



## FORMULATION, EVALUATION AND SOLUBILITY IMPROVEMENT OF TINIDAZOLE TABLET

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### Abstract

Tinidazole, a synthetic antiprotozoal and antibacterial compound that is nearly insoluble in water, is a BCS class II medication. Because of its poor solubility, tinidazole requires a relatively large oral dosage (2gm). The current study focuses on improving the solubility of tinidazole through the solvent method, which is said to be one of the straightforward methods for doing so by employing different amounts of hydrophilic polymers like poloxamer 188, beta cyclodextrin, sodium carboxymethyl cellulose, and HPMC. The formulation -7, (drug-polaxmer 188) 1:3 complexes had a substantially higher dissolving value of 72.48 percent after 60 minutes, according to the study's overall findings. It is chosen for more research since it is an optimum formulation. FTIR and DSC investigations were used to verify the medication and carrier compatibility. Tablet dosage forms were created to provide a delayed release of the medication for up to ten hours. The goal was to maximize medication release in the colon and minimize it in the stomach and small intestine. The drug content, drug release, and physicochemical properties of prepared tablet formulations were assessed. Following a drug content check, multimedia dissolution was conducted in several media, including water, 0.1 N HCl, and phosphate buffer. Poloxamer, Eudragit, and HPMC were shown to be able to maintain the release for up to 10 hours, with a final drug release of 78.98%. Comparing the formulations to the pure medication, it was discovered that they improved solubility and dissolution.

**Keywords:** Tinidazole, HPMC, Sodium CMC and Cyclodextrin Complexes, Eudragit, Tablets, Solubility Enhancement.

### 1. Introduction

Tinidazole is a synthetic antibacterial and antiprotozoal drug that is a member of the nitroimidazole family and is essentially insoluble in water. Tinidazole is a useful treatment for protozoa such giardiasis, amoebiasis, and *Trichomonas vaginalis*. Furthermore, one of the best medications for treating anaerobic bacterial infections is tinidazole. Additionally, tinidazole can treat rosacea, antibiotic-associated diarrhea, and Crohn's disease[1]. It was first authorized by the FDA in 1963 and comes

in topical, parenteral, and oral forms. Tinidazole has trichomonocidal, bactericidal, and amoebicidal properties. Anaerobic cells and organisms easily absorb unionized tinidazole. Because only anaerobic bacteria can intracellularly convert it to its active form, it operates specifically against them. When it is reduced, the helical helix of DNA is upset, which prevents bacteria from synthesizing nucleic acids. Bacterial cell death is the ultimate effect of this[2].

For many medications, oral drug delivery particularly

oral solid dosage forms like tablets and capsules is the preferred method of administration because it offers a number of benefits over other formulations. Because of its higher stability, simplicity of administration, high patient compliance, dose precision, cost-effectiveness, and design flexibility, it is the most often utilized route. One of the most crucial factors in achieving the essential pharmacological response is solubility, which helps the medication reach the appropriate concentration in the systemic circulation. In addition to having a sluggish rate of drug absorption, which results in insufficient and inconsistent bioavailability, poorly water-soluble medications may need larger dosages to achieve therapeutic plasma concentrations following oral delivery[3]. One of the most difficult parts of the drug development process is still improving the solubility of the medication, which in turn increases its oral bioavailability, particularly for an oral drug delivery system. There are several ways to enhance a drug's solubility and, consequently, its bioavailability if it is poorly soluble in water. Tinidazole's dissolution profile was enhanced by employing solvent-based hydrophilic polymers. Compared to previous formulations, this complex's drug:poloxamer ratio of 1:3 could help provide a superior drug release profile[4].

The current study set out to construct a drug-polymer combination that would enhance solubility for increased bioavailability, decrease the frequency of dose, and increase patient compliance. 1) To create various tablet dosage forms of tinidazole for the treatment of anaerobic bacterial infections is one of the goals of the research project. 2) To research preformulation parameters such Carr's index, melting point, and angle of repose. 3) To describe the dimensions, weight uniformity, content uniformity, hardness, thickness, and other characteristics of produced tablets. 4) To conduct a stability research on the tablet's ideal dose form[5].

## 2. Materials and Methods

### 2.1 Materials

Tinidazole (Micro Labs Pvt. Ltd, Hosur, India.), beta

cyclodextrin obtain from Yarrow Chem Products. HPMC, polaxamer 188, sodium carboxy methyl cellulose (NaCMC) obtain from chemical house of jaipur college of pharmacy. All other chemicals, reagent used of analytical grade.

### 2.2 Methods

#### Methods of Preparation of Solid Dispersions by Solvent Method

##### A. Formulation 1

This technique involves dissolving a physical combination of tinidazole and beta cyclodextrin (1:1) in alcohol and then drying the mixture until a transparent, solvent-free film is obtained. The film is then dried until its weight remains consistent. The solvent method's key benefit is that it may avoid thermal breakdown of carriers or pharmaceuticals. This is due to the fact that organic solvents evaporate at relatively low temperatures[6].

##### B. Formulation 2

The dosage of Tinidazole and the amount of complexing agent beta cyclodextrin are measured out in a 1:2 ratio in a china dish. Then, the medication is distributed in the solvent after adding a few millilitres of alcohol. A small solid complex is created as a result of open evaporation.

##### C. Formulation 3

The dosage of tinidazole and HPMC is 1:1 in a china dish. After adding a few millilitres of alcohol, the medication is dissolved in the solvent. Open evaporation causes the formation of a fine solid complex.

##### D. Formulation 4

The dosage of Tinidazole and HPMC is 1:2 in a china dish. Then, the medication is distributed in the solvent after adding a few millilitres of alcohol. A small solid complex is created as a result of open evaporation.

