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FORMULATION AND EVALUATION OF AN EXTENDED RELEASE TABLET OF AN ANTIDEPRESSANT DRUG

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ABSTRACT

The present study is to develop an extended release tablet of an Antidepressant. It is the serotonin-norepinephrine reuptake inhibitor derivative belongs to cyclohexanol chemical class primarily used in the treatment of major depressive disorder. Extended release dosage forms cover a wide range of prolonged action preparations that provide continuous release of their active ingredients for a specific period of time. Eight formulations (F1 to F8) were designed using Hydroxypropyl methyl cellulose (HPMC K100M), Microcrystalline Cellulose (MCC) as polymers and Hydroxypropyl Cellulose (Klucel), Isopropyl alcohol and Dichloromethane as granulating agent. HPMC was used in different ratios as intragranular and extra granular material. The granules were prepared by using HPMC K100M, Microcrystalline cellulose, drug and the granulating solution. The granules were air dried, subjected for pre-formulation studies and punched using an 8 stationed tablet punching machine bearing 10.5mm die capacity. The punched tablets were evaluated (for weight variation, hardness and friability) and film coated using Instacoat Universal Pink. The film coated tablets were evaluated for weight variation, hardness, drug content and *in vitro* drug release. Out of the 8 film coated formulations (F1 to F8), the optimized formulation (F8), prepared using 50mg of the drug, 22% HPMC K100M, 28% microcrystalline cellulose and 2% Hydroxypropyl Cellulose as binder. The studies showed 96% invitro drug release in 20 hours and were subjected to short term stability studies.

KEYWORDS

Antidepressant, Extended release tablet and HPMC.

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INTRODUCTION

Extended Release System

According to FDA, in an extended release dosage form there is a reduction in the dosing frequency as compared to a conventional dosage form. The extended release is also called as timed or sustained release dosage forms which make the drug available over an extended period of time following

administration and reduce the dosing frequency by two-fold as compared to conventional forms. Examples: Metformin HCl ER Tablets, Propranolol ER Tablets[1].

Extended release drug delivery system achieves a slow release of the drug over an extended period of time or the drug is absorbed over a longer period of time. Extended release dosage form initially releases an adequate amount of drug to bring about the necessary blood concentration (loading dose, DL) for the desired therapeutic response and the drug is further released at a controlled rate (maintenance dose, DM) to maintain the blood levels for some desirable period of time[2,3].

Antidepressants are the drugs used for the treatment of major depressive disorder and other conditions including dysthymia, anxiety disorders, obsessive compulsive disorder, eating disorders, chronic pain, neuropathic pain, dysmenorrhoea, snoring, migraines, attention-deficit hyperactivity disorder (ADHD), substance abuse and sleep disorders. They can be used alone or in combination with other medications but, only when prescribed.

Merits of extended release drug delivery system

Maintains therapeutic concentration over prolonged periods

High blood concentration is avoided

Reduced toxicity due to slow drug absorption

Minimized local and systemic side effects

Improved patient compliance

Minimized drug accumulation in chronic dosing

Provision to use special effects to attain improved therapeutic action

Drugs with short half-life can be developed as extended release.

Demerits of extended release drug delivery system

Difficulty in termination of release if necessary

Less flexibility in adjusting doses and dosage regimens

Risk of dose dumping

High cost of production

The rate of drug release may be affected by food and transit time[4].

Factors influencing the formulation of an Extended Release Drug Delivery System:

Physiochemical Factors

Aqueous Solubility

Partition Coefficient

Drug Stability

Protein binding

Molecular size and diffusivity

Biological Factors

Absorption

Distribution

Metabolism

Elimination and Biological Half life

Dose size[5].

Atypical antidepressants

There are variety of atypical antidepressants which target other neurotransmitters either alone or in addition to serotonin. For example, Wellbutrin blocks the reabsorption of the neurotransmitters dopamine and norepinephrine. On the other hand trazodone, Cymbalta, Effexor and Remeron affect both norepinephrine and serotonin (which is why they are sometimes called serotonin and norepinephrine reuptake inhibitors, or SNRIs). The side effects vary according to the specific drug. Symptoms of the atypical antidepressants include nausea, fatigue, weight gain, sleepiness, nervousness, dry mouth and blurred vision[6].

MATERIAL AND METHODS

Materials

Analytical methods

Determination of λ_{max} of API in dissolution media by UV-Visible spectroscopic method

Drug polymer compatibility studies by Fourier-Transform Infrared Spectroscopy (FT-IR) Study[7].

Evaluation of preformulation parameters

Angle of repose

Bulk density

Compressibility Index

Hausner Ratio[8].

Formulation development

Step I: Dispensing – All the ingredients, mentioned in table were weighed.

Step II: Sifting

The API was sifted through #40 mesh sieve.

MCC, HPMC and HPC were also sifted through #40 mesh sieve separately.

Talc and magnesium stearate were sifted through #60 mesh sieve.

Step III: Dry Mixing

The API, MCC and HPMC (intragranular) were blended in a planetary mixer and mix for 30 minutes at high speed.

Step IV: Binder Preparation – The required amount of HPC was dissolved in IPA and DCM.

Step V: Granulation – The binder solution was added to the mixture obtained from the planetary mixer to make granules. Additional amount of IPA and DCM were added to obtain optimum granules.

Step VI: Drying – The granules formed were air dried overnight. The granules were checked for LOD at 105°c for 5 mins.

Step VII: Sizing – The dried granules were sieved through #20 mesh sieve.

Step VIII: Lubrication – The HPMC (extra granular), Sized granules and lubricant materials were blended together in octagonal blender for 2 min.

