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Research Article

Formulation And Evaluation of Taste Masked Orodispersible Tablets of Satranidazole

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ABSTRACT

The present study focused on the formulation and evaluation of taste-masked Orodispersible tablets (ODTs) of Satranidazole, an antiprotozoal agent with limited aqueous solubility and an intensely bitter taste that often compromises patient compliance. To overcome this challenge, taste masking was achieved by complexing Satranidazole with Kyron T-314, a cation-exchange resin, using a batch adsorption technique. The drug–resin complex (DRC) was optimized by evaluating variables such as drug-to-resin ratio, soaking time, stirring duration, temperature, and pH. The optimal complexation was obtained at a 1:2 ratio with 30 minutes of soaking and stirring at 30 °C, yielding drug loading efficiency of 99.79%. FT-IR and DSC confirmed the absence of major drug–excipient interactions, while sensory evaluation demonstrated effective bitterness masking. The optimized DRC was formulated into ODTs by direct compression using Crospovidone and Croscarmellose sodium as super disintegrants. Prepared tablets were evaluated for pre- and post-compression parameters including hardness, friability, wetting time, disintegration time, drug content, and dissolution. Among six formulations, F6 exhibited superior performance with the shortest disintegration time (22 s), highest drug content (99.15%), and rapid drug release (99.46% within 30 min). Stability studies confirmed no significant changes in drug content or physical properties. Thus, the developed taste-masked ODTs of Satranidazole offer an effective, patient-friendly dosage form with enhanced palatability, rapid disintegration, and improved compliance.

INTRODUCTION

Taste perception plays a critical role in ensuring patient compliance in oral drug delivery systems. Orodispersible tablets (ODTs) have emerged as a patient-centric dosage form, characterized by their ability to disintegrate rapidly in the oral cavity without the need for water, thereby facilitating

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administration in individuals with dysphagia or swallowing difficulties. This delivery system not only improves ease of use but also enhances palatability and therapeutic efficacy. ODTs have garnered considerable attention for their potential to enhance the bioavailability of drugs, particularly those exhibiting poor aqueous solubility. Despite these advantages, a primary challenge in ODT formulation is the effective masking of unpleasant or bitter drug taste, which is imperative for patient acceptance and the successful commercialization of such products.[1] Satranidazole (SAT), chemically known as 1-methane sulphonyl-3-(1-methyl-5-nitro-2-imidazolyl)-2-imidazolidinone, belongs to the Biopharmaceutics Classification System (BCS) Class II category, characterized by low aqueous solubility and high permeability. It is widely employed in the management of protozoal infections such as amoebic liver abscess, giardiasis, and trichomoniasis due to its broad-spectrum antiprotozoal properties. The drug exhibits potent activity against pathogens including *Entamoeba histolytica*, *Trichomonas vaginalis*, and *Giardia intestinalis*. Despite its therapeutic significance, Satranidazole shares limitations common to nitroimidazole derivatives, including adverse effects like nausea, vomiting, and an intensely bitter taste, which can negatively influence patient compliance and ultimately compromise therapeutic outcomes. [2]

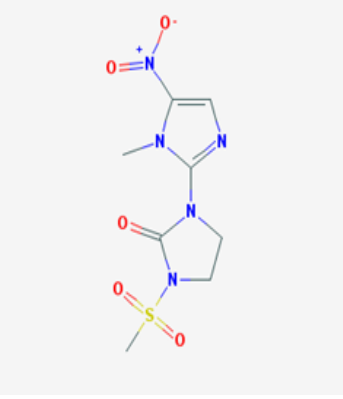

Figure 1: Chemical Structure of Satranidazole

In this research, taste masking of Satranidazole was achieved by forming a drug–resin complex using Kyron T-314, an ion exchange resin. These resins are cross-linked, water-insoluble yet swellable polymers containing ionizable functional groups that facilitate drug release in the gastrointestinal tract through ion exchange and diffusion mechanisms. By complexing Satranidazole with the resin, its inherent bitterness was effectively reduced, thereby improving palatability. This approach is particularly advantageous for the formulation of Orodispersible tablets (ODTs), as it enhances patient compliance and provides a more acceptable mouthfeel.[3]

MATERIALS AND METHODS

MATERIALS

Satranidazole was generously provided as a free sample by Alkem Health Science, Sikkim. Kyron T-314 resin is sourced from S D Fine – Chemical ltd. The polymers employed in the formulation were Crospovidone and Croscarmellose sodium both were sourced from ACS Chemicals and Otto Chemika-Biochemika respectively. Other excipients included magnesium stearate, microcrystalline cellulose, mannitol and aspartame were all procured from S D Fine – Chemical ltd. All chemicals and reagents used were of analytical grade.

