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FORMULATION AND *IN-VITRO* EVALUATION OF BUPROPION HYDROCHLORIDE CONTROLLED RELEASE TABLET

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Keywords:
Controlled release, Bupropion Hydrochloride, Polymers, Dissolution and Mathematical modeling.

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ABSTRACT: The aim of the study was to develop and evaluate matrix based controlled drug delivery system of Bupropion hydrochloride. Controlled release tablets were prepared by employing Guar gum, Eudragit RS 100, HPMC K15M, HPMC K100M at different concentration. All 13 batches passed friability, hardness, weight variation, assay but only four batches (CRB7W, CRB8W, CRB10W, and CRB11W) passed the dissolution as per USP 30 NF25 for extended release tablet of Bupropion hydrochloride. Among the four formulation CRB7W & CRB11W follows Higuchi Model and CRB8W & CRB10W follows First order model. The optimized formulations were compared with the marketed product for similarity and dissimilarity factor. CRB7W and CRB10W showed dissimilar result and CRB8W and CRB11W showed similar result with marketed product. HPMC (K15M 7& K100M) as a matrix polymer used in tablet formulation provide a good initial retardation in the release as well as helped to enhance the overall release rate of the drug than that of Gaur gum and Eudragit RS 100.

INTRODUCTION: Oral drug delivery has been known for decades as most preferred route of administration among all routes due to its ease of administration[1]. The term controlled release refers to the continuous release of their active ingredients at predetermined rate and predetermined time. Controlled release drug therapy reduces the dosing frequency, eliminates local and systemic side effects, improves efficacy in treatment and improves the bioavailability [2]. Bupropion hydrochloride (±)-2-(tert-butylamino)-3-chloro propiophenone hydrochloride (**Figure 1**) is an antidepressant drug belonging to the class amino-ketone with molecular weight 276.20 gm/mol and is widely used for the treatment of minimal brain dysfunction, tardive dyskinesia, impaired mental alertness.

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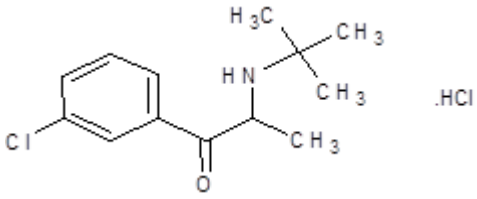

FIGURE 1: STRUCTURE OF BUPROPION HYDROCHLORIDE

It selectively inhibits the neuronal reuptake of catecholamines. The increase in norepinephrine may attenuate nicotine withdrawal symptoms. The increase in the dopamine at neuronal sites may reduce nicotine cravings and the urge to smoke. It is second generation antidepressant used in the management of smoking cessation [3]. Bupropion immediate release (three times a day), Bupropion sustain release (two times a day) and Bupropion extended/modified release (once a daily) tablets are the available formulations [4]. A controlled release Bupropion hydrochloride matrix tablet was prepared by using different polymers Guar gum [5, 6], Eudragit RS100 [7], HPMC K 15M [8], HPMC K 100M [7, 9].

MATERIALS AND METHODS: Bupropion hydrochloride, Microcrystalline cellulose PH 101, Guar gum was obtained as gift sample from OHM Pharmaceutical Laboratories Pvt. Ltd, Thatahli, Bhaktapur, Nepal. Eudragit RS100, HPMC K15M, HPMC K100M, Ethyl cellulose, Magnesium stearate were obtained as a gift sample from Elder Universal Pharmaceuticals Pvt. Ltd., Rupandehi, Bhairahawa, Nepal. Aerosil -200 was obtained as gift sample from Chemi Drug Industries Pvt. Ltd Thankot, Kathmandu, Nepal. Marketed formulation of 150mg Bupropion HCl Sustain release tablet was bought from local market of Kathmandu, Nepal. All other chemicals and reagents used were of pharmaceutical and analytical grade.

