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Formulation and Evaluation of Extended Release Tablet of Venlafaxine hydrochloride for the treatment of MDD

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ABSTRACT
Objective: The objective of this research is to prepare Extended Release Tablet of Venlafaxine hydrochloride with the aim to extend drug release profile for the treatment of MDD.**Materials and Methods:** Pure drug, polymer, and other excipients were characterized by infrared spectroscopy and differential scanning calorimetry. The extend release tablets of venlafaxine hydrochloride were prepared using different proportion of ER polymers such as Ethyl cellulose and Xanthan gum. **Results:** In a total of six batches of formulations from F1 to F6 were prepared by varying ER polymers concentration. Results of evaluation parameters revealed that formulation F3 containing 150mgEthyl cellulose found to be most optimized formulation in terms of extend release and percent drug release analysis also conferred F3 as a most optimized formulation with the evidence of maximum extend percent drug release calculated as 84.09% in 24 hras compared with all the other formulations. Conclusion: All the six formulations were successfully prepared and evaluated. However, results of parameters evaluated conclude that among all prepared formulations, F3 was observed as most optimized formulation

Keywords: -Venlafaxine Hydrochloride, Extent released, Ethylcellulose, Xanthan gum, Major depressive disoder

I. INTRODUCTION

Oral delivery of drug is the most accepted route of administration compare to all other routes that have been explored for systemic delivery of drugs via pharmaceutical products of the different dosage form. The oral route is considered most natural, uncomplicated, convenient and safe due to its ease of administration, patient acceptance and cost-effective manufacturing process.The Extened-release dosage forms are type of dosage forms developed to liberate a dose at a extened period of time in order to maintain a drug concentration for a longer period of time with minimum dosing frequency.This can be possible by using polymers.ER dosage consists of either sustained-release (SR) or controlled-release (CR) dosage.The aim of this study is to formulate extent release tablet of Venlafaxine for the treatment of depressive illness including depression, anxiety and panic attack. Matrix system is a novel concept that allow a drug to release for longer and sustain manner. [1-3]

II. MATERIALS AND METHODS

Materials: Venlafaxine hydrochloride (Anwita drugs & chemicals, Hyderabad), Ethyl cellulose(SD.fine chemlimited, mumbai),Xanthan gum(HiMedia Laboratories Pvt. Ltd. Mumbai), Magnesium stearate (Remedy Labs, Gujrat), Lactose (Loba Chemie, Mumbaiand Talc (Loba Chemie, Mumbai).The
Composition of ER Tabletswas mentioned in **Table: 1.**

Table 1: Composition of ER Tablets

Ingredients (mg)	F1	F2	F3	F4	F5	F6
Venlafaxine HCl	75	75	75	75	75	75
Ethyl cellulose	50	100	150	-	-	-
Xanthan gum	-	-	-	50	100	150
Mg. stearate	10	10	10	10	10	10
Lactose	160	110	60	160	110	60
Talc	5	5	5	5	5	5
Total	300	300	300	300	300	300

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Method:
ER Tablets of Venlafaxine hydrochloride were prepared by direct compression method. [4]

III. RESULTS

Results of pre-compression studies were mentioned in **table: 2**

Table 2: Pre-compression studies

Parameters	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**
Angle of Repose(θ)	23.72	25.01	22.05	22.08	19.78	24.22
Bulk density(gm/cm^3)	0.54	0.47	0.41	0.52	0.45	0.58
Tapped density (gm/cm^3)	0.58	0.60	0.55	0.63	0.51	0.62
Carr's index (%)	24.3	20.03	17.8	18.80	12.72	24.50
Hausner's ratio	1.41	1.32	1.28	1.21	1.17	1.29

Results of post-compression studies were mentioned in **table: 3**

Table 3: Post-compression studies

Parameters	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**
Thickness(mm)	5.53	5.52	5.51	5.48	5.52	5.48
Hardness(KP)	6.92	6.87	6.99	6.72	6.69	6.90
Friability (%)	0.84	0.8	0.85	0.87	0.92	0.89
Weight variation(mg)	298.9	294	295	297.2	299.6	297
Drug content (%)	98.55	99.59	99.81	99.50	99.87	99.39

Results of in-vitro drug release were mentioned in **table: 4 (Fig.1)**

Table 4:Results of in vitro drug release studies of Venlafaxine ER Tablets

Time (hr.)	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**
0	0	0	0	0	0	0
0.5 hr	25.5	23.5	18.8	25.69	25.71	20.5
1 hr	33.25	34.5	27.75	37.63	30.77	38.25
2 hr	58.15	52.75	45.75	42.25	46.7	43.61
4 hr	73.75	76.5	59.25	69.04	60.5	66.97
8 hr	81.23	85.5	63.25	82.05	84.95	86.75
16 hr	89.75	93.30	80.75	91.5	91.45	90.75
24 hr	94.07	96.88	84.09	93.28	95.38	92.51