METHOD

ANALYTICAL METHODS

Selection of λmax of drug

A standard stock solution of Satranidazole (STZ) was prepared by accurately weighing 100 mg of the drug and dissolving it in 20–30 mL of methanol within a 100 mL volumetric flask. The final volume was adjusted to 100 mL using

hydrochloric acid buffer (pH 1.2), resulting in a concentration of 1000 µg/mL. From this stock solution, 5 mL was transferred into another 100 mL volumetric flask and diluted with the same buffer to achieve a concentration of 50 µg/mL. This solution was then scanned in the range of 200–400 nm to determine the maximum absorption wavelength (λmax) of the drug.[4]

Preparation of standard calibration curve

A series of working solutions ranging from 2 to 30 µg/mL were prepared by diluting the standard stock solution with hydrochloric acid buffer (pH 1.2). The absorbance of each solution was determined using a UV spectrophotometer at the selected wavelength. A calibration curve was then constructed by plotting absorbance values against their corresponding drug concentrations to establish a linear relationship for quantitative analysis.[5]

Formulation of drug resin complex

The drug–resin complex (DRC) was formulated employing a batch adsorption technique. Kyron T-314 resin (100 mg) was hydrated in 25 mL of deionized water and allowed to swell for a predetermined period to ensure optimal ion-exchange capacity. Satranidazole was then introduced in drug-to-resin ratios of 1:1, 1:2, and 1:3 (w/w), and the mixture was subjected to continuous stirring for 30 minutes to facilitate complex formation. The suspension was subsequently filtered, and the residue was thoroughly rinsed with deionized water to remove any unbound drug. Quantification of unbound drug in the filtrate was carried out using a UV spectrophotometer at 319 nm, and the percentage drug loading was calculated based on the difference between the initial and unbound drug concentrations.

OPTIMIZATION DRUG LOADING CAPACITY OF RESIN

Optimization of Drug loading efficiency

A drug–resin complex corresponding to 100 mg of the pure drug was accurately transferred to a 100 mL volumetric flask and dissolved in a minimal volume of methanol. The solution was then diluted to the mark using pH 1.2 buffer. Appropriate dilutions were prepared, and the drug content was quantified using a UV spectrophotometer.[6]

Optimization of Ratio of drug: resin

The influence of varying drug-to-resin ratios on drug loading was evaluated by preparing complexes at ratios of 1:1, 1:2, and 1:3 (drug:resin). Accurately weighed quantities of Satranidazole were combined with resins preselected for their drug loading capacity. Prior to complexation, the resins were hydrated in 25 mL of deionized water for 30 minutes to ensure proper swelling. The mixtures were then stirred at 30 °C for 30 minutes to facilitate drug binding. Following this process, the dispersions were filtered, and the concentration of unbound drug in the filtrate was quantified using a UV spectrophotometer at 319 nm.

Optimization of soaking time

The influence of resin soaking time on drug loading efficiency was evaluated by pre-treating the selected ion-exchange resins in 25 mL of deionized water for varying durations of 10, 30, 45, 60, and 90 minutes. Following the soaking period, an accurately weighed amount of Satranidazole, corresponding to a drug-to-resin ratio of 1:2, was incorporated into the hydrated resins. The resulting mixtures were subjected to continuous stirring at 30 °C for 30 minutes to facilitate drug-resin complex formation. After

completion of the interaction process, the mixtures were filtered, and the concentration of unbound drug present in the filtrate was quantified using a UV spectrophotometer at 319 nm.

Optimization of stirring time

The influence of stirring duration on the drug loading efficiency of resins was investigated. Resins were initially hydrated by soaking in 25 mL of deionized water for 30 minutes. Subsequently, a precisely weighed amount of Satranidazole, maintaining a 1:2 drug-to-resin ratio, was incorporated into the pre-soaked resins. The mixtures were subjected to continuous stirring at 30 °C for varying time intervals of 5, 10, 30, 60, and 90 minutes. After stirring, the samples were filtered, and the filtrate was analyzed at 319 nm using UV spectrophotometry to determine the amount of unbound drug.

Optimization of temperature

The influence of temperature on the drug-loading process was evaluated by conducting experiments at varying temperatures. The selected resins were initially allowed to swell in 25 mL of deionized water for 30 minutes. Subsequently, a precisely weighed amount of Satranidazole, maintaining a drug-to-resin ratio of 1:2, was introduced to the hydrated resins. The mixtures were subjected to stirring for 30 minutes at different temperatures, specifically 10 °C, 20 °C, 30 °C, 40 °C, and 50 °C. After completion of the stirring period, the samples were filtered, and the amount of unbound drug present in the filtrate was quantified using a UV spectrophotometer at 319 nm.

Optimization of pH on drug loading

The influence of pH on the drug loading capacity of resins was assessed by preparing solutions with different pH values (1.2, 3, 5, 6, and 7) using standard hydrochloric acid and sodium hydroxide solutions. Pre-weighed quantities of Satranidazole, in a drug-to-resin ratio of 1:2, were incorporated into the resins previously soaked in 25 mL of the respective pH solutions for 30 minutes. The mixtures were stirred at 30 °C for 30 minutes to facilitate complex formation, followed by filtration to separate the resin-drug complex. The amount of unbound drug in the filtrate was quantified using a UV spectrophotometer at 319 nm, enabling the calculation of drug loading efficiency at each pH level.[7]

CHARACTERIZATION OF DRC [8]

Characterization of DRC by FT-IR and DSC

The compatibility between the drug and formulation components was assessed using Fourier Transform Infrared Spectroscopy (FT-IR) and Differential Scanning Calorimetry (DSC). FT-IR analysis was performed to identify any potential chemical interactions by comparing the characteristic absorption peaks of the pure drug, excipients, and formulated mixtures. Samples were prepared using the KBr pellet method, where the drug and excipients were mixed with potassium bromide, compressed into thin discs, and scanned to obtain spectra. Thermal behavior and possible physicochemical interactions were further evaluated using DSC. For this, approximately 15 mg of each sample (pure drug and its physical mixture with excipients) was accurately weighed, sealed in stainless steel pans, and stored for 48 hours to ensure complete drying. The analysis was carried out over a temperature range of 25–250 °C at a constant heating rate of 10 K/min. The obtained thermograms were examined for any changes in melting points, glass transition temperatures, or additional thermal events, which would indicate interaction or incompatibility between the drug and excipients.

