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Original Article

FORMULATION AND EVALUATION OF NEVARAPINE EXTENDED RELEASE MATRIX TABLETS

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ABSTRACT

Nevarapine is a non-nucleoside reverse transcriptase inhibitors (NNRTI) drug which is used in treatment in in Human Immunodeficiency Virus type 1 (HIV) infection. The present study is to develop a pharmaceutical stable, cost, effective, pharmaceutically equivalent, and quality improved formulation of NEVARAPINE Extended release Tablets. To achieve this goal various prototype formulation trials will be taken and evaluated with respect to the various quality control test such as dissolution, assay, acidresistance. The formula will be finalized by comparing the dissolution profile with that of the marketed VIRAMUNE XR tablets. In this study NEVIRAPINE Extended release Tablets were prepared by using hydrophobic polymers. 12 formulations of Extended release Tablets of nevarapine were developed by using Microcrystalline Cellulose as diluent andMagnesium Streate as lubricant in different proportion. The formulation F3 was found to be best of all the formulation showing drug release matching the innovator product. Hence it is considered as optimised Formulation.

Keywords: -Nevarapine, extended release, hydrophobic polymers, ethyl cellulose, magnesium sterate.

INTRODUCTION

Extended release drug therapy enhances the delivery of medications by prolonging the release of the active ingredient over a specified period, thus reducing the need for frequent dosing and maintaining therapeutic drug levels. Unlike conventional dosage forms that often lead to fluctuating drug levels and potential side effects, extended release systems aim to provide a steady and controlled drug release. This approach offers benefits such as improved patient compliance, reduced drug wastage, and minimized side effects. However, it comes with potential drawbacks including increased costs, risk of dose dumping, and the need for patient education. Ideal candidates for extended release formulations generally have a molecular weight under 1000 mg, are soluble, stable in the gastrointestinal environment, and have a suitable half-life and bioavailability. The design of these systems considers factors like the drug's biological half-life and its pharmacokinetic properties to ensure effective and safe delivery.

The absorption and metabolism of a drug significantly influence its suitability for extended-release formulations. Extended-release products are designed to release drugs at a rate slower than their absorption rate; otherwise, the drug may pass through absorptive areas of the gastrointestinal tract too quickly. For optimal absorption, the drug should ideally have a half-life of 3-4 hours and be absorbed in the upper gastrointestinal tract, where extended-release mechanisms like low-density pellets or bioadhesive materials can enhance retention. Additionally, drugs that undergo extensive pre-absorption metabolism may have reduced bioavailability in extended-release forms. Physicochemical factors, such as dose size, ionization, aqueous solubility, and partition coefficient, also impact the design of extended-release systems. Methods to retard drug release include reservoir systems, osmotic systems, ion-exchange resins, and matrix systems, with mechanisms such as dissolution-controlled, osmotic, diffusion-controlled, and erosion-controlled release playing key roles in achieving controlled drug delivery.

MATERIALS AND METHODS

Materials

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Table 1: List of materials:

Materials	Source
Nevirapine	Hetero laboratories
HPMC K4M	SD Fine Chemicals, Hyderabad
HPMV K15M	SD Fine Chemicals, Hyderabad
HPMCK100M	SD Fine Chemicals, Hyderabad
Magnesium stearate	SD Fine Chemicals, Hyderabad
Talc	SD Fine Chemicals, Hyderabad
MCC pH 102	Merk chemicals, Mumbai

Equipment's:

Table 2: List of equipment's:

Equipment's	Model/Company
Electronic balance	Wensar
Tablet compression machine	Karnavati , Rimek Mini Press II
Tablet hardness tester	Monsanto hardness tester
Dissolution test apparatus	Lab India Dissolution Apparatus Ds 8000(USP)
Disintegration test apparatus	Lab India Disintegration Apparatus(USP)
Friability test apparatus	Lab India Friability Apparatus FT 1020 (USP)
UV-Visible Spectrophotometer	Lab India
Hot air oven	VJ Instruments
pH meter	Lab India pH apparatus

Methodology:

Determination OF UV Absorption maxima

Nevirapine solution was prepared in 0.1 N HCL and diluted suitably. The UV spectrum of the solution was taken on Lab India 3200 UV/Vis double beam Spectrophotometer. The Solution exhibited UV maxima at 298 nm. The procedure was repeated with pH 6.8 phosphate buffer.

