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Original Article

Rapidly Disintegrating Ciprofloxacin Hydrochloride Tablets: A Novel Formulation Approach Using Superdisintegrant Technology

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ABSTRACT

Background: This study focused on developing fast-disintegrating tablets of ciprofloxacin hydrochloride by combining superdisintegrant technology with a novel drug-resin complex, Kyron T-314, to achieve improved dissolution and patient acceptability. Kyron T-314 (Polacrilin Potassium) was selected not only for its ability to enhance solubility and mask the drug bitter taste, but also for its capacity to promote rapid tablet breakdown, supporting an immediate-release profile. **Materials and Methods:** The drug-resin complex prepared with Kyron T-314 functioned as both the superdisintegrant and taste-masking component, while Hydroxypropyl Methylcellulose (HPMC) was incorporated as a binder in tablets formulated through direct compression. By altering the proportions of HPMC and Kyron T-314, nine different formulations (F1-F9) were produced. Each batch was evaluated for essential quality attributes, including hardness, friability, disintegration time, drug content, and *in vitro* dissolution behavior. **Results:** Among all the developed formulations, F9 showed the most favorable performance. It exhibited a rapid disintegration time of 47.0 ± 1.8 sec, adequate mechanical strength with a hardness of 5.2 ± 0.2 kg/cm^2, uniform drug content of 99.5 ± 0.4%, and cumulative drug release of 98.7 ± 0.8% within three minutes. Drug-release kinetics were best described by the zero-order model combined with non-Fickian diffusion (R^2 = 0.9783), indicating that both diffusion mechanisms and polymer relaxation contributed to the release profile. Accelerated stability testing conducted at 40 ± 2°C and 75 ± 5% relative humidity for six months revealed that the optimized formulation remained stable, with no meaningful alterations in its physical or chemical characteristics. **Conclusion:** The optimized Formulation (F9) produced a stable, cost-effective, and scalable rapidly disintegrating tablet of Ciprofloxacin Hydrochloride. The DRC-based strategy using Kyron T-314 offers a promising approach for developing fast-acting, palatable, and patient-friendly immediate-release tablets.

Keywords: Ciprofloxacin Hydrochloride, Drug-Resin Complex, Hydroxypropyl Methylcellulose, Immediate-Release Tablets, Kyron T-314, Super disintegrant.

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INTRODUCTION

Ciprofloxacin Hydrochloride is a broad-spectrum fluoroquinolone antibiotic widely prescribed for infections of the respiratory tract, urinary tract, gastrointestinal system, and soft tissues. It is active against both Gram-positive and Gram-negative bacteria due to its potent inhibition of DNA gyrase and topoisomerase IV, which disrupts bacterial DNA replication and repair.[1,2] Chemically, ciprofloxacin HCl (1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-(1-piperazinyl)-3-quinoline carboxylic acid) exhibits amphoteric behavior, resulting in pH-dependent solubility (Figure 1). Its solubility is highest in strongly acidic media but decreases substantially near neutral pH, leading to limited dissolution and variable absorption in the gastrointestinal tract.[2,3] Nevertheless, the challenges of the formulation of ciprofloxacin hydrochloride are still important despite its strong antibacterial action. This low rate of solubility results in poor dissolution in gastrointestinal fluids, which decreases the rate and degree of absorption. In addition, it has a bitter and unacceptable taste in the mouth of patients, especially in children and the elderly. Wet granulation, coating, or the use of conventional disintegrants are traditional methods that do not achieve both rapid release and good taste masking.[4,5] To address these limitations, the present study focuses on developing an immediate-release oral tablet of ciprofloxacin

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hydrochloride using a Drug-Resin Complex (DRC) prepared with Kyron T-314. This ion-exchange resin simultaneously enhances taste masking, solubility, and rapid disintegration. Kyron T-314, a cross-linked polycarboxylic acid-based ion-exchange resin, forms a reversible Drug-Resin Complex (DRC) with the cationic Ciprofloxacin Hydrochloride through ionic interactions and electrostatic binding. The porous nature of the resin and its high hydrophilicity enable rapid water penetration into the resin, which subsequently causes swelling of the Drug-Resin Complex (DRC) and efficient dispersion of the DRC in the dissolution medium. As the material hydrates and expands, the exposed surface area of the drug attached to it increases, improving wetting, accelerating disintegration, and ultimately increasing its apparent solubility. Once the complex is in the acidic environment of the stomach, naturally occurring ions such as H+, Na+, and K+ compete with the drug for binding to the resin. This ion-exchange process results in rapid displacement of the drug from the resin matrix, allowing rapid release while maintaining effective taste masking.[6-8]

Mannitol served as the diluent, and HPMC was used as the binder to ensure the blend's cohesiveness. Kyron T-314 was included as a super disintegrant as well as to enhance palatability to mask the natural bitterness of the drug. Microcrystalline Cellulose (MCC) played a vital role in combination with a compression aid, ensuring the tablets had good mechanical strength without sacrificing disintegration.

Using a batch preparation method, Jain B. *et al.*, prepared a taste-masked combination of Levamisole Hydrochloride and Tulsion-343, which is a strong cation-exchange resin. FTIR, XRD, DSC, and decomplexation studies checked the successful formation of the drug-resin complex. Efficient loading of the drug was achieved at drug-to-resin ratios of 1:1, 1:1.5, and 1:2 (w/w). Among these, the complex that was chosen exhibited low drug release in the salivary pH (pH value of 6.8), assuring the good taste masking while having complete release in the gastric (acidic) pH value of 1.2. Stability testing at 40°C for 1 month showed that the complexes retained their physical integrity and chemical stability. Considering the above-mentioned extent of complexation, pH-dependent properties of the complexed formulation, and overall formulation performance, it was identified that the 1:1 (w/w) Levamisole HCl-Tulsion-343 complex emerged as the most applicable case to develop a taste-masked oral dosage form.[9] In a study done by Kiran Bhise et al., severe bitterness of Diphenhydramine Hydrochloride (DPH) was well masked by two cation-exchange resins, Indion 234 and Tulsion 343. Drug-resin complexes were prepared at varying ratios (1:1, 1:2, and 1:3), and the optimal ratio and complexation time were determined through systematic evaluation. These complexes were evaluated for parameters such as drug loading efficiency, taste masking effectiveness, micromeritic behaviour, *in vitro* release, and PXRD characteristics. Dispersible and effervescent tablets using the optimized ratios, 1:2 and 1:1, respectively, for Indion 234 and Tulsion 343, showed good flow properties, rapid dispersion, and rapid disintegration. PXRD results showed that the drug was molecularly dispersed in the resin matrix, supporting successful complexation, while sensory testing revealed a significant decrease in bitterness. Both tablet formulations released nearly 95% of the drug within 15 min, thus proving the development of efficient, fast-dissolving DPH tablets with better patient acceptability.[10] Patra et al. reported that the pronounced bitterness of Etoricoxib could be effectively masked by forming a complex with the cation-exchange resin Indion 204. They prepared the drug-resin complexes by bulk processing, identified a drug-to-resin ratio of 1:3.3, and used the phosphorylated form of the inactivated resin as the most suitable for efficient drug loading. The optimized conditions involved immersing the drug in water for 30 min, followed by gentle agitation for 5 min. To ensure the complex had formed correctly, the researchers conducted dissolution studies and spectral analyses, which confirmed successful complexation. At salivary pH, the release of Etoricoxib from the complex remained very low, which effectively prevented the drug's bitter taste from being perceived. Volunteer taste assessments further demonstrated that the formulated complex was palatable, and its bitterness remained undetectable.[11] Sharma *et al.*, developed mouth-dissolving levocetirizine tablets by forming a drug-resin complex with Tulsion-335, a tasteless polymer that enhances palatability. They optimized several key formulation parameters, including the resin swelling time, resin activation method, drug-to-resin ratio, and stirring duration, to achieve better taste masking and ensure efficient drug loading onto the resin. The optimized complex was then examined by FTIR, DSC, and XRD, all of which confirmed the successful binding of the drug to the resin. The initial phase in tablet production was wet granulation, which utilized PVP as a binder and super disintegrants such as Sodium Starch Glycolate (SSG) and crospovidone. Even though the hardness was good, the first models took more than 70 sec to break down, indicating a need for improvement. Later tests demonstrated that tablets with 7.5% crospovidone performed best, breaking down in 25 sec, wetting in 20 sec, and being 0.60% friable. The study successfully optimized drug loading of Levocetirizine with Tulsion-335 and identified crospovidone as the most suitable super disintegrant for producing fast-disintegrating, patient-acceptable tablets.[12]The objective of the present study was to develop and characterize immediate-release tablets of Ciprofloxacin Hydrochloride by varying the concentrations of HPMC and Kyron T-314 in order to achieve the desired balance of hardness, friability, disintegration time, and dissolution performance. The formulations were designed to meet pharmacopeial requirements for immediate-release dosage forms and to ensure uniformity, mechanical stability, and rapid drug release. This work also aimed to establish a simple, cost-effective direct-compression process suitable for large-scale manufacturing while ensuring the stability of the tablets in accordance with ICH guidelines.