Evaluation of Taste of Resinate [9]

The sensory evaluation of the drug–resin complex (1:3 ratio) was carried out using the time-intensity method with a panel of ten trained members. The uncomplexed pure drug served as the control. Each sample, equivalent to a 50 mg drug dose, was held in the oral cavity for 10 seconds, and the perception of bitterness was recorded immediately, followed by assessments at 20, 30, 40, 50, and 60 seconds. Bitterness intensity was scored on a five-point scale, where 0 indicated no bitterness, 1 represented acceptable bitterness, 2 denoted slight bitterness, 3 corresponded to moderate bitterness, and 4 indicated strong bitterness. This evaluation aimed to compare the taste-masking efficiency of the drug–resin complex with that of the pure drug.

FORMULATION OF ODT OF TASTE MASKED DRC [10]

Tablets containing drug–resinate complexes (equivalent to 50 mg of drug) were prepared using the direct compression method. Crospovidone and Croscarmellose Sodium were incorporated as superdisintegrants in varying concentrations, as detailed in the formulation table. All raw materials were passed through a 40-mesh sieve to ensure uniform particle size. The accurately weighed quantities of drug-resinate and excipients were blended thoroughly in a mechanical mixer to achieve homogeneity. The resulting blend was compressed into tablets using an 8-station rotary tablet press (Shakthi, India), producing tablets with an average weight of 600 mg per unit.

Table no. 1. Formulation table of tablets batch F1-F6

Formulation Ingredients	F_1	F_2	F_3	F_4	F_5	F_6
Drug Resin Complex	150mg	150mg	150mg	150mg	150mg	150mg
Crospovidone	30mg	45mg	60mg	---	---	---
Croscarmellose Sodium	---	---	---	30mg	45mg	60mg
Microcrystalline Cellulose	309.6mg	294.6mg	297.6mg	309.6mg	294.6mg	297.6mg
Magnesium stearate	6mg	6mg	6mg	6mg	6mg	6mg
Mannitol	79.8mg	79.8mg	79.8mg	79.8mg	79.8mg	79.8mg
Talc	12mg	12mg	12mg	12mg	12mg	12mg
Aspartame	12mg	12mg	12mg	12mg	12mg	12mg
Mint	0.6mg	0.6mg	0.6mg	0.6mg	0.6mg	0.6mg
Total Weight	600mg	600mg	600mg	600mg	600mg	600mg

Pre-Compression Evaluation [11]

Pre-compression parameters including Angle of repose, Bulk and Tapped density, Carr's compressibility index and Hausner' s ratio of powder blends of all formulations were calculated.

Angle of Repose was measured by the fixed funnel and free-standing cone technique.

□= tan-1 (h / r)

Where, □ is the Angle of Repose.

h = height.

r = radius.

Bulk density was measured as per the guidelines of USP 32 described under Method 1 for the measurement of bulk density.

Db = M/Vb

Where, M = mass of the powder

Vb = bulk volume of powder

Db = bulk density

Tapped density (TD) was measured as per the guidelines of USP 32 described under Method 1.

Dt = M/Vt

Where, M = mass of the powder

Vt = tapped volume of the powder

Dt = tapped density

Compressibility Index was calculated by the formula

Carr's index (%) = [(Dt –Db) x 100]/Dt (3)
Where, D_t is the tapped density of the powder

D_b is the bulk density of the powder

Hausner's ratio was calculated by the formula

$$\text{Hausner's ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

POST-COMPRESSION EVALUATION [12]

General appearance, Thickness, Hardness test

A total of five tablets from each formulation batch were randomly selected to assess organoleptic characteristics, including color, odor, taste, and shape. The physical dimensions of the tablets, such as thickness and diameter, were measured precisely using a vernier caliper. Tablet hardness was evaluated using a Monsanto hardness tester to ensure mechanical strength and durability of the formulations.

Weight variation

A sample of ten tablets was randomly chosen to assess uniformity in weight. The average weight of these tablets was calculated, following which each tablet was weighed individually. The percentage deviation of each tablet from the calculated average weight was determined to evaluate compliance with weight variation standards. This analysis ensures consistency in tablet manufacturing and adherence to pharmacopeial specifications.

Friability (F)

The friability test of tablets was conducted using a Roche friabilator (Electro Lab, India). The instrument comprises a rotating plastic drum operating at approximately 25 rpm for a duration of 4 minutes, during which the tablets are repeatedly dropped from a height of about 6 inches in each revolution. A pre-weighed sample of tablets was placed in the chamber and subjected to 100 revolutions. After completion, the tablets were carefully removed, cleaned of any loose dust with a soft muslin cloth, and reweighed to determine weight loss. The friability (F %) is given by the formula.

F = W initial – W final /W initial × 100

Wetting time

The wetting time of the tablets was determined using a circular tissue paper (10 cm diameter) placed in a petri dish of the same size. Ten milliliters of distilled water maintained at 37 ± 0.5 °C was added to the dish. The tablet was then carefully positioned on the tissue paper surface, and the time taken for water to completely reach the upper surface of the tablet was recorded as the wetting time.

