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FORMULATION OF BUPROPION HCL PRESS COATED TABLETS FOR PULSATILE DELIVERY AND INVITRO EVALUATION

[1]*Rasheed Shaik, [2]Lakshmi Niharika Kinnera, [3]Venkata Vinod Kumar Gajula

[1]Department of Pharmaceutics, Chennupati Indo-American School of Pharmacy, Narasaropeta, 522601, Andhra Pradesh, India.

[2]Department of Pharmaceutical Analysis, A.M. Reddy Memorial College of Pharmacy, Narasaraopet, 522601, Andhra Pradesh, India.

[3]Department of Pharmaceutics, V.V. Institute of Pharmaceutical Sciences Gudlavalleru, 521356 Andhra Pradesh, India.

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***Corresponding Author**

Rasheed Shaik

Department of Pharmaceutics, Chennupati Indo-American School of Pharmacy, Narasaropeta, 522601, Andhra Pradesh, India.

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ABSTRACT

Development and evaluation of bupropion press coated tablets via core tablets comprising of polymers such as Ethyl cellulose, HPMC K4M and super disintegrants including lycoat and Ludiflash is what this study sets out to achieve. It can be reasonably stated that TC3 of core tablet was considered and prepared formulations PD1-PD5, from these preparations of coated tablet, PD5 was chosen as optimized formulation for designing a Pulsatile Device since repeatable results were obtained from trails of core and press coated tablets. This was due to the fact that among TC1-TC8 formulations, TC3 had the highest percentage drug release of 96.42% at 40 minutes. Thus, it has been proved that press coated bupropion can be used as time dependent chronopharmaceutical preparation. On this basis, it can be finally concluded that pulsatile drug delivery system for bupropion can be developed using ethyl cellulose and HPMC K4M.

KEYWORDS: Bupropion, Pulsatile Delivery, ludiflash, Lycoat, Ethyl cellulose & HPMC K4M.

INTRODUCTION

Bupropion Hydrochloride is an antidepressant that is usually given to treat major depression disorder (MDD) and seasonal affective disorder (SAD) and Smoking Cessation. In may also be used in aid of smoking quitting, called cocktail commercially as Zyban. Bupropion differs with SSRIs in the sense that not only does it raise serotonin but it also inhibits the re-absorption of norepinephrine and dopamine, thus increasing the availability of these neurotransmitters in the brain.[1] It is a system that helps it act as an antidepressant and to help reduce dependence on nicotine. Bupropion HCl is a BCS Class I meaning that it is highly soluble and highly permeable. It is readily absorbed in the gut and immediate-release forms peak at 2-3 hours of intake. It is however highly subject to first-pass metabolism thus synthesizing metabolites such as hydroxybupropion which is pharmacologically active.[2] Since it has a relatively short half-life with respect to elimination, i.e., 3 to 4 hours, and since it has various side effects including rebound effects , controlled or prolonged releases may be needed. Such systems aid in keeping the plasma drug levels at the same level which ultimately enhance the therapeutic treatment and curb the potential of negative response due to constantly changing levels of drugs. The current study is aimed to formulate pulsatile delivery of Bupropion Hcl to release the drug in a controlled manner for a longer period of time.[3]

The Core tablets of Bupropion Hcl were prepared by adding superdisntegrants like lycoat, ludiflash. The bottom part of the capsule is altered to make it insoluble in stomach by using crosslinking polymers like Formaldehyde and the Hydrogel plug was prepared by using Ethyl cellulose & HPMC K4M.

MATERIALS: All of the above ingredients, except Lycoat and Ludiflash, were obtained from Roquette, India PVT LTD, Mumbai. Microcrystalline cellulose, talc, and magnesium stearate were sourced from S.D. ine CHEM, Mumbai. HPMCK4M, and Ethyl Cellulose were acquired from NR CHEM, Mumbai. Bupropion Hcl was obtained from BMR Labs PVT Ltd.

METHODS

Preparation of core tablets of Bupropion: Core tablets of Buprion were prepared by direct compression by adding the following ingredients.[4]

Table 1: Formulation of Core tablets of Bupropion Hcl.