Step IX: Compression – The lubricated blend along with 15% of fines was compressed using 8 station single rotatory tablet compression machine using 10.5mm round normal concave punches. The in-process evaluation was performed during compression.

Step X: Coating – Preparation of film coating solution

Weigh accurately Instacoat Universal Pink and dissolve in required quantity of purified water. Fifty tablets were loaded in the coating pan having the capacity of about 100 tablets and the tablets were film coated using Spray method in R&D coater. The coating solution consisted of Instacoat Universal pink dissolved in water was sprayed. The core tablets were dried for 5 minutes in the coating pan, film coated for 10 min and again dried for 5 min. The coating was continued till the target weight per coated tablet increased up to 12mg.

Formulations

Eight formulations (F1 to F8) were prepared using the drug and excipients in various ratios and it has been described in Table No.2.

Post compression study

Weight Variation
Hardness test
Friability
Thickness

Evaluation of film coated tablets

Weight variation
Hardness
Thickness
Drug content (%)
In vitro dissolution studies

Kinetic Modelling of Extended release dosage forms

Zero order Kinetics

The zero-order rate equation describe that the drug release from the dosage form is independent of its concentration which is described through the following formula:

$Qt = Qo + Kot$

Where, 'Qt' corresponds to amount of drug dissolved in time 't',

'Qo' is an initial amount of drug in the solution which is often zero and

'Ko' is zero order release rate constant.

First order kinetics

The first order equation describes that the drug release from the dosage form is concentration dependant and described by the formula given below:

$\log C = \log Co - kt/2.303$

Where, Co is the initial concentration of drug and k is the order constant.

Higuchi model

Higuchi model was developed on the basis of Fick's law and it describes that the fraction of drug release from a matrix is proportional to square root of time as described by the given formula:

$Qt = KH \sqrt{t}$

Where, 'KH' is the Higuchi rate constant, and

'Qt' is the amount of drug released at time 't'

4. Korsmeyer-Peppas model.

To find out the mechanism of drug release, drug release data were fitted in Korsmeyer-Peppas equation:

$Mt / M\infty = Kt^n$

Where, $Mt / M\infty$ is a fraction of drug released at time t,

K is the release rate constant and

n is the release exponent.

The best formulation e was selected based on *in-vitro* drug release. In order to study the exact mechanism of drug release from the tablets, drug release data of the best batch was analysed according to Zero order, First order, Higuchi model and Korsmeyer-Peppas model. The data were

processed for regression analysis using MS EXCEL statistical function[9].

Accelerated stability test of best formulation (F8)

The optimized formulation was selected for the stability studies.

The accelerated stability studies were carried out according to ICH guidelines by storing the samples at 40 ± 2℃ and 75 ± 5 % RH for 1, 2 and 3 months. The tablets were evaluated for hardness, drug content and dissolution study and compared with that of tablets which were evaluated immediately after manufacturing[10,11].

DISCUSSION

Eight formulations (F1 to F8) of an extended release tablet of an antidepressant were prepared using polymers in different ratios as shown in the formulation table. FT-IR study was done to ensure the compatibility of the drug with the selected polymers and excipients. Pre-formulation study was done before the tablet punching to study the flow property of the granules so as to ensure the successful punching of the tablet. After tablets were punched they were subjected to the general test for tablets like weight variation, hardness and friability. The film coating was done and evaluated for weight variation, hardness, drug content and in-vitro drug release studies. The best formulation was subjected to stability studies.

Discussions of the results of the study done are given below

Standard calibration curve of drug

Five different concentrations 2, 4, 6, 8 and 10 µg/ml of the drug was prepared as stated in the methods. Absorbance of each concentration was taken in UV spectrophotometer at 223nm and the obtained values were plotted. The slope of the standard curve was found to be 0.026 with the correlation coefficient (R^2) value of 0.999. The results are shown in Table No.4 and Figure No.1.

FT-IR study

The FT-IR spectrum of combination of drug with polymer and excipients were obtained and analysed for the compatibility of drug with the excipients. No interaction of the drug with excipients was seen in FT-IR spectrums which confirmed that the drug was compatible with the excipients selected. The results are shown in Figure No.2 to Figure No.8.

Preformulation study

According to the Carr's index and Hausner ratio obtained, all the formulations (F1 to F8) were having good flow property and hence all the formulation passed the flow property test. Since every formulation was having above passable range of flow property they were suitable for compression into the tablets. The results are shown in Table No.5.

Postcompression study

The core tablets were subjected to post compression study evaluation such as Weight variation, hardness, friability and thickness.

Weight variation

All the formulations (F1 to F8) were subjected to weight variation test and none of the formulation showed a deviation of more than ± 5 % (IP limit) for any of the tablets tested. The prepared formulations comply with the weight variation test; thus, it fulfils the IP requirements. The results are shown in the Table No.6.

Tablet Hardness

Hardness of all the formulations (F1 to F8) was found different depending upon the ratio of polymer used in the formulation. All the formulations indicated good mechanical strength with an ability to withstand physical and mechanical stress condition while handling. The range of Hardness was found to be 5.5 to 6kg/cm^2.The results are shown in the Table No.6.

Friability

The friability value of all formulations (F1 to F8) was found less than 1% which ensured that formulated tablets were mechanically stable. The range of friability was found to be 0.11-0.16%. The results are shown in the Table No.6.

Tablet Thickness

Thickness of the developed formulations (F1 to F8) varied from 4.68 ± 0.00 mm to 4.82±0.00 mm. Each formulation was analysed in triplicate and the thickness was found to be uniform in each formulation. The results are shown in the Table No.6.