##### E. Formulation 5

A 1:1 ratio of tinidazole to sodium CMC is eaten in a china plate. Then, the medication is distributed in

the solvent after adding a few millilitres of alcohol. A small solid complex is created as a result of open evaporation[7].

#### F. Formulation 6

The dosage of Tinidazole and Sodium CMC is 1:2 on a china dish. After adding a few millilitres of alcohol, the medication is dissolved in the solvent. Open evaporation causes the formation of a fine solid complex.

#### G. Formulation 7

After weighing the drug and polaxmer 188 in a 1:3 ratio, they were ground together for five minutes each using a spatula in a mortar and pestle. Then, the medication is distributed in the solvent after adding a few millilitres of alcohol. A small solid complex is created as a result of open evaporation shown in table 1.

#### Preparation of Tinidazole Tablet

Using the moisture-based granular process, each tablet was manufactured. It was physically combined in a mortar and pestle using precisely measured amounts of the drug (Drug and poloxamer 188), polymer (HPMC / Eudragit), and binding agent (Polyvidone, 3% w/w), which is equal to 500 mg of tinidazole. To make a dough mass appropriate for granule production, after adding the required quantity of ethyl alcohol, the mixture was rapidly stirred. After drying the dough in a heated oven at 60 degrees Celsius, milled granules were generated by passing the majority of the dough through sieve #22. Crushed into tablets using nine millimeters circular parabolic punch at an appropriate pressure in a Ten-station revolving tablet mking machine (Rimek, Mumbai, India) set to Ten revolutions per minute, the granules were mixed with the required quantities of the lubricating agent and the diluting agent[8].

A number of tablet qualities, including hardness, dimension, weight variation, percent friability, and medication content, were assessed in the manufactured core tablets. Drug content experiments were conducted to assess the dosage of the finished tablet.

#### Coating of the prepared tablets

The main coat consisted of a ten percent ,fructo-oligosaccharides in hot water (80°C) in order to achieve the desired weight gain of four percent w/w on the pills. Citric acid triethyl ester and PEG 6,000, 4% w/w inulin were used as plasticizers, and magnesium stearate (12% w/w inulin) was added to decrease the filminess of the pills. Following this, an intestinal coating was applied to the tablets, increasing their weight by 2.5% w/w. A 20% w/v lacquer in ethyl alcohol solution had the desired effect. A plasticizer called PEG 6000 was used, in addition to 4% lacquer by weight. The two coating solutions were filtered using a 0.3 mm screen prior to applications. A solution of inulin was applied to the manufactured matrix tablets using a spray coating technique. It was the standard coating pan that was used to coat the pills. At 55 °C, the input temperature was maintained, with the pan rotating at 15 RPM, a spray pressure of 4 kg/cm<sup>2</sup>, and a spray rate of 10 ml/min. Using a 1 mm atomizing nozzle, the solution was used for spraying using a pilot type spray pistol (Bullocks 630). Verifying the hardness and drug content of the tablet coatings was the following approach[9].

#### Determination of Absorption Maxima

Mix 100 milligrammes of tinidazole with enough methanol to reach a volume of 100 millilitres; add 0.1 N HCL to bring the final volume to 100 millilitres. Using a pipette, transfer 1 millilitres of the solution to a new round bottom flask. Diluting with 0.1 percent HCL Then, scan it in the UV-visible spectrophotometer's 200-400 nm range [10].

#### Preparation of Calibration Curve in 0.1 N HCL

Pharmaceutical product 100 milligrammes; Add enough methanol to dissolve the compound, then add enough 0.1 N HCL (pH 1.2) to get the volume up to hundred milliliter. Take one milliliter of the aforementioned mixture and add enough water to bring it up to hundred milliliter., creating a secondary stock solution with a concentration of hundred micro gram milliliterl. Using 0.1 N HCL (pH 1.2),

standards for the calibration curve were produced from the secondary stock solution at concentrations of five, ten, ....., twenty µg/ml. Every standard on the calibration curve had its absorbance measured at 275 nm, and a straight line was drawn from the concentrations to the absorbance[11].

#### **Preparation of Standard Solution in Phosphate Buffer of pH 1.2 pH 7.4 and pH 6.8**

An exact 100 milligramme (mg) solution of tinidazole was preparing by mixing the pharmaceutical product in hundred millilitres of methyl alcohol. A standard solution with a amount of fifty microgram per milliliter were prepared by diluting five milliliter of the original sample with 100 ml of each of the three distinct pH buffers: 1.2 for stimulated stomach fluid, 7.4 for stimulated small intestinal fluid, and 6.8 for stimulated colonic fluid. To prepare the standard drug solution (50µg/ml), accurately measured quantities ranging from 1 to 5 ml were put into a 10 ml volumetric flask and diluted with the appropriate buffer until it reached the mark. Hence, the concentration at the end might vary between 5 and 25 µg/ml. Using the corresponding buffer as a blank, the absorbance of each solution was measured at 275 nm. The absorbance of a medication at different concentrations was graphed[12].

#### **Drug - Excipient Interaction Study**

Fourier transform infrared spectroscopy (FT-IR) and differential scanning calorimetry (DSC) investigations were made to detect possible drug and excipient interactions.

#### **Fourier Transform Infrared Spectral Assignment**

The infrared spectra of tinidazole were obtained using an IR Spectroscopy. The infrared chamber was used to scan a specimen pelleted at a resolution of four centimetres per inch with a frequency ranging from four thousand to four hundred per centimetre.

##### **6.1.1.9 DSC**

For the DSC analysis of the pure drug, the DSC 60 Simadzu were used. The sample has been heated

in an open aluminium pan at a rate of ten degrees Celsius per minute at temperatures ranging from thirty to three hundred degrees Celsius while being subjected to a NO<sub>2</sub> circulation rate of forty millilitres per minute of time.