Preparation of Standard Calibration Curve of Nevirapine

100 mg of Nevirapine was accurately weighed and dissolved in little amount of Methanol and makeup the final volume up to 100 ml with 0.1 N HCl (pH 1.2) to prepare stock solution. The 10 ml of stock solution was further diluted with 0.1 N HCl (pH 1.2) in 100ml to get 100µg/ml (working standard). Then 0.2,0.4,0.6.0.8, and 1 ml of working standard was taken in 10 ml standard volumetric flask and made up the volume with 0.1N HCl to prepare 2µg,4µg,6µg,8µg, and 10µg drug per ml solution. Then the absorbance was measured in a UV spectrophotometer at 298 nm against 0.1 N HCl (pH 1.2) as blank. The absorbance so obtained was tabulated as in Table 7.1. Calibration curve was constructed and shown in Fig. 7.1. The procedure was repeated with pH 6.8 phosphate buffer and absorbance's were measured at 299 nm. The absorbances and standard graph were mentioned in Table 7.2 and figure 7.2 respectively.

6.3 Tablet formulation:

Formulation of Nevirapine Extended Release Tablet by Direct- Compression

Composition of preliminary trials for Nevirapine Extended release Tablet by direct compression is shown in table 6.1. All the ingredients were weighed. Required quantity of drug and excipient mixed thoroughly in a polybag. The blend is compressed using rotary tablet machine-8 station with 12mm flat punch, B tooling. Each tablet contains 100mg of Quetiapine fumarate and other pharmaceutical ingredients.

3. Formulation of Nevirapine Extended release tablets

INGREDIENT	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
Nevirapine	100	100	100	100	100	100	100	100	100	100	100	100
HPMC K4M	25	50	75	100	-	-	-	-	-	-	-	-
HPMC K15M	-	-	-	-	25	50	75	100	-	-	-	-
HPMC K100M	-	-	-	-	-	-	-	-	25	50	75	100
Talc	4	4	4	4	4	4	4	4	4	4	4	4
Mg. Stearate	4	4	4	4	4	4	4	4	4	4	4	4
MCC pH102	161	142	117	92	161	142	117	92	161	142	117	92
Total	300	300	300	300	300	300	300	300	300	300	300	300

All ingredients are expressed in mg only

6.4 Evaluation parameters

Precompression parameters

1. Bulk Density (Db)

It is the ratio of total mass of powder to the bulk volume of powder. It was measured by pouring the weight powder (passed through standard sieve # 20) into a measuring cylinder and initial weight was noted. This initial volume is called the bulk volume. From this the bulk density is calculated according to the formula mentioned below. It is expressed in g/ml and is given by,

Db = M/ Vb

Where, M is the mass of powder

Vb is the bulk volume of the powder.

2. Tapped Density (Dt)

It is the ratio of total mass of the powder to the tapped volume of the powder. Volume was measured by tapping the powder for 750 times and the tapped volume was noted if the difference between these two volumes is less than 2%. If it is more than 2%, tapping is continued for 1250 times and tapped volume was noted. Tapping was continued until the difference between successive volumes is less than 2 % (in a bulk density apparatus). It is expressed in g/ml and is given by,

Dt = M / Vt

Where,

M is the mass of powder

Vt is the tapped volume of the powder.

3. Angle of Repose (θ)

The friction forces in a loose powder can be measured by the angle of repose (q). It is an indicative of the flow properties of the powder. It is defined as maximum angle possible between the surface of the pile of powder and the horizontal plane

$\tan(\theta) = h / r$

$\theta = \tan^{-1}(h / r)$

Where,

- θ is the angle of repose.
- h is the height in cm
- r is the radius in cm

The powder mixture was allowed to flow through the funnel fixed to a stand at definite height (h). The angle of repose was then calculated by measuring the height and radius of the heap of powder formed. Care was taken to see that the powder particles slip and roll over each other through the sides of the funnel. Relationship between angle of repose and powder flow property.

Table 4: Angle of Repose as an Indication of Powder Flow Properties

Sr. No.	Angle of Repose(0)	Type of Flow
1	<20	Excellent
2	20-30	Good
3	30-34	Passable
4	>34	Very Poor

4. Carr's index (or) % compressibility

It indicates powder flow properties. It is expressed in percentage and is give by,

$$I = \frac{D_t - D_b}{D_t} \times 100$$

Where,

Dt is the tapped density of the powder and

Db is the bulk density of the powder.

Table 5: Relationship between % compressibility and flow ability

Sr no.	% Compressibility	Flow ability
1	5-12	Excellent
2	12-16	Good
3	18-21	Fair Passable
4	23-35	Poor
5	33-38	Very Poor
6	<40	Very Very Poor

5. Hausner ratio

Hausner ratio is an indirect index of ease of powder flow. It is calculated by the following formula.

$$\text{Hausner ratio} = \frac{D_t}{D_b}$$

Where, Dt is the tapped density, Db is the bulk density.

