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DESIGN AND EVALUATION OF ETRAVIRINE SUSTAINED RELEASE TABLETS PREPARED BY LIQUISOLID COMPACT TECHNIQUE USING POLYMERS

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Abstract:

Background
Etravirine is a second-generation non-nucleoside reverse transcriptase inhibitor (NNRTI) used in the treatment of HIV-1 infection. Owing to its poor aqueous solubility and dissolution rate-limited absorption, development of a sustained release dosage form remains challenging. Liquisolid compact technology offers a promising approach to improve dissolution while simultaneously controlling drug release.
Objective:The present study aimed to formulate and evaluate sustained release (SR) tablets of Etravirine using the liquisolid compact technique with natural polymers such as guar gum and xanthan gum. Propylene glycol and Tween 80 were employed as non-volatile liquid vehicles.
Methods:Twelve formulations (F1–F12) were prepared using varying concentrations of guar gum and xanthan gum in combination with propylene glycol or Tween 80. Pre-compression parameters including bulk density, tapped density, Carr's index, Hausner ratio, and angle of repose were evaluated. The compressed tablets were characterized for weight variation, hardness, thickness, friability, drug content, and in vitro dissolution. Drug release kinetics were analyzed using Zero-order, First-order, Higuchi, and Korsmeyer–Peppas models. Drug–excipient compatibility was assessed by FTIR spectroscopy.
Results:All formulations exhibited satisfactory flow characteristics and compressibility. Post-compression evaluation demonstrated acceptable hardness (4.39–5.98 kg/cm²), friability (<1%), and drug content (98–102%). Dissolution studies revealed prolonged drug release up to 12 h. Among all formulations, F2 exhibited the most desirable sustained release profile with 100% drug release at 12 h. Kinetic analysis indicated that drug release followed first-order kinetics ($R^2 = 0.984$) and showed the highest correlation with the Higuchi diffusion model ($R^2 = 0.980$), suggesting diffusion-controlled release. The diffusion exponent ($n = 0.814$) indicated anomalous (non-Fickian) transport. FTIR studies confirmed the absence of drug–excipient interactions.
Conclusion:The study demonstrated that Etravirine sustained release tablets can be successfully developed using the liquisolid compact technique. The formulation containing xanthan gum with propylene glycol (F2) exhibited optimal sustained release behavior and may serve as a promising oral controlled-release system for improving patient compliance and therapeutic efficacy.

Keywords: Etravirine, Sustained Release Tablets, Liquisolid Compact, Xanthan Gum, Guar Gum, Drug Release Kinetics, HIV Therapy

1. Introduction

Oral drug delivery remains the most preferred route of administration due to its convenience, patient compliance, and cost-effectiveness. Conventional dosage forms generally release the drug immediately after administration, resulting

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in fluctuations in plasma drug concentrations. Sustained release drug delivery systems are designed to release the drug at a predetermined rate, maintaining therapeutic drug levels for an extended period while reducing dosing frequency and minimizing adverse effects.

Etravirine is a second-generation non-nucleoside reverse transcriptase inhibitor (NNRTI) approved for the treatment of HIV-1 infection. The drug exhibits poor aqueous solubility but high membrane permeability, classifying it as a Biopharmaceutical Classification System (BCS) Class II drug. Its poor dissolution behavior often limits oral bioavailability.

Liquisolid compact technology is a novel formulation approach wherein a liquid medication is transformed into a dry, free-flowing, and compressible powder using suitable carrier and coating materials. This technique enhances wetting properties and dissolution behavior of poorly soluble drugs while allowing modulation of drug release through matrix-forming polymers.

Natural polymers such as guar gum and xanthan gum have been extensively investigated as hydrophilic matrix formers owing to their biodegradability, biocompatibility, and ability to control drug release through swelling and gel formation mechanisms.

The present investigation was therefore undertaken to formulate Etravirine sustained release tablets using the liquisolid compact technique and evaluate the influence of natural polymers and liquid vehicles on drug release behavior.

2. Materials and Methods

2.1 Materials

Etravirine was obtained as a gift sample from Pharma Train. Propylene glycol, Tween 80, guar gum, xanthan gum, microcrystalline cellulose PH102, magnesium stearate, and Aerosil were procured from certified pharmaceutical suppliers.