##### **6.1.1.8 X-ray Diffraction Experiment**

To determine if unadulterated tinidazole exhibited crystalline or amorphous behaviour, an X-ray diffraction experiment was conducted under the following conditions: The target is exposed to monochromatized Copper K-α irradiation at room temperature using a forty kilovolt voltage and a 40 milliamperes power. The data was collected in scanned mode at a rate of 20 per second with a step size of 0.01 degrees. A range of thirty to three hundred degrees was scanned.

Precompression Parameters- Evaluation of tinidazole granules blend: The tinidazole-granules of all batches were evaluated for density ( bulk density and tapped density), angle of repose, Hausner's ratio and compressibility index.

##### **Post-Compression Analysis of the Prepared Bilayer Tablets**

As per pharmacopoeial procedures all batches of tablet were characterized for thickness, weight variation, hardness and friability & In vitro drug release.

##### **Disintegration Test**

Six tablets were used in the disintegration test, which was carried out with an adjusted disintegration procedure. The equipment used for disintegration testing was kept at of 37±0.5 degrees Celsius of temp in PO<sub>4</sub><sup>2-</sup> buffer solutions of pH of 6.8. The tablets were placed in the baskets of the equipment, and the amount of time that was required to finish the disintegration process was carefully recorded.

##### **In Vitro Drug Release**

In order to mimic the scenarios of the colonial-specified methods of drug deliver, the traditional

basket technique of testing for dissolution has often included doing the tests in various buffers for varying durations. The USP XXII dissolution equipment, namely the basket type, was used to conduct the dissolving investigations at one hundred revolutions per minute and  $37 \pm 1$  °C. Three different pH buffers were used for laboratory drug delivery studies: one with a pH of 1.2 (HCl buffer), one with a pH of 6.8 (phosphate buffer), and one with a pH of 7.4 (phosphate buffer). The experiments lasted for one hour each. A spectrophotometer reading of 275 nm was used to determine the rate of drug release from the samples taken at predetermined intervals.

### 6.7 Stability Studies

We conducted stability experiments on the optimised tablet formulation to find out how the formulation additives affected the drug's stability at the finished product and how stable it was physically. A 6-month stability study was conducted on the optimised formulation in accordance with ICH recommendations. Regular intervals were used to monitor the samples for changing in their physical characteristics and drug concentration. The samples were maintained at  $25 \pm 2$  °C with  $60 \pm 5\%$  relative

humidity and at  $30 \pm 2$  °C with  $65 \pm 5\%$  relative humidity, appropriately.

### 3. Result and Discussion

Tinidazole dissolves in 0.1 N hydrochloric acid. This led to the preparation of a methanol calibration curve for the pure drug. (Figure 1) demonstrate that the drug's absorption maxima in methanol were identified as 275 nm and 100 µg/ml of sample, respectively. A regression value of 0.9985 was determined after preparing the tinidazole drug calibration curve in 0.1 N HCL (Figure 2 a). A regression value of 0.994 was determined from the medication tinidazole's calibration curve in phosphate buffer pH 7.4 (Figure 2 b). After preparing the tinidazole calibration curve in a phosphate buffer with a pH of 6.8, the regression value was determined to be 0.999, indicating that the drug is linear (Figure 2 c), and the recovery rate was determined to be 99.0091 percent. The medicines were tested within the concentration range where Beer's law held according to the standard calibration curve. Tinidazole was determined to have a range of 5.0 to 20.0 µg/ml. We calculated the standard deviation (SD) and average absorbance value (MAV) from three separate measurements. A slope of 0.041 was determined.

