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Original Article

Formulation and Evaluation of Fast Dissolving Tablets of Oxcarbazepine Using Liquisolid Technology

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ABSTRACT

Background/Aim: The aim of the study was to improve the dissolution profiles of Oxcarbazepine (OXC) from its tablets. This study was done to evaluate the effects of different formulation variables, i.e. type of non-volatile liquid vehicles on oxcarbazepine dissolution rate from its tablets. **Materials and Methods:** The liquisolid tablets were formulated with three different liquid vehicles, namely Polyethylene glycol 200, Propylene glycol and 20% Tween 80 aqueous solution. Micro-crystalline cellulose was used as a carrier material, silicon dioxide as a coating material and sodium starch glycolate as super disintegrate. The empirical method introduced by Spireas and Bolton (1999) was applied strictly to calculate the amounts of coating and carrier materials required to prepare fast dissolving tablets of OXC using liquisolid technique. The tablets passed all the routine quality control tests prescribed by official books. *In vitro* drug dissolution testing of the liquisolid tablets were done and compared with commercial tablets in 1% SLS solution as dissolution media as per USFDA. **Results:** It was found that the dissolution rate of oxcarbazepine was highest from liquisolid tablets of oxcarbazepine formulated using PEG 200. Differential scanning calorimetry, PXRD and Fourier transform infrared evaluation of our best tablet Formulation (F2) indicated that there is no physico-chemical interaction between OXC and the excipients. **Conclusion:** *In vitro* dissolution testing, DSC, PXRD and FTIR studies confirmed F2 as the best formulation with respect to drug dissolution rate and revealed that there is no incompatibility between the drug and excipients used in the formulation.

Keywords: Oxcarbazepine, Fast dissolving tablets, Liquisolid technique, Solubility, Dissolution rate.

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INTRODUCTION

About, 40% of drugs never make it to the market because of their poor water solubility and low dissolution rates which results in low oral bioavailability.[1-3] For pharmaceutical chemists, the poor dissolving properties of water-insoluble drugs present a significant challenge.[4] The bioavailability of a tablet which depends on solubility and dissolution rate of the drug influences a medication's therapeutic effectiveness.[5]

BCS class II drugs are linked to a slower rate of GI tract dissolution due to their low solubility and dissolution rate which results in reduced bioavailability.[6] We need to increase their solubility and rate of dissolution in GIT to enhance their bioavailability. There are ongoing developments in formulation techniques for improving the dissolution of poorly soluble drug substances.[7] Drugs that are poorly water soluble are challenging to manufacture using conventional methods. To increase their solubility, dissolution rate and bioavailability, a variety of approaches can be used. Drug solubilisation enhancement methods commonly used include micronization, chemical modification, pH adjustment, solid dispersion, complexation, co-solvency, micellar solubilisation, hydrotropy, etc.,[8] According to some researchers, formulation of tablets by liquisolid technique is one of the most promising methods for improving drug dissolution rate and bioavailability of BCS class II drugs.[9] Formulation of solid tablets from liquid drugs has been the subject of numerous studies. Based on the idea of blending liquid pharmaceuticals with specific powder excipients to form free flowing, easily compressible powders, Jarowski *et al.* and Spireas *et al.* have developed liquisolid technology.[10-13]

According to Spireas *et al.* (1998), liquisolid technology is a revolutionary concept for an oral medication delivery method. Since solubility is a key issue for the majority of drugs during the development phase, this approach was used for drugs that were not water soluble. Due to the drugs increased wetting qualities when employing a non-volatile solvent and its economic effectiveness over regular tablets, the liquisolid technique is the most successful technique among the many water solubility augmentation techniques.[14] By simply blending liquid with a chosen carrier, the liquid is transformed into a free flowing, easily compressible,

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and seemingly dry powder. The porous carrier material absorbs the liquid portion, which may be a liquid medication, a liquid drug suspension, or a liquid drug solution in non-volatile liquid vehicle. This powder is now mixed with a coating material like silicon di oxide which will impart flow properties to the powder which is required for tablet compression process.

The most common liquid vehicles are inert, ideally water-soluble organic solvents like polyethylene glycols, propylene glycol, or glycerine.[15] Only a certain amount of liquid may be held in a powder while still maintaining acceptable flow and compression characteristics and this can be calculated by the mathematical model developed by Spireas *et al.*[16,17]

The study's objective was to enhance the dissolution rate of Oxcarbazepine a BCS class II drug by formulating liquisolid tablets containing various non-volatile liquid carriers.[18] To improve the dissolving qualities of oxcarbazepine, a number of methods have been tested, including centrifugal spinning-based formulation, melt sonocrystallization technique, solid dispersion utilizing skimmed milk, and β-cyclodextrin binary system.[19-22] Liquisolid fast dissolving tablet formulations are a method to enhance oxcarbazepine dissolution that has not yet been researched. As far as we are aware, there are no liquisolid dosage forms of oxcarbazepine on the market right now.