MATERIALS AND METHODS

Materials

Ciprofloxacin hydrochloride was bought at Venus Biosciences Pvt. Ltd., Baddi, Polacrilin potassium (Kyron T-314) was obtained from Coral Pharmaceutical Pvt. Ltd., in Ahmedabad. Hydroxypropyl Methylcellulose (HPMC) was purchased from Loba Chemicals in Mumbai. Sodium saccharine, talc, magnesium stearate, and mannitol were acquired from Sigma Laboratories Pvt. Ltd., Mumbai. Microcrystalline Cellulose (MCC) (Avicel pH 101) was obtained from India's Gujarat Micro Wax Pvt. Ltd. All other excipients utilized in this research were of laboratory grade.

Methods

Pre-formulation Studies

A pre-formulation study is a necessary precondition for the development of medication delivery systems. However, pre-formulation analyses included the construction of a standard calibration curve, Differential Scanning Calorimetry (DSC), Fourier Transform-Infrared Spectroscopy (FTIR), and X-ray diffraction (XRD) of the drug, excipients and prepared formulation.

Calibration curve of ciprofloxacin HCl

The primary stock solution, with a final concentration of 1 mg/mL, was prepared by dissolving 100 mg of ciprofloxacin HCl in 100 mL of phosphate buffer (pH 7.4). Following dilutions using phosphate buffer, a series of standard solutions comprising 2-12 µg/mL of the mixture was obtained from this stock solution. The standard solutions' spectra were run between 200 and 400 nm in order to determine the absorption maximum. At 276 nm, the λ_{max} of ciprofloxacin HCl was discovered. The absorbance of the previously mentioned dilutions was measured at 276 nm using phosphate buffer as a blank.[13]

Fourier Transform-Infrared Spectroscopy (FTIR)

An FTIR spectroscopy was used for the procedure to measure the polymorph of the drug. The experiment entailed the preparation of samples by placing a sample powder that was required with KBr completely at a ratio of 1:100. The instrument (FTIR-PerkinElmer Spectrum IR version 10.7.2) was then applied to the individual cells over a range of 4000-450 cm^{-1} of the wave numbers, and transmittance spectra were recorded. The analysis was aimed at the detection shifts in the medication spectra when polymer excipients are present, which helped determine the physical interactions between excipients and the medication.[14]

Differential Scanning Calorimetry

They used a Pyris 6 DSC model to perform DSC perkin Perkin-Elmer, USA with indium as the calibration. The recorded DSC thermograms of pure ciprofloxacin HCl, Hydroxypropyl methylcellulose, Kyron T-314, Microcrystalline cellulose, and the prepared/optimized formulation. In order to do this, samples weighing around 3 mg were put in an aluminum pan, sealed, and heated in an inert nitrogen environment from 40 to 300°C at a ramp rate of 10°C per minute environment. The tests were conducted at Morepen Laboratory Ltd., and measurements were made using the software that came with the equipment to ascertain the melting and transition points.[15]

X-ray diffraction

Diffractometers for X-rays were used for X-ray diffraction investigations. Model UltimalV, Rigaku Corporation, Japan, was employed to determine each powder's X-ray diffraction pattern under the following circumstances. At 45 kV and 40 mA, a monochromatic CuK radiation source was operated over 5°-45° (2θ) at a scanning rate of 3° (2θ)/min. The X-ray diffractogram's appearance was used to assess whether these items were crystalline or amorphous. The substance is regarded as crystalline or partly crystalline when distinct, sharp peaks of quantifiable intensity are seen. The diffractogram shows a "halo" when large peaks are seen, indicating that the test material is amorphous.[16]

Preparation of Drug Resin Complex

When the resin was soaked in 25 mL of distilled water, it was allowed to expand. Subsequently, the drug was introduced into the resin solution. The mixture of drug and resin was agitated vigorously using a magnetic stirrer operating at its maximum speed. Following agitation, the drug-resin slurry was filtered through the Whatman filter paper, and the residue obtained was recognized as the DRC. This complex was washed with 75 mL of double-distilled water to eliminate the H^+ ions. Various formulations were prepared to optimize factors such as swelling time, stirring duration, and the ratio of the drug to resin.[17,18]

Drug Resin Complex Optimization

The Drug-Resin Complex (DRC) was optimized by systematically evaluating the influence of swelling time of Kyron T-314, drug: resin ratio, and stirring duration on drug loading efficiency.

Effect of Resin Swelling Time

Kyron T-314 (500 mg) was allowed to swell in 25 mL of distilled water for 15, 30, or 45 minutes. After swelling, ciprofloxacin HCl was added (based on the selected drug: resin ratio), and the dispersion was stirred for 60 min at 600 rpm. The complexes were filtered, washed, dried, and evaluated for percent drug loading.[8,12]

Effect of Drug: Resin Ratio

Three drug-to-resin ratios (1:1, 1:2, and 1:3, drug: resin, w/w) were tested to determine how the ratio affected DRC formation and efficacy. Kyron T-314 was swollen in distilled water for 30 min for each ratio to hydrate and extend the polymeric network. The hydrated resin received enough ciprofloxacin HCl after swelling. Stirring the liquid for 60 min helped the ions exchange

and form complexes. Each batch of DRC was filtered and rinsed with 75 mL of distilled water to remove unbound medication and restore ions after stirring. They then dried at room temperature. At simulated salivary pH 6.8, the complexes were evaluated for drug loading after drying.[8,11]

Effect of Stirring Time

The influence of mixing duration on DRC formation was evaluated by stirring the drug-resin mixture for 30, 60, and 90 min, using a fixed resin swelling time of 30 min and the optimized 1:1 drug: resin ratio. After each designated stirring period, the complexes were filtered, washed, dried, and analyzed for drug loading efficiency to determine the optimal stirring time for maximum drug-resin binding.[8,19]

Determination of Drug Loading

An accurately weighed amount of DRC equivalent to 10 mg ciprofloxacin HCl was treated with 0.1N HCl to completely dissociate the complex. The released drug was quantified spectrophotometrically at 276 nm.[19]

Drug loading (%) was calculated as:

$$\%\text{Drug Loading} = \frac{\text{Actual Drug Content}}{\text{Theoretical Drug Content}} \times 100$$

Preparation of immediate-release tablets

The development approach for immediate-release tablets in batches F1 to F9 started with direct compression, which used a drug resin complex to add 10 mg of ciprofloxacin hydrochloride. The diluent was Microcrystalline Cellulose (MCC), with a binder (hydroxypropyl methylcellulose), Polacrilin potassium (Kyron T-314) as the super disintegrant, mannitol as the soothing agent, talc as the anti-adherent, saccharin as the sweetener, and magnesium stearate as the lubricant. Each ingredient was precisely measured, and all components were sifted through a 100# sieve before being blended together. The powder mix was then compressed using a single-punch tablet machine (Table 1).[17,20]

Evaluation Parameters of Prepared Tablets

Thickness, Hardness, Friability, and Weight Variation

The tablet's thickness was measured using a vernier caliper, hardness was measured using a Pfizer hardness tester, and friability was measured using a Roche friabilator. According to the USP, the weight variation test is weighing 20 tablets individually, estimating the average weight, and then comparing each tablet's weight to this mean.[21,22]

Wetting Time

To assess wetting time, it serves as a measure of the tablet's internal structure and the hydrophilicity of the excipients used. Consequently, wetting time demonstrates a correlation with the contact angle, where shorter wetting times signify faster tablet disintegration. The procedure is to place five circular tissue sheets of paper, each with a diameter of 10 cm, in a petri dish of the same dimensions. Then, 10-20 mL of a water-soluble dye, like eosin solution, is put into the prepared plate. The wetting time is calculated by carefully putting a tablet on the surface of the tissue paper and recording the time for water to reach the tablet's upper surface.[21,22] The water absorption ratio may be estimated using the following formula:

$$R = (\text{Wa-Wb})/\text{Wb}*100$$

Disintegration Time

The disintegration time of fast-release tablets was evaluated utilizing a disintegration test apparatus. Typically, these tablets dissolve within a minute, with observed disintegration times among patients ranging from 5 to 30 sec. In the assessment, one tablet is positioned in each of the six tubes, followed by the addition of a disc to each tube. However, the conventional method for conducting disintegration tests on these tablets

Table 1: Composition of ciprofloxacin HCl-loaded immediate-release tablets.

