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**Case Study**

# Cocrystal Strategy For Solubility Enhancement Of Ticagrelor Using Amino Acids

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## ABSTRACT

Ticagrelor is a BCS Class IV drug exhibiting poor aqueous solubility and low oral bioavailability, which may limit its therapeutic effectiveness. The present study was undertaken to improve the solubility of Ticagrelor through crystal engineering using amino acid coformers. L-Arginine and Glycine were selected as coformers based on their hydrogen-bonding ability, pharmaceutical acceptability, and aqueous solubility. Multicomponent crystal systems were prepared by the solvent evaporation method in different drug-to-coformer ratios. The prepared formulations were evaluated for saturation solubility, and the optimized formulation was further characterized using Differential Scanning Calorimetry (DSC), Fourier Transform Infrared Spectroscopy (FTIR), Powder X-Ray Diffraction (PXRD), and Scanning Electron Microscopy (SEM). UV spectrophotometric analysis in phosphate buffer pH 6.8 showed good linearity with a correlation coefficient ($R^2$) of 0.999. Among all formulations, the Ticagrelor–L-Arginine system at a 1:3 ratio (F3) exhibited the highest solubility of 10.33 µg/mL, corresponding to a 3.5-fold enhancement compared with pure Ticagrelor. DSC analysis demonstrated a shift in melting point from 140.03°C for pure Ticagrelor to 132.98°C for the optimized formulation, indicating the formation of a new crystalline phase. FTIR studies revealed shifts in characteristic functional group peaks, suggesting intermolecular interactions between Ticagrelor and L-Arginine. PXRD and SEM analyses further supported crystal modification and changes in surface morphology.The study concludes that amino acid-based crystal engineering, particularly using L-Arginine, is an effective approach for improving the solubility of Ticagrelor. The enhanced solubility achieved through the prepared crystal system may contribute to improved dissolution behavior and oral bioavailability of the drug.

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## INTRODUCTION

Ticagrelor is a reversible P2Y12 receptor antagonist widely used in the management of acute coronary syndrome and prevention of thrombotic cardiovascular events. However, its poor aqueous solubility and low oral bioavailability restrict its therapeutic performance, making solubility enhancement an important pharmaceutical challenge [1, 2].

Crystal engineering has emerged as an effective strategy for improving the physicochemical properties of poorly water-soluble drugs. Among various approaches, pharmaceutical cocrystallization offers the advantage of modifying solubility, dissolution rate, stability, and mechanical properties without altering the pharmacological activity of the active pharmaceutical ingredient (API) [3-6]. Cocrystals are crystalline materials composed of an API and a suitable coformer in a definite stoichiometric ratio, held together by non-covalent interactions such as hydrogen bonding [7, 8].

Amino acids have gained considerable attention as pharmaceutical coformers because of their biocompatibility, GRAS status, and ability to form extensive hydrogen-bonding networks. L-Arginine and Glycine are particularly attractive candidates due to their high aqueous solubility and functional groups capable of strong intermolecular interactions with drug molecules [9-11]. Previous studies have reported significant enhancement in the solubility and dissolution behavior of poorly soluble drugs through amino acid-assisted crystal engineering [12, 13].

Furthermore, co crystallization of Ticagrelor with suitable coformers has been shown to improve its physicochemical properties and dissolution performance [14, 15]. Therefore, the present study aimed to develop Ticagrelor-amino acid multicomponent crystal systems using L-Arginine and Glycine by the solvent evaporation method and evaluate their potential for enhancing the solubility and dissolution characteristics of Ticagrelor.

## MATERIALS AND METHODS

### Drug and coformers

**Table 1: Drug and Coformers**

| Sr. No | Drug and coformer | Manufacturing |
|---|---|---|
| 1 | Ticagrelor | Smruthi Organics, Solapur |
| 2 | L-Arginine | Research lab |
| 3 | Glycine | Research lab |

### Equipments

**Table 2: List of Equipments used**

| Sr. No | Name of the equipment | Supplier |
|---|---|---|
| 1 | Weighing balance | Sartorious secura225D-10IN |
| 2 | Sonicator | Oscar 103 |
| 3 | UV Spectrophotometer | Agilent |
| 4 | Dissolution Apparatus | Electrolab XXIII |

| | | |
|---|---|---|
| 5 | FTIR | Bruker Alpha II |
| 6 | DSC | Mettler Star SW 12.10 |
| 7 | XRD | Ultima IV, Riga Corporation, Japan |

**Calibration curve of Ticagrelor**

A stock solution of Ticagrelor (100 µg/mL) was prepared in phosphate buffer (pH 6.8). Working standard solutions in the concentration range of 5–25 µg/mL were obtained by appropriate dilution of the stock solution. The solutions were scanned using a UV–Visible spectrophotometer, and the maximum absorbance (λmax) was observed at 255 nm. Absorbance values of the working standards were recorded at 255 nm using phosphate buffer (pH 6.8) as the blank. A calibration curve was constructed by plotting absorbance against concentration, and linear regression analysis was performed to evaluate the linearity of the method.

**Solvent evaporation method for preparation of co amorphous**

Ticagrelor and the selected coformer were dissolved in a methanol:water (7:3) solvent system to obtain a homogeneous solution. The solvent was evaporated under reduced pressure using a rotary evaporator. The resulting solid was dried, pulverized, sieved, and stored in a desiccator until further evaluation.

**Table 3: Composition of Drug and coformers Formulations**

| **Formulation code** | **Drug (Ticagrelor) mg** | **Co-former 1 (L-Arginine) mg** | **Ratio** |
|---|---|---|---|
| F1 | 250 | 83.3 | 1:1 |
| F2 | 250 | 166.8 | 1:2 |
| F3 | 250 | 249.9 | 1:3 |

**Table 4: Composition of Drug and coformers Formulations**

| Formulation code | Drug (Ticagrelor) mg | Co-former 1 (Glycine) mg | Ratio |
|---|---|---|---|
| F4 | 250 | 35.9 | 1:1 |
| F5 | 250 | 71.8 | 1:2 |
| F6 | 250 | 107.7 | 1:3 |

**Saturation Solubility Study**

An excess amount of the sample was added to 10 mL of distilled water and shaken on a rotary shaker for 6 h to attain equilibrium. The dispersion was then kept undisturbed for further equilibration. Afterward, the solution was filtered through Whatman filter paper, suitably diluted with distilled water, and analyzed spectrophotometrically at 255 nm to determine the dissolved drug concentration.