Evaluation parameters for coated tablets

The coated tablets were evaluated for weight variation, hardness, thickness, %drug content and *in-vitro* drug release studies.

Weight variation

All the formulations (F1 to F8) were subjected to weight variation test and none of the formulation showed a deviation of more than ± 5% (IP limit) for any of the tablets tested, thus it fulfils the IP requirements. The results are shown in the Table No.7.

Tablet Hardness

All the formulations (F1 to F8) indicated good mechanical strength with an ability to withstand physical and mechanical stress condition while handling. The range of Hardness was found to be 6.1-7 kg/cm^2.The results are shown in the Table No.7.

Tablet Thickness

Each formulation was analysed in triplicate and the thickness was found to be uniform in each formulation. The results are shown in the Table No.7.

Percentage Drug Content

The drug content in different tablet formulations was uniform and in the range of 95.38 ± 2.43 % to 100.76 ± 1.54 %. The drug content was found within the limits. The results are shown in the Table No.7.

***In-vitro* release study**

All eight formulations (F1 to F8) were evaluated for *in vitro* release study. The drug release was 100.3%, 100%, 100.4%, 99.3 %, 97.6%, 98.2%, 85% and 96% for F1, F2, F3 F4, F5, F6, F7 and F8 respectively for 20 hours. The release rate of F8 was found to be within the specified limit so it is selected as the best formulation. The results are shown in the Table No.8.

Kinetic modelling of best formulation (F8)

F8 was selected as best formulation based on the in *vitro* drug release study. The *in-vitro* drug release data of F8 was fitted into zero order, first order, Higuchi model and Korsmeyer-Peppas model. The dissolution data was found best fitted in zero order and Korsmeyer-Peppas model showing that the drug release is independent of drug concentration and the drug release was through erosion of the polymeric chain. The results are shown in the Table No.9 to Table No.13 and Figure No.11.

Accelerated stability test of best formulation (F8)

The selected formulation (F8) was subjected to stability test at 40±2°C/ 75±5% Relative Humidity for 3 months. At each month tablets were taken and analysed for physical examination, hardness, % drug content and *in-vitro* drug release. The results indicate that there was no statistically significant difference between the initial values and the values obtained during stability studies. The FT-IR study was done for best formulation F8 and confirmed the absence of compatibility problem during the storage. From the stability study and FT-IR study of F8, the formulation was found to be stable. The results are shown in the Table No.14 and No.15, Figure No.12 and Figure No.13.

Table No.1: List of excipients

S.No	Materials
1	Microcrystalline cellulose
2	HPMC
3	Hydroxypropyl cellulose
4	Isopropyl Alcohol
5	Dichloromethane
6	Magnesium Stearate
7	Talc

Table No.2: Formula for core tablet

S.No	Ingredients	F1 (mg)	F2 (mg)	F3 (mg)	F4 (mg)	F5 (mg)	F6 (mg)	F7 (mg)	F8 (mg)
1	API	79.74	79.74	79.74	79.74	79.74	79.74	79.74	79.74
2	MCC	234.66	214.26	193.86	173.44	149.06	108.26	116.14	113.26
3	HPMC	40.80	61.20	81.60	81.60	81.60	102	102	90
4	Hydroxy Propyl Cellulose	9	9	9	9	9	9	9	9
5	Ipa and Dcm	Qs	Qs	Qs	Qs	Qs	Qs	Qs	Qs
6	Hpmc	40.80	40.80	40.80	61.20	81.60	81.60	102	105
7	Magnesium Stearate	4	4	4	4	4	4	4	4
8	Talc	7	7	7	7	7	7	7	7
9	Total Weight	408mg	408mg	408mg	408mg	408mg	408mg	408mg	408mg

Table No.3: Formula for Film coating solution

S.No	Ingredients	Quantity per tablet (mg)
1	Instacoat universal pink	12
2	Purified Water	25ml (Qs)

Table No.4: Standard calibration data

S.No	Concentration	Absorbance at 223nm
1	0	0
2	2	0.051
3	4	0.104
4	6	0.16
5	8	0.214
6	10	0.264

Evaluation of preformulation parameters

Table No.5: Flow Properties

Formulation Code	Bulk density *(g/cc)	Tapped density ^(g/cc)	Angle of repose $(°)	Carr's Index Δ	Hausner's ratio Ψ
F1	0.32±0.01	0.37±0.03	25.6±1.26	13.54±0.95	1.15±0.54
F2	0.31±0.03	0.36±0.02	24.1±1.04	13.88±1.34	1.16±0.57
F3	0.32±0.02	0.37±0.04	27.7±1.23	13.51±1.11	1.15±0.45
F4	O.30±0.14	0.35±0.01	28.67±1.24	14.28±1.58	1.16±0.12
F5	0.34±0.02	0.39±0.03	24.92±1.10	12.82±0.60	1.14±0.17
F6	0.33±0.12	0.39±0.01	26.12±1.14	15.38±0.30	1.18±0.12
F7	0.31±0.02	0.34±0.01	29.26±1.24	8.82±0.760	1.09±0.18
F8	0.32±0.02	0.36±0.01	24.26±1.04	11.1±0.912	1.12±0.12