Ingredient (mg/tablet)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Drug Resin Complex	45.0	45.0	45.0	45.0	45.0	45.0	45.0	45.0	45.0
Mannitol	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Hydroxy propyl methyl cellulose	2.5	5.0	7.5	2.5	5.0	7.5	2.5	5.0	7.5
Kyron T-314	5.0	5.0	5.0	7.5	7.5	7.5	10.0	10.0	10.0
Microcrystalline cellulose (Avicel PH-101)	63.0	60.5	58.0	60.5	58.0	55.5	58.0	55.5	53.0
Saccharine	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0
Talc	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0
Magnesium stearate	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Flavour (vanilla)	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.

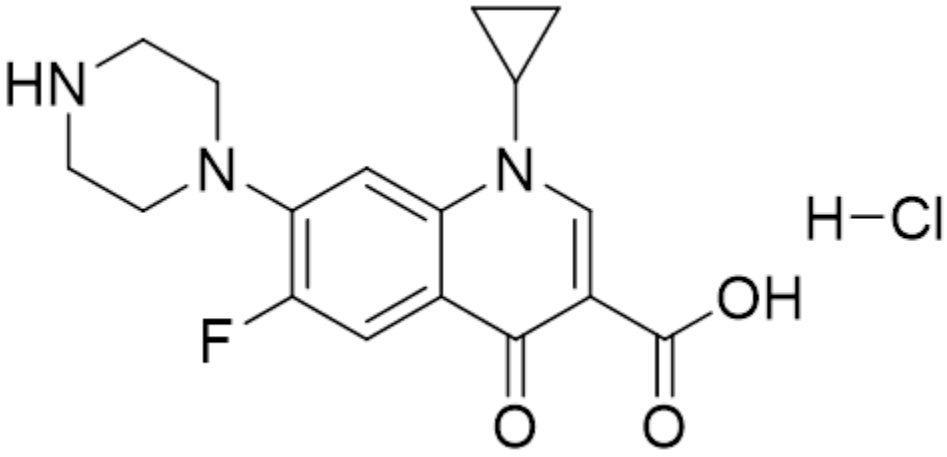


Figure 1: Chemical structure of Ciprofloxacin Hydrochloride.

presents limitations; ideally, the test should replicate the natural dissolution process in the oral cavity with saliva. A 1 L cylindrical vessel filled with 900 mL of medium maintained at 37°C and rotated at 100 revolutions per minute was used. Fast-release tablets were placed in a basket sinker positioned in the middle of the vessel, approximately 6 to 8.5 cm from the bottom.[21,22]

Drug Content

All formulations underwent testing for their drug content. A random selection of ten tablets from each formulation was finely ground into a powder. Triplicate samples were obtained, each having the quantity of powder needed for a single dosage and later analysed utilizing a UV-vis spectrophotometer set at 276 nm for drug content.[22]

In vitro Drug Release Study

The release study of prepared tablets of ciprofloxacin hydrochloride was conducted over 90 seconds using a dissolution apparatus of the USP paddle type (Electrolab TDP-08L, India). The apparatus contained 900 mL of phosphate buffer (pH 6.8) as the dissolution medium, which was maintained at 37 ± 0.5°C with a stirring speed of 50 rpm. During the study, 1 mL aliquots were withdrawn at regular intervals. To compensate for the withdrawn volume, 1 mL of phosphate buffer (pH 6.8) was added each time to maintain the total volume at 900 mL.[23,24] The absorbance of the samples was measured using a UV-vis spectrophotometer (Shimadzu 1800, Japan) at 276 nm after appropriate dilution and filtration.

Drug release kinetics studies

To investigate drug release mechanisms from prepared dosage form, four distinct models were used to examine drug release *in vitro* trials: zero order, Higuchi, first order, and Korsmeyer-Peppas model.[20]

Stability Studies

Stability analyses of the optimized fast-release tablets were carried out over a period of six months in accordance with ICH guidelines (International Conference on Harmonisation). The tablets were stored at elevated temperatures and humidity levels (40±2°C/75±5% RH). At specified intervals, the tablets were assessed for key quality variables, including hardness, duration of disintegration, drug concentration, and % cumulative drug release.[25,26] The procedure employed for the study was identical to that described above.

RESULTS

Preformulation Studies

Calibration Curve

The UV spectroscopic evaluation of Ciprofloxacin hydrochloride was performed within a concentration range of 2-12 µg/mL, and the related absorbance values are shown in Table 2. Figure 2 describes the standard calibration curve of Ciprofloxacin Hydrochloride, the absorbance versus the concentration was plotted between a concentration of 2-12 µg/mL. The relationship between the plot is almost linear, which means that the absorbance of Ciprofloxacin Hydrochloride is subject to the law of Beer-Lambert in this range of concentrations. The regression model derived using the calibration data is y = 0.0648 x -0.0589, where y is absorption, and x is concentration. The correlation value (R^2 = 0.993) shows that there was a strong positive linear relationship between concentration and absorbance, which indicates good linearity and reliability of the method to perform quantitative analysis. The small negative intercept is an indication of low instrumental or baseline deviation, which falls within acceptable analytical ranges. Thus, to measure the unknown concentration of Ciprofloxacin Hydrochloride in the pharmaceutical preparation, e.g. fast-release tablets, with the scheme of UV spectrophotometric analysis, this calibration curve can be successfully employed.

FTIR Spectroscopy

Fourier Transform Infrared (FTIR) spectrum of Ciprofloxacin Hydrochloride, and the typical vibrations of its functional

group. The wide ring of absorption seen around 3528-3379 cm^{-1} corresponds to stretching vibrations of O-H and N-H, confirming the existence of hydroxyl and amine groups in the molecule. The peaks appearing near 2920-2464 cm^{-1} indicate C-H stretching vibrations of aliphatic groups. A sharp and intense band at approximately 1708 cm^{-1} is explained by the C=O stretching of the carboxylic acid functional group, while another band around 1624 cm^{-1} is due to the C=O stretching of the quinolone ring and C=C aromatic expanding vibrations. The absorption near 1449-1272 cm^{-1} corresponds to C-N and C-F expanding vibrations, characteristic of the piperazinyl and fluorine substituents in ciprofloxacin. The peaks in the region of 1144-749 cm^{-1} represent C-H bending and C-F vibrations, while bands below 600 cm^{-1} are assigned to out-of-plane bending modes (Figure 3A). For instance, the peak around 3848.41 cm^{-1} could indicate O-H stretching, while peaks around 2929.76 cm^{-1} suggest C-H stretching. Other peaks, such as 1631.16 cm^{-1} and 1450.16 cm^{-1}, indicate various bond vibrations (Figure 3B). However, the peak around 3402.37 cm^{-1} could indicate O-H stretching, while the peak at 2931.20 cm^{-1} suggests C-H stretching. Other peaks, such as 1600.27 cm^{-1} and those in the fingerprint region (below 1500 cm^{-1}), correspond to different bond vibrations indicative of the molecular structure of the sample (Figure 3C). Significant peaks can be seen in the spectrum at 3355.02 cm^{-1}, which is an O-H stretch that is most likely brought on by an alcohol or hydroxyl group, and at 2900.31 cm^{-1}, which is a C-H stretch that alkane groups most likely bring on. The peak could represent a C=O or C=C stretch at 1639.77 cm^{-1}. Peaks in the fingerprint region (below 1500 cm^{-1}), such as those at 1428.61 cm^{-1}, 1318.71 cm^{-1}, and 1281.37 cm^{-1}, correspond to bending modes of various groups or bonds, such as C-O and C-C (Figure 3D).

