangalore
4	Digital Vernier callipers	Data Scientifics, Bangalore
5	Octagonal blender	Anchor mark Pvt. ltd, India
6	Tablet hardness tester	IEC, Mumbai
7	Disintegration test apparatus	Electro lab, Bangalore
8	Dissolution test apparatus	Electro lab, Bangalore

Table 2: List of Materials.

S. No.	MATERIAL	CATEGORY
1	Rabeprazole	Active Ingredient
2	Microcrystalline ellulose	Diluents
3	Talc	Lubricant and glidant
4	Magnesium stearate	Lubricant
5	Ethyl cellulose	Coating agent
6	Microcrystalline ellulose	Diluent
7	Talc	Lubricant and glidant

Formulation Development

Table 3: Core tablet formulation.

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Rabeprazole	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Microcrystalline ellulose	25.0	25.0	25.0	25.0	25.0	25.0	25.0	25.0	25.0
Magnesium stearate	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
Talc	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5

Table 4: Coating Formulation.

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
HPMCK4M	50	100	150	-	-	-	-	-	
HPMCK15M	-	-	-	50	100	150	-	-	-
Ethyl cellulose	-	-	-	-	-	-	50	100	150
Microcrystalline cellulose	140	90	40	140	90	40	140	90	40
Magnesium stearate	5	5	5	5	5	5	5	5	5
Talc	5	5	5	5	5	5	5	5	5
Total weight	250	250	250	250	250	250	250	250	250

Preparation of core tablets

Accurately weighed quantity of Rabeprazole, microcrystalline cellulose, and talc were sifted through sieve #30 and mixed thoroughly for 10 minutes in octagonal blender to ensure uniform mixing. Then accurately weighed magnesium stearate was sifted through sieve #40 and added to above blend and mixed properly for 5mins. The tablets we prepared by direct compression technique using 11x6mm oval shaped punch.

Preparation of compression coating formulation

Weighed the required amount of HPMCK15M, K4M (compression coating material), required amount of microcrystalline cellulose and add to above coating material. Finally add required quantity of magnesium stearate and talc, mixed well. 200mg coating formulation were prepared for each core tablet. Punch the tablet, keep the core tablet middle of the coating formulation (100mg up side of tablet and down side) using 8mm direct compression.

RESULTS AND DISCUSSIONS

Preformulation Results

Table 5: Results of Preformulation.

S. No.	Characteristics	Result
1	Organoleptic valuation	White to slightly yellowish-white solid
2	Solubility analysis	Very soluble in water, Very soluble in methanol Freely soluble in ethanol, chloroform, and ethyl acetate, in soluble in ether and n-hexane
3	Bulk density	0.5214gm/ml
4	Tap density	0.7684gm/ml
5	Compressibility index	32.14%
6	Hausner' ratio	01.473
7	Melting point	Because of gradual degradation of Rabeprazole during heating, the melting point cannot be determined
8	Molecular weight	381.43

In-vitro Dissolution

Table 6: Dissolution profile of Rabeprazole.

Time points	F1	F2	F3	F4	F5	F6	F7	F8	F9
30	17.06	11.07	5.38	6.26	14.98	14.01	6.89	10.56	4.13
1	23.72	17.87	11.01	16.75	27.71	17.78	11.23	14.83	12.76
2	32.11	21.76	27.76	21.98	38.62	23.98	13.25	22.71	20.94
3	48.89	48.09	35	39.06	53.86	38.33	26.78	39.56	27.38
4	54.98	59.45	41.52	56.83	69.78	47.42	33.56	47.87	31.65
5	61.66	71.56	48.72	74.57	80.42	54.83	37.49	52.94	39.96
6	70.07	87.69	56.83	87.94	91.92	65.19	48.46	61.47	46.61
7	78.43	94.01	61.38	97.59	99.85	72.46	56.79	69.10	51.75
8	86.07	101.43	70.57	103.67	100.10	77.15	64.91	72.80	59.63
9	90.89		77.48			84.96	76.49	74.13	64.19
10	98.84		86.82			93.78	82.46	82.97	73.46

In-vitro Dissolution Studies

Comparative Dissolution Profile of Rabeprazole

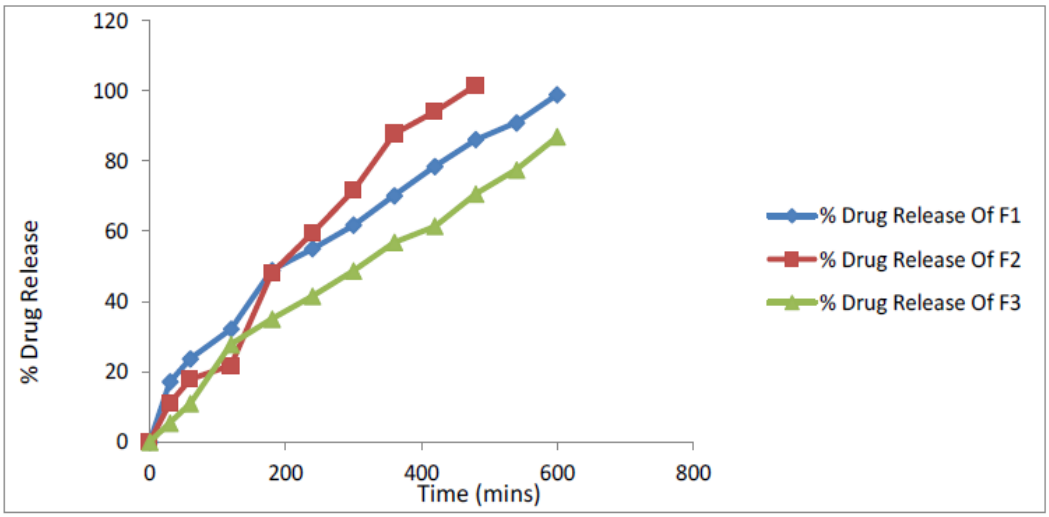

Figure 1: Comparative dissolution profile of Rabeprazole F1, F2 and F3.