Lower Hausner ratio (<1.25) indicates better flow properties than higher ones

(>1.25).

Post compression parameters

1. Weight variation

20 tablets were selected randomly from the lot and weighted individually to check for weight variation. Weight variation specification as per I.P. is

Table 6: Weight Variation Specification as per IP

Average Weight of Tablets	%Deviation
80 mg or less	±10
More than 80 mg but less than 250 mg	±7.5
250 mg or more	±5

2. Hardness

Hardness or tablet crushing strength (fc), the force required to break a tablet in a diametric compression was measured using Monsanto tablet hardness tester. It is expressed in kg/cm2.

3. Thickness

Three tablets were selected randomly from each batch and thickness was measured by using Vernier Caliper.

4. Friability (F)

Friability of the tablet determined using Roche friabilator. This device subjects the tablet to the combined effect of abrasion and shock in a plastic chamber revolving at 25 rpm and dropping a tablet at the height of 6 inches in each revolution. Pre weighed sample of tablets was placed in the friabilator and were subjected to the 100 revolutions. Tablets were dusted using a soft muslin cloth and reweighed. The friability (F) is given by the formula.

5. In-Vitro drug release

Invitro dissolution studies were carried out by using 900ml of 0.1 N HCl in USP dissolution apparatus by using paddle method for about 2 hours. After 2 hours the dissolution medium was withdrawn keeping the tablet in the dissolution basket. Then pH 6.8 phosphate buffer was added to the dissolution medium (900ml) and the dissolution was carried out for about 6 hours. The samples were withdrawn at regular time intervals of 30 min,1 hour,2 hr,3,5,5,6,7 & 8 hours respectively.

6. Assay

10 tablets were weighed and triturated. The tablet triturate equivalent to 10 mg of the drug was weighed accurately, dissolved in pH 1.2 buffer and diluted to 100 ml with the same. Further dilutions were done suitably to get a concentration of 10 µg/ ml with simulated gastric fluid pH 1.2. Absorbance was read at 220 nm against the reagent blank, and the concentrations of

Nevirapine in µg/ ml was determined by using the regression equation.

Y= 0.007x + 0.001

Drug content in mg / tablet = conc. µg/ml * dilution factor

% Drug content = drug content in mg * 100 / label claim.

RESULTS & DISCUSSION

Standard Calibration curve of Nevirapine

Table 7: Concentration and absorbance obtained for calibration curve of Nevirapine in 0.1 N hydrochloric acid buffer (pH 1.2)

S. No.	Concentration (µg/ml)	Absorbance* (at 220 nm)
1	2	0.193
2	4	0.34
3	6	0.461
4	8	0.579
5	10	0.709
Correlation Coefficient = 0.9985 y = 0.0636x + 0.0751		

It was found that the estimation of Nevirapine by UV spectrophotometric method at λmax 220 nm in 0.1N Hydrochloric acid had good reproducibility and this method was used in the study. The correlation coefficient for the standard curve was found to be closer to 1, at the concentration range, 2-10µg/ml. The regression equation generated was y = 0.0636x + 0.0751.

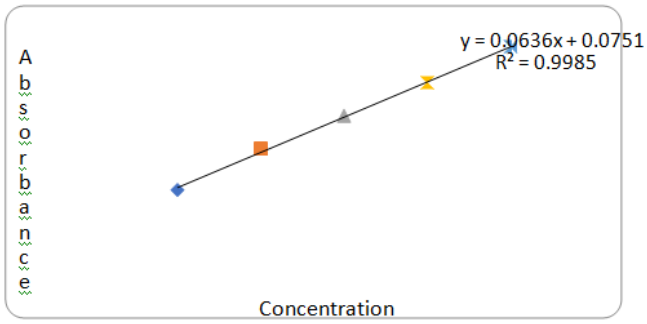

Fig 1: Standard graph of Nevirapine in 0.1 N HCl

Table 8: Concentration and absorbance obtained for calibration curve of Nevirapine in pH 6.8 Phosphate buffer.

S. No.	Concentration (µg/ml)	Absorbance* (at 220 nm)
1	2	0.193
2	4	0.331
3	6	0.446
4	8	0.553
Correlation Coefficient = 0.9982 y = 0.0595x + 0.083		

It was found that the estimation of Nevirapine by UV spectrophotometric method at λmax 222 nm in pH 6.8 Phosphate buffer. had good reproducibility and this method was used in the study. The correlation coefficient for the standard curve was found to be closer to 1, at the concentration range, 2-10µg/ml. The regression equation generated was y = 0.0595x + 0.083.