All data are presented in Average ± SD, n=3

Evaluation of postcompression parameters

Table No.6: Postcompression Study of Core Tablets

Formulation	Hardness (kg/cm²)	Friability (% w/w)	Thickness (mm)	Weight variation* (%)
F1	5.9±1.23	0.11±0.04	4.75±0.01	408±4.23
F2	5.5±2.56	0.12±0.08	4.82±0.00	408±4.78
F3	6±1.9	0.15±0.01	4.68±0.00	408±4.33
F4	5.7±3.45	0.16±0.06	4.79±0.01	408±4.54
F5	5.5±4.2	0.18±0.05	4.83±0.02	408±4.65
F6	6.1±2.34	0.11±0.02	4.69±0.00	408±4.12
F7	5.5±2.11	0.14±0.06	4.83±0.00	408±4.34
F8	5.8±2.11	0.13±0.07	4.79±0.00	408±4.11

All data are presented in Average ± SD, n=3, *n=20

Evaluation parameters of film coated tablets

Table No.7: Evaluation of film coated tablets

Formulation	Hardness (kg/cm²)	Thickness (mm)	Weight variation (mg)	%Drug Content
F1	6.8 ±2.11	4.8±0.01	420±5.12	95.38±2.43
F2	6.3 ±3.76	4.85±0.00	420±5.44	95.94±1.09
F3	7.0 ±1.43	4.71±0.00	420±5.51	96.52±0.98
F4	6.3 ±2.11	4.82±0.01	420±5.23	97.16±1.87
F5	6.1 ±1.3	4.87±0.02	420±5.44	98.56±1.66
F6	7.1 ±1.22	4.73±0.00	420±5.68	99.71±1.56
F7	6.3 ±2.44	4.86±0.00	420±5.11	99.98±1.76
F8	6.1 ±1.11	4.82±0.00	420±5.01	100.76±1.54

***IN VITRO* DRUG RELEASE DATA**

Table No.8: *In vitro* drug release data of F1 to F8 (% CDR)

S.No	Time(hrs)	F1	F2	F3	F4	F5	F6	F7	F8
1	2	48	43	40	38	35	30	28	28
2	8	80.5	77	73	73	71	72	60	64
3	12	100.2	95	94.8	90	88	83	75	80
4	20	100.3	100	100.4	99.3	97.6	98.2	85	96

Kinetic modelling of optimized formulation (F8)

Table No.9: Zero Order Kinetic Data

S.No	Time (H)	%CDR
1	0	0
2	2	28
3	8	64
4	12	80
5	20	96

Table No.10: First Order Kinetic data

S.No	Time (H)	Log % Drug Remaining
1	0	2
2	2	1.85733
3	8	1.5563
4	12	1.30103
5	20	0.60206

Table No.11: Higuchi Kinetic Data

S.No	Square root of time	%CDR
1	1.41421	28
2	2.82843	64
3	3.4641	80
4	4.47214	96

Table No.12: Korsmeyer-Peppas kinetic data

S.No	Log time	Log %CDR
1	0.30103	1.44716
2	0.90309	1.80618
3	1.07918	1.90309
4	1.30103	1.98227

Correlation of various Kinetic Models

Table No.13: Correlation coefficient of F8 in various kinetic models

S.No	Formulation 8	Zero Order	First Order	Higuchi Model	Korsmeyer-Peppas Model
1	R^2	0.901	0.984	0.987	0.991
2	N	4.617	-0.068	22.58	0.548

Accelerated Stability study

Table No.14: Study of Various Parameters during Stability Study Period

S.No	Parameters	Condition (40±2°C/75±5%RH)		
		1st Month	2nd Month	3rd Month
1	Appearance	Pink coloured	Pink coloured	Pink coloured
2	Hardness (kg/cm$^{2)}$	6.05	5.95	5.54
3	Drug Content (%)	100.56	100.31	100.15

Table No.15: *In-vitro* Drug Release during Stability

S.No	%CDR (40±2°C/75±5%RH)			
	Time (H)	1st Month	2nd Month	3rd Month
1	0	0	0	0
2	2	28.02	28.23	28.004
3	8	64.024	64.047	64.031
4	12	80.012	80.13	80.043
5	20	96.031	96.052	96.16