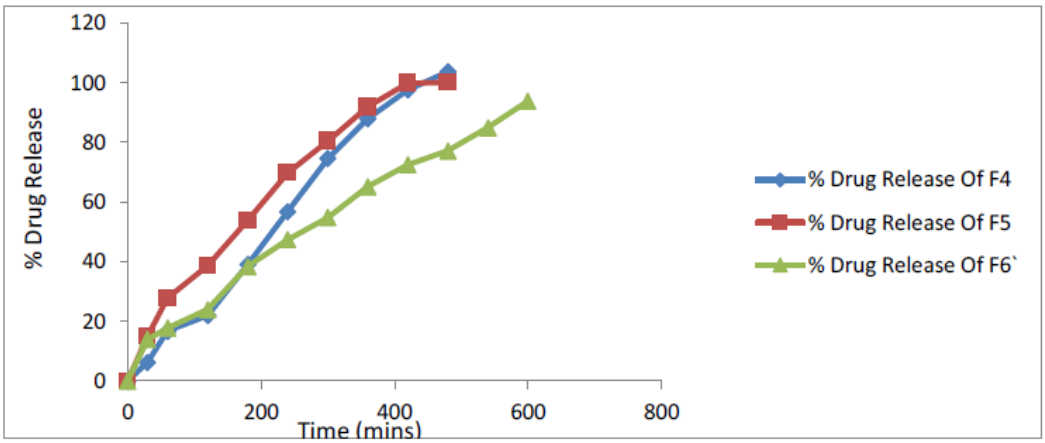

Figure 2: Comparative dissolution profile of Rabeprazole F4, F5 and F6.

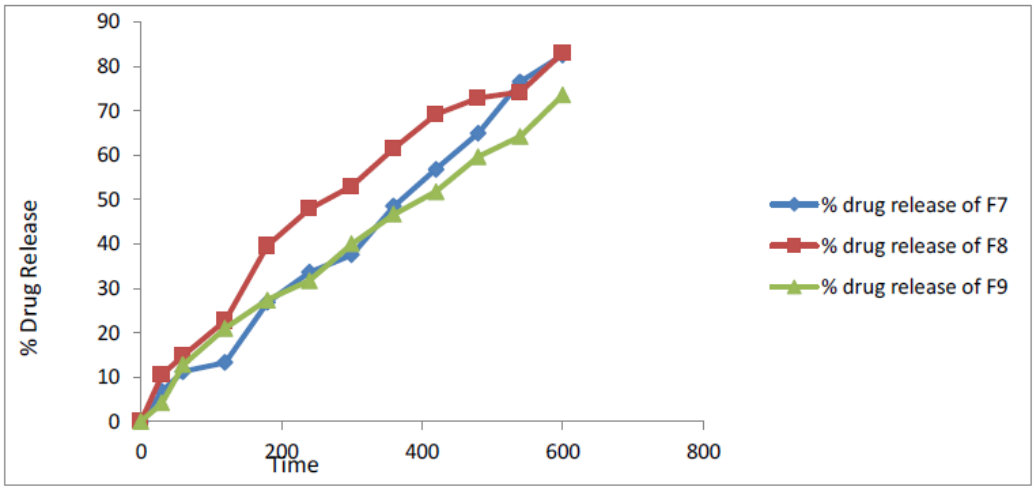

Figure 3: Comparative dissolution profile of Rabeprazole F7, F8 and F9.

Stability Studies

Table 7: Stability studies of formulation.

Batch number And stability condition	Description	Acid release in 0.1N HCL (%)	Dissolution study in pH 6.8 buffer
Room temperature	Light yellow coloured compression coated tablet	1.90%	94.38%
40C /75% (1month)	Light yellow coloured compression coated tablet	2.09%	92.23%
40C /75% (2month)	Light yellow coloured compression coated tablet	2.20%	92.01%
25C/60% (1month)	Light yellow coloured compression coated tablet	2.12%	93.04%
25C/60% (2month)	Light yellow coloured compression coated tablet	1.80%	91.36%

CONCLUSION

The Rabeprazole sodium is a proton pump inhibitor which is used in the treatment of peptic ulcer. In this study Rabeprazole compression coated tablets were prepared by using HPMCK4M as a compression coating polymer. Nine formulations of compression coated tablets of Rabeprazole were developed by preparing core tablets using microcrystalline cellulose as diluent as in different proportions and varying the composition of compression coating using HPMCK4M, HPMCK15M, ethyl cellulose. The core tablets were prepared by direct compression method. Among all the formulations, F1 was found to be best of all the formulation showing drug release matching the innovator product so to that formulation all the quality control tests were done for conformation. Stability study is carried out at 25°C; 60% RH and 40 °C; 75% RH according to ICH guidelines. The tablets were tested for acid release during the stability period and conformed that results were found within the limits. The identified formula shall be utilized for the formulation development and other studies for successful launching of the product.

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