2.2 Preparation of Phosphate Buffer (pH 6.8)

Phosphate buffer pH 6.8 was prepared using potassium dihydrogen phosphate and sodium hydroxide according to standard procedures and used for analytical and dissolution studies.

2.3 Analytical Method Development

Determination of λmax

A standard solution of Etravirine was prepared in phosphate buffer pH 6.8 and scanned between 200–400 nm using a UV-Visible spectrophotometer. The maximum absorbance was observed at 282 nm.

Calibration Curve

Serial dilutions (2–10 µg/mL) were prepared and analyzed at 282 nm. A linear relationship between concentration and absorbance was obtained with a regression coefficient (R^2) of 0.9993, confirming compliance with Beer-Lambert's law.

2.4 Formulation of Etravirine Sustained Release Tablets

Liquisolid compacts were prepared using propylene glycol or Tween 80 as liquid vehicles. Etravirine was dispersed in the selected vehicle and blended with carrier and matrix-forming polymers. Magnesium stearate and Aerosil were added as lubricant and glidant, respectively. The final blends were compressed into tablets using a rotary compression machine.

Twelve formulations (F1–F12) were developed by varying the concentrations of guar gum and xanthan gum and the type of liquid vehicle employed.

2.5 Evaluation of Powder Blends

Pre-compression evaluation included:

- Angle of repose
- Bulk density
- Tapped density
- Carr's compressibility index
- Hausner ratio

2.6 Evaluation of Tablets

Compressed tablets were evaluated for:

- Weight variation
- Thickness
- Hardness
- Friability
- Drug content uniformity

2.7 In Vitro Dissolution Studies

Dissolution studies were conducted using USP Type II paddle apparatus containing 900 mL phosphate buffer pH 6.8 maintained at 37 ± 0.5°C and stirred at 50 rpm. Samples were withdrawn at predetermined intervals up to 12 h and analyzed spectrophotometrically at 282 nm.

2.8 Drug Release Kinetics

Drug release data were fitted to:

- Zero-order model
- First-order model
- Higuchi model
- Korsmeyer–Peppas model

to elucidate the release mechanism.

2.9 FTIR Compatibility Studies

FTIR spectroscopy was employed to evaluate possible interactions between Etravirine and formulation excipients.

3. Results and Discussion

Construction of Standard calibration curve of Etravirine in 6.8 phosphate buffer:

The absorbance of the solution was measured at 282nm, using UV spectrometer with 6.8 phosphate buffer as blank. The values are shown in table no 20. A graph of absorbance Vs Concentration was plotted which indicated in compliance to Beer's law in the concentration range 2 to 10 µg/ml

Concentration (µg / ml)	**Absorbance**
0	0
2	0.102
4	0.181
6	0.271
8	0.359
10	0.452

Table 9: Standard Calibration graph values of Etravirine in 6.8 phosphate buffer

Standard plot of Etravirine plotted by taking absorbance on Y – axis and concentration (µg/ml) on X – axis, the plot is shown in fig.

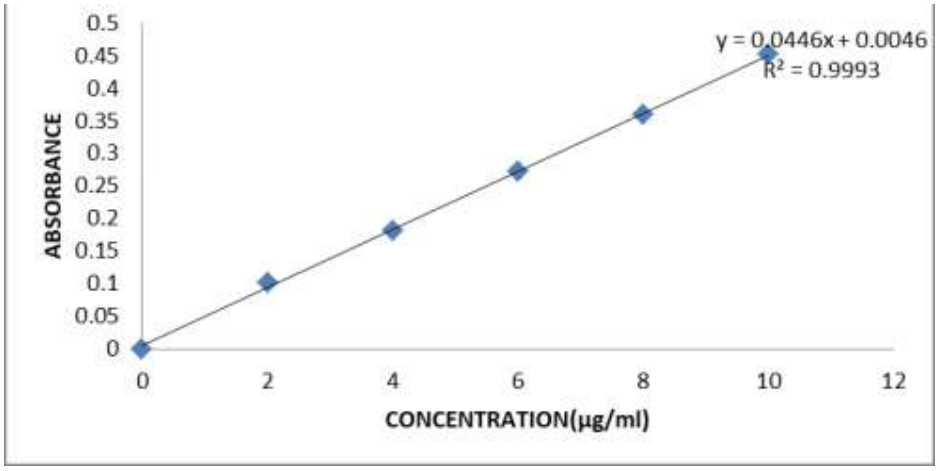

Figure 3: Standard calibration curve of Etravirine in 6.8 phosphate buffer

Inference: The standard calibration curve of Etravirine in 6.8 phosphate buffer showed good correlation with regression value of 0.9993