**Fourier transform infrared spectroscopy (FTIR)**

Fourier Transform Infrared spectroscopy was employed to examine the molecular interactions and functional groups present in the optimized formulation using a Bruker Alpha II FTIR spectrometer.

**Differential scanning calorimetry (DSC)**

The thermal characteristics of the optimized formulation were investigated using a METTLER TOLEDO DSC1 STARe System.

**Powder X-ray diffraction (PXRD)**

The solid-state properties and degree of crystallinity of the optimized formulation were assessed by powder X-ray diffraction using an Ultima IV instrument (Rigaku Corporation, Japan).

**Scanning electron microscopy (SEM)**

Scanning electron microscopy was utilized to observe the particle morphology and surface characteristics of the optimized formulation.

**In-vitro dissolution studies**

The dissolution profiles of pure Ticagrelor and the optimized cocrystal formulation were evaluated using an Electrolab XXIII dissolution tester equipped with the basket apparatus. Samples equivalent to the required dose were filled into hard gelatin capsules and placed in 900 mL of phosphate buffer (pH 6.8) maintained at 37 ± 0.5°C. The dissolution study was conducted at a paddle speed of 75 rpm. Aliquots (5 mL) were withdrawn at predetermined intervals (15, 30, 45, 60, 75, and 90 min) and replaced with an equal volume of fresh dissolution medium to maintain sink conditions. The collected samples were filtered, appropriately diluted, and analyzed by UV spectrophotometry.

**RESULTS AND DISCUSSTION**

**Calibration curve of Ticagrelor**

**Table 5: Absorbance of Ticagrelor in phosphate buffer 6.8 pH**

| Concentration (µg/ml) | Absorbance |
|---|---|
| 5 | 0.1620 |
| 10 | 0.3275 |
| 15 | 0.4930 |
| 20 | 0.6585 |
| 25 | 0.8500 |

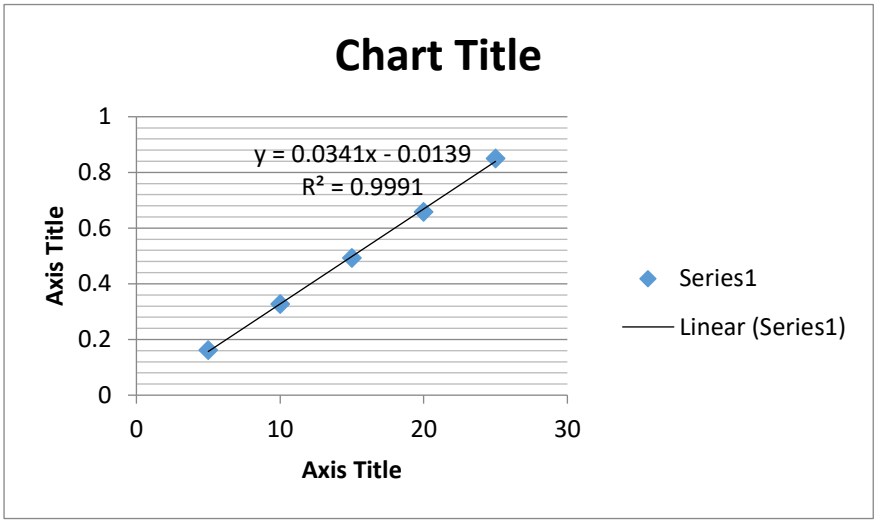


**Figure 1: Calibration Curve of Ticagrelor**

The UV spectrophotometric method developed for Ticagrelor using phosphate buffer pH 6.8 exhibited linear response within the concentration range of 5–25 µg/mL. The calibration equation was y = 0.034x − 0.013 with a correlation coefficient ($R^2$ = 0.999), indicating reliable quantification of Ticagrelor.

**Saturation solubility study**

**Table 6: Solubility of prepared batches (Ticagrelor+L-Arginine)**

| Batch | Enhanced solubility (µg/mL) | Fold increases |
|---|---|---|
| F1 | 7.08 | 2.4 |
| F2 | 9.14 | 3.1 |
| F3 | 10.33 | 3.5 |

**Table 7: Solubility of prepared batches (Ticagrelor+Glycine)**

| Batch | Enhanced solubility (µg/mL) | Fold increases |
|---|---|---|
| F4 | 6.20 | 2.1 |
| F5 | 7.67 | 2.6 |
| F6 | 8.26 | 2.8 |

Among all the prepared Ticagrelor formulations, F3 was identified as the optimized formulation due to its superior solubility performance. The optimized batch exhibited an apparent solubility of 10.33 µg/mL, corresponding to approximately 3.5-fold higher solubility compared with pure Ticagrelor. Additional characterization studies including FTIR, DSC, and XRD will be conducted to further evaluate intermolecular interactions and assess changes in crystallinity.