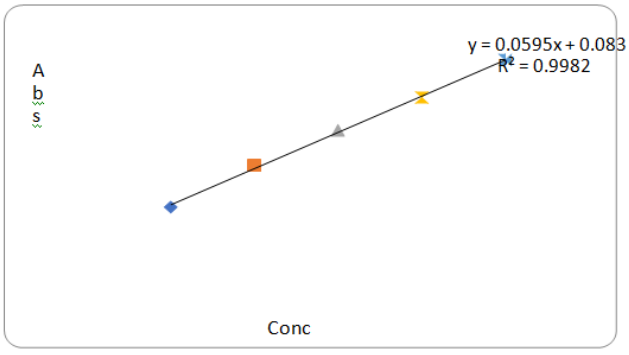

Fig 2: Standard graph of Nevirapine in pH 6.8 Phosphate buffer

7.2 Evaluation Parameters for Extended release tablets of Nevirapine:

7.2.1 Pre-compression parameters:

The data's were shown in Table 7.3.The values for angle of repose were found in the range of 25°-30°. Bulk densities and tapped densities of various formulations were found to be in the range of 0.41 to 0.50 (gm/cc) and 0.50 to 0.58 (gm/cc) respectively. Carr's index of the prepared blends fall in the range of 13.06% to 18.18%. The Hausner ratio n fall in range of 1.14 to 1.22. From the result it was concluded that the powder blends had good flow properties and these can be used for tablet manufacture.

Table 9: Pre-compression parameter

Formulations	Bulk Density (gm/cm2)	Tap Density (gm/cm2)	Tap Density (gm/cm2)	Hausner ratio	Angle Of Repose(Θ)
F_1	**0.45±0.35**	**0.55±0.31**	**18.18±0.65**	**1.22±0.51**	**27.91±1.32**
F_2	**0.47±0.26**	**0.55±0.26**	**14.54±0.37**	**1.17±0.53**	**28.23±0.80**
F_3	**0.50±0.30**	**0.58±0.29**	**13.79±0.61**	**1.16±0.50**	**29.34±0.47**
F_4	**0.46±0.34**	**0.55±0.32**	**16.36±0.67**	**1.19±0.94**	**26.71±1.03**
F_5	**0.50±0.25**	**0.58±0.23**	**13.79±0.81**	**1.16±1.03**	**29.34±0.79**
F_6	**0.47±0.20**	**0.55±0.36**	**14.54±0.94**	**1.17±0.70**	**28.23±0.52**
F_7	**0.50±0.30**	**0.58±0.19**	**13.79±0.68**	**1.16±0.89**	**29.34±0.24**
F_8	**0.41±0.39**	**0.50±0.36**	**18.24±0.47**	**1.21±0.96**	**26.78±1.29**
F_9	**0.41±0.33**	**0.50±0.30**	**18.12±0.67**	**1.21±0.68**	**26.78±1.28**
F_{10}	**0.42±0.32**	**0.51±0.10**	**18.24±0.93**	**1.20±0.68**	**26.68±0.83**
F_{11}	**0.48±0.21**	**0.56±0.23**	**18.12±0.98**	**1.21±0.50**	**26.70±0.55**
F_{12}	**0.41±0.23**	**0.54±0.25**	**18.11±0.72**	**1.22±0.31**	**26.71 ±1.30**

7.2.2. Post compression Parameters:

Weight variation test

Tablets of each batch were subjected to weight variation test, difference in weight and percent deviation was calculated for each tablet and was shown in the Table 7.4. The average weight of the tablet is approximately in range of 295 to 305 mg, so the permissible limit is ±5% (>220 mg). The results of the test showed that, the tablet weights were within the pharmacopoeia limit.

Hardness test

Hardness of the three tablets of each batch was checked by using Pfizer hardness tester and the data's were shown in Table 7.4. The results showed that the hardness of the tablets is in range of 4 to 4.5 kg/cm2 ,which was within IP limits.

Thickness

Thickness of three tablets of each batch was checked by using Vernier Caliper and data shown in Table-10 The result showed that thickness of the tablet is raging from 5.00 to 6.14 mm.

Tablets of each batch were evaluated for percentage friability and the data's were shown in the Table 7.4. The average friability of all the formulations lies in the range of 0.30 to 0.51% which was less than 1% as per official requirement of IP indicating a good mechanical resistance of tablets.