Fast-dissolving liquid-solid tablets containing the medication oxcarbazepine have been made using polyethylene glycol 200, propylene glycol, and 20% Tween 80 aqueous solution as a non-volatile liquid vehicle. According to El-Gizawy, when combined with meloxicam,[23-25] polysorbate 80 dissolves the drug more quickly than propylene glycol and PEG 200. As a result, while creating liquisolid quick dissolving tablets, there isn't a single non-volatile liquid vehicle that is ideal for a variety of hydrophobic medications. In the current investigation, non-volatile liquid vehicles were used in liquisolid systems containing oxcarbazepine. These non-volatile liquid vehicles included polyethylene glycol 200, propylene glycol, and 20% Tween 80 aqueous solution, which have, as far as we are aware, never been explored before in liquisolid fast dissolving tablets.

MATERIALS AND METHODS

Materials

Oxcarbazepine was a gift sample from Hetero Labs in Hyderabad, Microcrystalline Cellulose, PEG 200 and Sodium Starch Glycolate were from S D Fine Chem Limited in Mumbai, Silicone Dioxide from Rolex Chemical Industries in Mumbai, Magnesium Stearate and Talc from LOBA chemie Pvt. Ltd., in Mumbai.

Calibration curve of OXC by UV spectroscopy method

Preparation of primary standard stock solution

In order to prepare OXC stock standard solution with a concentration of 500 µg/mL, precisely 50 mg of the pure drug (OXC) was dissolved in 10 mL of methanol. The volume of this solution was made up to 100 mL using 1% SLS solution.

Preparation of secondary standard stock solution

20 mL of the primary standard stock solution was diluted in a volumetric flask to make a total volume of 100 mL using a 1% SLS solution. This resulting solution had a concentration of 100 µg/mL.

Preparation of the test solutions

For the purpose of method development and validation in 1% SLS solution, the secondary stock solution was diluted to different volumes. Specifically, 0.8 mL, 1.2 mL, 1.6 mL, 2 mL, 2.4 mL, and 2.8 mL of the secondary stock solution were diluted with q.s 10 mL of 1% SLS, resulting in test solutions with concentrations of 8 µg/mL, 12 µg/mL, 16 µg/mL, 20 µg/mL, 24 µg/mL, and 28 µg/mL, respectively.

Estimation of λ_{max} in media

The solution with a concentration of 12 µg/mL was subjected to scanning in a UV spectrophotometer within the wavelength range of 200 nm to 400 nm using 1% SLS solution as blank. The wavelength at which the highest absorbance occurred was noted and recorded.

Solubility studies

Studies on the solubility of oxcarbazepine in propylene glycol, polyethylene glycol 200, water, and 20% Tween 80 were conducted. Oxcarbazepine was added in excess to a test tube containing 10 mL of solvent to prepare saturated solutions. The test tubes were sealed and rotated continuously for 72 hr at room temperature. After that, a filter paper (whatmann) was used to filter the supernatant. After the required dilution with 1% SLS, the drug concentration was assessed using a UV/vis spectrophotometer at 256 nm. The calibration curve was used to estimate oxcarbazepine solubility in the solvent.

Determination of liquid retention value of MCC and silicon di oxide

A powder blend containing MCC and silicon di oxide in 10:1 ratio was taken in a mortar and 0.5 mL/1.0 mL/1.5 mL/2 mL of the non-volatile solvent was added and mixed. The angle of repose of the powder was found out by fixed funnel method. Each powder-non-volatile liquid admixture's flowable liquid-retention potential (Φ-value) was calculated by below equation 7.

$$\Phi - \text{value} = \text{weight of liquid/weight of solid} \text{ ------- (7)30}$$

The flowable liquid-retention potential, or Φ-value, of a powder-non-volatile liquid admixtures indicated by an angle of repose (for optimal flow qualities) correlating to 33° was used to manufacture liquisolid tablets.

Preparation of tablets

The formula for the preparation of tablets is given in Table 1. The drug was dissolved in PEG 200 and was mixed with MCC in a mortar. Later, silicon dioxide and other ingredients were mixed and the powder blend was subjected to routine pre compression evaluation tests. The powder blend was then compressed into tablets on a rotary tablet machine and were evaluated for routine QC tests of USP.

Quality control tests of the prepared tablets

Liquisolid compacts and conventional tablets underwent quality control testing that were carried out in compliance with USP guidelines.

In vitro dissolution studies

Utilizing the USP dissolution testing apparatus type II, *in vitro* dissolution tests were carried out. The dissolving medium (1% SLS) was 900 mL in volume, kept at a temperature of 37±1°C, and paddle was stirred at 75 RPM. At definite time intervals, 5 mL samples of dissolution fluid were taken. To keep the volume consistent, identical quantities of the dissolving media were substituted for the withdrawn samples. Using the calibration curve the dissolution samples were spectrophotometrically analysed at 256 nm to determine their oxcarbazepine content.

Differential Scanning Calorimetry (DSC)

Oxcarbazepine, and F2 formulations Differential Scanning Calorimetry (DSC) thermograms were obtained using the DSC Refrigerated Cooling System. Samples (0.8-6.3 mg) were weighed and put into the apparatus in sealed, hermetically sealed aluminium pans for analysis. Before running the samples, the device was calibrated using sapphire and indium. From 0°C to 180°C, the thermal behaviour of the samples was examined at a scanning rate of 10°C/min.