Water Absorption Ratio

The water absorption study was conducted by positioning a twice-folded tissue paper in a 10 cm diameter petri dish containing 6 ml of distilled water. A tablet was placed on the tissue and allowed to absorb water until complete wetting

occurred. After saturation, the tablet was carefully removed, and its weight was recorded to calculate water uptake. This test helps assess the tablet's hydrophilic property and structural integrity upon contact with moisture. Water absorption ratio, R was determined using following equation,

$R = 100 \times Wa - Wb / Wb$

Where, Wa = weight of tablet after water absorption

Wb = weight of tablet before water absorption.

Drug Content

Drug content uniformity was assessed by selecting ten tablets, which were weighed and finely powdered. A quantity of the powder equivalent to 100 mg of the drug-resinate complex was accurately measured and transferred to 100 mL of pH 1.2 buffer solution. The mixture was continuously stirred on a magnetic stirrer for five hours to ensure complete drug release. Following agitation, the suspension was filtered, and the filtrate was appropriately diluted. The drug content was quantified using a UV–visible spectrophotometer (Shimadzu 1700) at the specified wavelength

***In-vitro* disintegration time**

The disintegration time was assessed using a modified method, wherein a petri dish containing 10 ml of water maintained at 37 ± 0.5 °C was employed. The tablet was placed at the center of the dish, and the time taken for it to completely break down into fine particles was recorded.

***In-vitro* dissolution study of all formulations**

In vitro dissolution studies were performed on the formulated resin-based tablets using a USP type II (paddle) apparatus operating at 50 rpm and maintained at 37 ± 0.5 °C. The dissolution medium consisted of pH 1.2 buffer, and samples of 5 ml were withdrawn at predetermined intervals, with an equal volume of fresh medium added to maintain sink conditions. Collected samples were filtered, and the absorbance was measured using a UV spectrophotometer to determine drug release.

Stability study

Stability of a dosage form refers to its capacity to maintain the intended physical, chemical, therapeutic, and safety characteristics throughout its shelf life when stored in a specified container. To predict long-term stability and identify potential degradation pathways, accelerated stability studies were conducted in accordance with ICH guidelines under controlled environmental conditions.

RESULT AND DISCUSSION

Melting point of Satranidazole

The melting point was found **185** to **187^0 C**. The reported melting point for Satranidazole was **186^0 C**. Hence, experimental values were in good agreement with official value. Thus, obtained melting point is in agreement with literature melting point, confirming the purity of drug.

Selection of λmax of drug

The standard solut ion was scanned in the range of 200-400 nm and absorpt ion maximum was found to be 319nm.

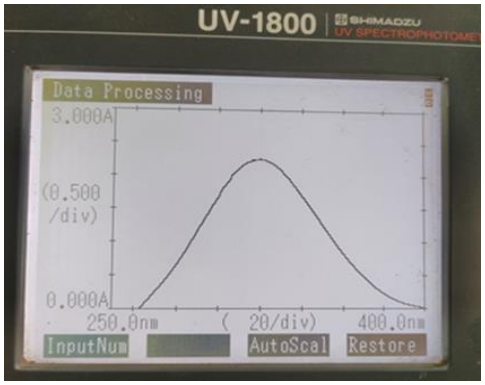

Figure 2. Analytical wavelength of Satranidazole

Standard calibration curve of Satranidazole

Table 2 shows the absorbance reading of Satranidazole standard solution containing 0-25 µg/ml of the drug in 1.2 pH buffer. Figure no 6.8 shows standard calibration curve for Satranidazole in 1.2 pH buffer. The calculation of the drug content and *in-vitro* drug release rate studies are done with this standard curve. The absorbance was measured at λmax 319nm.

Table 2. Data of calibration curve of Satranidazole in 1.2 pH buffer

Sr.no	Concentration (µg/ml)	Absorbance at 319nm
1	0	0
2	5	0.079 ±0.003
3	10	0.16 ±0.015
4	15	0.243 ±0.017
5	20	0.319 ±0.002
6	25	0.405 ±0.0014

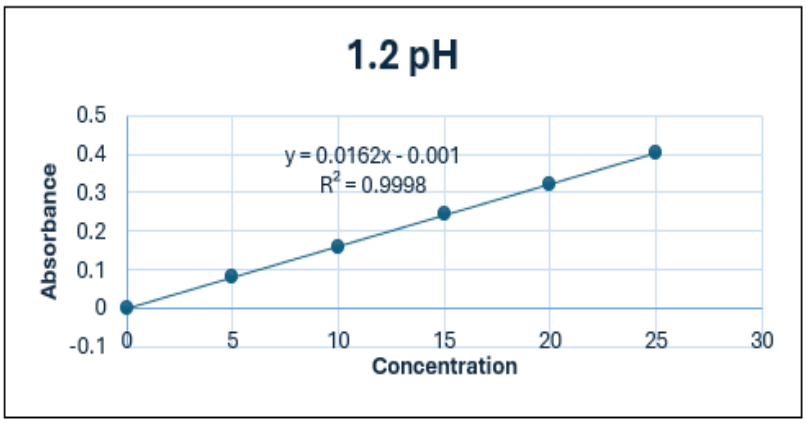

Figure 3. Standard Calibration curve of Satranidazole in 1.2 pH Buffer

Effect of Drug Resin Ratio on complex formation

Effect of concentration of resin on drug loading, maximum drug loading was found in ratio 1:2 (drug: kyron-T-314) (Table no 6.3). Complexation between the drug and resin is essentially process of diffusion of ions between the resin and surrounding drug solution. As the reaction is an equilibrium phenomenon, maximum efficiency is best achieved in batch process.