Friability

7.4. Post-Compession parameters:

FD	Weight variation (mg)	Hardness (kg/cm²)	Thickness (mm)	Friability (%)	Assay (%)
F_1	304±1.25	4.5±0.90	2.5±0.08	0.43±0.06	97.23±1.01
F_2	304±1.12	4.3±0.68	2.5±0.12	0.34±0.07	98.55±1.19
F_3	300±1.30	4.2±0.89	2.5±0.04	0.49±0.11	98.16 ±1.19
F_4	305±1.03	4.2±1.2	2.4±0.09	0.47±0.07	99.34±1.16
F_5	302±1.05	4.3±1.13	2.5±0.06	0.49±0.08	98.16 ±1.34
F_6	298±1.15	4.3±0.60	2.5±0.01	0.34±0.05	98.55±1.42
F_7	300±1.61	4.4±1.29	2.4±0.08	0.49±0.01	98.16 ±0.94
F_8	304±1.81	4.5±0.83	2.5±0.09	0.34±0.08	99.25±1.10
F_9	306±1.18	4.4±0.85	2.5±0.09	0.34±0.12	99.25±1.05
F10	301±1.10	4.4±0.73	2.5±0.08	0.43±0.06	98.6±1.10
F11	302±1.05	4.3±0.97	2.5±0.08	0.54±0.55	98.7±1.39
F12	304±1.18	4.5±1.05	2.5±0.06	Ye0.43+0.10	98.5±0.91

Assay

Assay studies were performed for the prepared formulations. From the assay studies it was concluded that all the formulations were showing the % drug content values within 97.23 -99.25%

***Invitro* Dissolution studies**

Invitro dissolution studies were carried out by using 900ml of 0.1 N HCl in USP dissolution apparatus by using paddle method for about 2 hours. After 2 hours the dissolution medium was

withdrawn keeping the tablet in the dissolution basket. Then pH 6.8 phosphate buffer was added to the dissolution medium (900ml) and the dissolution was carried out for about 6 hours. The samples were withdrawn at regular time intervals of 30 min, 1 hour, 2 hr, 3, 5, 5, 6, 7 & 8 hours respectively. The results were displayed in table 11.

Table 11: *Invitro* dissolution data

Time(Hrs)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
0.5	25.57±0.86	20.15±0.165	16.45±0.52	11.47±0.43	15.44±0.50	10.42±0.79	9.41±0.74	8.58±0.54	49.53±0.65	38.2±0.66	26.42±0.92	18.95±0.66
1	46.74±0.87	39.47 ±0.43	26.76±0.45	18.64±0.50	29.45±0.50	16.55±0.31	15.65±0.65	14.55±0.67	78.83±0.68	41.94±0.98	38.27±1.01	28.36±0.67
2	76.54±0.88	55.33 ±0.55	34.68±0.55	29.55±0.51	38.57±0.68	28.67±0.89	241.4±0.45	18.46±1.27	96.95±0.68	62.46±1.23	43.44	36.44±0.97
3	98.42±0.91	75.39 ±0.82	42.43±0.27	39.59±0.50	55.43±0.52	39.55±0.62	36.74±0.75	23.45±0.50	96.12±0.53	78.25±0.66	59.33±1.15	49.53±1.30
4	0	87.36±0.36	55.47±0.48	49.68±0.51	68.45±0.62	48.56±1.03	42.48±0.78	28.24±0.52	0	81.43±1.03	76.35±0.96	69.38±0.81
5	0	99.44 ±0.50	67.43±0.30	57.42±1.10	87.14±0.84	59.43±0.80	49.64±0.95	34.87±0.88	0	96.82±1.15	88.44±0.87	78.14±0.67
6	0	0	85.49±0.56	69.37±0.37	98.36±1.08	69.28±0.61	55.36±0.09	40.23±1.24	0		95.47±0.78	89.75±0.84
7	0	0	91.54±0.81	78.54±0.61	0	74.5±1.14	60.37±0.88	44.86±0.65	0	0	98.58±0.80	97.56±0.85
8	0	0	97.38±0.75	82.34±0.51	0	82.36±0.51	72.84	50.45±0.70	0	0	0	0