Evaluation of Tablets:

A) Pre Compression studies:

Formulation Code	Bulk density (Kg/cm^3)	Tapped density (Kg/cm^3)	Cars index	Hausners ratio	Angle of repose (˚)
F1	0.43	0.52	17.3	1.41	12.62
F2	0.40	0.46	13.0	1.5	12.29
F3	0.50	0.58	13	1.16	11.58
F4	0.44	0.51	13.7	1.25	9.29
F5	0.39	0.47	17.0	1.56	18.23
F6	0.42	0.52	19.2	1.45	13.24
F7	0.36	0.39	7.6	1.0	11.03
F8	0.41	0.50	18	1.5	17.4
F9	0.39	0.48	18	1.23	11.96
F10	0.41	0.51	19.6	1.53	12.26
F11	0.44	0.52	15.3	1.40	13.62
F12	0.41	0.45	8.8	1.0	11.85

Table: 10: Pre compression studies of Etravirine ER tablets *n=3

Inference:

- The Etravirine SR tablets were evaluated for their flow properties; the results for the blends of compression tablets were shown in Table:10
- The bulk density and the tapped density for all formulations were found to be almost similar.
- The Carr's index and Hausner's ratio were found to be in the range of ≤ 18 and 1.0 to 1.56 respectively, indicating good flow and compressibility of the blends.
- The angle of repose for all the formulations was found to be in the range of 11.03-18.23˚ which indicating passable flow (i.e. incorporation of glidant will enhance its flow).

B) Post compression studies:

Formulation Code	% weight vaiation	Thickness	% Friability	%Drug Content	Hardness (Kg/cm^2)

F1	pass	3.16±0.11	0.22	102.0 ±1.1	4.68 ±0.17
F2	pass	3.53±0.15	0.15	101.3 ±1.5	5.13 ±0.15
F3	pass	4.06±0.057	0.12	99.8±1.3	5.58 ±0.13
F4	pass	5.1±0.1	0.43	101.7 ±0.8	5.98 ±0.04
F5	pass	3.03±0.05	0.32	100.6±1.2	4.63 ±0.05
F6	pass	3.83±0.15	0.14	98.9 ±2.1	5.2 ±0.02
F7	pass	4.93±0.05	0.20	99.2± 1.7	5.7 ±0.10
F8	pass	5.26±0.1	0.33	99.5± 1.4	5.93 ±0.05
F9	pass	3.02±0.2	0.18	99.2±1.3	4.39 ±0.02
F10	pass	3.48±0.14	0.21	100.3 ±1.4	4.86 ±0.03
F11	pass	4.91±0.18	0.32	101.2± 1.6	5.72 ±0.12
F12	pass	5.14±0.12	0.16	100.3 ±1.8	5.89 ±0.13

Table11: Post compression studies of Etravirine SR tablets

*Test for Friability was performed on single batch of 20 tablets

Inference:

- The variation in weight was within the limit
- The thickness of tablets was found to be between 3.03 -5.26 mm.
- The hardness for different formulations was found to be between 4.39 to 5.98 kg/cm^2, indicating satisfactory mechanical strength
- The friability was < 1.0% W/W for all the formulations, which is an indication of good mechanical resistance of the tablet.
- The drug content was found to be within limits 98 to 102 %.

INVITRO DISSOLUTION STUDIES OF ETRAVIRINE ER TABLETS:

Dissolution profile:

Parameter	**Details**
Dissolution apparatus	USP -Type II (paddle)
Medium	6.8 phosphate buffer
Volume	900 ml

Speed	50rpm
Temperature	37± 0.5 ºC
Sample volume withdrawn	5ml
Time points	1,2,3,4,6,8,10 and 12hr
Analytical method	Ultraviolet Visible Spectroscopy
λ_{max}	282 nm

Table12: Dissolution profile

Note: 5 ml of sample was with draw at each time point & replace the same volume of **6.8 phosphate buffer** preheated to 37± 0.5 ºC