The presence of specific functional groups is indicated by several distinctive peaks in the infrared spectrum of the prepared tablets. The presence of an O-H bond, most likely from hydroxyl groups or moisture, is indicated by the broad peak at 3447.52 cm^{-1}. C-H stretching vibrations, possibly from alkyl groups, are indicated by peaks at 2975.73 cm^{-1} and 2906.37 cm^{-1}. The peak at 1751.82 cm^{-1} is a C=O stretch, most likely from a carbonyl group in an ester or carboxylic acid. In pharmaceutical contexts, the peak at 1629.00 cm^{-1} might indicate a C=C stretching vibration or an amide carbonyl. The peak suggests C-H bending vibrations at 1377.61 cm^{-1} (Figure 3E).

Table 2: Calibration Curve for ciprofloxacin HCl at 276 nm.

Sl. No.	Concentrations (µg/mL)	Absorbance (nm)
1.	2	0.098 ± 0.003
2.	4	0.187 ± 0.005
3.	6	0.298 ± 0.0
4.	8	0.462 ± 0.008
5.	10	0.598 ± 0.010
6.	12	0.726 ± 0.012

Note: Mean ± SD (n=3)

X-ray Diffraction

The XRD (X-ray Diffraction) pattern of Ciprofloxacin hydrochloride, shown in Figure 4A, indicates the crystalline nature of the compound. The graph displays peaks at specific 2Θ values, which correspond to the diffraction angles of X-rays by the crystal lattice of Ciprofloxacin hydrochloride. The existence of sharp peaks indicates a great level of crystallinity. The most important peaks are found at different values, such as approximately 8.561, 11.245, 13.986, etc., which are typical of the crystal structure of the given compound. The trend is identifiable and can be applied to determine the purity or polymorphism of Ciprofloxacin hydrochloride. The distribution is a wide hump centered at 20-30°, 2Θ indicating the existence of an amorphous or poorly crystalline structure. The general shape implies the absence of sharp peaks, indicating very crystallized materials, indicating a more disordered structure of the sample (Figure 4B).

Table 3: Optimization of Drug-Resin Complex (DRC) Parameters.

DRC Optimization Parameter	Levels Tested	% Drug Loading (Mean ± SD)	Drug Release at pH 6.8 after 2 min (%)
Swelling Time (min)	15	78.12 ± 1.6	14.5 ± 0.8
	30	93.45 ± 1.2	5.8 ± 0.6
	45	91.32 ± 1.4	6.2 ± 0.5
Drug: Resin Ratio (w/w)	1: 1	93.45 ± 1.2	5.8 ± 0.6
	1: 2	94.12 ± 1.5	5.6 ± 0.7
	1: 3	94.35 ± 1.4	5.4 ± 0.6
Stirring Time (min)	30	81.54 ± 1.3	12.1 ± 0.9
	60	93.45 ± 1.2	5.8 ± 0.6
	90	92.87 ± 1.4	5.7 ± 0.5

*Note: (Mean ± SD) *n*=3.

Differential Scanning Colorimetry

The DSC curve of Ciprofloxacin HCl depicts a sharp endothermic peak with the melting point of the substance being 329.731 °C. This transition has an enthalpy change (Delta H) of 513.537 J / g with an area under the peak of 1027.074 mJ. It is an indication that Ciprofloxacin HCl melts at this temperature (Figure 5A). The thermodynamics after the melting may contain indications of decomposition or further changes. The melting point and thermal stability of Ciprofloxacin HCl are important factors in the pharmaceutical formulation and stability investigations**.** Thermal transitions of the DSC thermogram of the prepared Ciprofloxacin hydrochloride-loaded immediate release tablets reveals the behaviour of the drug and the formulation components. There are two prominent peaks, the first endothermic peak at 146.004°C with an area of -208.516 mJ and the second Delta H of -104.268 J/g. There was a second peak of 307.680°C with an area of 130.713 mJ and a Delta H of 65.356 J/g, indicating melting or degradation of Ciprofloxacin HCl or reactions between the formulation. These peaks and enthalpies provide an idea about the thermal stability and compatibility of Ciprofloxacin HCl in the immediate release tablet formulation (Figure 5B).

Drug Resin Complex Optimization

Effect of Resin Swelling Time

Prolonging the hydration time of the resin had an evident influence on how much drug it was able to incorporate. When the resin was allowed to swell for only 15 min, it did not hydrate sufficiently, resulting in a comparatively low drug loading of 78.12 ± 1.6%. Allowing the resin to hydrate for 30 min produced the best outcome; the matrix reached optimal swelling, enabling a much higher drug loading of 93.45 ± 1.2%. This improved incorporation also corresponded with the lowest drug release in simulated salivary pH, confirming effective taste masking. Increasing the swelling time to 45 min did not provide a meaningful advantage; the drug loading decreased slightly to 91.32 ± 1.4%, and taste-masking performance showed minimal change. These findings suggest that extending hydration beyond 30 min provides no additional benefit (Table 3).

Effect of Drug: Resin Ratio

Adjusting the drug-to-resin ratio had a clear impact on how effectively the drug interacted with the resin. The best performance was observed when both were used in equal proportion (1:1), achieving a high drug loading of 93.45 ± 1.2% while releasing only 5.8 ± 0.6% of the drug at pH 6.8, an outcome that meets the requirements for effective taste masking. Increasing the amount of resin beyond this level (1:2 or 1:3 ratios) offered no meaningful improvement in drug loading; 94.12 ± 1.5% was observed with the 1:1.5 ratio, nor did it enhance taste-masking efficiency. Instead, the additional resin only increased the excipient load, making the formulation unnecessarily heavier. A lower ratio (1:0.5) resulted in inadequate loading and taste masking due to insufficient resin capacity (Table 3).

Effect of Stirring Time

The drug-resin ion-exchange worked better when the mixture was stirred for an extended period. It took 30 min of shaking to get a dose of just 81.54 ± 1.3%, which means that the drug and resin did not thoroughly mix. Allowing the most ion exchange by increasing the time to 60 min led to a drug loading of 93.45 ± 1.2%, which matched the best swelling and resin ratio. Mixing for more than one hour (up to 1.5 hr) did not help, so 1 hr is the best mixing time.

The combination of a 30-min swelling time, 1:1 drug: resin ratio, and 60-min stirring time was identified as the optimal condition for producing a stable DRC with high drug loading, excellent