**Infrared spectroscopy**

**IR spectrum of Ticagrelor**

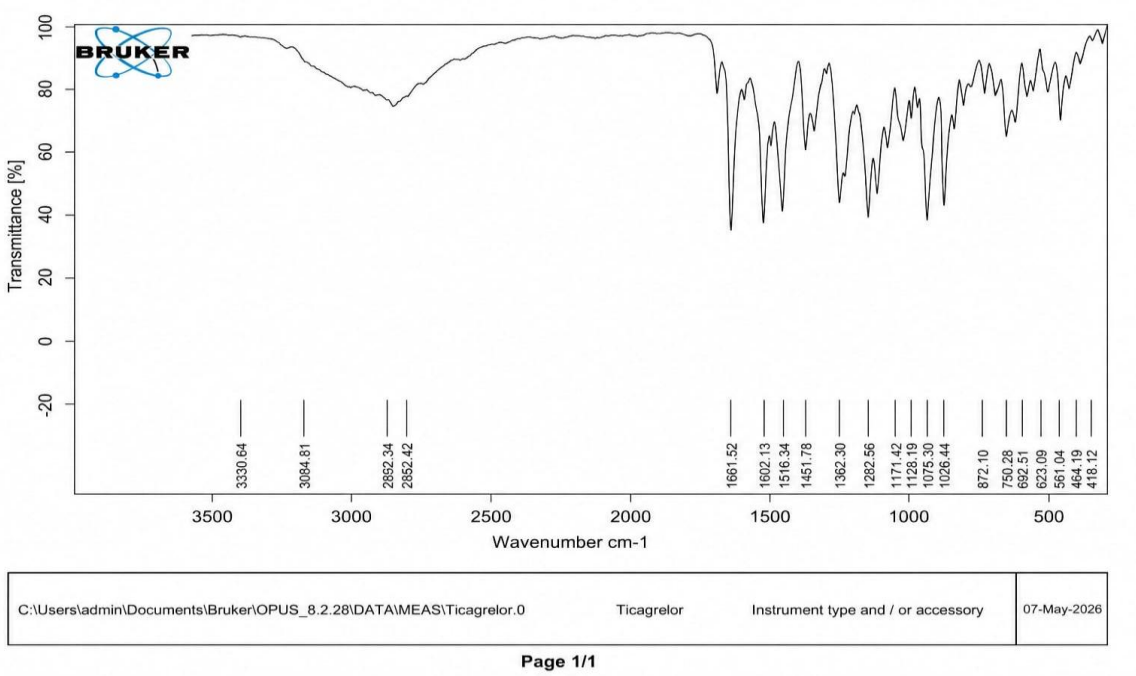


**Figure 2: IR Spectra of Ticagrelor**

**Table 8: Characteristic peaks from Ticagrelor**

| Wavenumber ($cm^{-1}$) | Functional Group |
|---|---|
| 3330.64 | N-H stretching |
| 3084.81 | Aromatic C-H stretching |
| 2922.34 | Aliphatic C-H stretching |
| 1661.52 | C=N stretching |
| 1602.13 | Aromatic C=C stretching |
| 1282.56 | C-N stretching |
| 1171.42 | C-O stretching |

## IR spectrum of L-Arginine


**Figure 3: IR Spectrum of L-Arginine**

**Table 9: Characteristic peaks from L-Arginine**

| Wavenumber ($cm^{-1}$) | Functional Group |
|---|---|
| 3400.05 | N-H stretching (primary amine) |
| 3375.22 | N-H (Aliphatic primary amine) |
| 3227.47 | primary amine |
| 2951.06 | C-H Stretching (Alkane) |
| 1677.99 | C=C stretching (Imine) |
| 1253.86 | C=O stretching (Carboxylic group) |

***IR spectrum of Glycine***

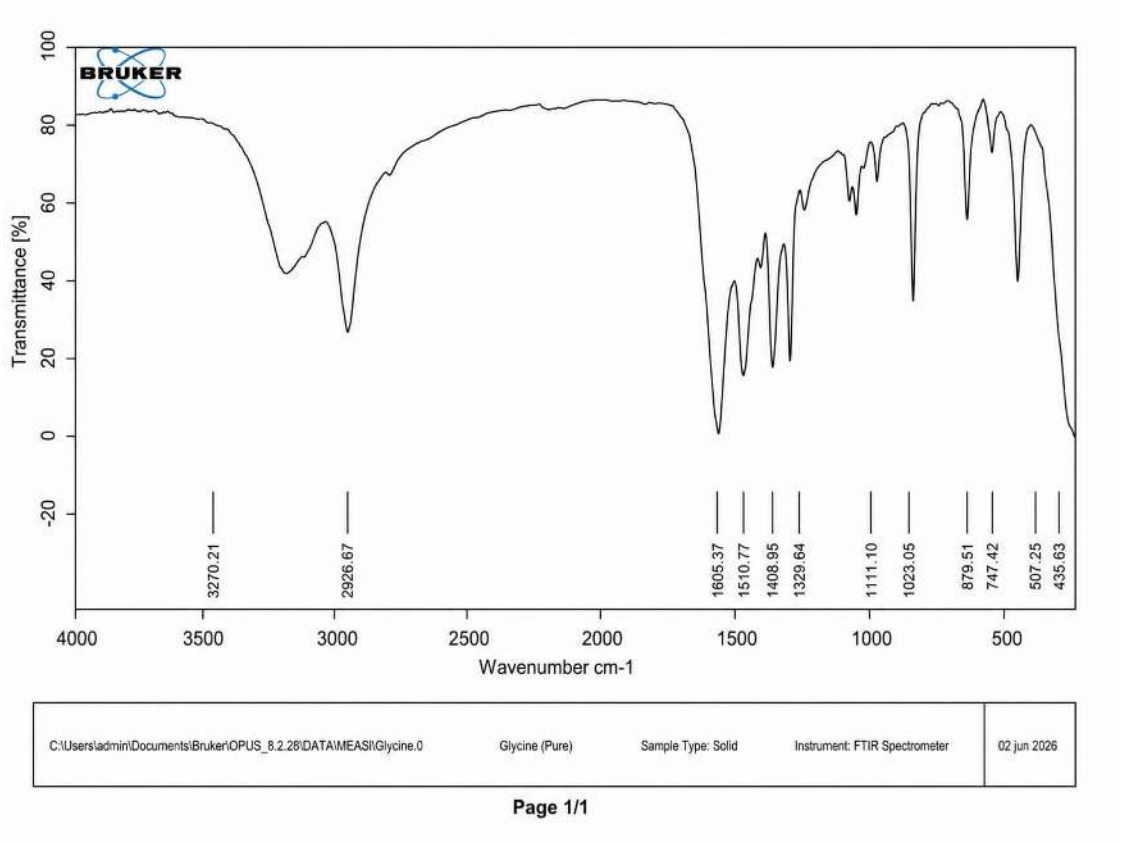


**Figure 4: IR Spectra of Glycine**

**Table 10: Characteristic peaks from Glycine**

| Wavenumber ($cm^{-1}$) | Functional Group |
|---|---|
| 3270.21 | N-H stretching (primary amine) |
| 2926.67 | C-H stretching (Alkane) |
| 1605.37 | C=O stretching (Carboxylic group) |
| 1023.05 | C-N stretching (Amine) |