Table 3. Effect of Ratio of Drug: resin complex on drug loading efficacy

Drug: resin Ratio	% Drug Loading
1:1	70.65±0.74
1:2	99.79±0.70
1:3	98.76±0.69

Effect of soaking time of resin on drug loading

Effect of soaking time of resin on drug loading showed that, the percentage of drug bound to resin was found to increase as the soaking time for resin increased, as shown in Table no 6.4. A marginal increase in percentage of drug bound to resin was

observed from 10 to 90 min. Hence, soaking time of 30 min was selected for further study.

Table 4. Effect of soaking time on drug loading

Soaking Time (min)	% Drug Bound to Resin
10	96.44
30	98.86
45	98.25
60	98.26
90	98.32

Effect of stirring time of resin on drug loading

Effect of stirring time on drug loading showed that, the percentage of drug bound to resin was found to increase as the stirring time increased, as shown in Table no 6.5. A marginal increase in percentage of drug bound to resin was observed from 5 to 90 min. Hence, stirring time of 30 min was selected for further study.

Table 5. Effect of stirring time on drug loading

Stirring Time (min)	% Drug Bound to Resin
5	98.34
10	98.21
30	98.31
60	97.98
90	97.95

Effect of temperature on drug loading

Effect of temperature on drug loading was not very significant, as shown in Table no 6.6. Hence, the operational temperature was selected for further study.

Table 6. Effect of temperature on drug loading

Temperature (^{0}c)	% Drug Bound to Resin
10	98.34
20	98.21
30	98.81
40	98.76
50	98.67

Effect of pH on drug loading

Effect of pH on drug loading showed that, the percentage of drug bound to resin decreased as the pH decreased, as shown in Table no 6.7. Maximum loading was obtained between pH 6–7.

Table 7. Effect of pH on drug loading

pH	% Drug Bound to Resin
1.2	96.92
3	98.002
5	97.99
6	97.82
7	98.13

Optimized Parameters for Prepared DRC

Table 8. Optimized Parameters for DRC Preparation

Parameter	Optimized Value	Comment
Drug: Resin Ratio	1:2	Highest drug loading (99.79%)
Soaking Time	30 min	No major increase beyond this time
Stirring Time	30 min	Optimal for maximum binding
Temperature	30°C	Suitable as temperature had little effect
pH	6–7	Maximum drug binding at near-neutral pH

Results of taste evaluation

A panel of 9 volunteers evaluated the taste-masking efficiency of the drug-resin complex using the time intensity method. Seven participants reported no bitterness, indicating complete taste masking, while only two (volunteers 4 and 7) experienced mild bitterness between 10 to 40 seconds. By 50 seconds, no bitterness was perceived by any subject. Overall, the complexation with Kyron-T-314 effectively masked the drug's bitterness, and most volunteers found the formulation tasteless and acceptable.

Table 9. Taste panel evaluation of resinate

Volunteers	Bitterness level after					
	10 sec.	20 sec.	30 sec.	40 sec.	50 sec.	60 sec.
1	0	0	0	0	0	0
2	0	0	0	0	0	0
3	0	0	0	0	0	0
4	1	0	0	0	0	0
5	0	0	0	0	0	0
6	0	0	0	0	0	0
7	0	0	0	1	0	0
8	0	0	0	0	0	0
9	0	0	0	0	0	0

Fourier Transform Infra-Red Spectroscopy study (FTIR)

FTIR studies were conducted on pure Satranidazole and its physical mixtures with selected polymers to evaluate compatibility. The IR spectra of the mixtures closely resembled those of the pure drug, with no significant shifts in the principal peaks. Major functional group peaks of Satranidazole were retained in the combinations, as shown in Figures 4 to 7 and Table 10. This indicates that the characteristic IR bands remained unchanged, suggesting no chemical interaction between the drug and excipients. Overall, the results confirmed good compatibility between Satranidazole and the selected polymers.

Table 10. Major Peaks of Satranidazole in FT-IR Spectra

Parameter	Satranidazole	AS-01	AS-02	AS-03
O–H/N–H Stretch	~3440 cm^{-1}	3446.91	3408.13	3470.06
C=O Stretch	1740–1743 cm^{-1}	1743.71	1743.71	1743.71
NO_2 Group (Asym/Sym)	~1530/1380 cm^{-1}	Present	Present	Present
C–N / C–O Stretch	1200–1100 cm^{-1}	Present	Present	Present