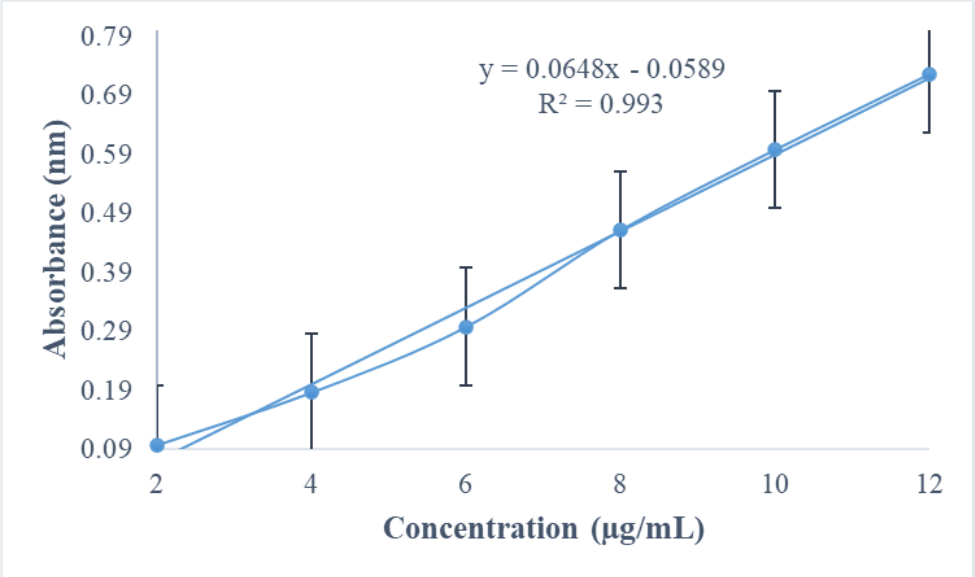
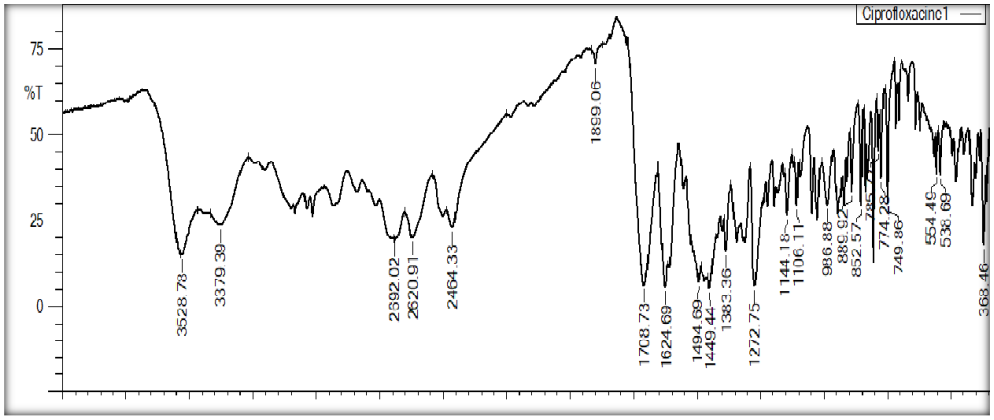
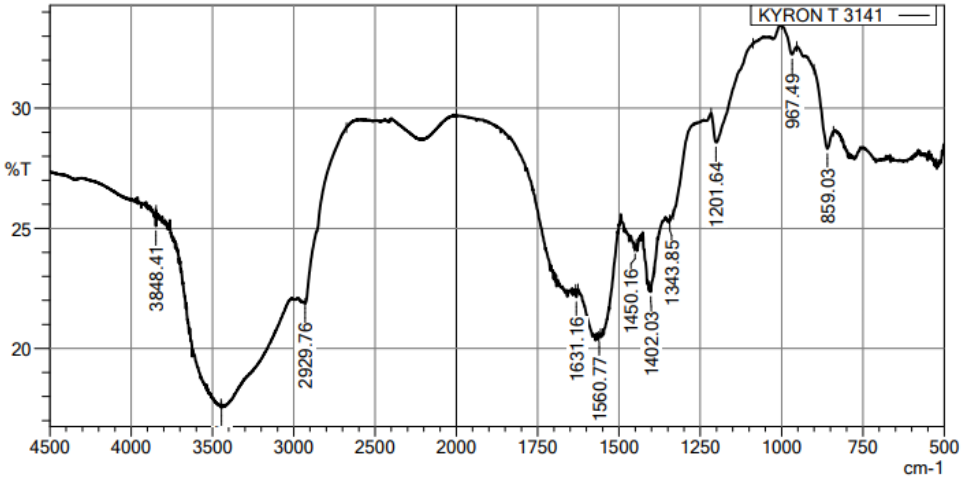


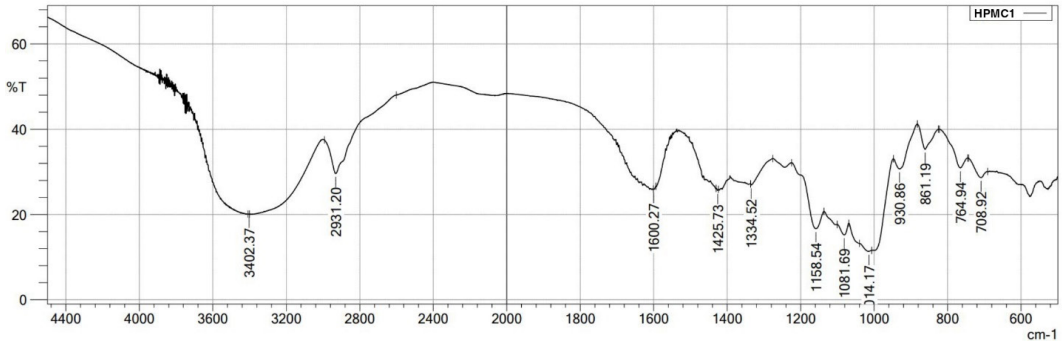
Figure 2: Calibration Curve of Ciprofloxacin HCl.


Ciprofloxacine1
%T
3528.78
3379.39
2392.02
2620.91
2464.33
1859.06
1708.73
1624.69
1494.69
1449.44
1383.36
1272.75
1144.18
1106.11
936.88
889.92
852.57
774.28
749.36
554.46
536.69
368.46

(A)


KYRON T 3141
%T
3848.41
2929.76
1631.16
1560.77
1450.16
1402.03
1343.85
1201.64
967.49
859.03
cm-1

(B)


HPMC1
%T
3402.37
2931.20
1600.27
1425.73
1334.52
1158.54
1081.69
1014.17
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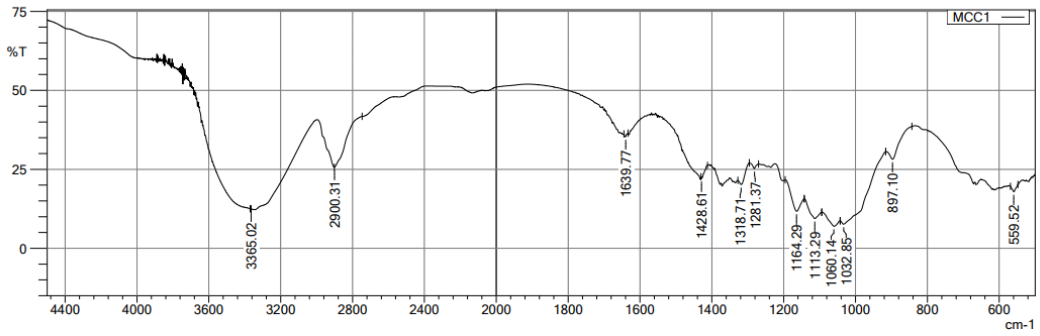
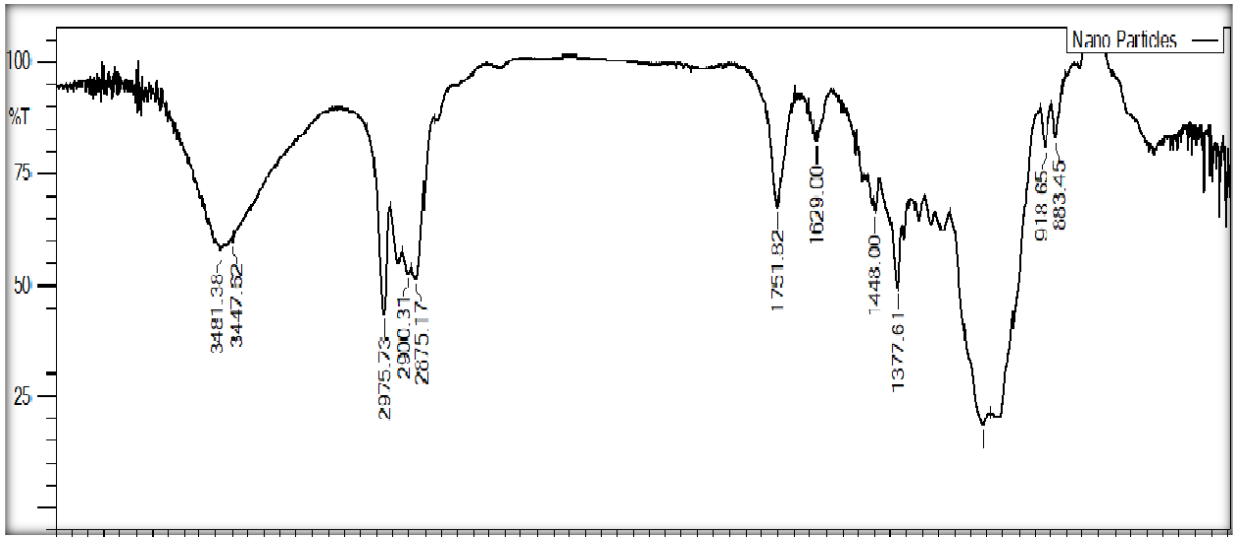
861.19
764.94
708.92
cm-1

(C)


MCC1
%T
3365.02
2900.31
1639.77
1428.61
1318.71
1281.37
1164.29
1113.29
1060.14
1032.85
897.10
559.52
cm-1

(D)



(E)

Figure 3: FTIR Spectra. (A)- Ciprofloxacin Hydrochloride, (B)- Kyron T 314, (C)- Hydroxypropylmethylcellulose, (D)- Microcrystalline cellulose, (E)- Prepared Formulation.

taste masking, and suitable physicochemical characteristics for tablet formulation (Table 3).