X-ray diffraction (XRD)

The XRD patterns of Oxcarbazepine and liquisolid formulation (F2) were recorded on PanAlytical, X-Pert pro X-ray diffractometer, using Cu as anode material and Kalpha1 radiation of 1.54060 A°. The data were recorded over a scanning range of °2 θ of 10 to 90.

Fourier Transform Infrared (FT-IR) spectroscopy

Fourier transform Infrared spectroscopy (FT-IR) system Spectrum was used to collect the infrared spectra of the materials (oxcarbazepine, MCC, Silicone dioxide, SSG, PEG 200, PG, 20% W/W Tween 80, (liquisolid formulations) in the frequency range of 4000-550 cm^{-1} at 4 cm^{-1} resolution. A very small amount of each sample was utilized in the procedure, which was then put directly into the system. Peak positions were calculated using Spectrum Bruker software.

RESULTS

Calibration curve of OXC by UV spectroscopy method

Calibration curve of oxcarbazepine in 1% SLS is represented in Figure 1. The Beer's law limits are from 8 to 28 mcg/mL. A

Table 1: Formulation of liquisolid tablets.

Sl. No.	Ingredients	Formulation code and Weight of ingredients for one Tablet in mg					
		F1	F2	F3	F4	F5	F6
1	Oxcarbazepine	20	10	20	10	20	10
2	PEG 200	40	40	-	-	-	-
3	PG	-	-	40	40	-	-
4	20% w/w Tween 80 aqueous solution	-	-	-	-	40	40
5	Ca : Co (R)	10	10	10	10	10	10
6	Lf	0.25	0.25	0.13	0.13	0.15	0.15
7	MCC (Q)	240	120	461.53	163.84	400	200
8	Silicon dioxide (q)	24	12	46.15	16.38	40	20
9	SSG	40	20	40	20	40	20
10	Magnesium stearate	20	10	20	10	20	10
11	Talc	20	10	20	10	20	10
12	Unit weight (mg)	404	222	647.68	270.22	580	310

correlation coefficient of 0.9951 obtained for the line in Figure 1 indicates that there is good correlation between the concentration of drug solution and absorbance. The calibration curve is presented as Figure 1.

Solubility studies

Results of solubility studies of oxcarbazepine in different non-volatile solvents are given in Table 2. From Table 2, it can be seen that the drug oxcarbazepine has maximum solubility in poly ethylene glycol 200. Hence this solvent was used in preparation of the liquisolid tablets.

Determination of liquid retention value of MCC and silicon di oxide

From the angle of repose values of powder blend of MCC and silicon di oxide (of 10:1 ratio on weight basis) with different quantities of PEG 200, it was found that the optimal liquid retention value was 0.25. This means that 1 g of MCC/Silicon dioxide mixture (of 10:1 ratio on weight basis) can carry 0.25 mL of PEG 200. This powder blend-solvent composition has an angle of repose of 33°, which indicates that the powder has the ability to flow and will not create problems during compression of tablets.

Table 2: Solubility of oxcarbazepine in various non - volatile solvents.

Sl. No.	Solvent	Solubility (mg / 100 mL)
1	Water	1.49
2	Propylene glycol	2.19
3	Polyethylene glycol 200	2.79
4	20 % Tween 80 aqueous solution	2.55

Pre compression properties of powder blends for making tablets

The pre compression properties of the different formulations to prepare tablets are given in Table 3. All the powder blends except of formulation F3 and F4 passed the tests.

Post compression properties of tablets

The post compression properties of the different formulations are given in Table 4. All the tablets passed the routine official quality control tests of USP.

In vitro dissolution testing results

The data of dissolution testing are given in Table 5 and the same is presented as Figure 2.

FTIR/DSC/PXRD

The IR spectrum/DSC thermograms/PXRD of OXC and F2 formulation are presented as Figures 3 to 8. The characteristic peaks of OXC in FTIR Spectra are given in Table 6.

DISCUSSION

Oxcarbazepine is a BCS class II drug and its bioavailability is dissolution rate limited. Solubility studies of OXC in propylene glycol, poly ethylene glycol 200 and 20% aqueous tween 80