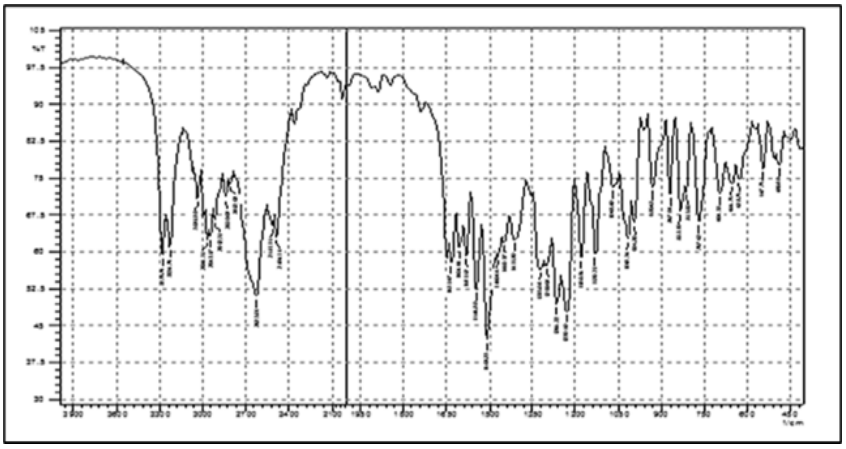

Figure 4. FTIR spectra of Pure Drug

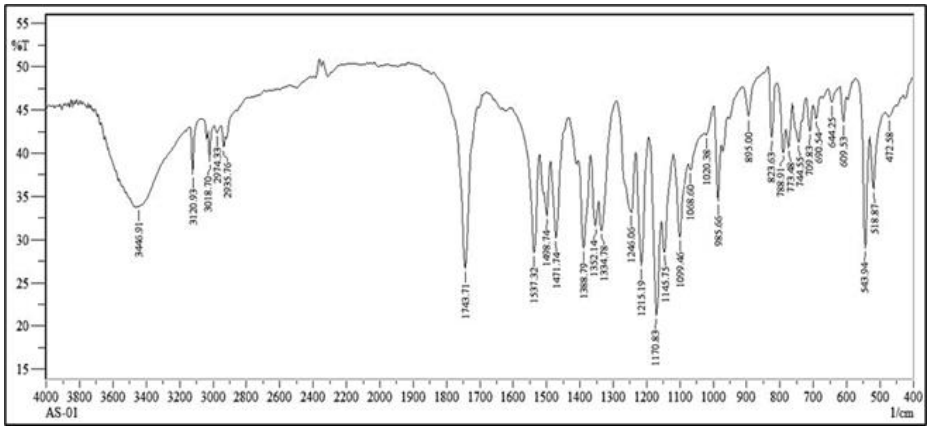

Figure 5. FT-IR spectra of Drug resin complex (Drug: kyron-T-314)

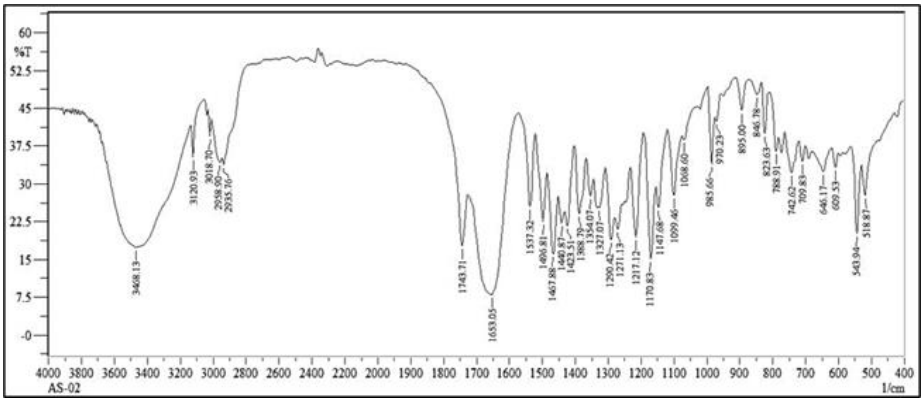

Figure 6. FT-IR spectra of Physical Mixer of Drug & Polymer (Crospovidone)

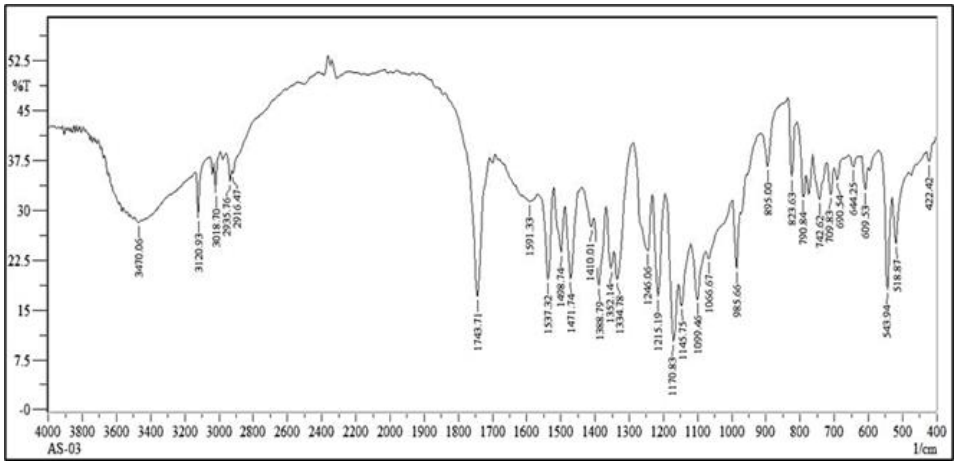

Figure 7. FT-IR spectra of Physical Mixer of Drug & Polymer (Croscarmellose Sodium)

Differential scanning calorimetry (DSC)

Differential Scanning Calorimetry (DSC) was performed to investigate solid-state interactions between Satranidazole and excipients. The DSC thermogram of pure Satranidazole showed a sharp endothermic peak at 185.66°C, indicating its melting point. In contrast, the physical mixture exhibited a reduced melting point at 179.85°C, suggesting possible complexation of the drug with the resin. Additionally, an endothermic transition around 124.57°C was observed, likely corresponding to the glass transition temperature

of the polymer. These thermal shifts indicate interactions between the drug and excipients.