Ingredients (mg)	TC1	TC2	TC3	TC4	TC5	TC6	TC7	TC8
Bupropion	150	150	150	150	150	150	150	150
Ludiflash	5	10	15	20	--	--	--	--
Lycoat	--	--	--	--	5	10	15	20
MCC	90	85	80	75	90	85	80	75
Mg.stearate	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
Total wt (mg)	250	250	250	250	250	250	250	250

Evaluation of Powder blend & core Tablets

The blended powders & core tablets are evaluated for their flow properties like Bulk Density, Tapped Density, Compressability Index, Hausner's Ratio & angle of repose and post compression parameters like Weight Variation Test, Thickness, Hardness, Friability, disintegartion and dissolution.[5]

Preparation of Coated Tablets

Direct compression the compression was done by blending various powder mixtures of Ethyl Cellulose & HPMCK4M for 10 Minutes then the optimized core tablet composition was coated the core blend and the coating material was transferred into dye and the core is coated with the coating material.[6]

Table 2: Formulation of Coated Tablets of Bupropion Hcl.

Coat	PD1	PD2	PD3	PD4	PD5
Tablet core	250	250	250	250	250
Ethyl Cellulose	100	--	25	75	50
HPMC K4M	--	100	75	25	50
Total	350	350	350	350	350

Post Compression Parameters of the Coated tablets[7]

Weight Variation Test

In order to determine whether there is the right amount of medicine in a tablet, the weight of the tablet was continuously measured during the process of manufacturing of the tablet. This process is done by weighing 20 tablets separately for the USP weight variation test.

Thickness

Thickness is measured by using screw gauge 10 weighed tablets were taken and the average thickness is measured and the standard deviation is reported.

Hardness

It is measured by using Monsanto hardness tester three tablets from each batch were taken and the hardness of the individual tablet is measured.

Friability

The Roche Friabilator has a rotating plastic drum containing the tablets that rotate at a speed of 55 rpm for 4 minutes. The friability test was done by taking twenty tablets, weighing them, loading them in the device, and spinning the tablets at 100 rpm. Then, the tablets were wiped with a smooth muslin cloth.

Friability = 1-Wo/W x 100

Disintegration

Six tablets from each batch are randomly selected and placed in a disintegration apparatus with 900 milliliters of Ph 6.8 buffer maintained at 37±0.5 °C and operated at 30±2 cycles per minute.[8]

Dissolution Studies: The study of dissolution tests on coated tablets was done using two dissolution media viz. 0.1N Hcl and 6.8PH phosphate buffer solution. Initially the study is done using 500 ml of dissolution media (0.1N HCl). In dissolution apparatus 25 ml of the dissolution medium was withdrawn and the remaining 475ml will be used in the buffer medium dissolution studies. To 475ml of the sample solution (0.1N hydrochloric acid), 425ml of 6.8pH phosphate buffer solution containing SLS (0.3%). Adjust the pH to 6.8 by the addition of dilute orthophosphoric acid / dilute sodium hydroxide. The test was done in dissolution apparatus maintained at temperature of 37±0.5°C with speed of agitation of 75 rpm. Every hour, 5ml of solution was withdrawn and 5 ml fresh dissolution medium was added. Filter the solutions and measure the absorbance of the solutions at 237nm.[9]

Dissolution Parameter Evaluation

Dissolution Parameters like Zero order, First Order Kinetics Higuchi's and Peppa's Plot were plotted.[10]

Determination of Drug Excipient Compatability

FTIR

FTIR spectra for Bupropion Hcl, Excipients and the optimized formulation were obtained using a Brucker FTIR spectrophotometer. This analysis assessed the drug-carrier interactions

in the patches.[11] The sample analysis required 2 mg of drug substance mixed with 200 mg potassium bromide followed by spectral analysis between 400 to 4000 cm^{-1}. Results are shown in Figures.

RESULTS AND DISCUSSION

Evaluation of Core Tablets: Core tablets of Bupropion Hcl were prepared according to formulations CT1 to CT8 by employing various ratios of Lycoat and Ludiflash as Superdisintegrating agents to facilitate immediate release at the intestine.