***IR spectrum of Ticagrelor+L-Arginine***

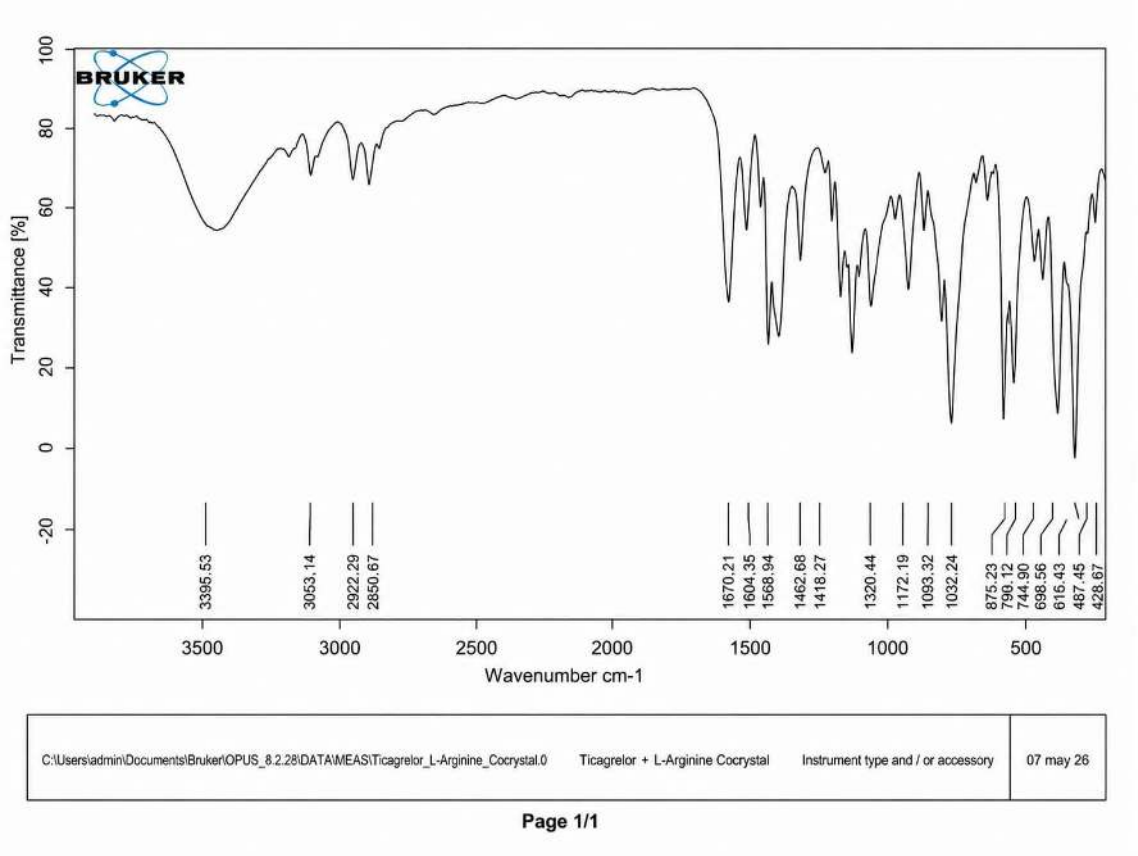


**Figure 5: IR Spectra of Ticagrelor+L-Arginine**

**Table 11: IR Spectra of Ticagrelor+L-Arginine**

| Wavenumber ($cm^{-1}$) | | Interpretation |
|---|---|---|
| **Ticagrelor peaks** | **Co-crystal peaks** | |
| 3330.64 | 3395.53 | Shift in N–H stretching indicates hydrogen bonding interaction between Ticagrelor and co-former |
| 3084.81 | 3053.14 | Shift in aromatic C–H stretching confirms molecular interaction in co-crystal formation |
| 2922.34 | 2922.29 | Slight variation in aliphatic C–H stretching indicates preservation of drug structure with intermolecular interaction |
| 1661.52 | 1670.21 | Shift in C=N stretching suggests strong intermolecular interaction and successful co-crystal formation |
| 1602.13 | 1604.35 | Aromatic C=C stretching peak shift indicates change in molecular environment |
| 1282.56 | 1320.44 | Shift in C–N stretching suggests interaction between Ticagrelor and co-former molecules |
| 1171.42 | 1172.19 | C–O stretching peak shift confirms intermolecular interaction in the co-crystal system |