Preparation of calibration curve: 25mg accurately weighed drug was dissolved in 25 ml of distilled water in 25ml volumetric flask. From this stock solution different dilution were made and absorbance were measured at 298 nm in UV spectrophotometer. The calibration curve was prepared by plotting the concentration on X-axis and absorbance on Y-axis. The equation obtained was used to estimate the drug release in the dissolution study.

Preparation of Controlled Release Tablet: The tablets of Bupropion hydrochloride were prepared by wet granulation technique. Polymers HPMC (K15M, K100M), Eudragit RS100 and Guar gum were used to develop the core tablet. Accurately weighed quantity of the ingredients Bupropion HCL, MCCP PH 101, different polymers and stearic acid were sifted through sieve #20 and mixed geometrically for 10 minutes. The binder was prepared by dissolving 3gm of ethyl cellulose in 50ml dichloromethane.

The above binder solution was poured over geometrically mixed powder and prepared granules by stirring the powder with hands for 15 minutes. The above wet granules were dried at about 60°C in the hot air oven. These dried granules were passed through sieve #20 and magnesium stearate, aerosol (previously sifted from # 60) were added and further mixing was done for 10 minutes using double cone blender. Total 13 different formulations were prepared from the mixed powder using a 12- station rotatory tablet compression machine with 12.50mm diameter flat and round shaped punches.

Evaluation of Granules [5-9]:

Angle of Repose: Angle of repose of granules was determined by funnel method. Accurately weighed granules were taken in a funnel. The height of the funnel was adjusted such that it just touches the apex of the heap of the granules. The granules were allowed to flow through the funnel freely on to the surface, the height and diameter of the powder cone were measured and angle of repose was calculated using the following equation.

$$\text{Tan } \theta = h/r$$

Where h and r are the height and radius of the powder cone respectively.

Compressibility index: The compressibility index (CI) of the granules was determined by Carr's compressibility index.

Carr's index (%) = [(TBD –LBD)/ TBD]*100

Where, TBD: weight of the powder/tapped volume of the powder; LBD: weight of the powder/volume of the powder

Evaluation of Tablets [5-9]:

1. **Hardness:** Hardness variations of 10 tablets were measured using Monsanto hardness tester. The average hardness was calculated and the result is shown as mean ±S.D.

2. **Friability (F):** Tablet strength was tested by Roche friabilator. Initial weight of 11 tablets was weight taken and allowed for 100 RPM. Then final weight of tablets was taken after dedusting. The % friability was then calculated by;

$$F = (W_{initial} - W_{final}) / W_{initial} * 100\%$$

3. **Weight variation:** Randomly selected 20 tablets from each batch were weighed on analytical balance (KERN & Sohn GmbH, d = 0.1mg) and average weight was calculated, minimum and maximum weight were obtained. The tablets passed the test, if not more than two

tablets falls outside the percentage limit as per the IP. (±5.0%, for more than 250mg tablet).

4. **Assay:** Drug content of the manufactured tablets of each batch was determined by weighing and finely crushed 10 tablets from each batch. The powder sample equivalent to 25mg Bupropion HCl was weighed and dissolved in 25ml distilled water. Again 10ml of this solution was diluted to 100ml with distilled water and absorbance was measured in UV spectrophotometer at 298nm.

5. **Dissolution:** The dissolution studies were carried out by using the tablet dissolution test apparatus USP type II. The study was carried out at 50 rpm for 8 hour at temperature 37± 0.5°C using 900 ml distilled water as the dissolution medium. 10 ml of sample was withdrawn at 1, 4 and 8 hr and sink condition was maintained. The withdrawal samples were filtered and absorbance was measured by using UV spectrophotometer at 298nm. The release amount of drug was calculated by using standard calibration curve. Cumulative drug release (%) versus time, curve was plotted [11].

Mathematical Modeling of drug release profile: [12-14]: The cumulative amount of Bupropion hydrochloride release data from the formulated tablets at different time interval of dissolution were fitted to zero order kinetics, 1st order kinetics, Higuchi model, Korsmeyer Peppas models to characterize kinetics of drug release.