RESULTS

Standard calibration data of drug

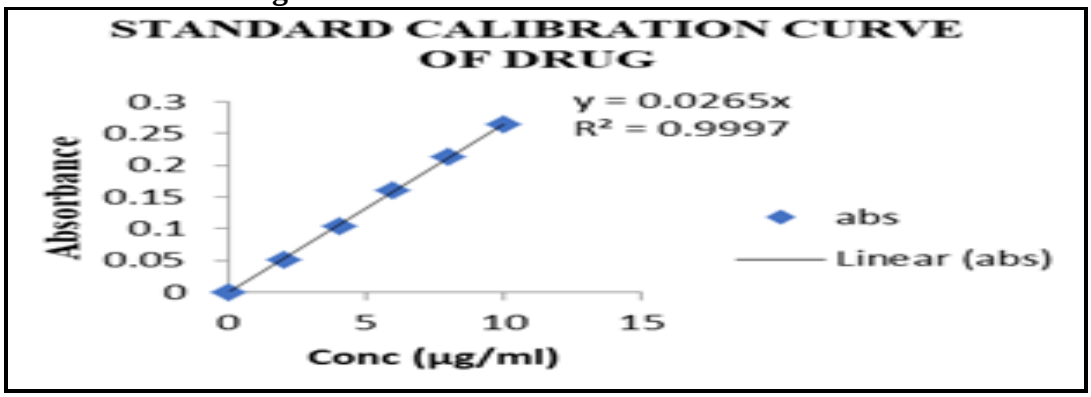


Figure No.1: Standard calibration curve

Compatibility study: FT-IR study

FT-IR GRAPHS

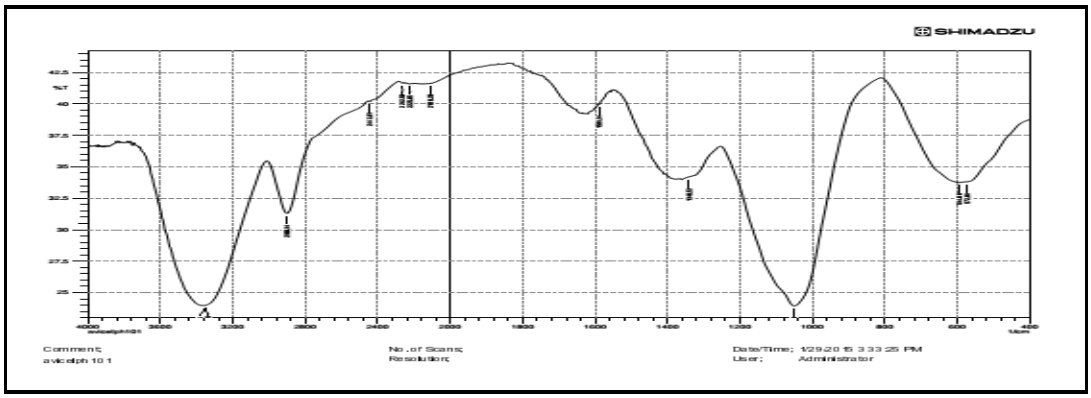


Figure No.2: Microcrystalline Cellulose

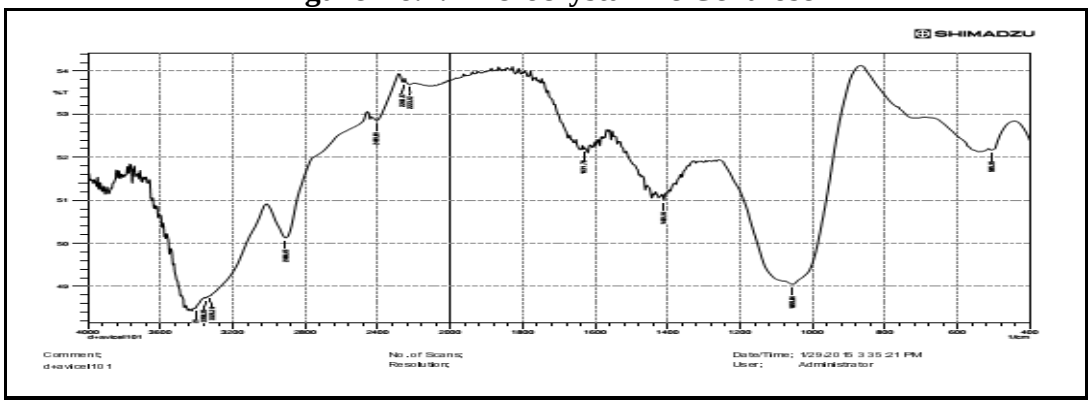


Figure No.3: Drug +Microcrystalline cellulose

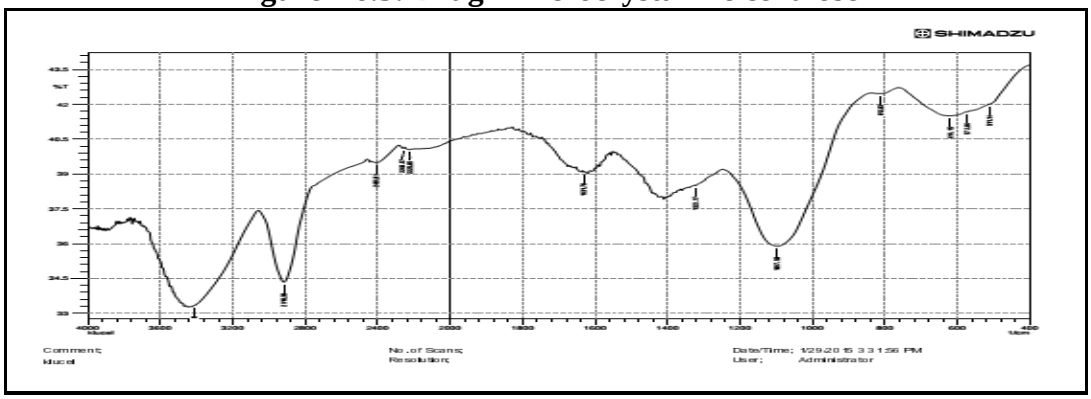


Figure No.4: Hydroxypropyl cellulose