***IR spectrum of Ticagrelor+Glycine***

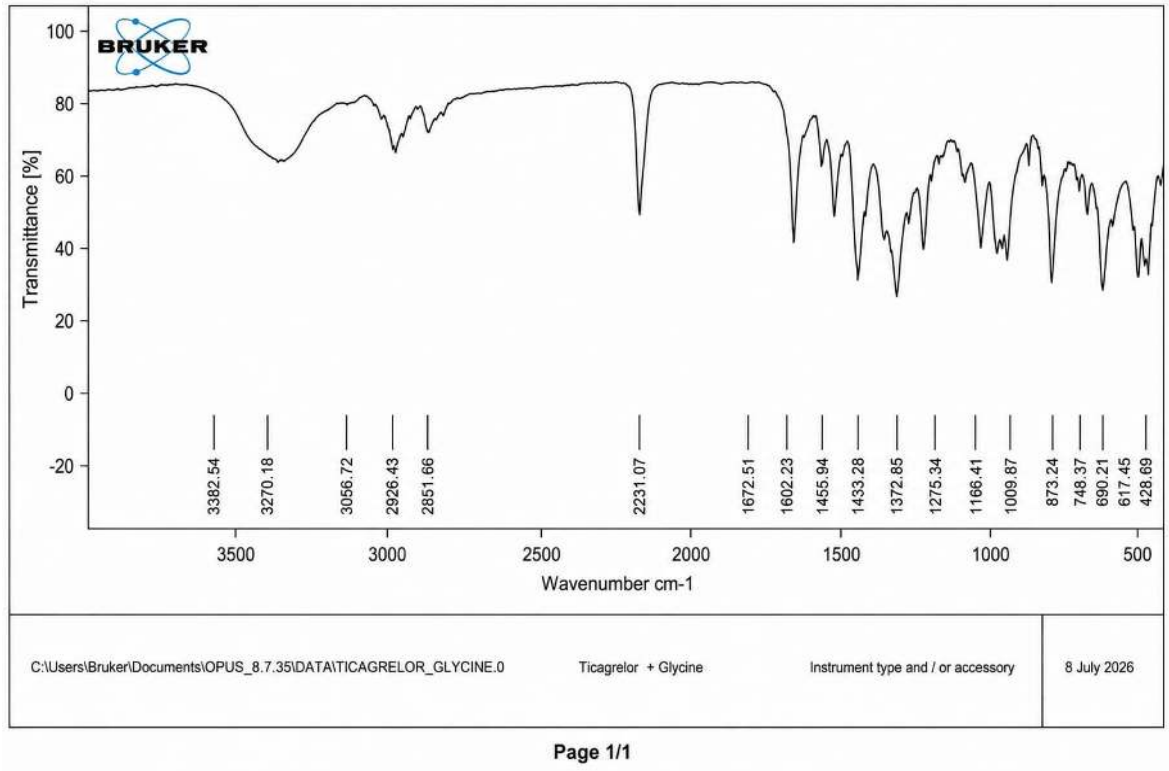


**Figure 6: IR Spectra of Ticagrelor+Glycine**

**Table 12: IR Spectra of Ticagrelor+Glycine**

| Wavenumber ($cm^{-1}$) | | Interpretation |
|---|---|---|
| **Ticagrelor peaks** | **Co-crystal peaks Ticagrelor+Glycine** | |
| 3330.64 | 3382.54 | Shift and broadening of the N–H stretching band indicate hydrogen bonding between Ticagrelor and Glycine, suggesting co-crystal formation. |
| 3084.81 | 3056.72 | Slight shift in aromatic C–H stretching confirms the aromatic structure is retained while indicating molecular interaction. |
| 2852.34 | 2851.66 | Negligible shift in aliphatic C–H stretching indicates the hydrocarbon backbone remains unchanged. |
| 1661.52 | 1672.51 | Shift in C=N stretching indicates interaction of Ticagrelor with Glycine through hydrogen bonding. |
| 1602.13 | 1602.23 | Aromatic C=C stretching is retained, confirming preservation of the Ticagrelor structure. |
| 1282.56 | 1275.34 | Slight shift in C–N stretching suggests intermolecular interaction without chemical degradation |
| 1171.42 | 1166.41 | Minor shift in C–O stretching supports hydrogen-bond formation while maintaining the molecular framework. |

## Powder X-ray diffraction

### *Powder X-ray diffraction of Ticagrelor*

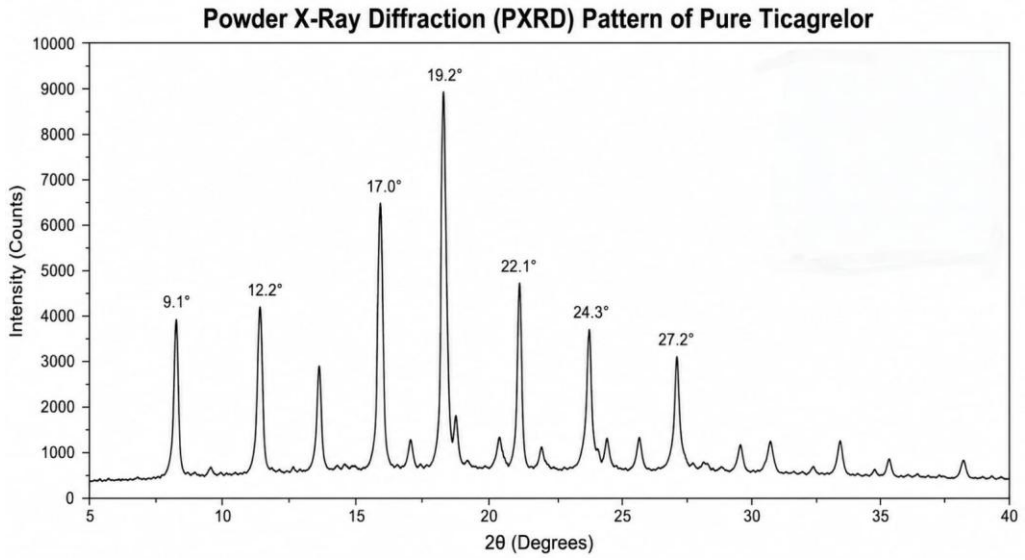


**Figure 7: PXRD Pattern for Ticagrelor**

The PXRD pattern of Ticagrelor is presented in Figure 7. The powder sample exhibited several distinct diffraction reflections with varying intensities at specific 2θ positions. Characteristic peaks were observed at 2θ values of 7.344°, 9.512°, 10.744°, 16.844°, 18.436°, 20.245°, 24.093°, and 30.659°, confirming the crystalline nature of Ticagrelor.

### *Powder X-ray Diffraction of Ticagrelor+L-Arginine*

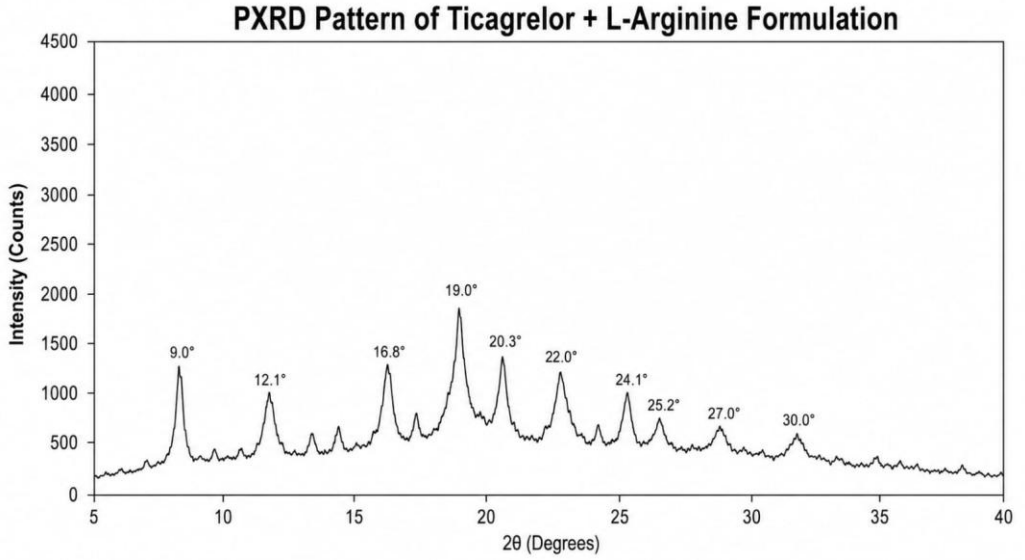


**Figure 8: PXRD Pattern for Ticagrelor+L-Arginine**

The PXRD pattern of Ticagrelor+L-Arginine is presented in Figure 8. diffractogram of the Ticagrelor–L-Arginine formulation revealed distinct crystalline reflections at 2θ values of 9.0°, 12.1°, 16.8°, 19.0°, 20.3°, 22.0°, 24.1°, 25.2°, 27.0°, and 30.0°. The reflection observed at 19.0° exhibited the greatest intensity, whereas the other diffraction peaks were comparatively less intense.