Model independent analysis of dissolution profiles: Dissolution profiles of two or more different sustained release products of the same drug substance can be compared for similarity as well as dissimilarity of the dissolution profiles. If f_s (similarity factor) values higher than 50 and close to 100 show the similarity of the dissolution profiles. f_d (difference factor) values should be close to 0 to be similar.

RESULT AND DISCUSSION:

Calibration curve of Bupropion HCl: The standard calibration curve was prepared by plotting concentration versus absorbance. The absorbance of the different concentration of Bupropion HCl was measured by using distilled water as a blank (λ_{max} = 298nm) and the correlation co-efficient (R^2) was found to be 0.997 which is shown in **Figure 2**.

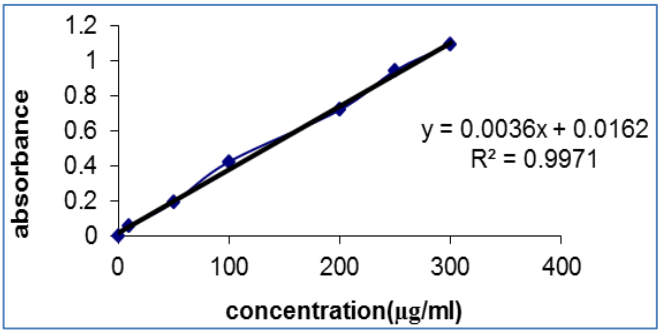

FIGURE 2: STANDARD CALIBRATION CURVE OF BUPROPION HCl

Evaluation of granules: The prepared granules of each 13 batches were evaluated on the basis of angle of repose and Carr's index.

1. **Angle of repose**: Angle of repose of all granules of 13 formulations was determined by funnel method. Among all formulation CRB11W has good flow properties (11.95°) and CRB10W has greatest angle of repose (27.07°). All the values are given in the table no.2
2. **Compressibility index**: Compressibility index of granules of all 13 batches was determined. CRB4W has least CI (12.25%) and the CRB5W has greatest compressibility index (22.88%). All the values are given in the **Table 1**.

TABLE 1: TABLE SHOWING ANGLE OF REPOSE AND CARR'S INDEX

Formulation	Angle of Repose (θ)	Carr's index (%)
CRB1W	12.68	16.63
CRB2W	12.38	19.63
CRB3W	17.9	17.86
CRB4W	12.89	12.25
CRB5W	11.96	22.88
CRB6W	12.45	14.96
CRB7W	22.61	17.1
CRB8W	26.9	21.42
CRB9W	11.95	13.84
CRB10W	27.07	17.5
CRB11W	24.3	20
CRB12W	13.54	16.32
CRB13W	14.7	18.37

Formulation of Controlled release tablet: Thirteen different formulations of controlled release tablet of Bupropion HCl were developed by employing different polymers with different concentrations as shown in **Table 2**. All the formulated batches were evaluated for the thickness, hardness, friability, weight variation and dissolution.

TABLE 2: COMPOSITION OF CONTROLLED RELEASE TABLET OF BHCl

Ingredients	CRB 1	CRB 2	CRB 3	CRB 4	CRB 5	CRB 6	CRB 7	CRB8	CRB9	CRB10	CRB11	CRB12	CRB13
Bupropion HCl	150	150	150	150	150	150	150	150	150	150	150	150	150
MCCP PH 101	377	227	177	327	302	277	364.5	352	302	352	327	302	227
EC	30	30	30	30	30	30	30	30	30	30	30	30	30
Gaur gum	100	150	200	-	-	-	-	-	-	-	-	-	-
Eudragit RS	-	-	-	50	75	100	-	-	-	-	-	-	-
HPMC K-100M	-	-	-	-	-	-	12.5	25	75	-	-	-	-
HPMC K 15M	-	-	-	-	-	-		-	-	25	50	75	150
Stearic acid	30	30	30	30	30	30	30	30	30	30	30	30	30
Aerosil-200	3	3	3	3	3	3	3	3	3	3	3	3	3
Mg. stearate	10	10	10	10	10	10	10	10	10	10	10	10	10
TOTAL (mg)	600	600	600	600	600	600	600	600	600	600	600	600	600