Evaluation Parameters

Thickness, Hardness, Friability, and Weight Variation

The physical evaluation findings of Ciprofloxacin Hydrochloride immediate-release pills (Formulations F1-F9) showed that good reproduction is achieved because all the prepared batches showed uniformity and consistency in their physical evaluation outcomes. The thickness of the tablets was 3.20 ± 0.06 mm to 3.31 ± 0.04 mm, meaning that the die fill was uniform and the compression was uniform across the batches. Minimal change in thickness was measured, which is within reasonable limits, indicating the homogeneity of the powder blend and the effectiveness of the process of granulation. The formulation's hardness ranged between 4.0 ± 0.2 to 5.2 ± 0.2 kg/cm^2 with a progressive change in values of F1 to F9. This tendency can be explained by the fact that there was a gradual rise in the concentration of binder (HPMC), and the compression force was optimized, which did not lead to a decrease in the mechanical strength of the tablets, and the disintegration properties of the tablets were not worsened.

The wetting time of all formulations was 82 ± 2.1 sec (F1) down to 36 ± 1.6 sec (F9) with a gradual fall in time as a result of increasing concentration of Kyron T-314. Compounds with elevated concentrations of the super disintegrant were found to have fast water uptake and quick surface wetting since Kyron T-314 had excellent swelling and wicking properties. Such a reduction in wetting time led directly to a reduction in the disintegration time and an increase in the rate of drug release (Table 4).

Disintegration Time

The disintegration time of the prepared tablets showed a clear decreasing trend with increasing levels of Kyron T-314. Across all nine formulations, the disintegration time ranged from 118 ± 3.2 sec (F1) to 47 ± 1.8 sec (F9). This progressive enhancement in disintegration efficiency can be attributed to the combined effect of higher concentrations of Kyron T-314 and the optimized proportion of HPMC, which together provided adequate mechanical strength while enabling rapid uptake of the dissolution medium (Table 5).

Drug Content

All formulations contained the acceptable pharmacopeial range (97.2-99.5) of the drug content, and showed even distribution of Ciprofloxacin Hydrochloride in the granulation blend. The standard deviation is very low (not more than 0.6), which means that there are a high mixing efficiency and reproducibility of the manufacturing process (Table 5).

In vitro Drug Release Studies

The percent cumulative drug release rose continuously between 85.90 1.2% (F1) and 98.6 0.8% (F9) (Table 5). This gradual enhancement is associated with the accelerated rate of wetting and disintegration, such that the dissolution medium is readily available with the drug. Recipes of more disintegrant (F7-F9) resulted in almost 100% dissolution of the drug in 3 min, or 100 percent in 4 min, which validates their usage as true immediate-release tablets (Figure 6).

Drug Release Kinetics Studies

The Kinetic Drug Release of Ciprofloxacin Hydrochloride immediate release tablet formulations (F1-F9) were carried out

Table 4: Post-compression Evaluation Immediate-Release Tablet Formulations.

Formulations	Hardness (kg/cm^2)	Thickness (mm)	Friability (% w/w)	Weight Variation (mg)
F1	4.0 ± 0.2	3.20 ± 0.06	0.80 ± 0.04	150.4 ± 1.2
F2	4.4 ± 0.3	3.22 ± 0.05	0.75 ± 0.03	149.9 ± 1.1
F3	4.7 ± 0.2	3.24 ± 0.04	0.71 ± 0.03	150.6 ± 0.9
F4	4.3 ± 0.3	3.25 ± 0.05	0.77 ± 0.04	150.3 ± 1.0
F5	4.6 ± 0.2	3.26 ± 0.06	0.70 ± 0.03	150.0 ± 0.9
F6	4.9 ± 0.3	3.28 ± 0.05	0.68 ± 0.03	150.2 ± 1.0
F7	5.0 ± 0.2	3.27 ± 0.05	0.66 ± 0.02	150.1 ± 0.8
F8	5.1 ± 0.3	3.30 ± 0.04	0.64 ± 0.02	150.5 ± 0.9
F9	5.2 ± 0.2	3.31 ± 0.04	0.62 ± 0.02	150.1 ± 0.8

*Note: Hardness, Thickness, and Friability: $n = 3$, Weight variation: $n = 20$.

Table 5: Post-compression Evaluation of Immediate Release Tablet Formulations.

Formulations	Disintegration time (s)	Wetting time (s)	Drug content	% CDR at 180 sec
F1	118 ± 3.2	82 ± 2.1	97.2 ± 0.6	85.90 ± 1.2
F2	105 ± 2.8	76 ± 2.3	97.8 ± 0.5	87.95 ± 1.0
F3	96 ± 2.6	69 ± 2.0	98.1 ± 0.6	89.72 ± 1.1
F4	88 ± 2.4	62 ± 2.4	98.4 ± 0.5	91.45 ± 0.9
F5	79 ± 2.7	56 ± 2.1	98.7 ± 0.5	93.17 ± 1.1
F6	69 ± 2.3	50 ± 1.9	98.9 ± 0.4	95.95 ± 1.0
F7	60 ± 2.1	44 ± 2.1	99.2 ± 0.5	96.45 ± 1.0
F8	53 ± 2.0	40 ± 1.8	99.4 ± 0.4	97.11 ± 0.9
F9	47 ± 1.8	36 ± 1.6	99.5 ± 0.4	98.6 ± 0.8

*Note: (Mean ± SD) n=3.

to explain the mechanism and trend of the drug release of the prepared matrices. The release data was plotted against different kinetic models, which were Zero-order, First-order, Higuchi and Korsmeyer Peppas, and the correlation coefficients (R^2 values) were computed to identify the best-fit model and release mechanism (Table 6). The R^2 of the Zero-order model was between 0.9449 and 0.9783, and the First-order model was between 0.7811 and 0.9435. The Zero-order plots had higher values of correlation coefficients among most formulations, implying that the rate of drug release was not highly dependent on drug concentration. It means that a fixed dosage of a drug was discharged in unit time, which is a preferred aspect of immediate-release dosages to ensure the predictability of pharmacological response. The Higuchi model also had fairly good R^2 values (0.8868 to 0.9618) meaning that the diffusion through the matrix was a major contributor to the drug release process. The non-Fickian (anomalous) diffusion mechanism observed for formulations F1-F9, as indicated by the Korsmeyer-Peppas release exponent (n = 0.80-0.87), reflects the combined contributions of water-mediated drug diffusion and polymer matrix relaxation. Upon first contact with the dissolving media, Kyron T-314 rapidly hydrates and expands, therefore forming micro-channels that accelerate the flow of water. This occurs as a result of the initial contact. While this is happening, the polymer chains of the hydrophilic HPMC binder gradually relax, transforming from a rigid, glassy state to a swelling, rubbery state. As a result of this relaxing process, the internal matrix becomes less cohesive, which, in turn, makes it easier for medications to move about. Drug molecules can permeate outward as swelling proceeds because the partially loosened polymer network allows them to do so. While this is happening, the diffusion channels become even more extensive due to localized matrix degradation. A combination of Fickian diffusion through the hydrated, enlarged pores created by Kyron T-314 and non-Fickian polymer relaxation/erosion of the HPMC-MCC matrix is responsible for the observed peculiar diffusion behavior. This dual process is typical of hydrophilic matrices, which exhibit simultaneous water absorption, polymer swelling, and erosion. As a result, the improved formulation (F9) rapidly releases practically all the medicine within 180 sec. The researchers Singh *et al.*, demonstrated that the zero-order kinetics of Zolmitriptan mouth-dissolving tablets manufactured with Kyron T-314 were consistent. The fact that the medication was delivered at a consistent rate was demonstrated by both the Weibull and the Hixson-Crowell models, which provided