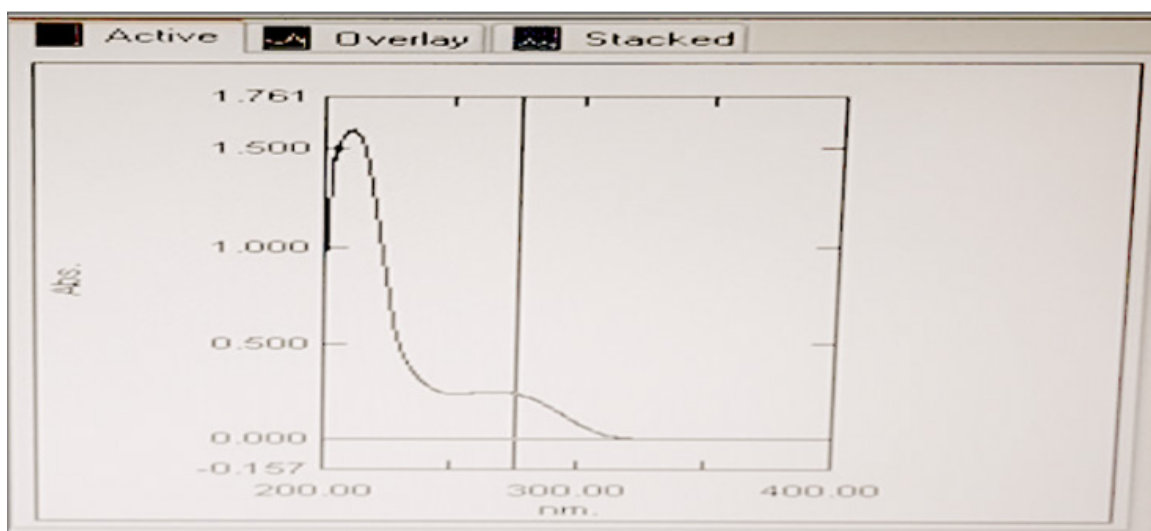
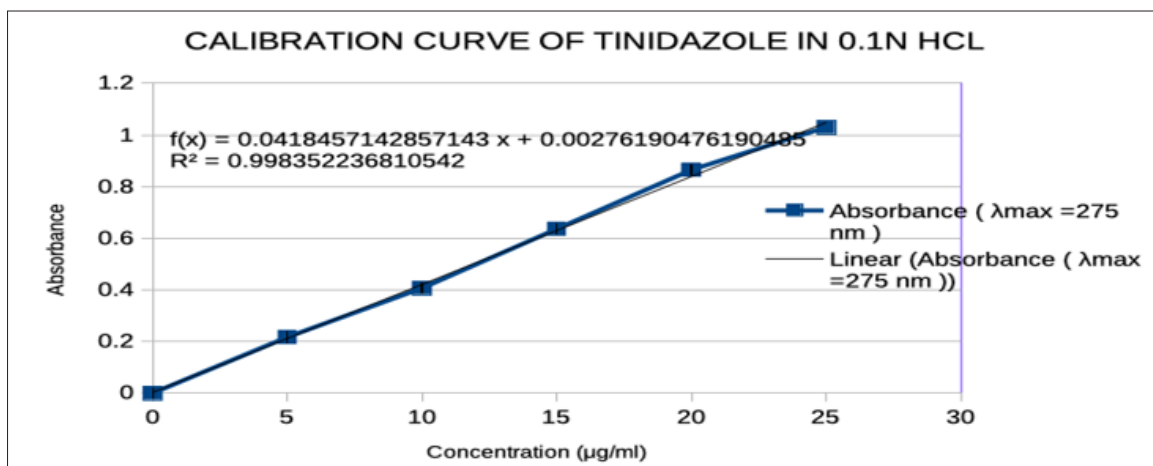
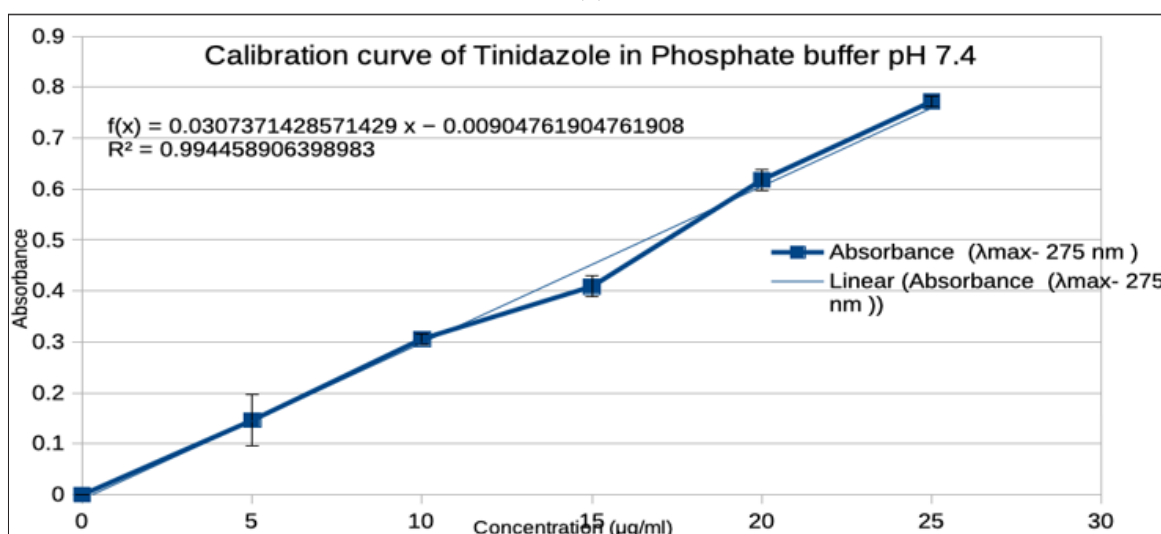


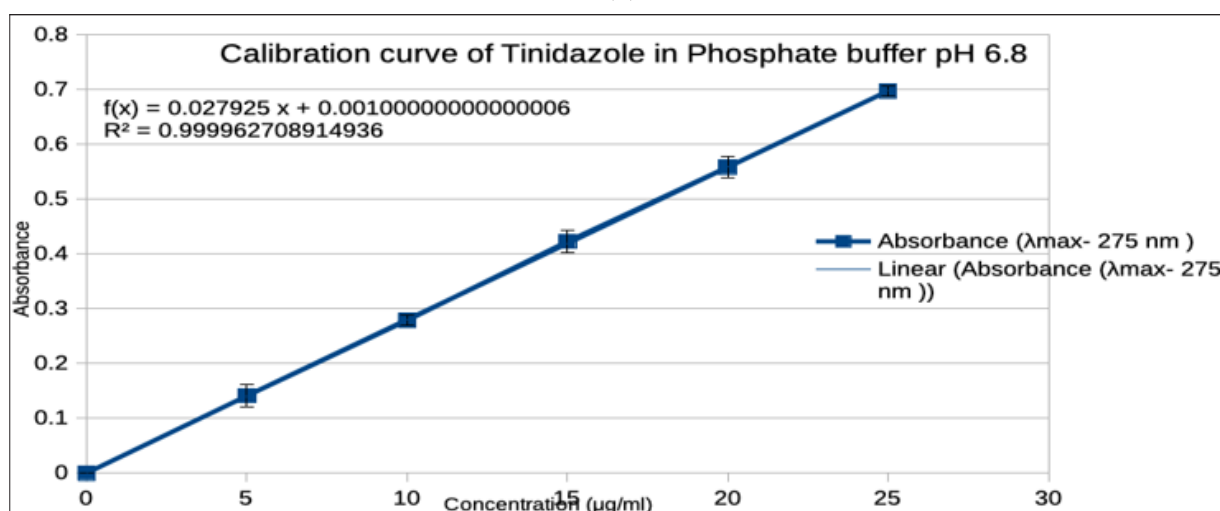
Figure 1: Determination of  $\lambda_{max}$  of pure drug Tinidazole in methanol