TIME (hrs)	**% DRUG RELEASED**											
	F1	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**	**F10**	**F11**	**F12**
0	0	0	0	0	0	0	**0**	0	0	0	0	0
1	44	15	20	14	51	43	23	22	18	11	10	5
2	55	24	32	22	62	49	38	34	23	19	15	11
3	66	36	44	37	73	58	52	41	29	23	19	18
4	79	49	52	45	83	65	59	49	38	33	22	28
6	89	71	66	57	91	78	67	56	45	41	28	36
8	98	84	78	66	100	88	75	62	54	49	36	42
10	100	98	85	74	100	96	83	69	68	51	46	49
12	100	100	90	81	100	100	91	76	78	63	55	56

Table13: In-vitro Dissolution results of Formulation trails

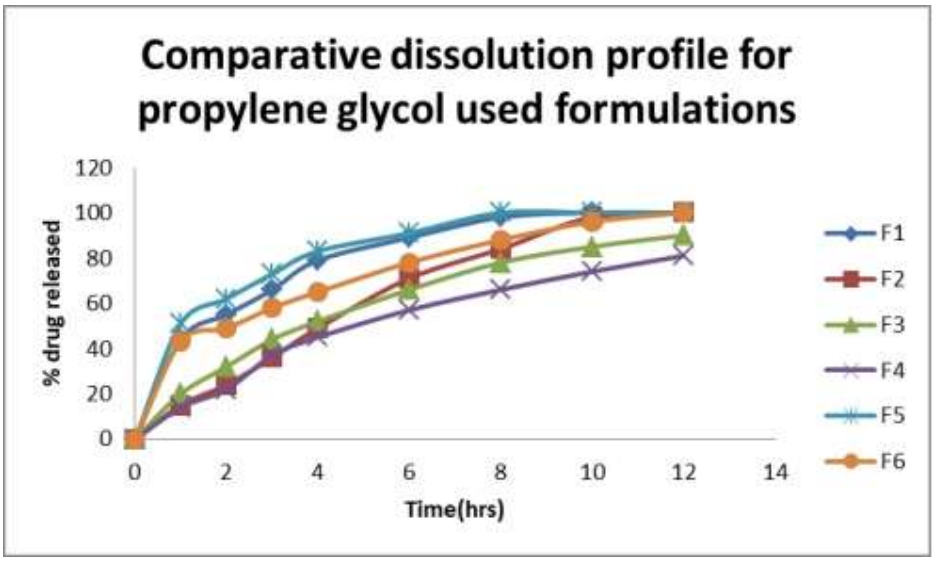

Figure 4: Comparative dissolution profile for Eudragit RLPO used series

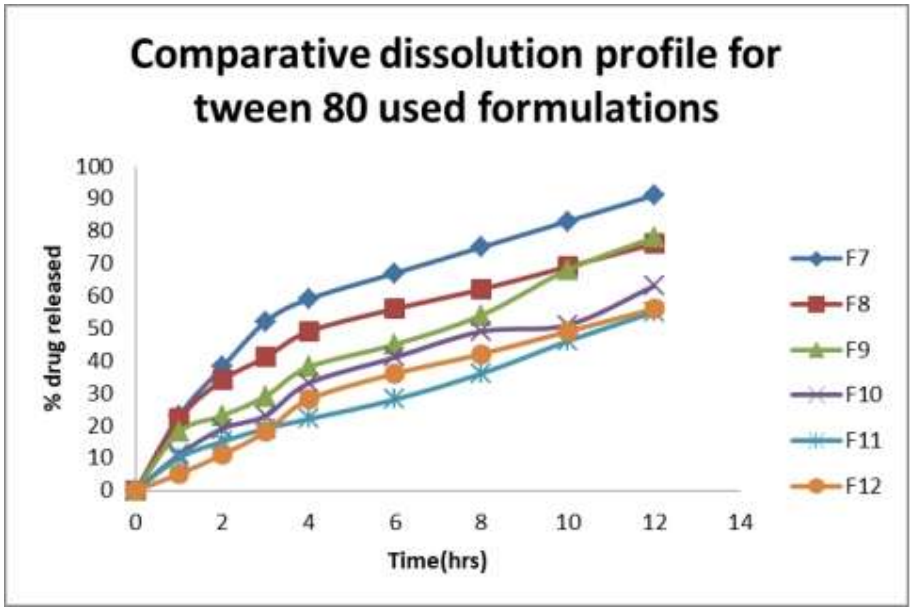

Figure 5: Comparative dissolution profile for Eudragit RSPO used series

Formulation Code	R square value				n value
	Zero order	First order	Higuchi plot	Peppas plot	
F1	0.867	0.994	0.973	0.972	0.355
F2	0.980	0.984	0.980	0.988	0.814
F3	0.961	0.999	0.996	0.990	0.613