The parameters for pre-compression for CT1 to CT8 have been calculated like bulk density, tapped density, compressibility index, Hausner's ratio, and angle of repose. The results are tabulated in Table No.

Table 3: Precompression Parameters of Core Tablets of Bupropion.

Formulation Code	Bulk Density	Tapped Density	Compressability Index	Hausner's Ratio	Angle of Repose
TC1	0.373±0.15	0.470±0.86	14.61±0.02	1.20±0.53	27.85±0.15
TC2	0.387±0.23	0.484±0.24	17.54±0.52	1.29±0.49	25.28±0.18
TC3	0.353±0.78	0.468±0.39	15.74±0.36	1.28±0.63	29.32±0.63
TC4	0.398±0.64	0.489±0.15	14.31±0.98	1.11±0.18	28.51±0.85
TC5	0.375±0.26	0.462±0.50	17.25±0.42	1.15±0.42	27.12±0.21
TC6	0.369±0.41	0.452±0.26	18.84±0.15	1.22±0.15	29.47±0.15
TC7	0.372±0.28	0.453±0.30	19.68±0.15	1.20±0.24	27.54±0.24
TC8	0.375±0.35	0.472±0.18	14.79±0.15	1.24±0.17	28.42±0.14

Table4: Post Compression Parameters of Core Tablets of Bupropion Hcl.

Formulation Code	Weight Variation	Thickness	Hardness	Friability	Disintegration
TC1	2.32	2.43	3.8	0.70	20
TC2	2.27	2.30	3.9	0.40	16
TC3	1.02	2.58	3.8	0.64	29
TC4	1.45	2.52	4.1	0.76	10
TC5	2.26	2.41	3.7	0.98	21
TC6	2.05	2.43	3.2	0.84	18
TC7	2.12	2.47	3.1	0.72	17
TC8	2.30	2.86	3.4	0.68	19

Dissolution Studies: The prepared Core tablets of Bupropion were subjected to dissolution studies in order to know the amount drug release from the dissolution studies conducted CT3 was found to have better release compared to other formulations hence it is used to formulate the coated tablets.

Table 5: Dissolution Profile of Core Tablets of Bupropion Hcl.

Time (Mins)	TC1	TC2	TC3	TC4	TC5	TC6	TC7	TC8
0	0	0	0	0	0	0	0	0
5	15.25	27.36	40.18	44.18	25.48	35.08	45.89	42.89
10	27.76	40.42	55.83	58.83	37.82	40.48	58.24	55.24
15	38.23	55.35	63.45	68.49	47.45	48.05	69.42	64.42
20	42.48	65.63	76.62	82.65	58.21	64.78	74.19	76.19
30	60.52	78.49	89.42	89.48	61.48	75.36	80.46	85.46
40	76.43	85.31	96.42	91.51	70.82	85.09	89.78	92.53
50	82.75	93.53		96.24	78.49	90.31	96.53	
60	96.41				84.46	95.75		