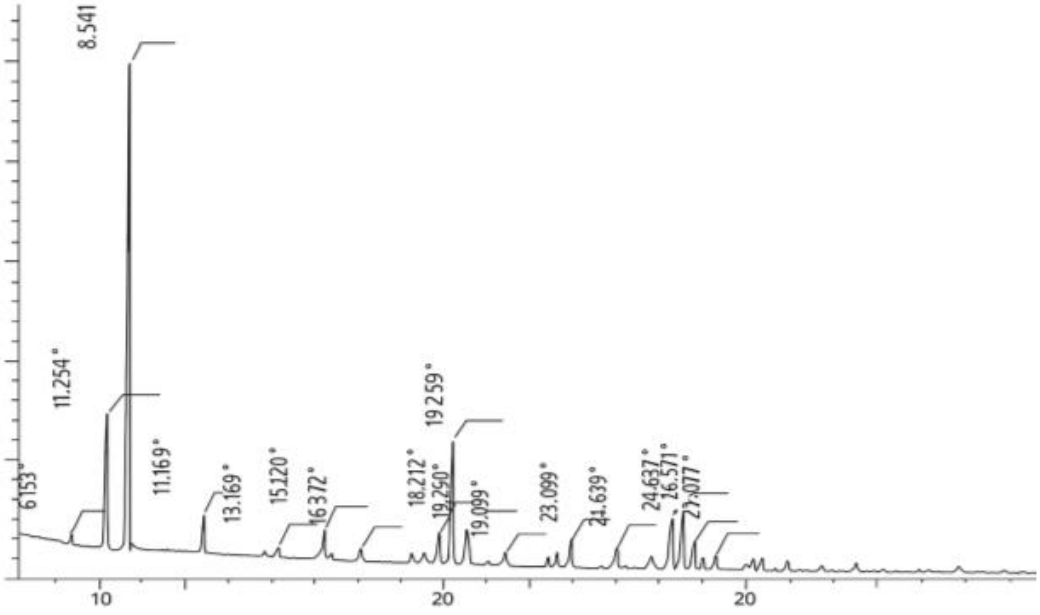
evidence to that effect. Their findings support the hypothesis that Kyron T-314, in combination with the manner in which super disintegrants facilitate the matrix's operation, has the potential to generate drug release patterns that are both regulated and uniform. This is consistent with the release pattern we observed in our optimized formulation, providing further evidence that frameworks based on super disintegrants exhibit predictable, zero-order dissolution.[27]

Stability Studies

Accelerated stability study of optimized Ciprofloxacin Hydrochloride immediate-release formulation (F9) was performed at (40±2°C/75±5% RH) over six months as per ICH guidelines. The parameters measured were hardness, disintegration time, drug content, and % CDR after every month (Table 7).

DISCUSSION

The present investigation focused on formulating immediate-release tablets of Ciprofloxacin Hydrochloride by integrating a drug-resin complex with super disintegrant technology to address the limitations of conventional ciprofloxacin tablets. The study's optimization revealed that a 30-min resin swelling period, a 1:1 drug-to-resin ratio, and a 60-min stirring



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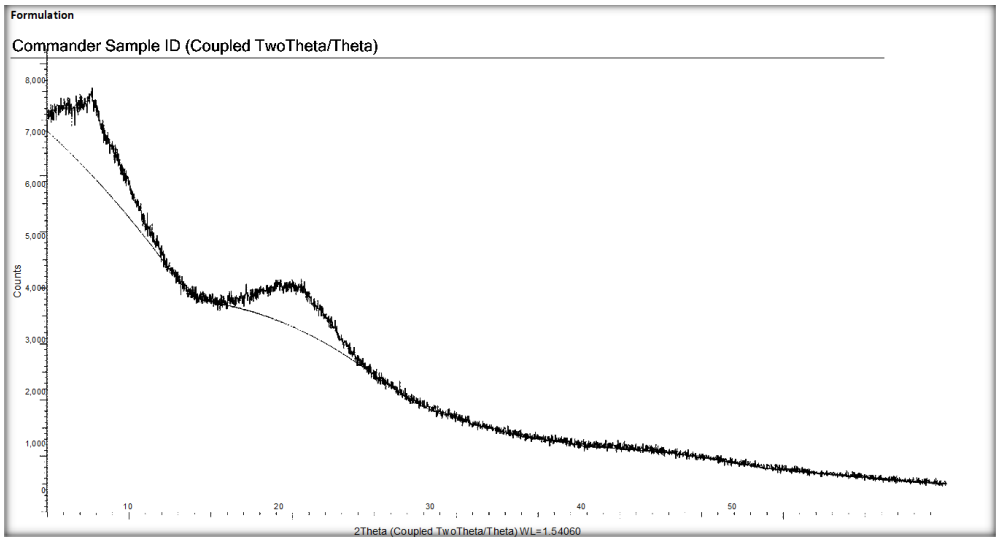
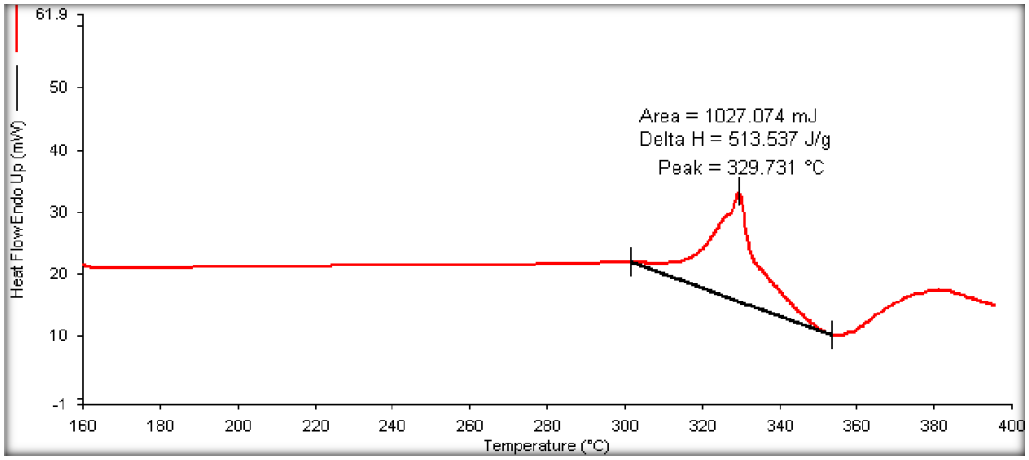
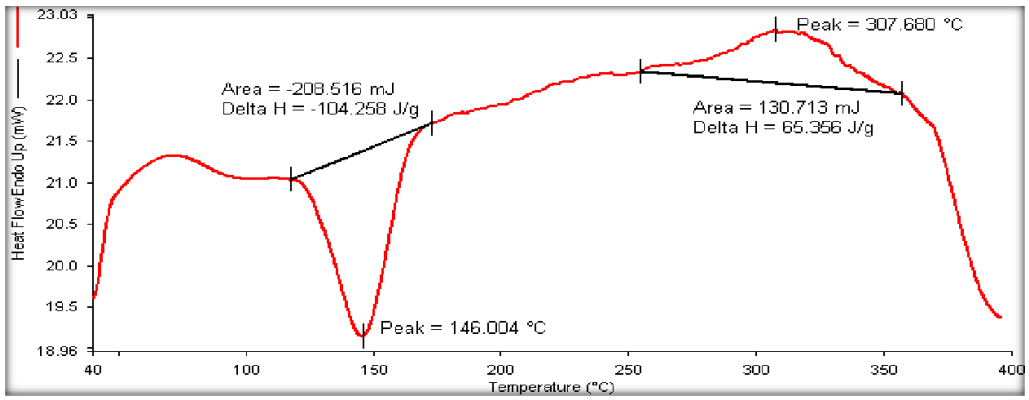


(B)

Figure 4: XRD. (A)- Ciprofloxacin Hydrochloride, (B)- Prepared Formulation.



(A)



(B)

Figure 5: DSC. (A)- Ciprofloxacin Hydrochloride, (B)- Prepared Formulation.

Table 6: Drug release kinetics studies of prepared formulations.