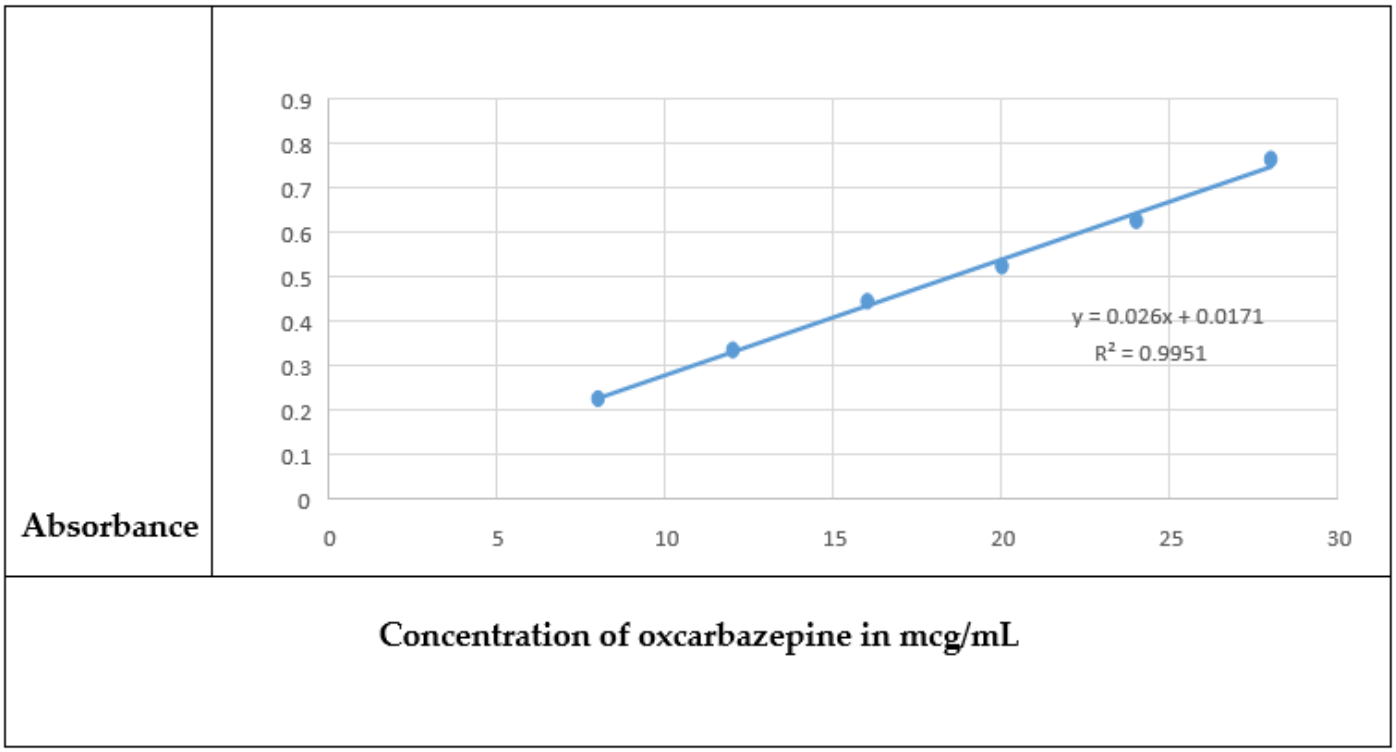

Figure 1: Calibration Curve of Oxcarbazepine in 1 % SLS at 256 nm.

solution (Table 2) indicated that it has the highest solubility in poly ethylene glycol 200. The solubility in poly ethylene glycol is two fold when compared with that in water. Liquisolid tablets were prepared with all the three non-volatile solvents (Table 1) by direct compression method and were subjected to *in vitro* dissolution testing and all routine QC tests. The powder blends of all tablet formulations except of F3 and F4 passed the pre compression properties tests. The powder blends of F3 and F4 formulations were not having sufficient flow properties and hence were not compressed into tablets. The prepared tablets passed the entire routine QC test prescribed for tablets by USP (Table 4). *In vitro* dissolution studies of pure drug, best formulation F2 and commercial tablet (Table 5 and Figure 2) indicate that 98% of drug dissolved within 2 min, whereas the commercial product took 60 min to dissolve 80% of the drug. The T50 values of our best F2 tablet, commercial formulation and pure drug are 1 min, 30 min and 40 min respectively. This is because, in our best formulation oxcarbazepine has been dissolved/suspended in polyethylene glycol 200 and was adsorbed on to the carrier MCC and was compressed into tablets. From FTIR spectra, and DSC thermograms it can be concluded that there is no incompatibility between oxcarbazepine and the excipients used in the best formulation F2. All the characteristic FTIR peaks given in Table 6 for pure drug were present for formulation F2 also, however the intensities differed because of the presence of excipients in formulation F2. PXRD of oxcarbazepine and formulation F2 indicates that the drug has lost its crystalline nature and is in amorphous form in the formulation F2. This could be the reason for its increased dissolution rate, 98% of the drug dissolving in two min from F2 tablet (Figure 2).

Table 3: Pre-compression properties of powder blends (Average of 3 trials).

Formulation code	Bulk density (g/mL)	Tapped density (g/mL)	Hausner's ratio	Carr's index	Angle of repose
F1	0.387	0.468	1.20	17.5	17.05
F2	0.362	0.408	1.12	11.2	11.20
F3	0.318	0.382	1.16	27.9	27.90
F4	0.309	0.408	1.34	26.1	26.17
F5	0.390	0.488	1.26	20.8	16.82
F6	0.409	0.469	1.16	14.3	16.35

Table 4: Post-Compression Properties of Tablets Average of 3 trials.

Formulation Code	Hardness kg/cm^2	% Friability	Disintegration time (sec)	Drug content %
F-1	3.5	0.55	56 sec	93.09
F-2	4	0.33	40 sec	99.44
F-5	4	0.12	47 sec	96.77
F-6	4.5	0.62	55 sec	96.77

Note: Powder blends of F3 and F4 formulations failed pre compression tests and hence were not compressed into tablets.

Table 5: Dissolution Testing results of tablet formulations.