***Powder X-ray Diffraction of Ticagrelor+Glycine***

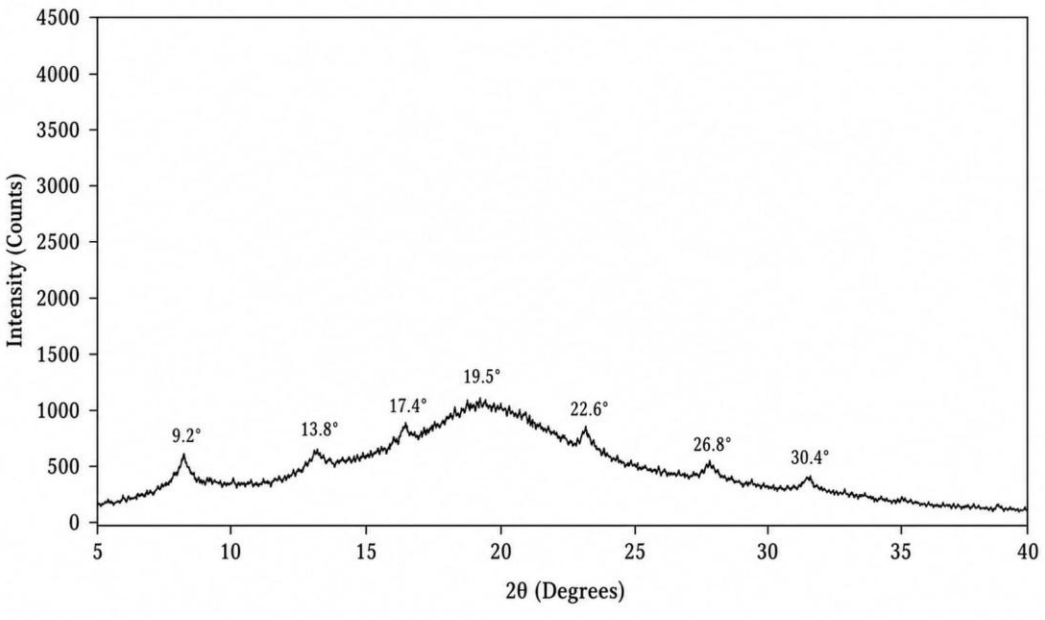


**Figure 9: PXRD Pattern for Ticagrelor+Glycine**

The PXRD pattern of the Ticagrelor–Glycine cocrystal is shown in Figure 9. Distinct diffraction reflections were observed at 2θ values of 9.2°, 13.8°, 17.4°, 19.5°, 22.6°, 26.8°, and 30.4°. In comparison with the PXRD pattern of pure Ticagrelor, the cocrystal exhibited broader and comparatively weaker diffraction signals, suggesting alterations in the crystal structure and lattice arrangement following interaction with Glycine.

**Differential scanning calorimetry**

***Differential Scanning Calorimetry of Ticagrelor***

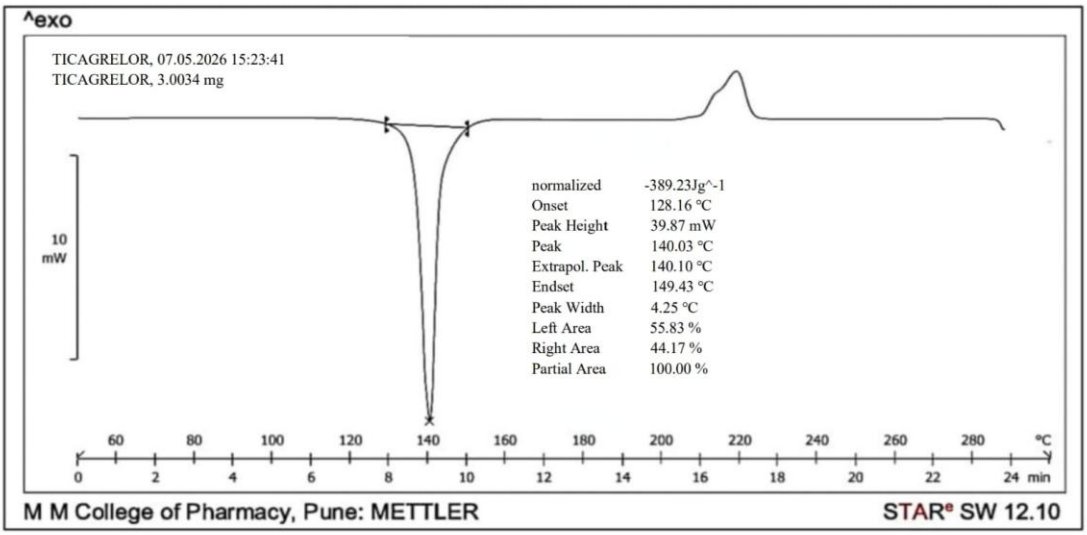


**Figure 10: DSC Thermogram of Ticagrelor**

The DSC analysis of Ticagrelor exhibited a distinct endothermic transition at 140.03 °C, which corresponds to its melting point. The onset temperature of the thermal event was recorded at 128.16 °C. The DSC thermogram is presented in Figure 10. The observed thermal profile was consistent with previously reported findings and showed close agreement with the theoretical melting point of Ticagrelor.