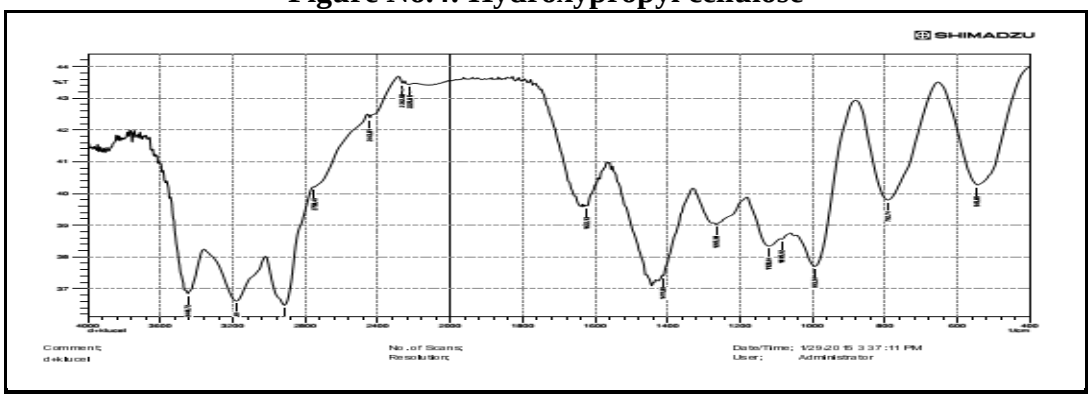


Figure No.5: Drug + Hydroxypropyl cellulose

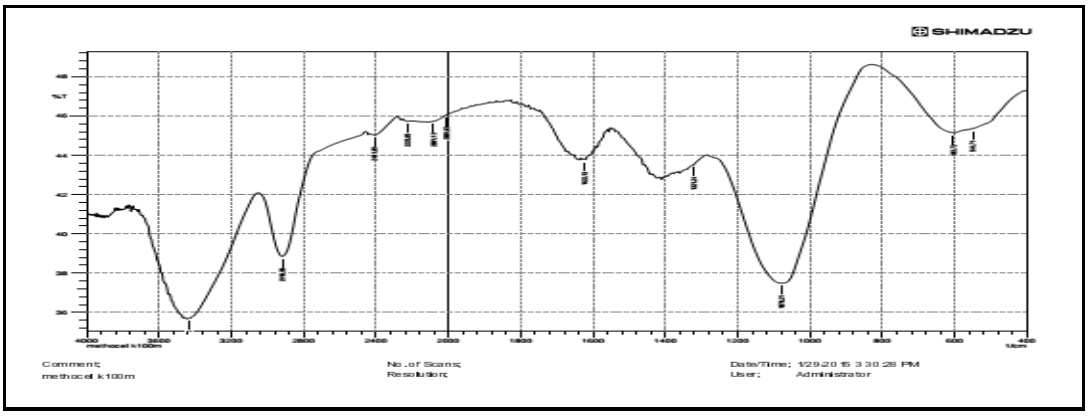


Figure No.6: Hydroxypropyl methylcellulose

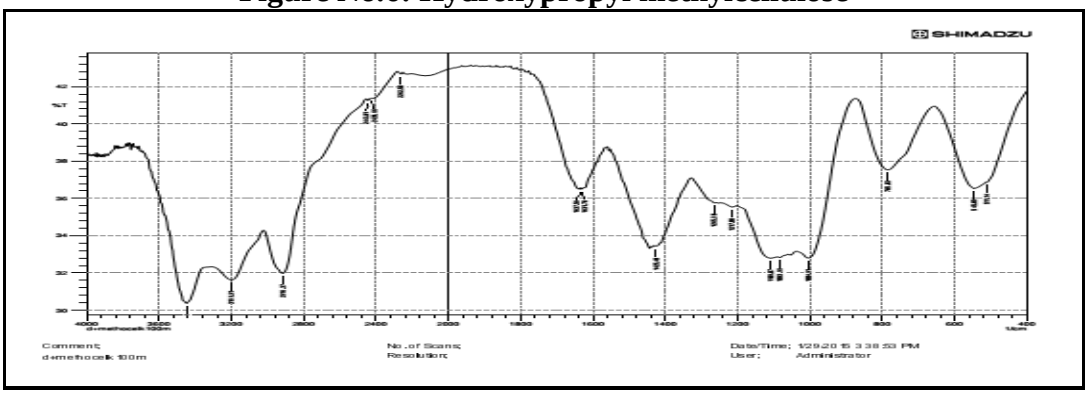


Figure No.7: Drug+ hydroxypropyl methylcellulose

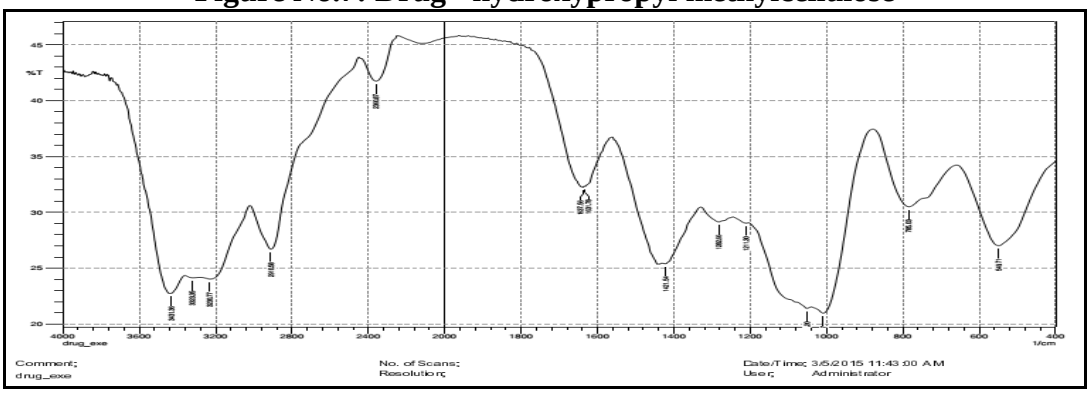


Figure No.8: FT-IR graph of mixture of drug and excipients

Dissolution profile of Formulations% CDR GRAPH (F1 to F8)