% Oxcarbazepine dissolved (Average of 3 Trials)									
Product Code		Pure Drug	F1	F2	F5	F6	CT 1	CT 2	CT 3
Sl. No.	Time in minutes								
1	2	-	88	98	92	95	-	-	-
2	5	28	100	100	100	100	36	31	29
3	10	34	100	100	100	100	46	39	35
4	20	42	100	100	100	100	49	46	41
5	30	49	100	100	100	100	55	57	58
6	40	55	100	100	100	100	62	64	65
7	50	58	100	100	100	100	73	69	68
8	60	62	100	100	100	100	75	71	71

Note: Powder blends of F3 and F4 formulations failed pre compression tests and hence were not compressed into tablets.

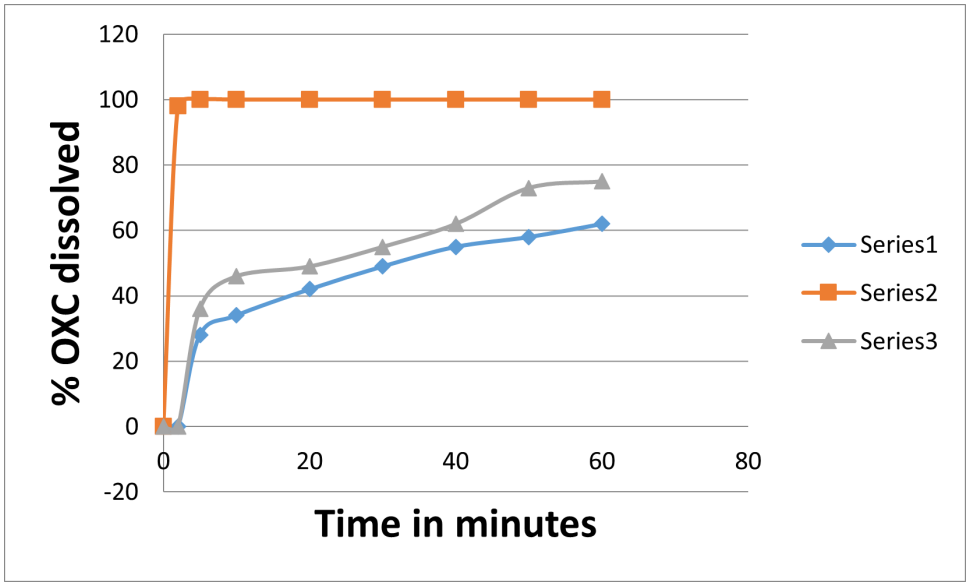

Figure 2: *In vitro* dissolution profiles of pure drug OXC, best formulation F2 and commercial tablet. Series 1 is pure OXC, series 2 is our best tablet F2, series 3 is commercial tablet.

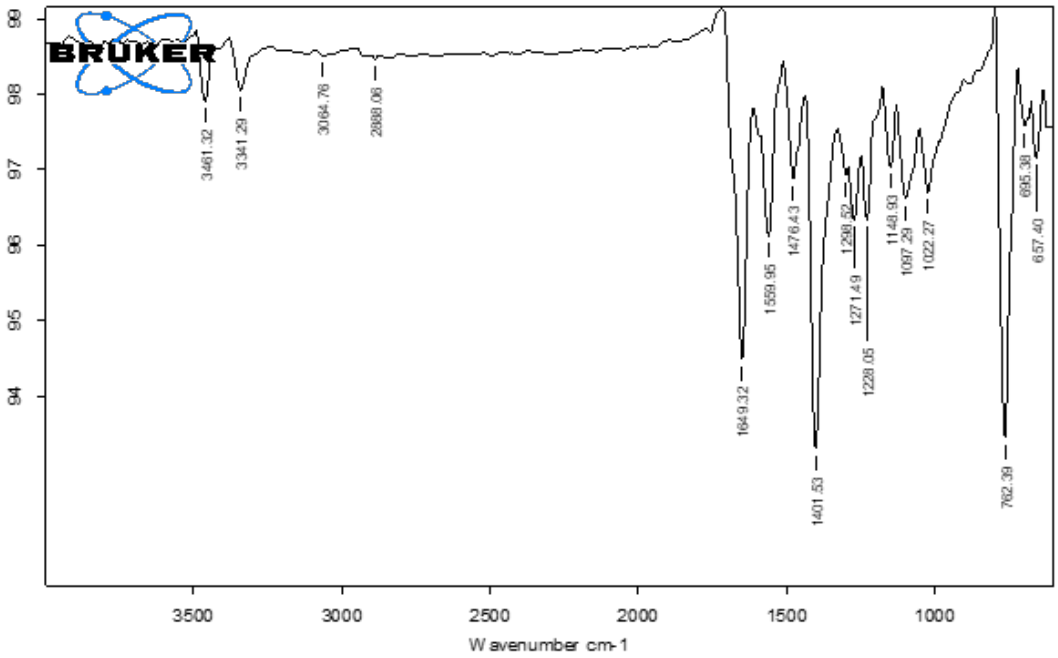

Figure 3: FTIR of pure drug OXC.

Table 6: Characteristic Peaks of OXC in FTIR Spectra.