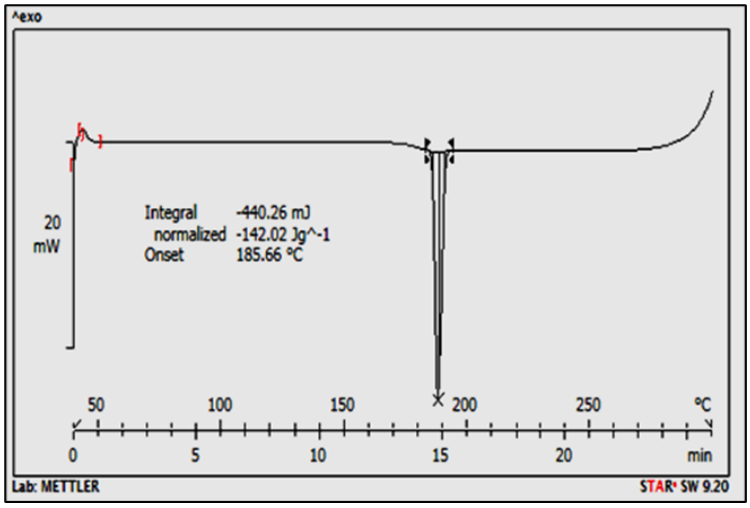

Figure 8. DSC of Pure Satranidazole

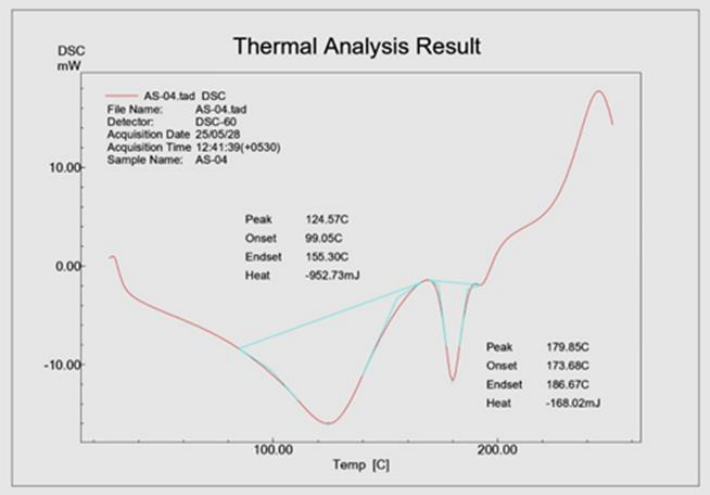

Figure 9. DSC of Physical Mixer of Drug and Polymers

PRE-COMPRESSIONAL PARAMETERS

Bulk density, tapped density, Carr's consolidation index and Angle of repose (θ)

The pre-compressional parameters of all the formulations (F1–F6) indicate good flow and compressibility. Bulk densities ranged from 0.45±0.026 to 0.54±0.025 gm/ml, while tapped densities were between 0.56±0.02 and 0.65±0.030 gm/ml. Carr's index values varied from 10.7±2.8% to 14.9±4.1%, suggesting acceptable compressibility characteristics. The angle of repose for all formulations was below 30°, ranging from 21.43±0.05° to 22.68±0.26°, indicating good flow properties with minimal variation.

Table 11. Pre-compressional parameters of all the formulations

Formulation	Bulk density (gm/ml)	Tapped density (gm/ml)	Carr's index (%)	Angle of repose (θ)
F1	0.45±0.026	0.56±0.02	10±3.8	21.43±0.05
F2	0.54±0.025	0.64±0.015	13±1.2	22.05±0.16
F3	0.5±0.026	0.56±0.025	10.7±2.8	22.35±0.06
F4	0.51±0.026	0.65±0.030	14.9±4.1	21.65±0.08
F5	0.512±0.015	0.58±0.02	11.7±3.01	22.45±0.06
F6	0.52±0.03	0.59±0.015	12±3.42	22.68±0.26

POST COMPRESSIONAL PARAMETERS

Hardness, Friability, Weight variation and Thickness

The post-compressional parameters of six formulations (F1 to F6). Hardness values range from 3.2 ± 0.20 kg/cm² (F4) to 3.6 ± 0.20 kg/cm² (F2), indicating acceptable mechanical strength. Friability is below 0.5% for all formulations, with F6 showing the lowest at $0.38 \pm 0.016\%$, ensuring tablet durability. Weight variation remains within pharmacopoeial limits, with values ranging from $4.40 \pm 0.179\%$ (F3) to $4.93 \pm 0.058\%$ (F5). Thickness of tablets varies slightly between 2.95 ± 0.03 mm (F4) and 3.25 ± 0.04 mm (F2), suggesting uniform compression across batches. Overall, the formulations exhibit consistent physical characteristics suitable for oral tablet dosage forms.