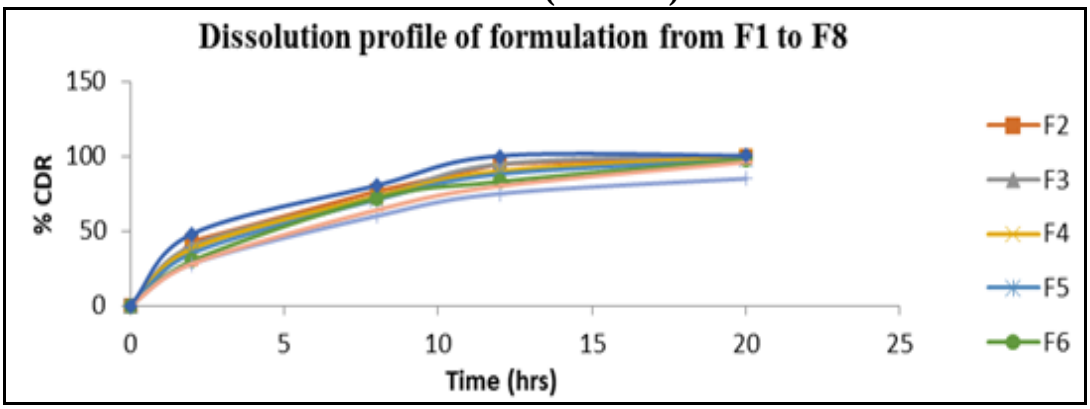


Figure No.9: Comparative *In-vitro* drug release

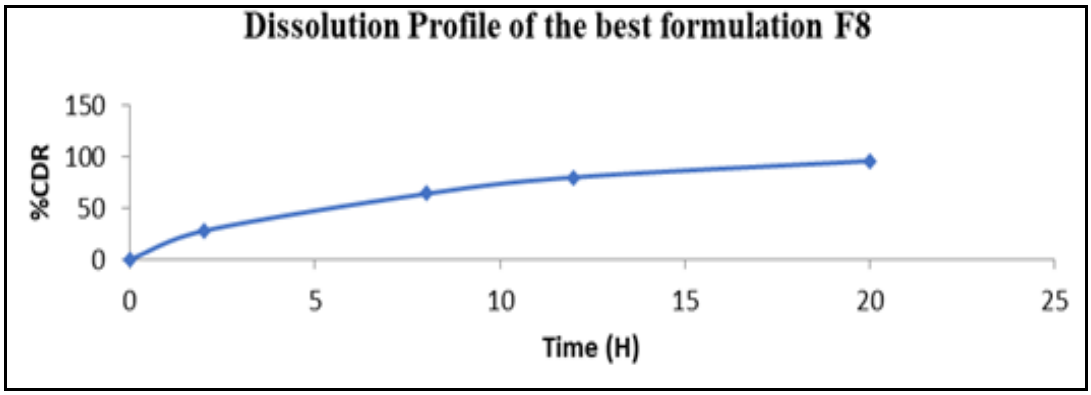
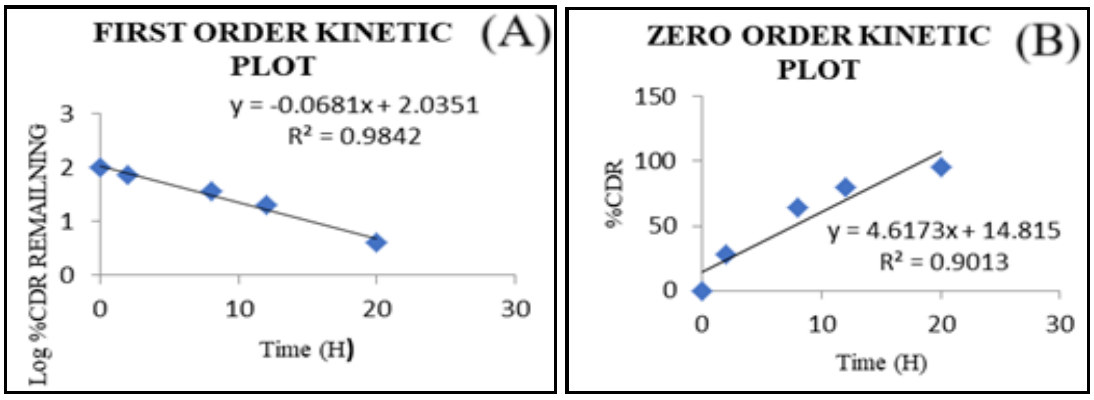


Figure No.10: Dissolution Profile of the best formulation

Graphical presentation of various kinetic models



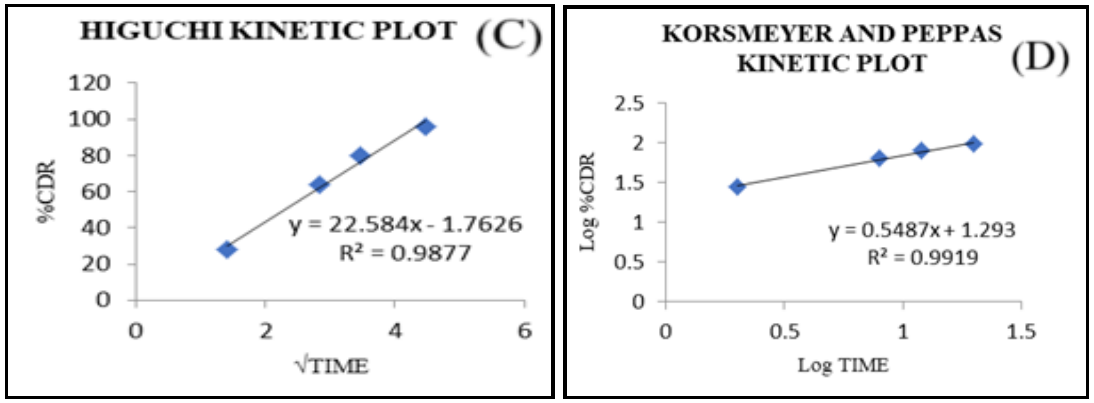


Figure No.11: Kinetic model plot of various models for F8 (A, B, C and D)