Sl. No.	Wave number and absorption bands (cm^{-1})	Assignment (stretching /bending)
1	3353 (weak)	N-H Stretch of amide
2	2885 (medium)	Asymmetric C-H stretch of – CH_2
3	2824 (weak)	Symmetric C-H stretch of –CH_2
4	1215 (medium)	C-O Stretch of ester

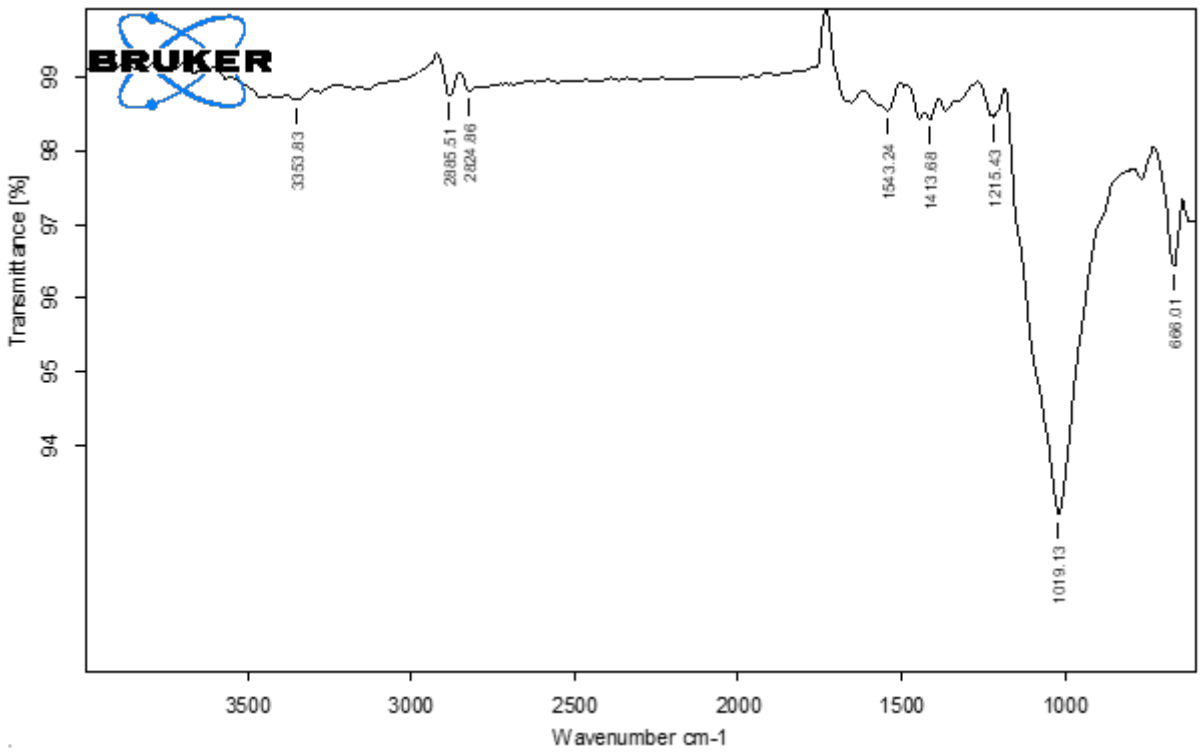

Figure 4: FTIR Spectra of F2 formulation.