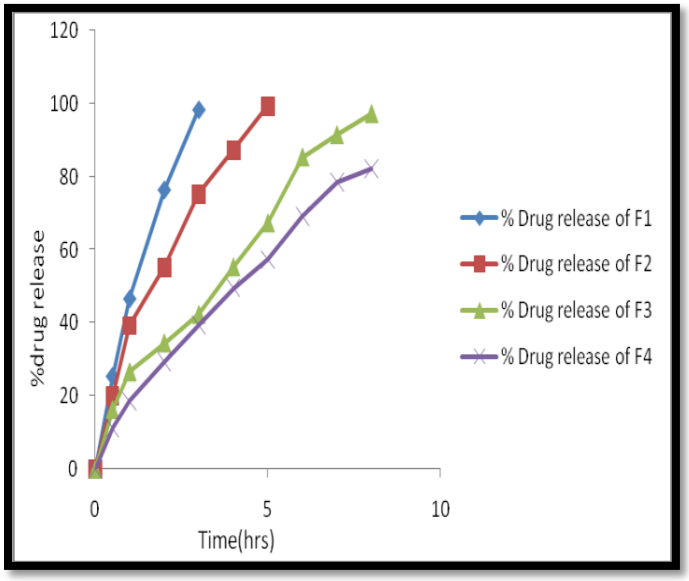

Fig 3: Dissolution profile of formulations prepared with HPMC K4M polymer

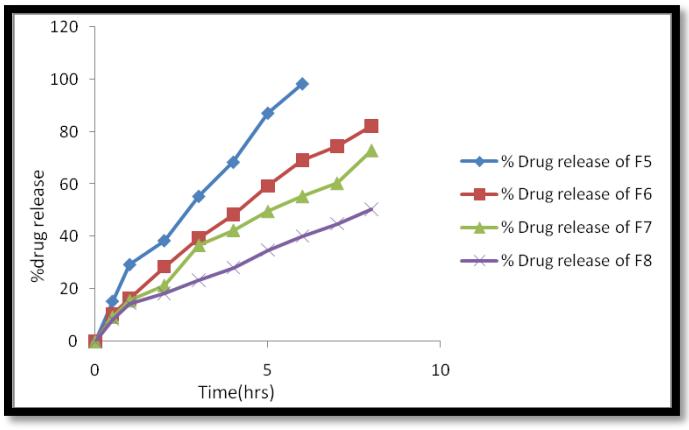

Fig 4: Dissolution profile of formulations prepared with HPMC K15M polymer

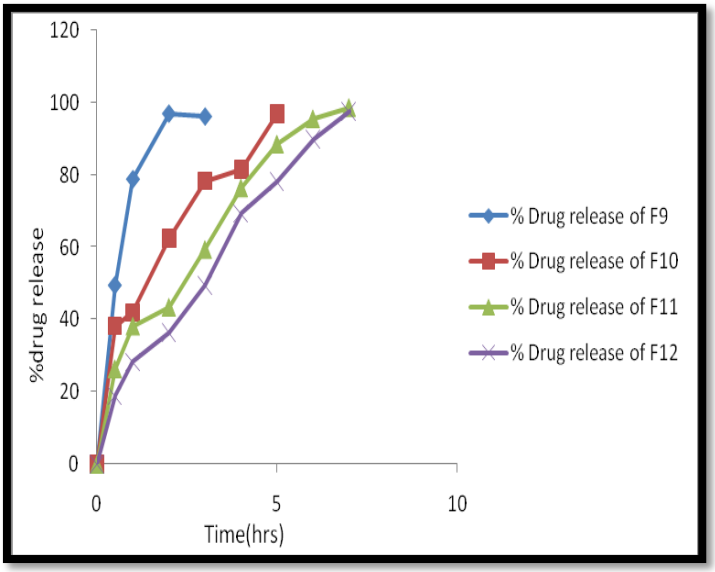

Fig 5: Dissolution profile of formulations prepared with HPMC K4M as polymer

From the tabular column 11 it was evident that the formulations prepared with HPMC K4M as retarding polymer in low concentrations the polymer was unable to produce the required retarding action to the tablets. As the concentration of polymer increases the retarding nature was also increased. HPMC K4M in the concentration of 75 mg showed good % drug release i.e., 97.3 in 8 hours.

Where as in case of formulations prepared with HPMC K15M as retarding polymer, the formulations with 25 mg concentration of polymer showed complete drug release in 3 hours only, whereas the concentration of polymer increases the retarding nature also increased. The Formulation Containing HPMC K15M in 20 Mg Concentration Showed good retarding nature with required drug release.

Where as in case formulations prepared with HPMC K4M as retarding polymer, as the concentration of polymer increases the retarding nature was also increased. When compared with HPMC polymers it was failed to produce desired drug release pattern.

From the above results it was evident that the formulation F3 is best formulation with desired drug release pattern extended up to 8 hours.

Application of Release Rate Kinetics to Dissolution Data:

Various models were tested for explaining the kinetics of drug release. To analyze the mechanism of the drug release rate kinetics of the dosage form, the obtained data were fitted into zero-order, first order, Higuchi, and Korsmeyer-Peppas release model.