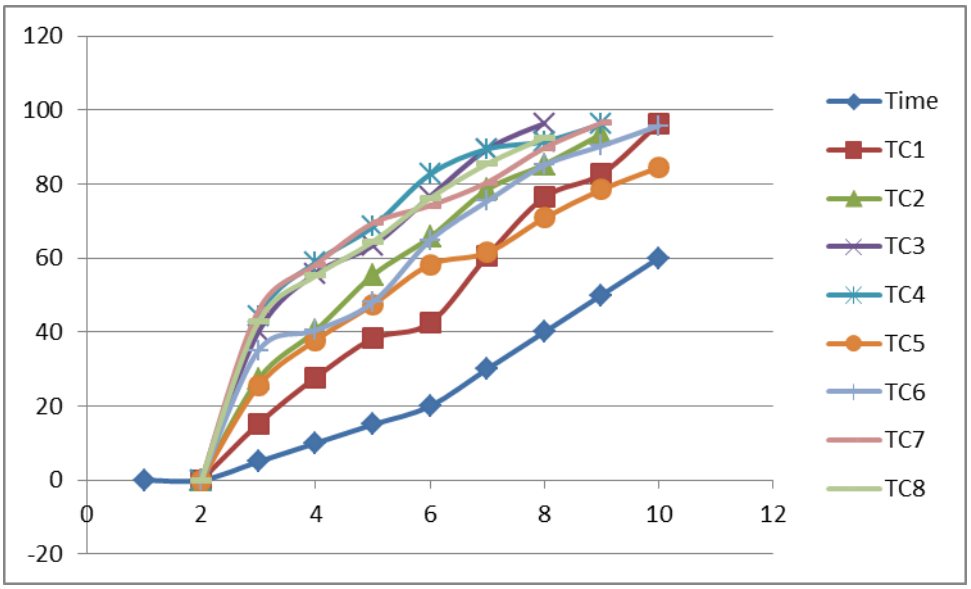

Figure1: Dissolution Profile of Core Tablets of Bupropion Hcl.

Evaluation of Press Coated Tablets.

Table 6: Post Compression Parameters of Coated Tablets Bupropion Hcl.

Formulation Code	Weight Variation	Thickness	Hardness	Friability	Disintegration
PD1	2.12	2.43	3.8	0.70	20
PD2	2.01	2.40	3.9	0.40	16
PD3	1.26	2.58	3.8	0.64	29
PD4	0.77	2.52	4.1	0.76	10
PD5	2.11	2.30	3.7	0.98	21

Dissolution Studies: The dissolution studies for the coated tablets were conducted in two media i.e 0.1N Hcl and 6.8 pH Phosphate buffer.

Table 7: Dissolution Profile of Coated Tablets of Bupropion Hcl.

Time (hrs)	PD1	PD2	PD3	PD4	PD5
0	0	0	0	0	0
1	32.43	25.52	30.52	22.69	24.26
2	49.63	32.86	45.95	34.63	32.96
3	55.35	42.29	50.26	40.98	44.45
4	64.63	59.49	60.39	55.43	52.42
5	79.43	69.35	72.45	64.86	60.89
6	90.63	78.12	82.96	78.05	72.56
7		91.01	95.43	85.49	85.46
8				97.42	95.63
9					98.18

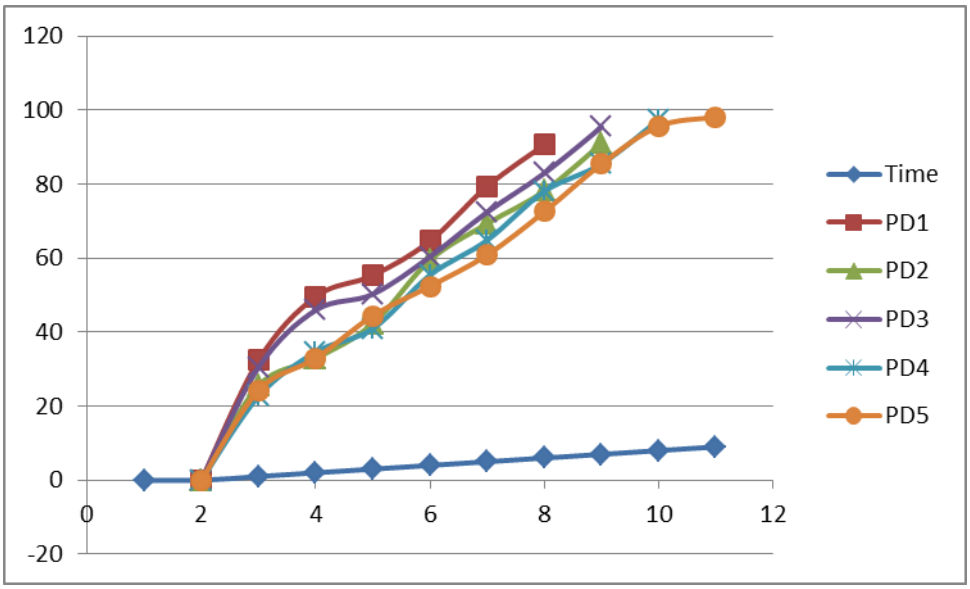

Figure 2: Dissolution Profile of Coated Tablets of Bupropion Hcl.