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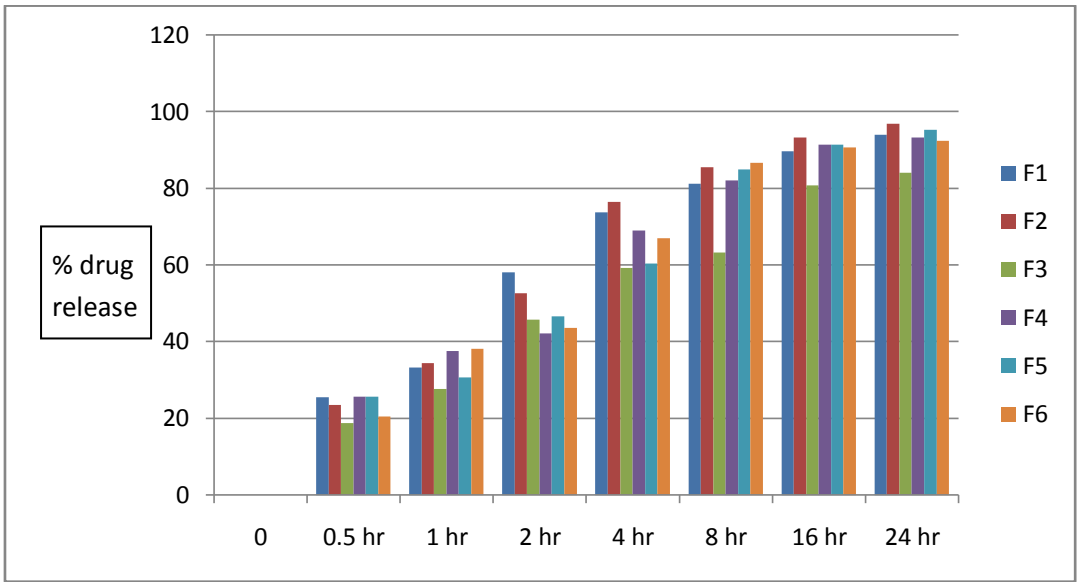

FIGURE.1 **In vitro drug release studies of Venlafaxine ER Tablets**

FT-IR (Fourier Transform Infrared) Spectrometry- The FT-IR study was performed
FT-IR spectra of pure drug (Venlafaxine Hydrochloride) (Fig.2)

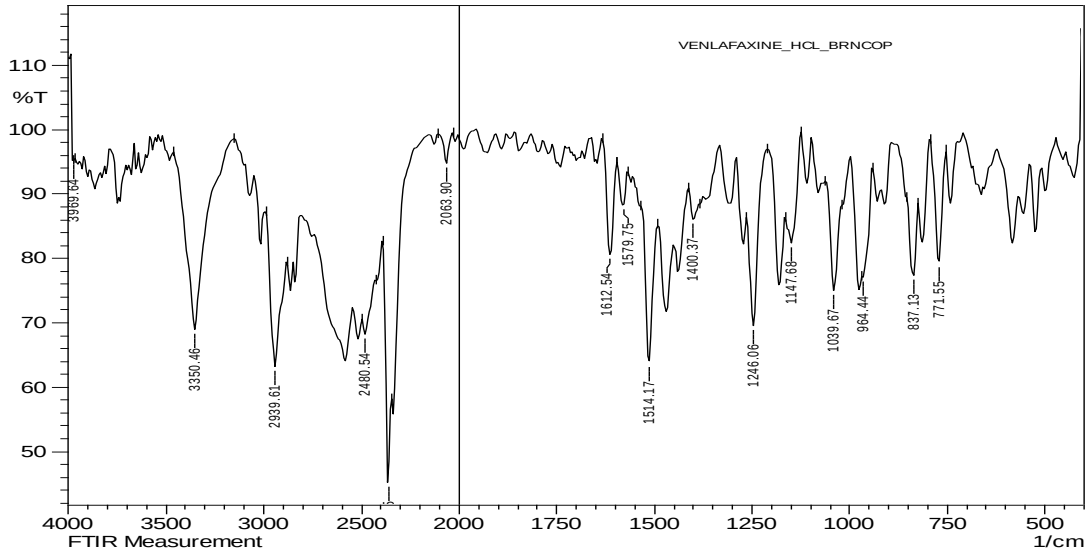

Figure 3: FT-IR of pure drug (Venlafaxine Hydrochloride)

IV. DISCUSSION

A total of six formulations (F1-F6) were prepared,by using different ratios of extent relase polymers. Firstly, the powder blends of all the six formulations were studied for their granule properties such as Angle of repose, Bulk density, Tapped density, Compressibility index, and Hausner's ratio which were found to be satisfactory and within the limit. All the prepared extent relase tablet formulations were evaluated for following parameters such as thickness, hardness, friability, weight variation,drug content and in-vitro drug release**.** The results were found within the standard specifications. From overall study, it was concluded that formulation F3 gave best results and also showed better extent release profile.

V. CONCLUSION

The above discussion concluded that the formulation F3 containing 150 mg of Ethyl

cellulose prepared by direct compression method found to be better formulation in terms of extent release profile.Thus the study gave a complete overview about the use of extent release polymers for delaying release of drug as compared to the release given by other formulations of drug and finally it reducing frequency and help in the treatment of MDD.

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