Formulation	Drug release kinetics studies of Prepared Formulations (F1 to F9)				
	R^2 Value				
	Zero Order	First Order	Higuchi	Korsmeyer Peppas (*n*-value)	Drug Release Mechanism
F1	0.961	0.9435	0.9618	0.8435	For both diffusion and relaxation (Erosion)
F2	0.9696	0.8883	0.9378	0.8305	
F3	0.9601	0.9341	0.9252	0.8239	
F4	0.9494	0.9411	0.9569	0.8727	
F5	0.9449	0.8931	0.9012	0.8148	
F6	0.9659	0.8893	0.9118	0.8261	
F7	0.9667	0.8862	0.9571	0.8707	
F8	0.9706	0.8057	0.8868	0.8036	
F9	0.9783	0.7811	0.8892	0.812	

duration produced the most effective complex. Ciprofloxacin was loaded with a success rate of 93.45 ± 1.2, demonstrating minimal drug release at salivary pH, indicating high efficiency in promoting the growth of the complex. Characterization results using FTIR, DSC, and XRD demonstrated that ciprofloxacin. The DSC profile indicated no significant drug-excipient interactions and exhibited a stable thermal profile, which may be linked to rapid disintegration systems. The XRD report indicated that the optimized formulation exhibited reduced crystallization, a characteristic that likely contributed to the enhanced wettability and dissolution rate.[28,29] Direct compression produced mechanically stable tablets in all nine batches, with consistent hardness, minimal friability, and excellent weight variation. In performance testing, high concentrations of Kyron T-314

Table 7: Stability Study of Optimized Immediate-Release Tablets Stored at 40 ± 2°C.

Parameters	Initial (0 Month)	1 Month	3 Months	6 Months
Hardness	5.2 ± 0.2	5.2 ± 0.3	5.1 ± 0.2	5.1 ± 0.3
Disintegration Time	47 ± 1.8	48.2 ± 1.6	49.0 ± 1.7	49.6 ± 1.8
Drug Content	99.5 ± 0.4	99.2 ± 0.5	98.9 ± 0.5	98.5 ± 0.6
% Cumulative Drug Release	98.6 ± 0.8	98.1 ± 0.9	97.5 ± 1.0	97.1 ± 1.1

*Note: (Mean ± SD, n = 3)

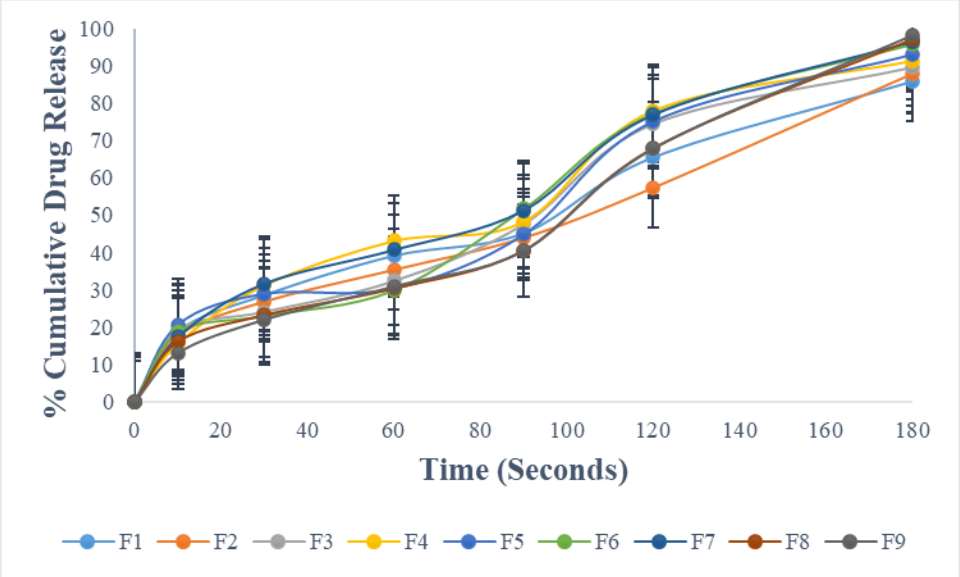


Figure 6: *In vitro* drug release studies of prepared formulations (F1 to F9).

improved wetting time, disintegration behavior, and drug release, supporting its use as a super disintegrant and taste-masking agent. F9 had the quickest breakdown (47 ± 1.8 s) and released the most (98.6 ± 0.8% in 3 min). The optimum proportion of HPMC and Kyron T-314 had the best water absorption, swelling, and matrix dispersion. The F9 dissolution profile showed zero-order kinetics (R2 = 0.9783), indicating that the release rate is independent of drug concentration, which is favorable for immediate-release dose formulations. The non-Fickian (uniform) diffusion curve, evaluated with the Korsmeyer-Peppas model (n = 0.80-0.87), indicated that polymer relaxation/erosion and hydrated network diffusion regulated release. The two effects are combined using super disintegrant- and resin-based oral formulations.[8,19] The improved stability test strengthened the optimized formulation. Over six months, no significant changes in hardness, disintegration time, drug content, or dissolution rate were observed, indicating that the tablets were physically and chemically stable and met the ICH stability standards. These findings support prior studies showing that ion-exchange resins such as Kyron, Indion, and Tulsion can mask bitterness and improve tablet performance. The literature supports the current study's findings that Kyron T-314's improved hydration and swelling properties help break tablets more quickly and dissolve them faster.[12,27]

CONCLUSION

The present study successfully developed and evaluated immediate-release tablets of Ciprofloxacin Hydrochloride using a drug-resin complex approach and super disintegrant technology to overcome the challenges of poor solubility, bitter taste, and delayed drug release associated with conventional formulations. A series of formulations (F1-F9) was prepared by direct compression using varying concentrations of Hydroxypropyl Methylcellulose as a binder and Kyron T-314 as a super disintegrant and taste-masking agent. Among all, the optimised formulation (F9) exhibited excellent mechanical strength and rapid disintegration, with a hardness of 5.2 ± 0.2 kg/cm², a disintegration time of 47 ± 1.8 sec, a drug content of 99.5 ± 0.4%, and 98.6 ± 0.8% cumulative drug release within 3 min. Kinetic modeling demonstrated that the drug was released via both diffusion and polymer relaxation, confirming a zero-order release profile with a non-Fickian diffusion mechanism. Experiments on stability conducted under accelerated conditions demonstrated minimal alterations in hardness, drug content, and dissolution characteristics. This confirmed that the formulation was physically and chemically stable. The formulation is appropriate for large-scale manufacturing due to its compatibility with the direct compression technique, the utilization of standard excipients, and demonstrated stability under accelerated stability testing conditions.

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ABBREVIATIONS

DRC: Drug-resin complex; **HPMC:** Hydroxypropyl methylcellulose; **MCC:** Microcrystalline cellulose; **XRD:** X-ray diffraction; **FTIR:** Fourier transform infrared spectroscopy; **DSC:** Differential scanning calorimetry; **RH:** Relative humidity; **CDR:** Cumulative drug release; **USP:** United States Pharmacopoeia; **ICH:** International Council for Harmonisation; **UV-vis:** Ultraviolet-visible spectrophotometer.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

SUMMARY

This study focused on developing and accessing rapidly disintegrating Ciprofloxacin Hydrochloride tablets to improve patient acceptability and enhance drug performance. To achieve this, the formulation strategy combined a super disintegrant with drug-resin complexation, ensuring both effective taste masking and faster dissolution. Kyron T-314 was incorporated not only as a potent super disintegrant but also as a key contributor to taste masking, while Hydroxypropyl Methylcellulose acted as the primary binder. Mannitol was selected as a diluent to impart a pleasant mouthfeel, and Microcrystalline Cellulose (Avicel PH-101) served as a filler to support tablet integrity. All ingredients were blended using the direct compression method, and nine trial formulations (F1-F9) were prepared by varying the proportions of Kyron T-314 and HPMC to balance mechanical strength with rapid disintegration and efficient drug release. Among all the batches, formulation F9 exhibited the most desirable characteristics. It disintegrated in 47 ± 1.8 sec, showed a hardness of 5.2 ± 0.2 kg/cm^2, maintained uniform drug content (99.59 ± 0.4%), and released 98.6% of the drug within the first 3 min. Drug release followed Zero-order kinetics (R^2 = 0.9783), indicating a non-Fickian mechanism driven by both diffusion and polymer relaxation. Accelerated stability testing for six months at 40 ± 2°C and 75 ± 5% relative humidity confirmed that the optimized formulation remained physically and chemically stable. The newly developed tablet provides a cost-effective, stable, and patient-friendly alternative to conventional Ciprofloxacin tablets. Its rapid onset of action, improved taste, and enhanced dissolution profile make it a promising option for better therapeutic outcomes.

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