(a)



(b)



(c)

Figure 2: Calibration Curve for Tinidazole (a) 0.1 N HCL (b) Phosphate Buffer pH 7.4 (c) Phosphate Buffer pH 6.8

### 3.1 FTIR

An assigned vibrational frequency of 2856 cm<sup>-1</sup> was seen in the FT-IR spectra of the control compound tinidazole, which was determined to be C-H stretching. Three asymmetric stretchings were identified in the infrared spectrum: one at 1649 cm<sup>-1</sup>, one at 2289 cm<sup>-1</sup>, and one at 1442 cm<sup>-1</sup>, which were ascribed to the imidazole ring, the imidazole ring, and NO<sub>2</sub>, respectively. The stretching of C-C bonds and the bending of CH<sub>2</sub> were respectively characterised by absorption peaks at 2250 cm<sup>-1</sup> and 754 and 700 cm<sup>-1</sup>. N=O symmetric stretching, S=O asymmetric stretching, and C-O stretching were denoted by the IR peaks that cropped up at 1317, 1301, and 1265 cm<sup>-1</sup>, respectively. In conclusion, the vibrational peaks at 1192-1123 cm<sup>-1</sup> and 1002 cm<sup>-1</sup> were determined to correspond to C-N stretching and S=O symmetric stretching, among other things. Pure drug FTIR analysis Spectrum (figure 3) demonstrates

the presence of tinidazole.

### 3.2 Differential scanning calorimetry (DSC)

A DSC investigation: In figure 4, we can see the tinidazole DSC. The presence of a prominent exothermic peak in the DSC spectrum of tinidazole suggests that the compounds are crystalline. Tinidazole's intrinsic melting points are indicative of its purity; TN exhibits an individual peak at 127.44°C and a heat of process of 160.7 J g<sup>-1</sup>.

### 3.3 X-ray diffraction Study (XRD Study)

A research was conducted using XRD to examine the crystal structure of pure paracetamol, the medication in question. Figure 5 shows the X-ray disc pattern of pure paracetamol. In the X-ray diffractogram of paracetamol, the existence of strong peaks at 16.13°, 20.52°, 24.45°, 25.6°, and 33.15° suggested that the compound was extremely crystalline.

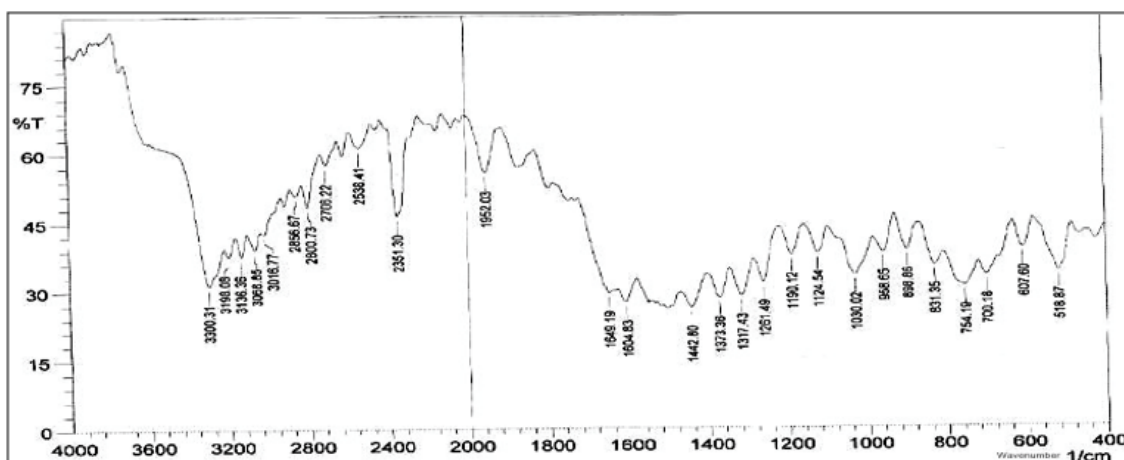


Figure 3: FTIR spectra of pure drug tinidazole

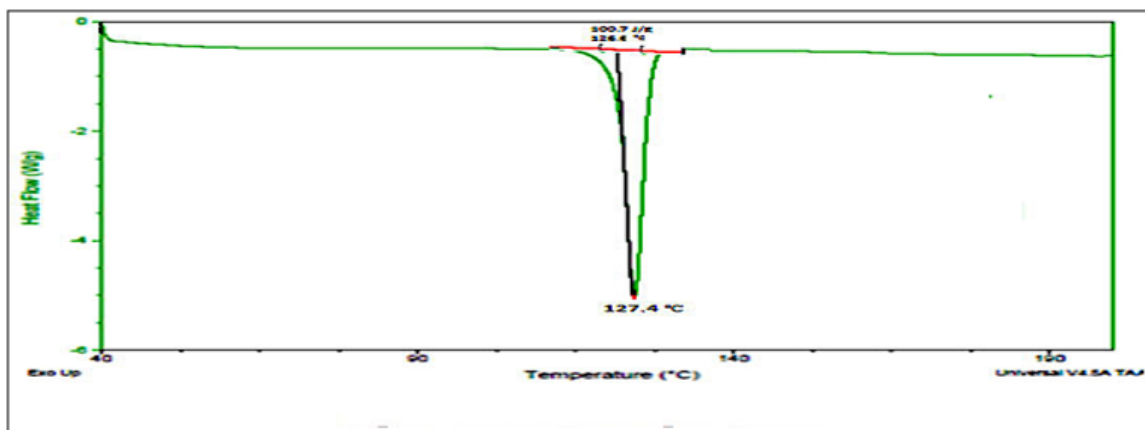


Figure 4: DSC Study of Tinidazole (pure drug)