Table 12: Release kinetics data for optimised formulation

CUMULATIVE (%) RELEASE Q	TIME (T)	ROOT (T)	LOG (%) RELEASE	LOG (T)	LOG (%) REMAIN	RELEASE RATE (CUMULATIVE % RELEASE / t)	1/CUM% RELEASE	PEPPAS log Q/100	% Drug Remaining	Q01/3	Qt1/3	Q01/3 Qt1/3
0	**0**	**0**			**2.000**				**100**	**4.642**	**4.642**	**0.000**
9.89	**0.5**	**0.707**	**0.995**	**-0.301**	**1.955**	**19.780**	**0.1011**	**-1.005**	**90.11**	**4.642**	**4.483**	**0.158**
16.76	**1**	**1.000**	**1.224**	**0.000**	**1.920**	**16.760**	**0.0597**	**-0.776**	**83.24**	**4.642**	**4.366**	**0.275**
22.53	**2**	**1.414**	**1.353**	**0.301**	**1.889**	**11.265**	**0.0444**	**-0.647**	**77.47**	**4.642**	**4.263**	**0.379**
27.43	**3**	**1.732**	**1.438**	**0.477**	**1.861**	**9.143**	**0.0365**	**-0.562**	**72.57**	**4.642**	**4.171**	**0.470**
33.66	**4**	**2.000**	**1.527**	**0.602**	**1.822**	**8.415**	**0.0297**	**-0.473**	**66.34**	**4.642**	**4.048**	**0.593**
37.11	**5**	**2.236**	**1.569**	**0.699**	**1.799**	**7.422**	**0.0269**	**-0.431**	**62.89**	**4.642**	**3.977**	**0.665**
44.67	**6**	**2.449**	**1.650**	**0.778**	**1.743**	**7.445**	**0.0224**	**-0.350**	**55.33**	**4.642**	**3.811**	**0.831**
53.87	**7**	**2.646**	**1.731**	**0.845**	**1.664**	**7.696**	**0.0186**	**-0.269**	**46.13**	**4.642**	**3.586**	**1.055**
61.3	**8**	**2.828**	**1.787**	**0.903**	**1.588**	**7.663**	**0.0163**	**-0.213**	**38.7**	**4.642**	**3.382**	**1.259**
69.1	**9**	**3.000**	**1.839**	**0.954**	**1.490**	**7.678**	**0.0145**	**-0.161**	**30.9**	**4.642**	**3.138**	**1.504**
78.2	**10**	**3.162**	**1.893**	**1.000**	**1.338**	**7.820**	**0.0128**	**-0.107**	**21.8**	**4.642**	**2.794**	**1.848**
84.22	**11**	**3.317**	**1.925**	**1.041**	**1.198**	**7.656**	**0.0119**	**-0.075**	**15.78**	**4.642**	**2.508**	**2.133**
90.33	**12**	**3.464**	**1.956**	**1.079**	**0.985**	**7.528**	**0.0111**	**-0.044**	**9.67**	**4.642**	**2.130**	**2.511**