Dissolution Parameter Evaluation

Table 8: Dissolution Parameter Evaluation.

Models	R values
Zero order	0.983
First order	0.708
Higuchi	0.982
Koresmayer peppas	0.639
Peppas “n”	1.337

FTIR Spectras The drug and ecxipients showed no incompatibilities in the FTIR analysis the spectras are visualized in the figures 2&3.

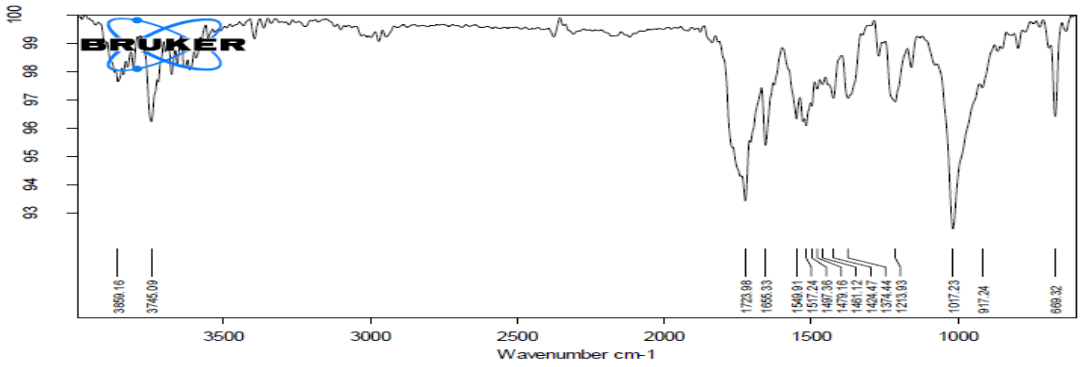

Figure 3: FTIR Spectra of Bupropion Pure Drug.

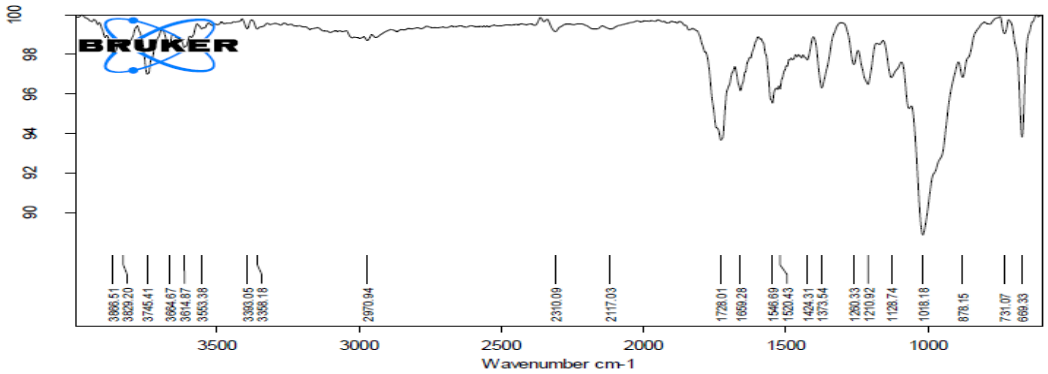

Figure 4: FTIR Spectra of Optimized formulation F5.

CONCLUSION

The aim of this study was to explore the feasibility of time specific pulsatile drug delivery system of Bupropion to treat blood clot, and to lower the risk of stroke and help in smoking cessation. The Core tablets CT1 to CT8 were prepared by using lycoat and ludiflash as superdisintegrating agents the core tablet formulation CT3 showed better drug release hence it is chosen to formulate the coated tablets PD1to PD5 the formulation PD5 containing equal quantities of HPMC K4M and Ethyl cellulose has shown better lag time of 9 hours compared to other formulations hence it is chosen as the optimized formulation. The drug and the excipients has shown compatibility in FTIR studies. Hence it can be concluded from the current experiment that Bupropion Hcl can be formulated as Coated tablets to lag the drug release and achieve pulsatile delivery.

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