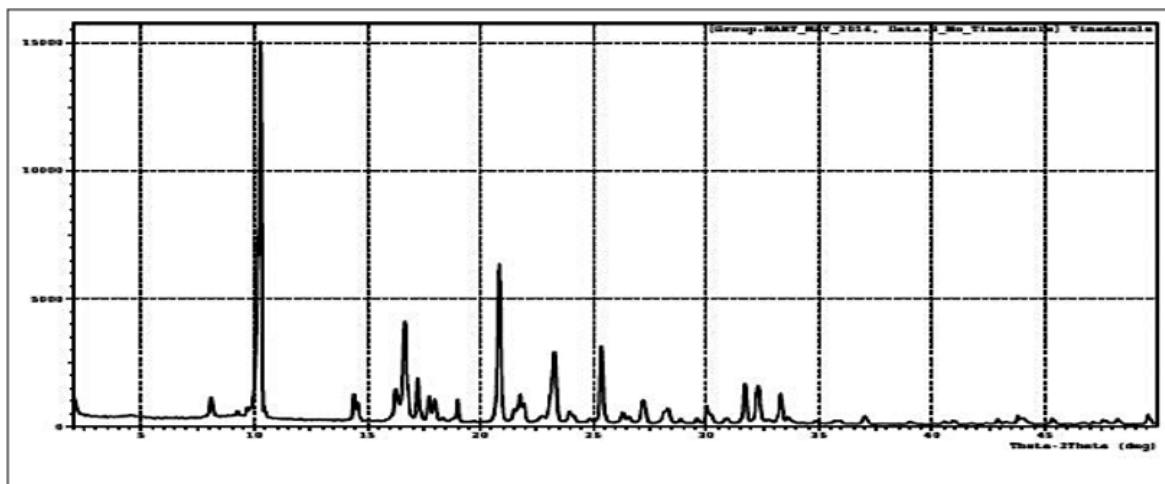


Figure 5: XRD of pure drug tinidazole

**Solubility enhancement**

If the drug is soluble, it will dissolve more easily. Tinidazole is a medicine that has a hard time dissolving in water, so we made drug complexes to help it dissolve better and increase its bioavailability. Hydrophobic medication The drug’s solubility may be enhanced by including hydrophilic polymers such as HPMC, Sodium Carboxymethyl cellulose, beta cyclodextrin, and poloxamer 188.

In comparison to other drug-carrier complexes, drug-polaxmer 188 complexes had a significantly greater dissolution value of 72.48 percent after 60 minutes, according to the analysis shown in (figure 6) and (table 2). By the end of 60 minutes, formulation 4 had released 69.45% of the medicine

while formulation 3 had released 65.68 percent. Formulation 5 demonstrates a medication release of 48.34% in 60 minutes, whereas formulation 6 shows a release of 58.7%.

Evidence suggests that hydrophilic polymers may improve the solubility of drugs with low solubility. Research on release kinetics has shown that first-order kinetics is followed by the majority of formulations. We observed that the dissolving rate was proportional to the concentration of water loving polymers in the complex. All things considered, the data show that formulation-7 has the best drug release. Both its solubility and its dissolution are at their peak.

Table 1: Composition of drug and carrier complex

Formulation	Drug	Carrier	Composition	Solvent (ethanol)
F1	1000 mg	Cyclodextrin	1:1	10 ml
F2	1000 mg	Cyclodextrin	1:2	10 ml
F3	1000 mg	HPMC	1:1	10 ml
F4	1000 mg	HPMC	1:2	10 ml
F5	1000mg	Sodium CMC	1:1	10 ml
F6	1000mg	Sodium CMC	1:2	10 ml
F7	1000 mg	Poloxamer 188	1:3	10 ml

Table 2: Dissolution data of F1, F2, F3,F4,F5,F6 and F7 formulations

Time	F1	F2	F3	F4	F5	F6	F7
0	0	0	0	0	0	0	0
5	6.58	10.1	12.33	9.34	15.4	7.45	12.48
10	13.5	12.4	15.89	17.27	27.45	17.8	27.59



20	14.7	14.67	22.45	24.34	34.31	22.4	41.39
30	15.5	17.5	33.90	35.56	390.21	31.6	54.32
45	18.8	21.6	48.02	49.45	44.11	42.6	62.67
60	25.89	28.45	65.68	69.45	48.34	58.7	72.48

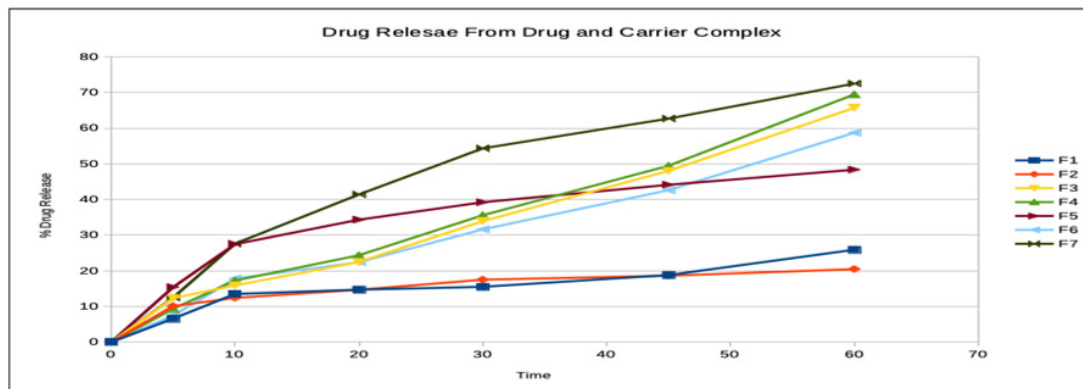


Figure 6: Dissolution data of drug and carrier complex F1, F2, F3,F4,F5,F6 and F7 formulations