3. **Hardness:** Hardness variations of 10 tablets were measured using Monsanto hardness tester. The average hardness was calculated and the result is shown as mean ±S.D. All the 13 batches show good hardness in range of 9.9 ± 0.65 to 10.8± 0.58 kg/cm^2. All the data are shown in Table 3.

4. **Friability:** All the 13 batches passed the friability parameter as per the IP. 11 tablets from each batch were weighed and were subjected to friability test apparatus for 100 rpm. The final results are shown in **Table 3**.

5. **Weight variation:** 20 individual tablets from each batches were weighed in analytical balance (KERN& Sohn GimbH, d= 0.1mg) and average weight, maximum and minimum weight variation were obtained, which is shown in **Table 3**. As per IP the weight variation must be ± 5% for tablet having weight 250mg or more.

6. **Assay:** Drug content of the manufactured tablets of each batch was determined by weighing and grinding finally 10 tablets from each batch. The powder sample equivalent to 25mg of Bupropion HCl was weighed accurately and was dissolved in 25ml of distilled water. Again 10ml of this solution was diluted to 100ml volumetric flask using same distilled water. The latter solution was filtered and measured in UV spectrophotometer at 298nm. All the 13 formulation passed the assay limit as per the USP30- NF25 with the assay range of 90.15 to 103.78% which is shown in **Table 3**.

TABLE 3: HARDNESS, FRIABILITY, AVERAGE WEIGHT, WEIGHT VARIATION AND ASSAY.

Formulation	Hardness *(kg/cm^2) ±S.D	Friability (%)	Average wt** ± S.D (mg)	Maximum wt variation (%)	Minimum wt variation (%)	Assay* ± S.D (%) (n=3)
CRB1W	10.7±0.27	0.24	600±1.013	1.15	2.46	102.27±1.048
CRB2W	9.9±0.65	0.5	598±2.01	2.13	3.38	96±1.194
CRB3W	10.3±0.27	0.33	603±1.316	3.46	2.19	98.4±2.286
CRB4W	10.8±0.57	0.35	599±1.713	1.98	3.58	94.09±2.473
CRB5W	10.4±0.41	0.35	604±2.501	3.07	2.04	99.62±0.967
CRB6W	10.1±0.41	0.41	590±1.916	3.04	1.93	100±0.52
CRB7W	10.8±0.27	0.28	605±2.313	2.78	2.82	96.96±1.397
CRB8W	10.2±0.27	0.43	600±1.284	2.13	3.07	101.2±0.06
CRB9W	10.8±0.27	0.2	600±1.983	3.09	3.68	103.78±1.525
CRB10W	10±0.35	0.45	600±0.590	1.07	1.89	99.45±1.967
CRB11W	10.4±0.41	0.32	591±2.056	4.26	3.09	102.27±1.182
CRB12W	10.6±0.41	0.2	598±1.785	3.31	3.23	95.38±2.692
CRB13W	10.8±0.27	0.33	601±2.601	1.99	2.78	90.15±3.055

*= 10 tablets from each batch & ** 20 tablets from each batch

Dissolution studies: The dissolution studies of 13 formulations were carried out using the tablet dissolution apparatus USP type II (paddle), the study was carried out at 50 rpm for 8 hours at temperature 37 ±0.5°C using 900 ml of distilled water as the dissolution medium. Each 10 ml of sample was withdrawn at 1, 4, and 8 hour interval with replacement of same volume of the dissolution medium maintained at temperature 37 ± 0.5°C. The withdrawal samples were filtered and analyzed by using UV spectrophotometer at the wave length 298nm. The released amount of drug was calculated by using the equation from the standard calibration curve. Cumulative % drug release versus time curve was plotted. Among 13 batches only CRB7W, CRB8W, CRB10W, CRB11W meets the USP30-NF25 parameter. The entire cumulative drug release % is given in **Table 4.** The comparative dissolution studies are shown in **Figure 3, Figure 4, Figure 5 & Figure 6.**