F4	0.970	0.996	0.990	0.979	0.718
F5	0.825	0.991	0.953	0.967	0.289
F6	0.915	0.976	0.991	0.984	0.366
F7	0.935	0.990	0.994	0.970	0.526
F8	0.936	0.987	0.997	0.988	0.479
F9	0.986	0.985	0.986	0.981	0.600
F10	0.976	0.990	0.988	0.988	0.687
F11	0.992	0.990	0.974	0.983	0.670
F12	0.985	0.996	0.976	0.975	0.965

Table14: R^2 value and n result table

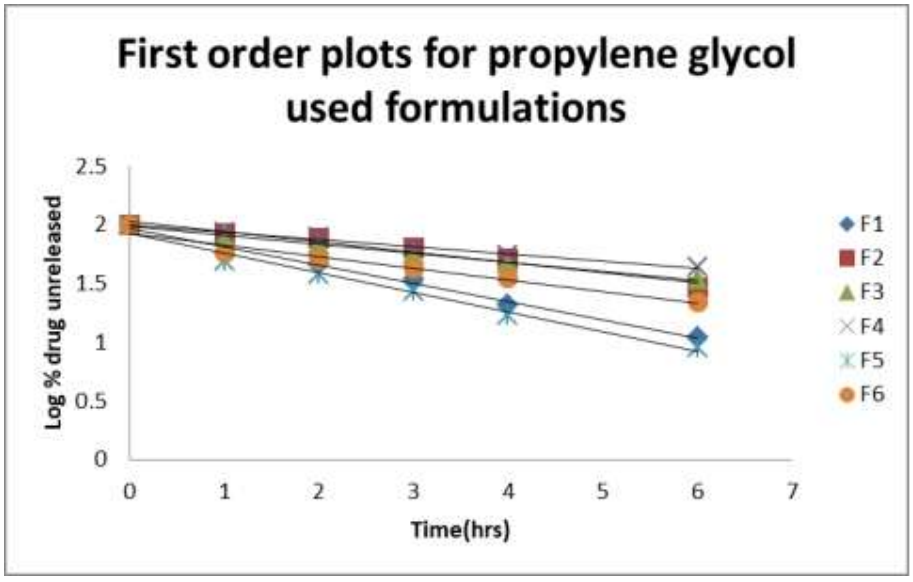

Figure 8: First order plot for best formulations F3 & F7

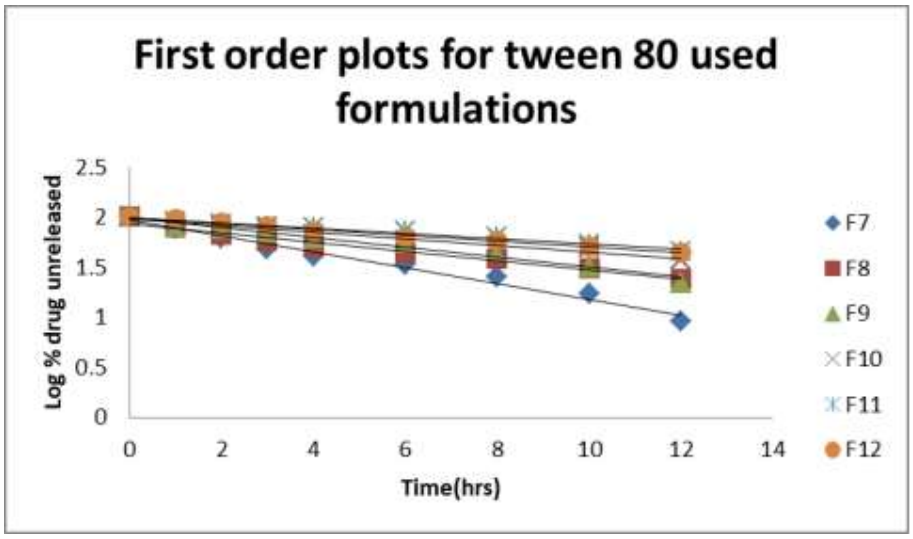

Figure 8: First order plot for best formulations F3 & F7

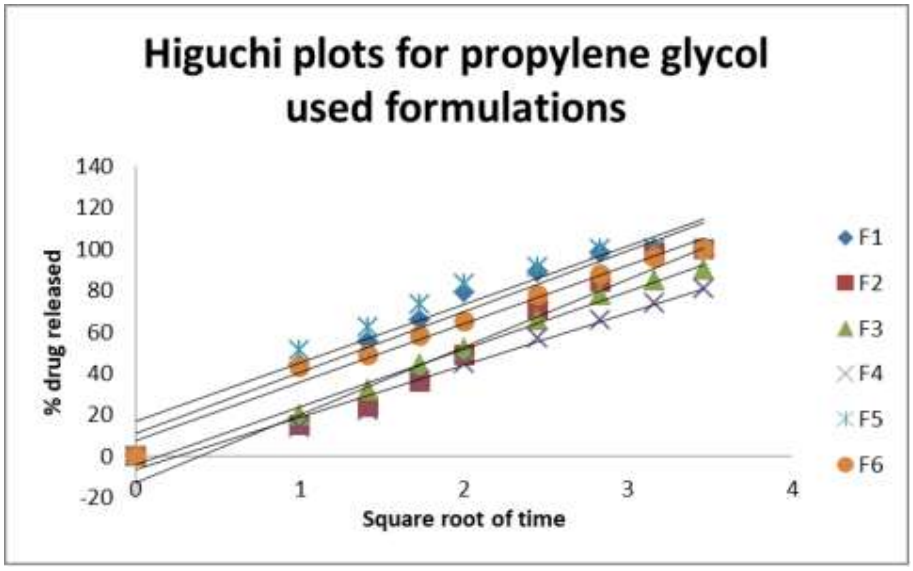

Figure 9: Higuchi plot for best formulations F3 & F7