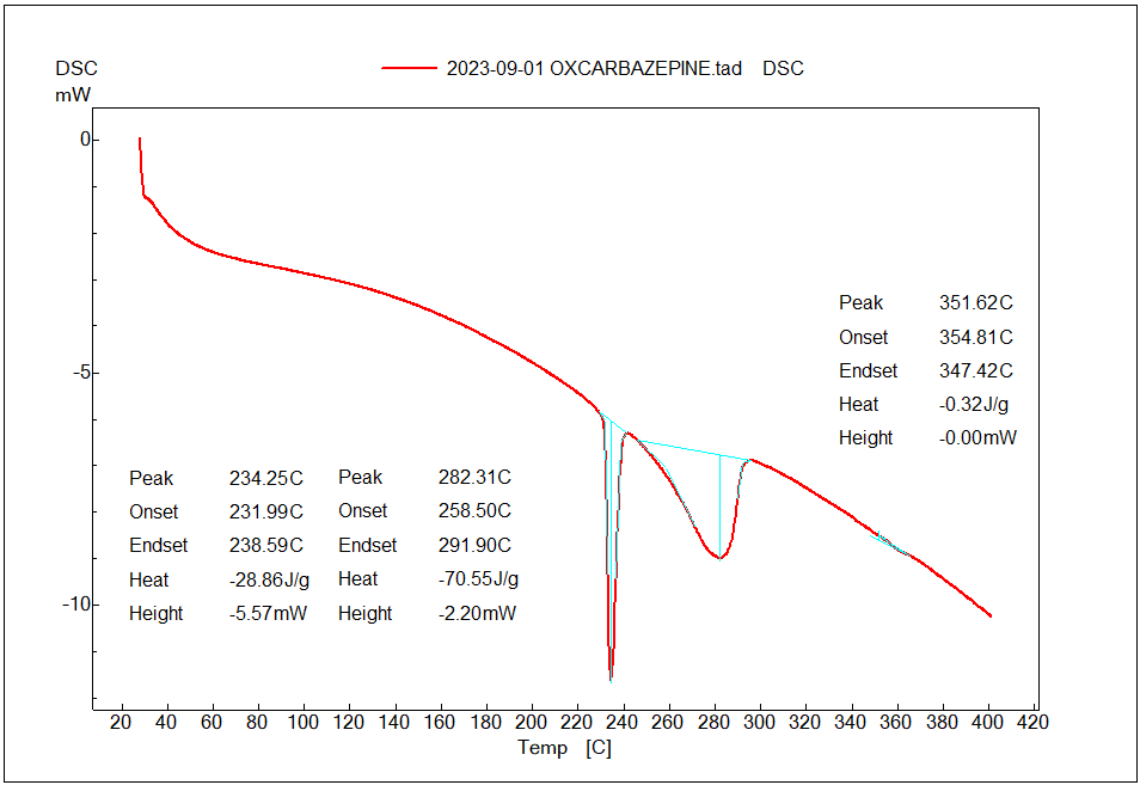

Figure 5: DSC thermogram of Oxcarbazepine pure drug.

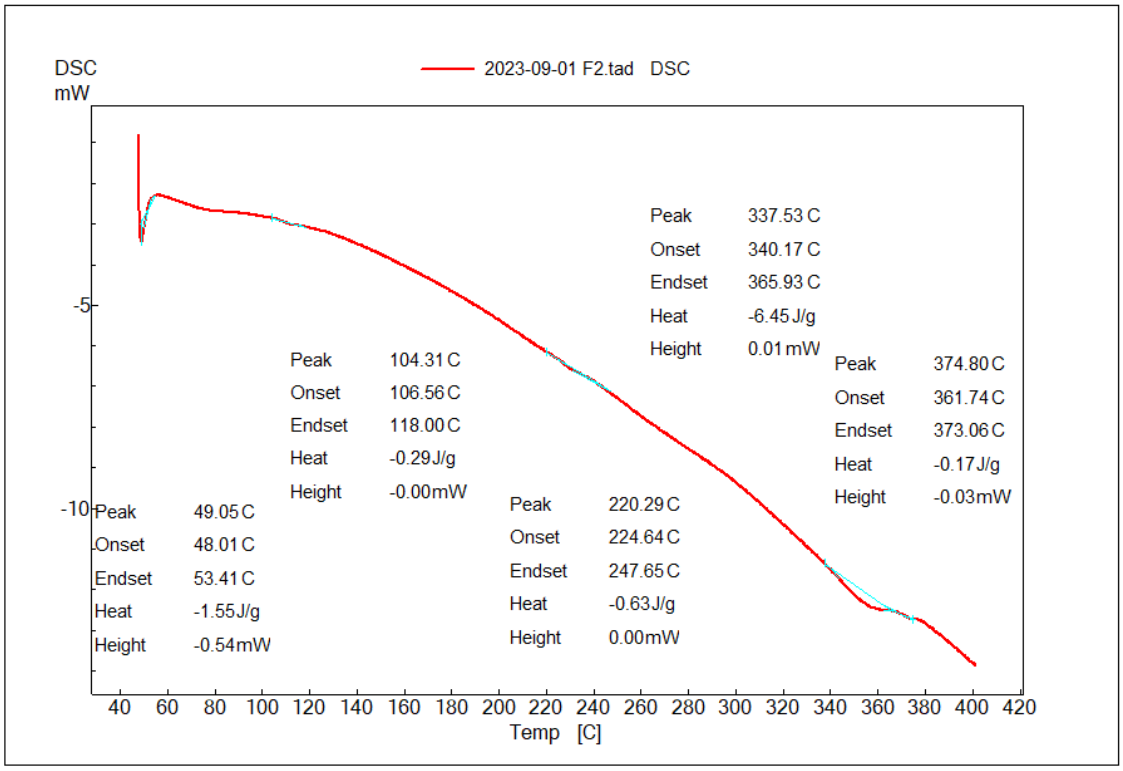

Figure 6: DSC thermogram of F2 formulation.