TABLE 4: CUMULATIVE DRUG RELEASE (%) AT 1, 4, 8h

FORMULATION	C. drug release at 1h	C. drug release at 4h	C. drug release at 8h	Remarks
CRB1W	30.39±0.910	55.5±0.930	66.62±1.231	100mgGAUR GUM
CRB2W	30.05±1.89	47.55±1.281	58.97±0.914	150mgGAUR GUM
CRB3W	20.84±1.115	43.4±1.213	54.65±1.169	200 mg GUAR GUM
CRB4W	62.44±1.189	69.37±1.107	71.75±1.018	50mgEUDRAGIT RS
CRB5W	60.85±1.048	65.22±1.201	68.06±0.967	75mgEUDRAGIT RS
CRB6W	36.64±0.957	78.91±1.19	75.22±0.851	100mgEUDRAGIT RS
CRB7W	41.87±1.308	81.92±1.173	84.77±0.918	12.5mg HPMC K100M
CRB8W	42.09±1.175	67.6±1.238	83.43±1.009	25mg HPMC K100M
CRB9W	25.79±0.962	58.95±1.134	73.86±1.241	50mg HPMC K100M
CRB10W	44.29±0.821	71.82±0.931	86.82±1.109	25mg HPMC K15M
CRB11W	30.05±1.149	68.4±0.845	79.9±1.117	50mg HPMC K15M
CRB12W	22.67±0.993	51.8±1.097	74.08±1.238	75mg HPMC K15M
CRB13W	19.2±0.0245	35.05±0.0145	43.06±0.936	150mg HPMC K15M
Marketed formulation	27.07±1.139	62.35±1.120	76.82±1.019	

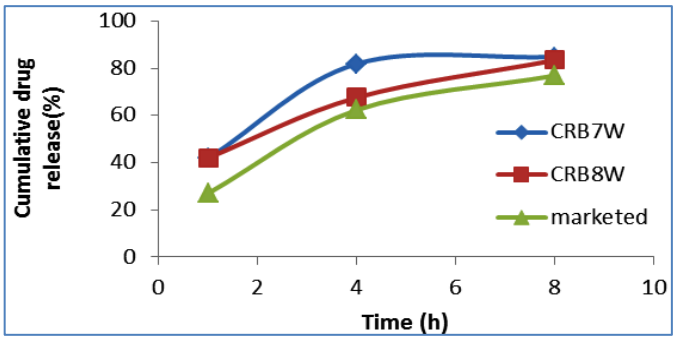

FIGURE 3: COMPARATIVE DISSOLUTION STUDIES WITH MARKETED TABLET

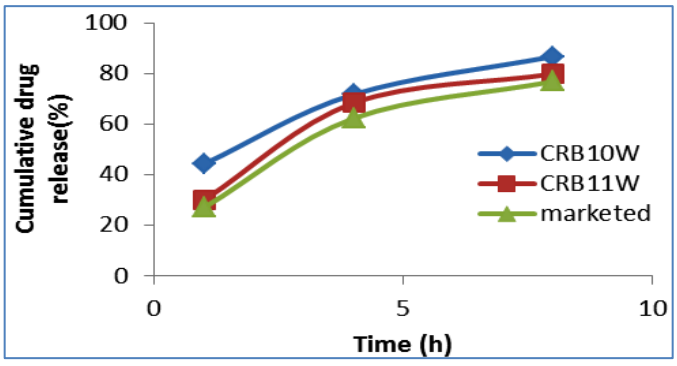

FIGURE 4: COMPARATIVE DISSOLUTION STUDIES WITH MARKETED TABLET

Drug release kinetics: To study the release mechanism of drug release from the matrix tablets, the release data were fitted into the kinetics equation of Zero order, First order, Higuchi model and Peppas power law.