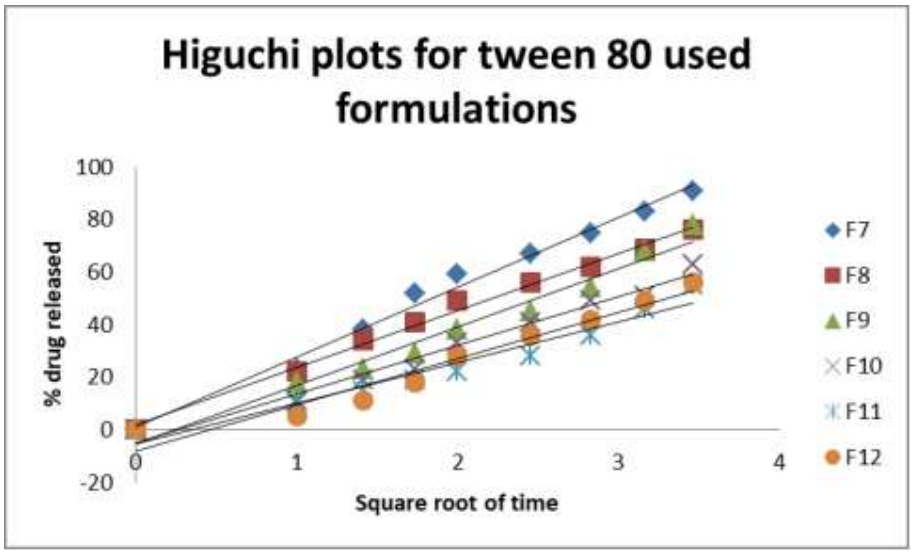

Figure 9: Higuchi plot for best formulations F3 & F7

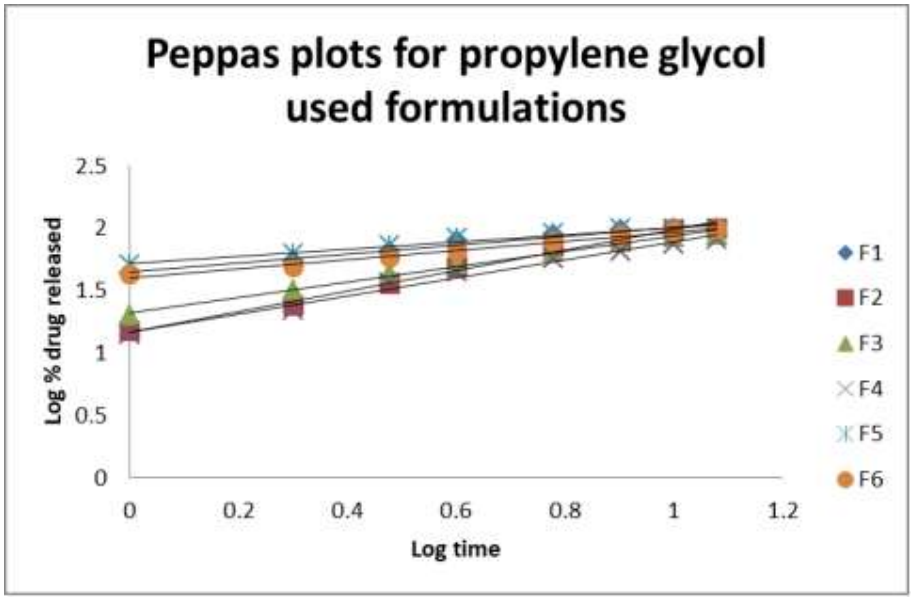

Figure 10: Korsmayerspepas plot for best formulationF3

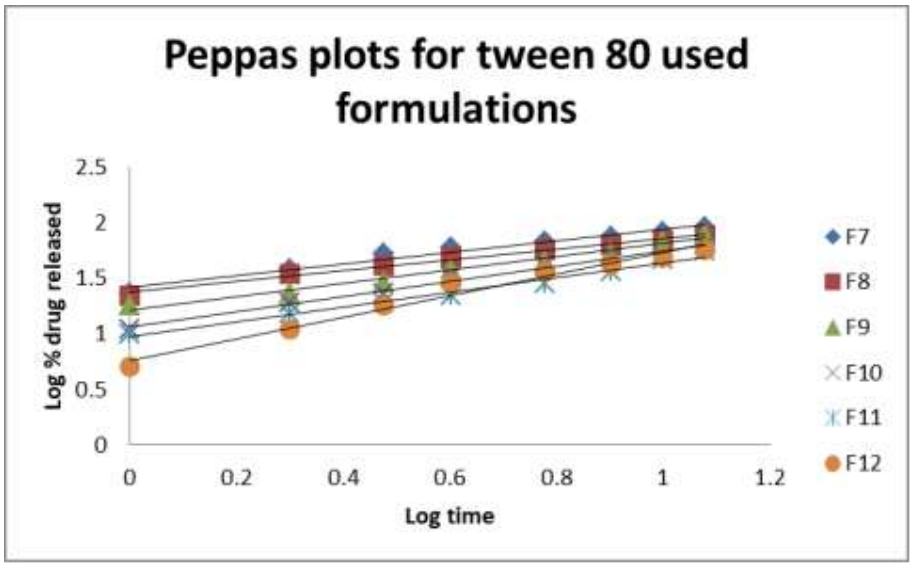

Figure11: Korsmayers pepas plot for best formulationF7

Inference

- Among all formulations F2 was showing the satisfactory results.
- For the F2 formulation diffusion exponent n value is in between 0.45 to 0.89 so they are following non fickian anmolous diffusionmodeol
- Higuchi plots for F2 formulation is having good correlation values so the drug is releasing diffusion mechanism

FT-IR spectroscopy

The FTIR spectra‟s, observed that the characteristic absorption peaks of pure Etravirine were obtained at 3087.56, 2994.16, 1707.56, 1460.7, 13620.10 and 705.5cm-1 corresponding to O-H, C-H, C=O C-C, C-O stretching and OH-bending (Figure1). The spectral data suggests that the major peaks for drugs are obtained as nearer value and there were no considerable changes in IR peaks in all physical mixtures of drug and polymers. This indicates that the drugs were molecularly dispersed in the polymers or in drug loaded formulations thus thereby indicating the absence of any interactions.