Table 3: Micromeritic study of blend of tinidazole tablet

Formulation Code	Bulk Density (g/ml)	Tapped Density (g/ml)	Carr's Index (%)	Hausner's Ratio	Angle of Repose
F1	0.321	0.372	5.34	1.04	26.5
F2	0.331	0.412	9.12	1.11	29.9
F3	0.342	0.422	11.35	1.13	31.21
F4	0.322	0.396	7.94	1.04	30.01
F5	0.333	0.408	5.50	1.05	29.01
F6	0.335	0.415	4.94	1.04	27.06
F7	0.375	0.479	6.25	1.15	30.02
F8	0.354	0.446	12.04	1.167	32.16

Table 4: Preparation of different batches of tinidazole tablet

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8
Drug (Tinidazole+ Poloxzmer188)	500	500	500	500	500	500	500	500
Microcrystalline cellulose	125	150	175	125	150	175	125	125
HPMC	150	125	100	-	-	-	75	100
Eudragit	-	-	-	150	125	100	75	50
PVP K- 30	12.5	12.5	12.5	12.5	12.5	12.5	12.5	12.5-
Magnesium Stearate	12.5	12.5	12.5	12.5	12.5	12.5	12.5	12.5
Total Weight	800	800	800	800	800	800	800	800

**Table 5: Evaluation data obtained from after coated tablets**

Formulation Code	Hardness (kg/cm <sup>2</sup> )	%Content of active ingredient
F1	5.9	101
F2	6.6	97.76
F3	6.8	101.12
F4	6.2	100.2
F5	7.01	100.18
F6	6.6	100.6
F7	7.3	98.3
F8	6.14	97.26

**Pre-Compression Parameters- Evaluation of Tinidazole Granules blend**

The tinidazole granules was evaluated for angle of repose, bulk density, tapped density, Hausner’s ratio (HR), and compressibility index. The bulk density was found in the range of 0.322–0.375 g/cm<sup>3</sup>. The tapped density was range 0.372–0.479 g/cm<sup>3</sup>. The angle of repose varied from 26.5° to 32.16°. The compressibility index was in the range of 4.94–12.04%. The HR was in the range of 1.04–1.167 shown in Table 3. Excellent flow qualities were noted for F1, F2, F4, F5, F6, and F7, while very good flow values were noted for F3 and F8. Nevertheless, F4 had fair flow characteristics due to its greatest value for angle of repose.

**Preparation & Post Compression Parameter of Tinidazole Solid Tablet**

The prepared tablets were tested for characteristics like hardness thickness, disintegration time weight variation, % friability, and drug content. (table 4,) & (table 5) displays the data collected for both coated and uncoated tablets. Out of all the formulations tested, the one with 75 mg of HPMC and eudragit had the hardest surface. The thickness of tablet of each formulation was found in the range of 4.87 – 7.1 mm. The hardness of tablet of each formulation was found in the range of 4.50 - 6.12 kg/cm<sup>2</sup> before coating the tablets and from 5.9 to 7.3kg/cm<sup>2</sup> after coating. The friability was in the range of 0.282%.- 0.726 %. The weight of tablet of each formulation

varied from 803 mg to 905 mg . The % of drug content ranges from 98.16 to 101.32 percent before coating the tablets and from 97.76 to 101.12 percent after coating, as shown in the (table 4) & (table 5). This finding confirms a little decrease in drug content happened throughout the coating procedure. All of the prepared batches were subjected to dissolution tests, and the results ranged from 68.45 to 78.98. This led to the assessment of the tinidazole tablet with a drug concentration of 11.5% after 1 hour according to the in vitro dissolution results, it’s safe to say that the drug release in the stomach’s physiological milieu was minimal. There was a significant increase in the drug’s release rate to 78% after three hours of breakdown. Which show that the colon’s physiological conditions allow for the most powerful medication release. Once the formulation passed through the stomach, it fulfilled the criteria. Research on drug delivery has shown that inulin-coated tablets (4% w/w) limit drug release in the small intestine environment and shellac-coated tablets (2.5% w/w) minimise drug release in the stomach environment. Once the inulin coat reaches the colonic environment, it biodegrades in the media, exposing the medication in the core to the solution.

After conducting the dissolution investigation, formulation’s in vitro release pattern in the image and compare the drug release kinetics in the (table 6). The Kosmeyer-Papas Model Based on the Correlation Coefficient was shown to be the most appropriate for drug release in colon.