The cumulative percentage drug release verse time, the logarithm cumulative percentage drug release verse time, cumulative percentage drug release verse square root of time and logarithm of cumulative % drug release verse logarithm of time were used to evaluate for Zero order kinetic, First order kinetics, Higuchi model and power law respectively.

Considering correlation co-efficient obtained using different kinetics equations, the formulation which passed the dissolution parameter as per UPS 30-NF 25 were found to follow First order and Peppas model kinetics.

The result is shown in **Table 5**.

TABLE 5: R^2 VALUE OF DIFFERENT KINETIC EQUATIONS

B.NO	Zero order Model R^2	First order Model R^2	Higuchi Model R^2	Peppas model R^2	n value
CRB7W	0.73	0.7893	0.8411	0.9587	0.7555
CRB8W	0.9538	0.9977	0.9936	0.9503	0.5536
CRB10W	0.9384	0.9987	0.987	0.9449	0.7148
CRB11W	0.8739	0.9551	0.9495	0.9965	0.5869

CRB8W and CRB10W batches followed first order kinetics. CRB7W and CRB11W followed Peppas model. The release exponent "n" value for the different formulation were ranged from 0.5536 (CRB8W) to 0.755(CRB7W). All these four batches followed non Fickian diffusion through matrix swelling.

Model Independent analysis of dissolution profiles: A model-independent mathematical method was used to compare dissolution profile viz, f_s and f_d as shown in **figures 7 & 8** respectively. The factors are similarity (f_s) and dissimilarity (f_d), which measures the closeness between the marketed product and formulated dissolution profiles. The results obtained are tabulated in **Table 6**. In the comparative analysis of dissolution profile of market product and HPMC K100M; the formulation CRB7W showed dissimilar result with market product while formulation CRB8W showed near similar result with market product.

TABLE 6: SHOWING SIMILAR AND DISSIMILAR FACTOR

Product pair	Similar factor	Dissimilar factor
Market product and CRB10W	44.6	22.06
Market product and CRB11W	66.18	8.06
Market product and CRB7W	41.31	25.45
Market product and CRB8W	50.01	16.16