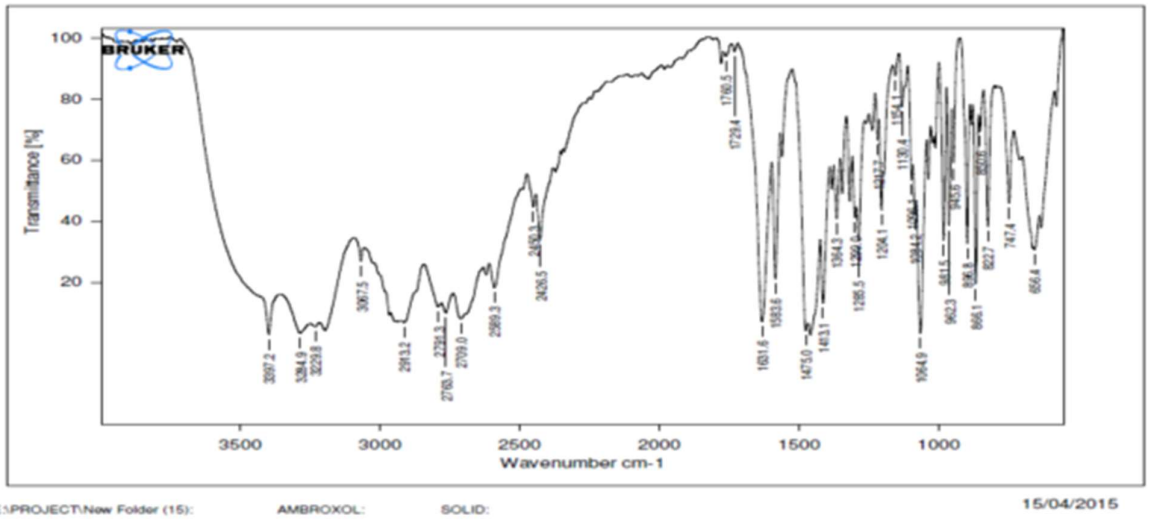

Figure 12: FTIR graph for Etravirine pure drug

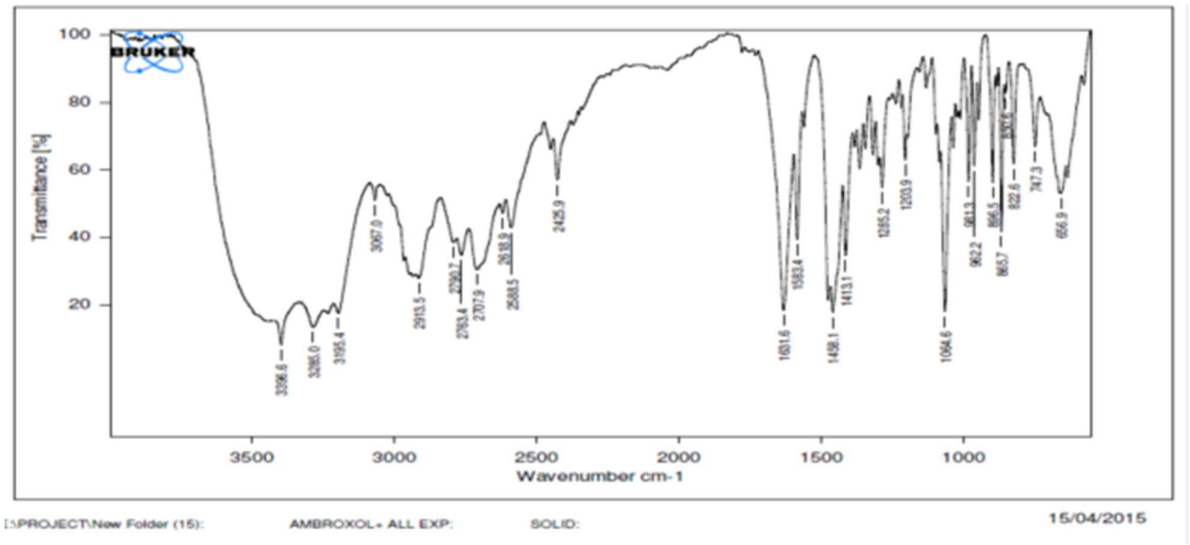

Figure 13: FTIR graph for formulation

4. Conclusion

The present study successfully developed sustained release tablets of Etravirine using the liquisolid compact technique. The formulations exhibited satisfactory physicochemical properties and sustained drug release for up to 12 h. Xanthan gum-based formulation F2 demonstrated the most desirable release characteristics, following Higuchi diffusion kinetics with anomalous transport behavior. FTIR studies confirmed compatibility between Etravirine and excipients.

The results suggest that the liquisolid compact approach represents an effective strategy for developing sustained release formulations of poorly water-soluble drugs such as Etravirine. Further in vivo studies are recommended to establish in vitro–in vivo correlation and clinical performance.

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