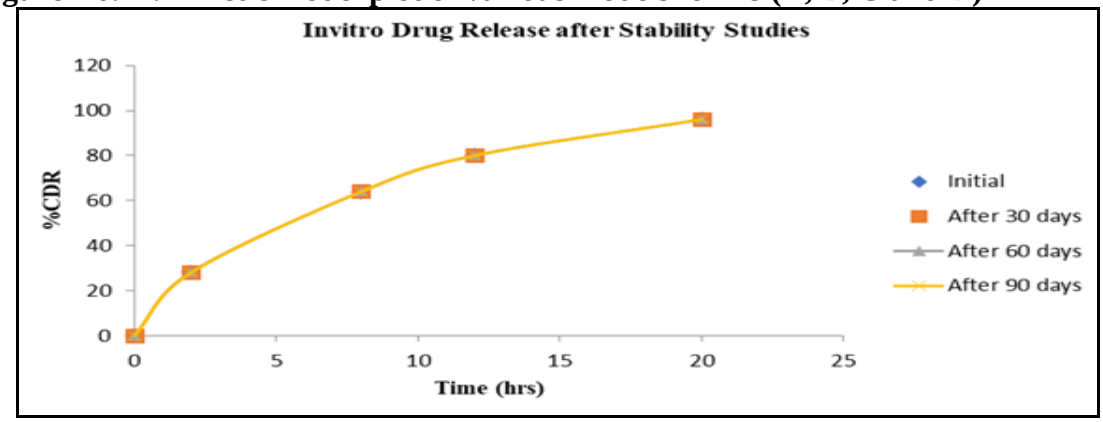


Figure No.12: Comparative dissolution profile of f8 during stability study period

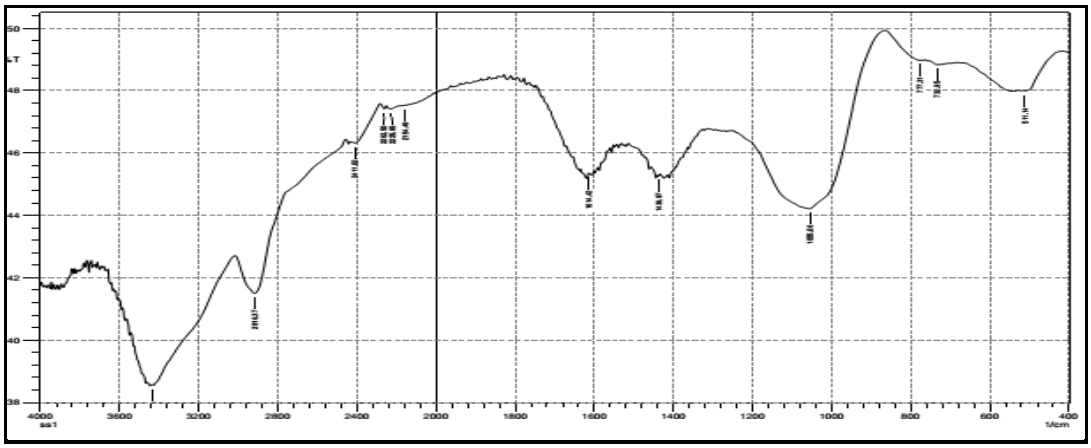


Figure No.13: FT-IR graph of formulation F8 after 3 months of stability period

CONCLUSION

Depression is caused by altering the levels of chemicals in the brain called neurotransmitters. There are many types of depression which may be very fatal in some cases. One among them is Major depressive disorder. To treat MDD the model drug which was formulated into 50mg extended release tablet as antidepressant.

The present study was to develop an extended release tablet of an Antidepressant. It is the serotonin-norepinephrine reuptake inhibitor derivative belongs to Cyclohexanol chemical class primarily used in the treatment of major depressive disorder. Extended release dosage forms cover a wide range of prolonged action preparations that provide continuous release of their active ingredients for a specific period of time. A satisfactory attempt was made to develop extended release tablet of antidepressant and evaluated it.

The design of dosage form was performed by choosing hydrophilic Hydroxypropyl methyl cellulose (HPMC K100M), Microcrystalline cellulose (MCC) as polymers and Hydroxypropyl Cellulose (Klucel) as granulating polymer which can release the drug up to 24hrs in predetermined rate. Granules were prepared by mixing thoroughly HPMC K100M, Microcrystalline cellulose with the drug and then kneading with granulating solution of Hydroxypropyl Cellulose with Isopropyl alcohol and Dichloromethane & air dried overnight. The dried granules were evaluated and then compressed into the core tablets. The core tablets were evaluated in terms of their pre-compression parameters and post-compression parameters like hardness, friability, weight variation. These core tablets were film coated using Instacoat Universal pink and evaluated for weight variation, hardness, % drug content and *in vitro* drug release. The optimized formulation of 50 mg Antidepressant was formed by using 22% HPMC K100M, 28% microcrystalline cellulose and 2% ratio of Hydroxypropyl Cellulose as binder and subjected to stability studies.

From the reproducible results obtained from the executed experiments it was concluded that:

On the basis of drug content, *in-vitr*o release studies and its kinetic data, F8 was selected as optimized formulations for designing extended release.

The study showed that coated model drug of SNRI class of antidepressant can be successfully used as an extended release tablet to treat Major Depressive Disorder.

Stability studies proved that the formulation is quite stable and drug content was affected to lesser extent in case of the core tablet, while in case of coated formulations no change was observed.

In conclusion, extended release over a period of 20-24hours was achieved. Thus, it can be considered as one of the promising formulation techniques of extended release for Major Depressive Disorder.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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