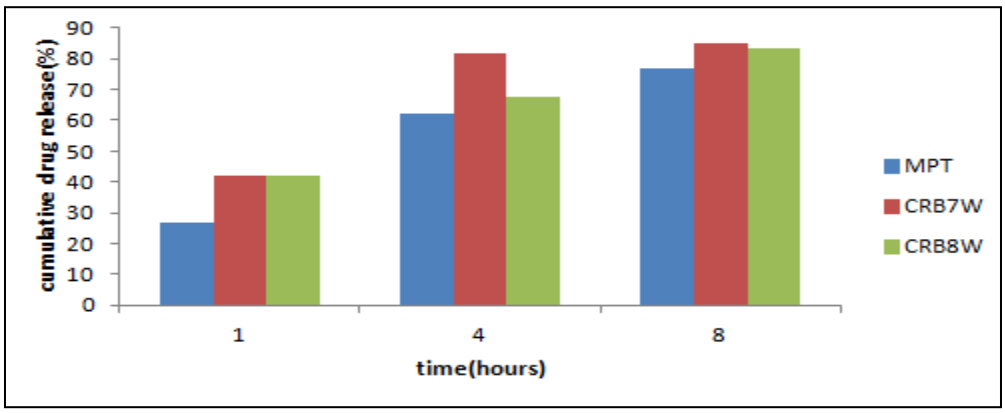

FIGURE 5: COMPARATIVE DISSOLUTION PROFILE OF MARKETED PRODUCT AND FORMULATED PRODUCT OF HPMC K100M: CRB7W AND CRB8W

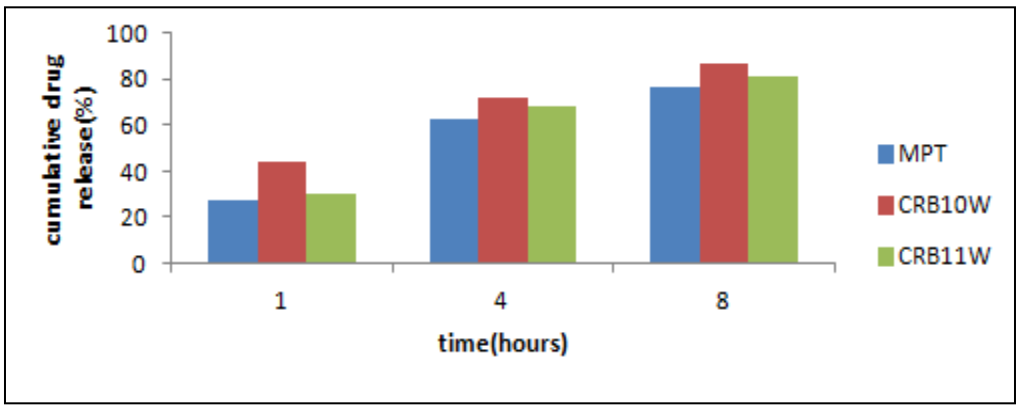

FIGURE 6: COMPARATIVE DISSOLUTION PROFILE OF MARKETED PRODUCT AND FORMULATED PRODUCT OF HPMC K15M: CRB10W AND CRB11W

In the comparative analysis of dissolution profile of market product and HPMC K15M; the formulation CRB10W showed dissimilar result with market product while formulation CRB11W showed similar result with market product.

SUMMARY: A controlled drug delivery systems of Bupropion HCI was formulated to improve the therapeutic effectiveness of the drug and to reduce the total drug needed and minimizing the toxic side effect. Formulation of controlled release tablets were developed by employing different proportion of HPMC, Eudragit RS and Gaur gum as the rate controlling polymers. In the formulation, the drug-polymer ratio was 1.5:1, 1:1 and 0.75:1 of drug and Gaur gum. Similarly, the ratio of 3:1, 2:1, 1.5:1 of drug and Eudragit RS, 12:1, 6:1, and 2:1 of drug and HPMC K100M and 6:1, 3:1, 2:1 and 1:1 were used.

The formulated matrix tablets meet the pharmacopoeial requirement of uniformity of weight, hardness, % friability and Assay was within the acceptance point as per USP 30-NF 25 and IP. The dissolution was followed by the tablet dissolution apparatus USP type II (paddle), the study was carried out at 50 rpm up to 8 hours at temperature 37 ±0.5°C using 900 ml of distilled water as the dissolution medium.

CONCLUSION: Controlled release tablets of Bupropion HCl were prepared by using matrix based polymers (Gaur gum, Eudragit RS and HPMC (K15M AND K100M). In the study, we found that formulated tablet with the use of HPMC (K15M AND K100M) as matrix polymer helped to provide a good initial retardation in the release as well as helped to enhance the overall release rate of the drug than that of Gaur gum and Eudragit RS.

The 13 formulations were prepared using wet granulation technique. Out of all the formulations CRB7W, CRB8W, CRB10W and CRB11W of wet granulated formulation complies the dissolution testing of USP monograph.

From the comparative study with the market product, CRB7W, CRB8W, CRB10W and CRB11W showed better release rate of the drug than that of marketed formulation.

Hence, it may be concluded that the incorporation of a different viscosity grade of polymer in the controlled release matrix might offer a simple means of modulating the release behavior in order to minimize drug release in stomach and in maximizing the therapeutic benefit of the drug with optimal patient compliance and minimum local or systemic toxicity.

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