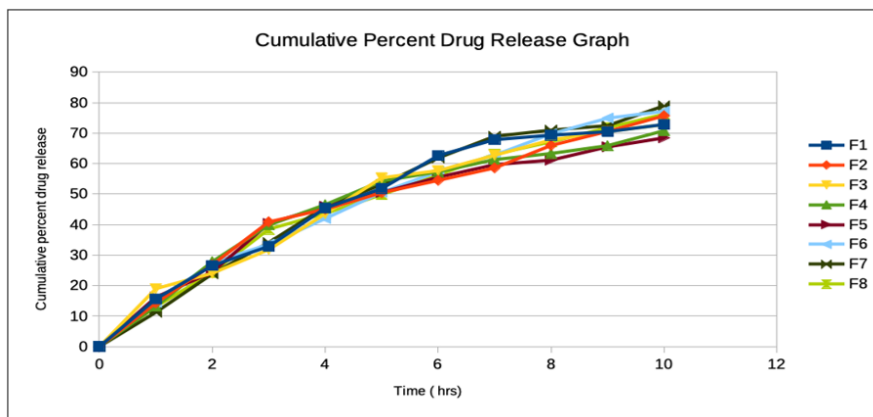


Figure 7. Comparative drug release of tinidazole tablets

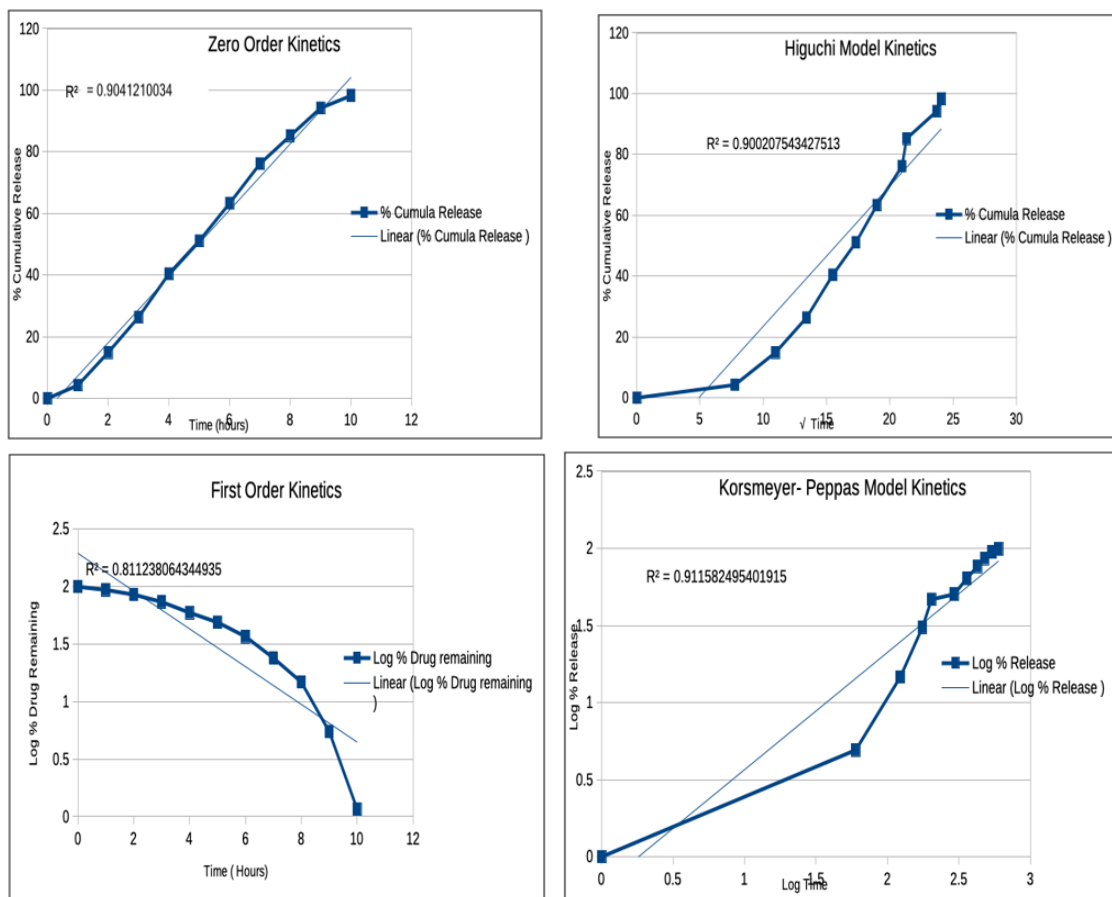


Figure 8: Kinetics of tinidazole tablets

Table 6: Stability study data of optimized formulation F7

Stability condition	Sampling interval (Months)	Formulation F7	
		Physical appearance	% Drug content
25±2 °C/ 60±5 % RH	0	No change	98.3
	3	No change	98.1
	6	No change	97.89
30±2 °C/ 65±5 % RH	0	No change	98.3
	3	No change	98.08
	6	No change	97.80

### Optimization of each formulated layer

By using HPMC/Eudragit as a compression layer on top of the tinidazole tablets, an effort was made to reduce drug release in the stomach and small intestine and maximise drug release in the colon. In order to alleviate inflammation in the colon, compression-coated tablets containing tinidazole were created for local action. The optimised formulation was chosen as F7. Both the DSC and FTIR spectra reveal that the optimised formulation does not exhibit any interaction.

### Stability Study

After being placed in the oven and humidity chamber for storage, the tablets were carefully packaged into appropriate containers. Ensuring a steady temperature and humidity level was a major priority. The pills were evaluation for certain criteria at regular intervals of months. A comparison was made between the results acquired from the examination of the tablet and the results gained from the stability investigations.

Over the course of the trial, it was evident that the medicine was stable in its optimal formulation. Neither the substance nor the visual appeal of the medicine changed noticeably (Table 6). So, the formulation stayed stable.

### 4. Conclusion

The best technique for solid dispersion (SD) is the solvent method. Poloxamer, which has recently been widely used as a wetting agent, solubilizing agent, and surface adsorption excipient, benefits greatly from this method. They have been used to improve the solubility, dissolution, and bioavailability of hydrophobic drugs in a variety of ways. For some medications, poloxamer worked better than complicated building agents like cyclodextrin and other meltable polymers like PEGs. Because of its superior surfactant properties and oral safety, the hydrophilic carrier used in this experiment was empirically selected as poloxamer. The findings indicate that HPMC and Eudragit, two superior

polymers, might be employed as carriers in the development of colon-targeting drug delivery systems. The manufactured 800 mg tinidazole colon tablets might be used in place of three or four doses of the standard 800 mg tablet since they have superior control over drug release for targeted medication administration. Based on the dissolution study findings, this may result in less gastrointestinal side effects and better patient compliance. With an emphasis on the colon, F7, which contained microcrystalline cellulose, PVP-K, and a combination of HPMC and Eudragit (RF), showed a controlled release over ten hours. The best formulation was this one.

### 5. Acknowledgement

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### 8. References

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