***DCS Thermogram of Ticagrelor+L-Arginine***

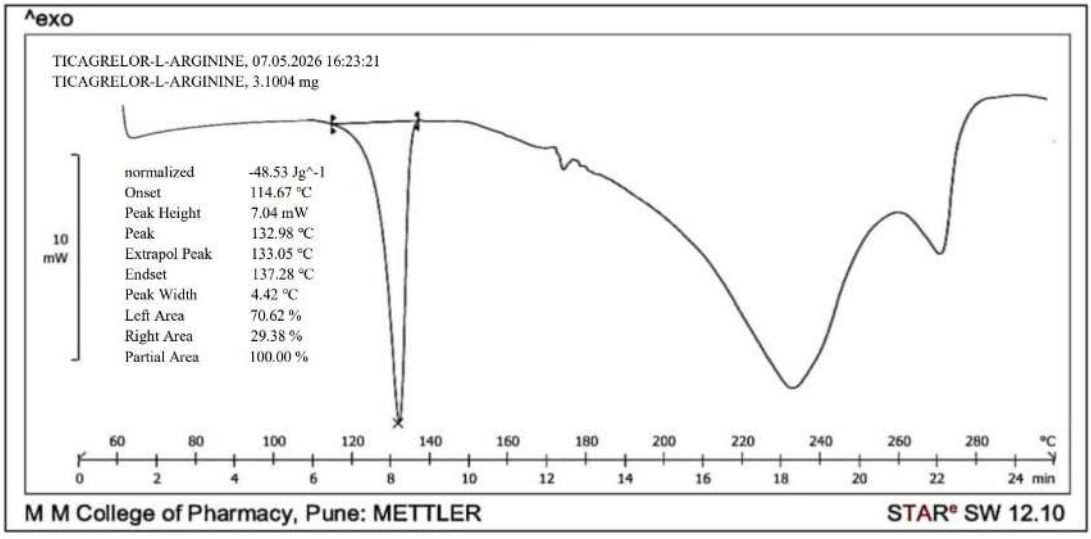


**Figure 11: DSC Thermogram of Ticagrelor+ L-Arginine**

The DSC thermogram of the Ticagrelor–L-Arginine cocrystal, presented in Figure 11, revealed a melting endotherm at 132.98 °C, which was lower than that of pure Ticagrelor (140.3 °C). The onset temperature also decreased from 128.16 °C for the pure drug to 114.67 °C for the cocrystal. These changes in the thermal transitions suggest

an alteration in the crystal lattice and support the possible formation of a new cocrystalline phase.

***DCS Thermogram of Ticagrelor+Glycine***

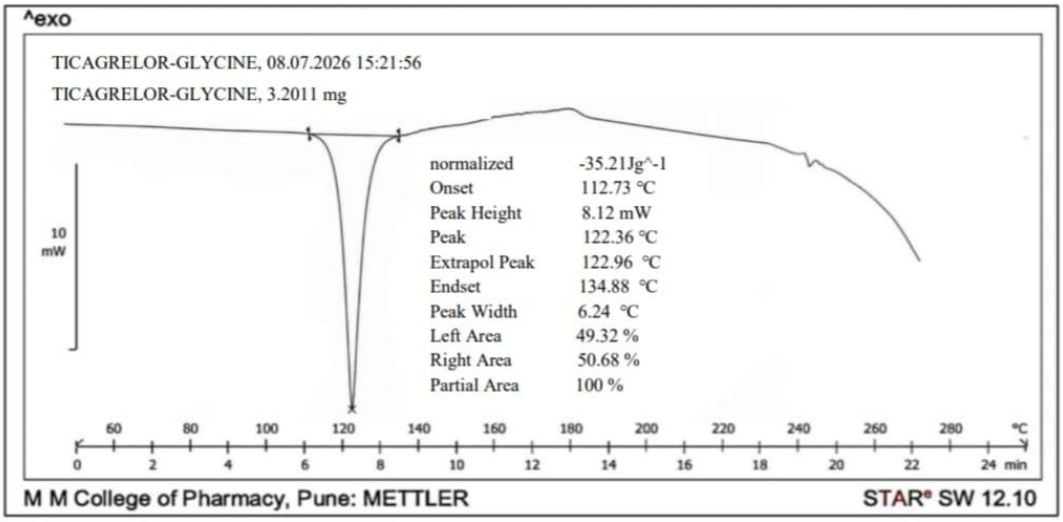


**Figure 12: DSC Thermogram of Ticagrelor+Glycine**

The DSC thermogram of the Ticagrelor–Glycine cocrystal, shown in Figure 12, demonstrated a melting endotherm at 122.36 °C, compared with 140.3 °C for pure Ticagrelor. A reduction in the onset temperature was also observed, decreasing from 128.16 °C for the pure drug to 112.73 °C for the cocrystal. These notable changes in the thermal profile indicate a modification of the crystal lattice and provide evidence supporting the potential formation of a cocrystalline phase.

## Scanning electron microscopy

***Scanning Electron Microscopy of Ticagrelor***

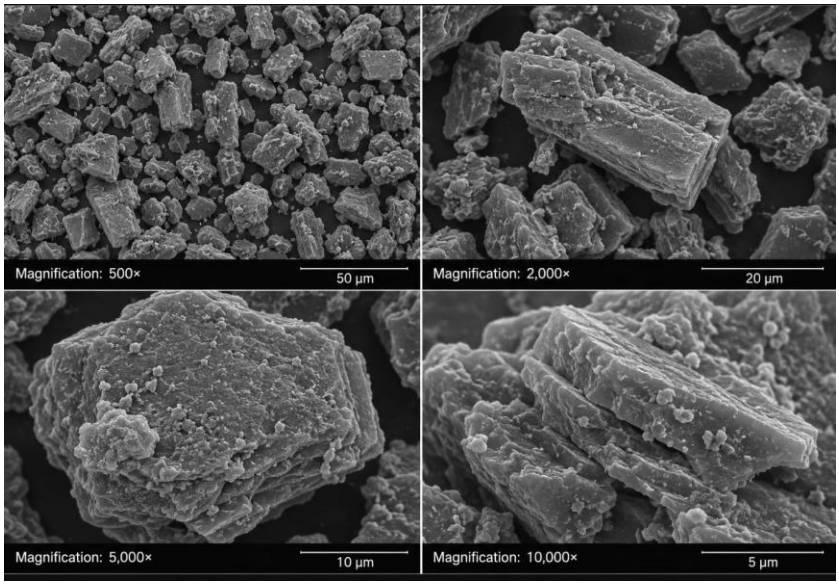


**Figure 13: Scanning Electron Microscopy of Ticagrelor**

The surface characteristics of pure Ticagrelor were examined using scanning electron microscopy (SEM). The SEM micrographs obtained at magnifications of 500×, 1000×, 2000×, and 5000× revealed the characteristic crystalline morphology of Ticagrelor, as illustrated in Figure 13.