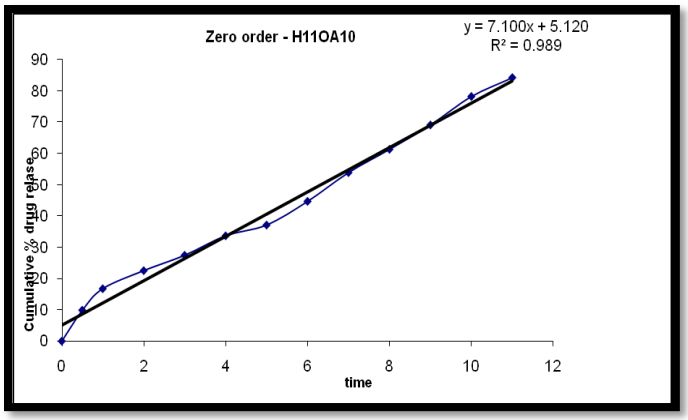

Fig 6: Zero order release kinetics graph

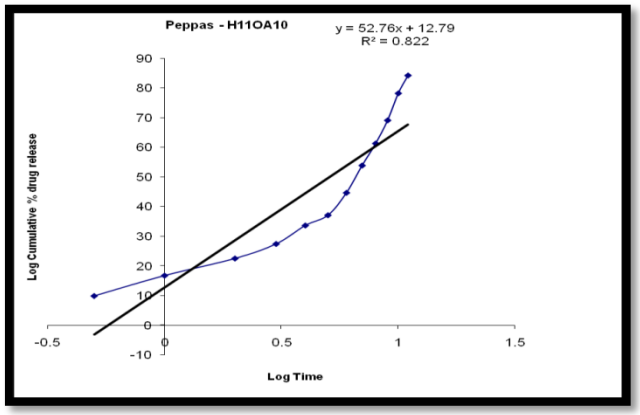

Fig 8: Kars mayer peppas graph

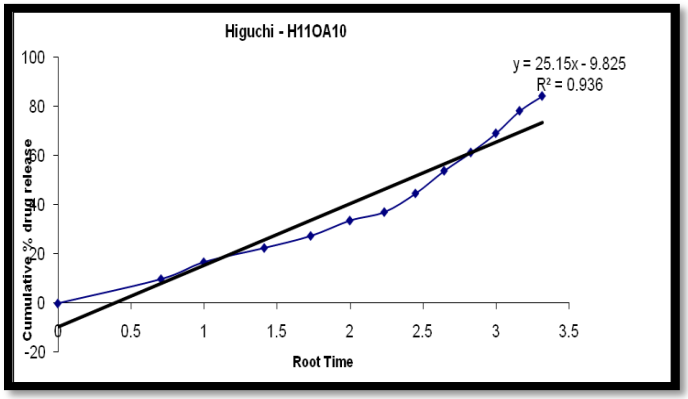

Fig 7: Higuchi release kinetics graph

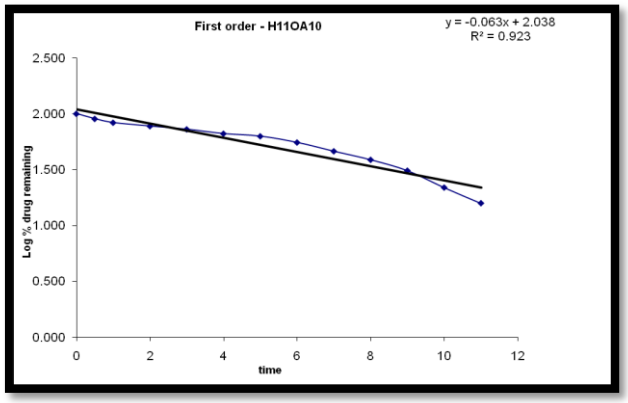

Fig 9: First order release kinetics graph

From the above graphs it was evident that the formulation F3 was followed Zero order release mechanism

FTIR STUDIES

IR spectra was obtained by using The FTIR spectrometer, scanning range was (4000to 400) Cm^{1}at scan period of 1 min.

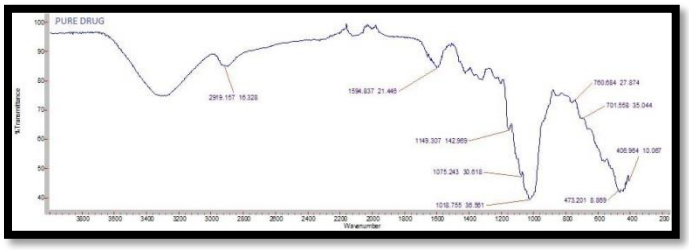

Fig 10.The FTIR spectra of pure drug, was shown

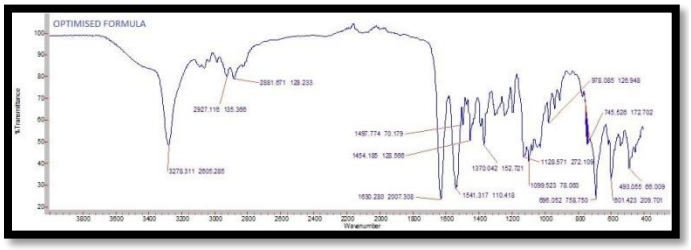

Fig 11: The FTIR spectra of optimised Formulation was shown

SUMMARY & CONCLUSION

In the present work, an attempt has been made to develop extended release tablets of Nevirapine by selecting various polymers as retarding polymers. All the formulations were prepared by direct compression method using 6mm punch on 8 station rotary tablet punching machine. The blend of all the formulations showed god flow properties such as angle of repose, bulk density, tapped density. The prepared tablets were shown good post compression parameters and they passed all the quality control evaluation parameters as per I.P limits. Among all the formulations F3 formulation showed maximum % drug release i.e., 97.38 % in 8 hours. Hence it is considered as optimized formulation. Whereas the formulations containing HPMCK15M showed more retarding with increasing concentration of polymer. The formulations with HPMCK4M were unable to produce the desired rug release pattern.

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