Table 12. Post compressional parameters of all the formulations

Formulation code	Hardness ($kg/cm^{2)}$	Friability (%)	Weight variation (%)	Thickness (mm)
F1	3.4±0.2	0.45±0.016	4.66±0.058	3.18±0.05
F2	3.6±0.20	0.42±0.019	4.73±0.025	3.25±0.04
F3	3.5±0.20	0.39±0.018	4.40±0.179	3.20±0.06
F4	3.2±0.20	0.48±0.016	4.47±0.157	2.95±0.03
F5	3.26±0.20	0.43±0.017	4.93±0.058	3.15±0.05
F6	3.56±0.32	0.38±0.016	4.56±0.115	3.22±0.04

Wetting time, water absorption ratio, Uniformity of drug content and Disintegration time

The post-compression parameters of six different tablet formulations (F1 to F6) reveal variations in wetting time, water absorption ratio, disintegration time, and drug content. Among them, F6 exhibited the best performance with the shortest wetting time (30 sec), highest water absorption ratio (97%), fastest disintegration time (22 sec), and highest drug content ($99.15 \pm 0.028\%$). In contrast, F1 had the longest wetting (45 sec) and disintegration time (58 sec) with the lowest water absorption (93%) and drug content ($95.03 \pm 0.063\%$). These results indicate that F6 is the most effective formulation for rapid disintegration and optimal drug delivery.

Table 13. Post compression parameters of all formulation

Formulation code	Wetting time(sec)	Water absorption ratio (%)	Disintegration time(sec)	Drug content (%)
F1	45 sec	93%	58 sec	95.03±0.063
F2	35 sec	94%	33 sec	97.03±0.06
F3	33 sec	96%	25 sec	98.5±0. 06
F4	42 sec	92%	50 sec	95.03±0.057
F5	36 sec	94%	28 sec	96.03±0.063
F6	30 sec	97%	22 sec	99.15±0.028

IN- VITRO DISSOLUTION STUDIES

In-vitro drug release study was performed using USP XXIII dissolution test apparatus-II at 50 rpm using 900 ml pH 1.2 buffer as the dissolution medium maintained at 37±0.5ºC. The dissolution studies of various tablet formulations revealed that Satranidazole release from all the prepared tablets was very rapid. This effect may be due to initial rapid swelling capacity of super disintegrants, which is associated with the explosion and destruction of tablet. These effects are shown in the table 14 and all the formulations showed enhanced dissolution rate. Maximum increase in the dissolution rate was observed with higher concentration of Croscarmellose Sodium.

Table 14. Cumulative % of drug release of Satranidazole

Time (min)	F1	F2	F3	F4	F5	F6
5	3.56±0.15	4.92±0.65	5.87±0.74	3.29±0.35	5.47±0.25	7.24±0.16
10	9.17±1.23	12.32±0.43	14.37±0.36	8.78±0.75	14.1±0.17	14.52±0.54
15	17.04±0.54	22.22±0.18	25.77±0.65	16.2±0.35	25.63±0.23	30.35±0.67
20	26.74±0.43	33.39±0.12	40.1±0.16	25.45±0.76	40.36±1.56	51.41±0.27
25	38.06±0.65	46.39±0.38	57.49±0.53	36.54±0.26	58.03±0.27	72.7±0.15
30	50.34±0.86	62.33±0.89	76.2±0.25	49.03±0.75	77.7±0.36	99.46±0.65
35	64.91±0.56	79.54±0.75	98.97±0.65	63.6±0.85	99.93±0.75	
40	80.91±0.98	98.13±1.43		81.49±0.95		
45	98.36±0.85			99.92±0.47		

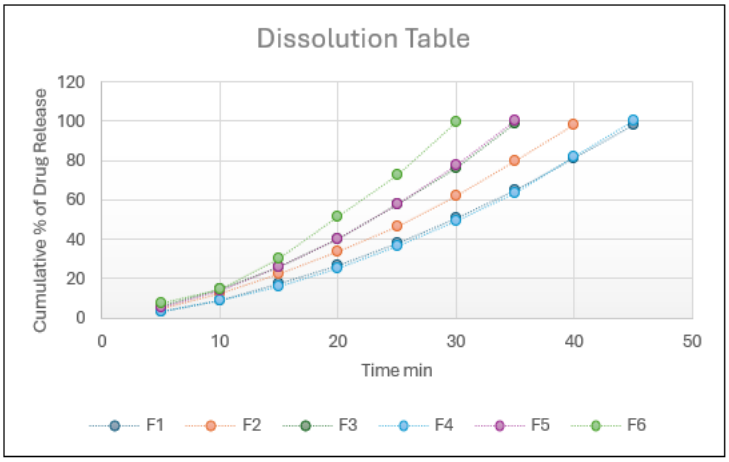

Figure 10. *In-vitro* dissolution study of taste masked Orodispersible tablets of Satranidazole

Stability Studies

Short-term accelerated stability study was performed on the promising formulation F6 by storing the sample at 40° C ± 2°C/75 % ± 5% relative humidity. The sample was tested for any changes in physical appearance and drug content at monthly intervals. The result of stability studies showed that there was no significant change in the physical appearance and drug content of above formulation as shown in the table.

Table 15. Stability study of optimized formulation

Time(month)	Drug content (%)
Zero	99.15±0.028
First	99.08±0.021
Second	98.86±0.96
Third	98.54±0.88

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