***Scanning Electron Microscopy Ticagrelor+L-Arginine***

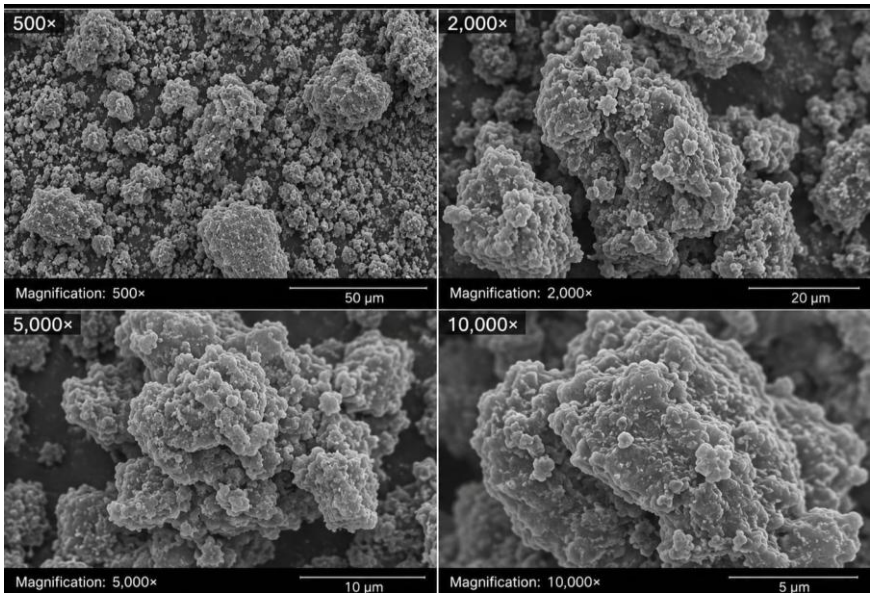


**Figure 14: SEM of Ticagrelor+L-Arginine**

The surface morphology of the Ticagrelor–L-Arginine cocrystal was evaluated by SEM, and the images are shown in Figure 14. A distinct change in surface morphology and crystalline characteristics was observed, supporting the successful formation of the cocrystal.

***Scanning Electron Microscopy Ticagrelor+Glycine***

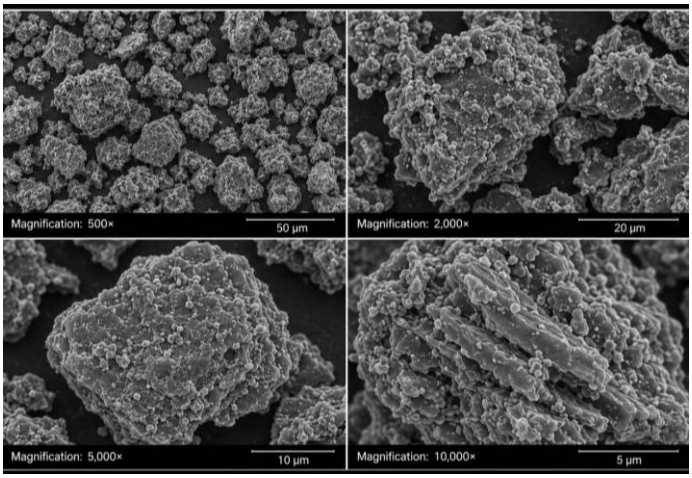


**Figure 15: SEM of Ticagrelor+Glycine**

SEM analysis of the Ticagrelor–Glycine cocrystal showed irregular particles with rough surfaces and some agglomeration at various magnifications, as presented in Figure 15. The modified surface morphology indicates changes following cocrystallization, supporting the formation of the Ticagrelor–Glycine cocrystal.

### Dissolution studies

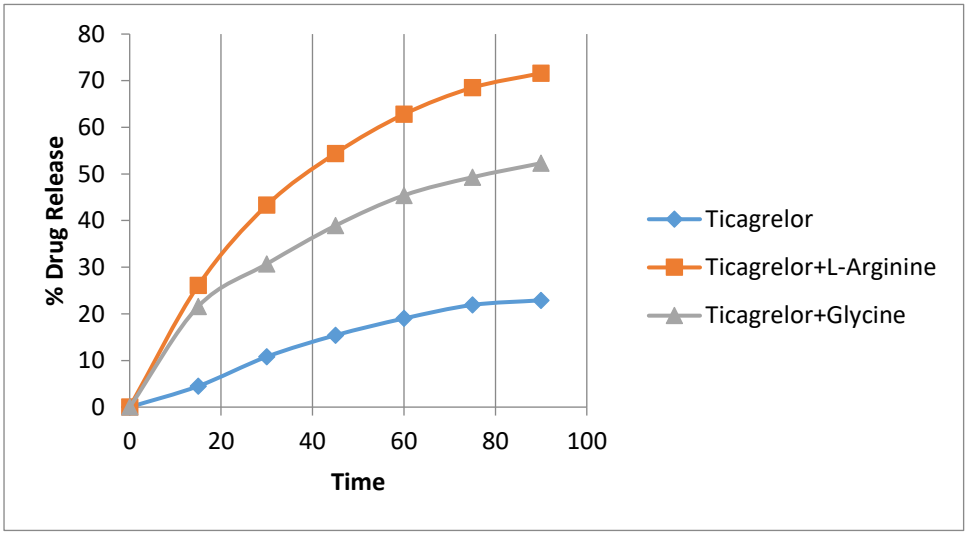


**Figure 15: Cumulative Drug Release Profile of pure Ticagrelor and Cocrystals**

The dissolution study showed that pure Ticagrelor had poor drug release, reaching only 23.5% at 90 min. Co-amorphous formulations significantly improved dissolution. Ticagrelor + L-arginine showed the highest release (70.2%), while Ticagrelor + Glycine showed 51.3% drug release at 90 min. The improved dissolution indicates enhanced solubility due to reduced crystallinity and intermolecular interactions in co-amorphous systems.

## CONCLUSION

The present study showed that cocrystallization with L-Arginine and Glycine improved the solubility and dissolution performance of Ticagrelor compared with the pure drug. Among the two coformers, L-Arginine demonstrated better performance, with a 3.5-fold enhancement in apparent solubility and 70.2% drug release at 90 min, whereas the Ticagrelor–Glycine system showed a 2.8-fold enhancement and 51.3% drug release. Overall, both coformers improved the physicochemical properties of Ticagrelor, but L-Arginine was found to be the more effective coformer and the Ticagrelor–L-Arginine cocrystal was considered the most promising system.

## ACKNOWLEDGEMENT

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