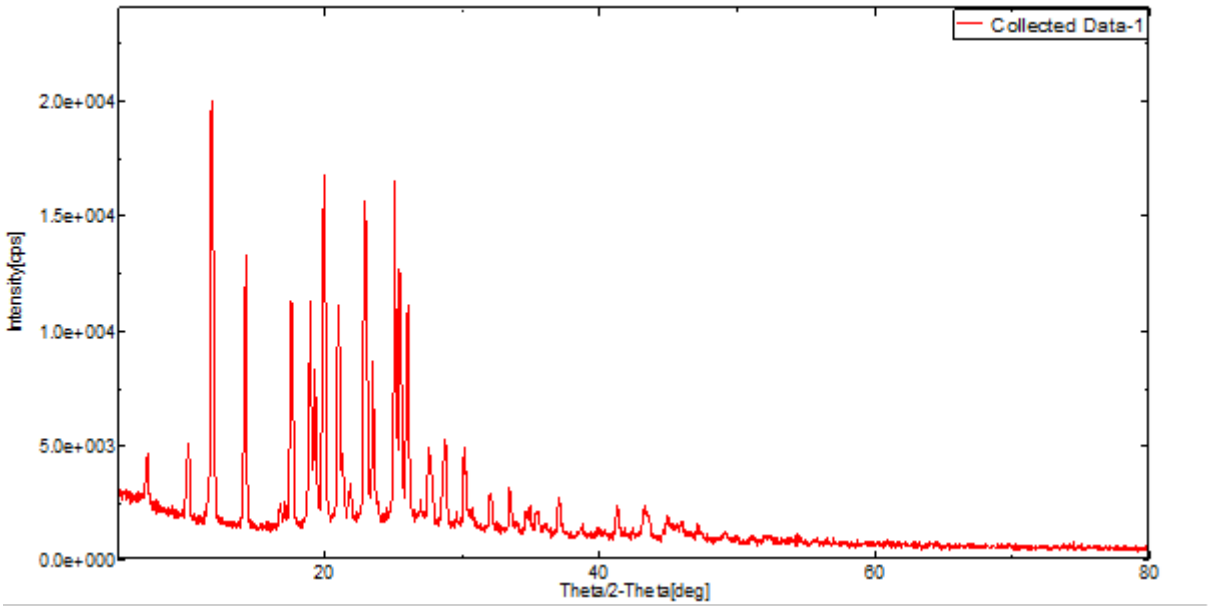

Figure 7: PXRD of OXC pure drug.

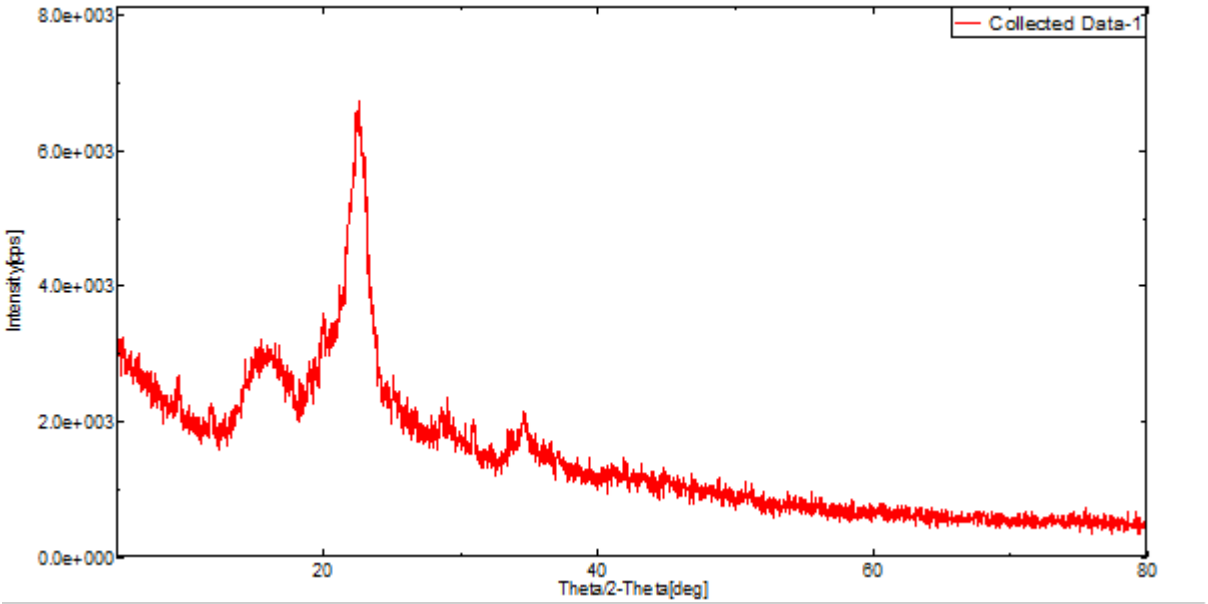

Figure 8: PXRD of F2 formulation.

CONCLUSION

The liquisolid tablets were formulated with three different non-volatile liquid vehicles, namely Polyethylene glycol 200, Propylene glycol and 20% Tween 80 aqueous solution. Micro-crystalline cellulose was used as a carrier material, silicon dioxide as a coating material and sodium starch glycolate as super disintegrate. The empirical method introduced by Spireas and Bolton (1999) was applied strictly to calculate the amounts of coating and carrier materials required to prepare fast dissolving tablets of OXC using liquisolid technique. The tablets passed all the routine quality control tests prescribed by official books. *In vitro* drug dissolution testing of the liquisolid tablets were done and compared with commercial tablets in 1% SLS solution as dissolution media as per USFDA. It was found that the dissolution rate of oxcarbazepine was highest from liquisolid tablets of oxcarbazepine formulated using PEG 200. Differential scanning calorimetry, PXRD and Fourier transform infrared evaluation of our best tablet formulation (F2) indicated that there is no physico-chemical interaction between OXC and the excipients.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

UV: Ultraviolet; **OXC:** Oxcarbazepine; **BCS:** Biopharmaceutical classification system; **PEG:** Polyethylene glycol; **PG:** Propylene glycol; **F1-F6:** Formulation code; **DCT:** Directly compressible tablets; **DSC:** Differential scanning calorimetry; **PXRD:** Powder X-ray diffraction; **FTIR:** Fourier transform infrared spectroscopy; **HLB:** Hydrophillic-lipophillic balance; **USP:** United States Pharmacopoeia; **CI%:** Carr's index; **µm:** Micro meter; **SLS:** Sodium lauryl sulphate; **MCC:** Microcrystalline cellulose; **SSG:** Sodium starch glycolate; **RPM:** Rotation per minute; **nm:** Nano meter.

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