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Polymeric Ion-Exchange Complexes of Carbomer for Taste Masking and Enhanced Drug Bioavailability: A Physicochemical and In Vivo Study

Manu Tripathi[1,*], Pankaj Kumar Yadav[2]

Abstract

Famotidine (FAM) was recognized as a crystalline powder that varies in color from white to pale yellow and possesses an extremely bitter flavor. This study aimed to conceal the unpleasant flavor of FAM through employing unconventional ion-exchange resins sourced from Carbomer polymer Evaluation (Carbopol 974P). We used FTIR, DSC, and XRD to look at the drug-resin combination in its hard form to learn more about its physical and chemical properties. The drug-Carbopol complex was blended with appropriate excipients and compressed into orally disintegrating tablets (ODT). Follow-up studies showed that the weight, hardness, and drug content were within acceptable range, with drug content ranging from 97.59 ± 0.02 to 100.13 ± 0.04%. The drug-Carbopol complex completely covered up the bitter taste of FAM during the functional surface modification test. Pharmacokinetic studies demonstrated that the Carbopol complex of FAM exhibited superior bioavailability compared to commercially available products. This was clear from the fact that the AUC_{0}–t (35,422.5 ± 2,150.4 ng•h/ml) and Cmax (2990 ng/ml) were both higher. Also, the Carbopol complex had a lower Tmax (2.0 hours), which meant that it absorbed faster than other preparat4ons on the market. The test formulation had better pharmacokinetic performance, better functional surface modification, and better absorption characteristics overall. This could make treatments for peptic ulcers and GERD more effective and make patients more likely to follow their treatment plans.

Keywords: Carbomer, polymeric complex, ion-exchange composite, drug release, structural characterization

INTRODUCTION:

Carbomers are synthetic, high-molecular-weight, crosslinked poly(acrylic acid) polymers that have become useful excipients in modern biomedical and pharmacological uses. These polymers are made by free radical polymerization of acrylic acid monomers with multifunctional allyl ether crosslinkers, usually allyl pentaerythritol or allyl sucrose. This makes a three-dimensional network structure [1,2]. The degree of crosslinking, molecular weight distribution, and polymer grade (e.g., Carbopol® 934, 940, 971P, and 974P) all work together to define how they behave in formulations [3]. Because of its adjustable polymeric structure, Carbomers are often utilized as gelling agents, bioadhesive polymers, controlled-release matrices, and drug delivery enhancers.

A unique structural characteristic of Carbomers is the high number of carboxylic acid groups that

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hang off the polymer backbone. In water, these functional groups ionize to make negatively charged carboxylate ions, which lets them absorb a lot of water and swell. This ionic dissociation gives the substance a high viscosity even at low polymer concentrations and weak cation-exchange capacities [4]. Carbomers can form complexes with basic pharmaceuticals that have protonated amine groups through electrostatic interactions. This makes them good polymeric matrices for changing the speed at which drugs are released and improving their taste and smell.

Taste masking is very important for making oral dosage forms that are easy for patients to take, especially for bitter medications that make it hard for kids and older people to follow their treatment plans. Famotidine (FAM), an H2 receptor antagonist commonly recommended for hyperacidity disorders, has a notably harsh taste that restricts its usability in standard oral tablets [5,17]. Different ways to hide the taste of FAM have been tried, such as microencapsulation, ion-exchange complexation, and hot-melt extrusion. However, many of these methods either make it harder for the medicine to be released or cost a lot to process [6].

Carbomer-based drug–polymer complexes constitute a novel functional surface modification technique owing to their ion-exchange properties, biocompatibility, and stability [7]. Carbomer (especially Carbopol® 974P) has more benefits than regular polystyrene-based cation exchange resins. These benefits include a high swelling capacity, easy processing, and compatibility with orally disintegrating tablet (ODT) technologies. In this investigation, a drug–polymer complex (DPC) comprising Famotidine and Carbopol 974P was synthesized through ionic contact between the protonated amine of Famotidine and the carboxylate groups of the polymer. The resulting compound was made into tablets that quickly break down utilizing the right excipients to make sure that the medicine is released quickly after it is taken and that it doesn't interact with taste buds in the mouth too soon [8].

We extensively looked at the FAM–Carbopol complex's physicochemical properties[9-13] such as how effectively it can hold drugs, how it interacts with other substances, how much it swells, and how it releases drugs in vitro[14]. In addition, the effectiveness of functional surface modification in vitro studies was evaluated by simulating salivary circumstances to measure the release of unbound medication in the oral cavity [15]. We did experiments on disintegration time and dissolution to make sure that the orally disintegrating systems met the standards set by the pharmacopeia.
This study shows that Carbomer could be a useful ion-exchange polymer for making polymer-drug complexes and hiding the taste of bitter APIs while yet allowing for quick drug release and bioavailability. This research combines polymer chemistry with formulation technology to create a practical and scalable way to get patients to follow their treatment plan, especially for groups that need dose forms that are easy to swallow and taste good [16, 17].

MATERIALS AND METHODS:

All materials used in the present study were of pharmaceutical or analytical grade and were used as received without further purification. The active pharmaceutical ingredient (API), ion-exchange resin, and excipients employed for the preparation of orally disintegrating tablets (ODTs) were procured from reliable commercial suppliers.

The drug–resin complex (DRC) was prepared using an optimized batch process to achieve effective taste masking. Various formulation and process parameters such as drug–resin ratio, swelling time, stirring time, and pH of the medium were systematically studied to obtain maximum drug loading.

ODTs were prepared using the optimized DRC along with suitable superdisintegrants, diluents, sweeteners, and lubricants. Tablets were manufactured by the direct compression method after ensuring uniform blending of all components.

Materials

FAM was acquired from Jubilant Life Sciences, Noida, while Taste Masker Carbopol 974P was received as a gift sample from Lubrizol Life Science, Mumbai, Microcrystalline cellulose, Lactose, Crospovidone, Magnesium stearate, Aspartame and chemicals of ultrapure grade were purchased from research lab Mumbai.

Methods

Following below methods are used.

The analytical technique of Liquid chromatography with high performance (HPLC) for fluorescein amidite (FAM)

An established HPLC methodology was employed for the examination of FAM. The analytical HPLC method (Agilent 1200) utilized an Eclipse plus The C-18 column is kept at ambient temperature. The mobile phase consisted of a 30:70 mixture of methanol and 0.1 M ammonium acetate buffer, with the pH calibrated to 5.5 using glacial acetic acid, to facilitate the effective separation of FAMO from the intricate endogenous components in rat plasma. A 20 µl volume was injected, with elution detected at 266 nm, yielding a sensitivity of 0.0010 AU. The analyses were performed at a flow rate of 1 ml per minute at 25 degrees Celsius, including the sample quantification carried out through peak regions [18].

Synthesis of Pharmaceutical–Resin Complex (DRC)

Batch processing was employed to produce the drug-resin combination. Three drug-resin complexes were produced utilizing Carbopol 974P polymer. The ratios of drug to resin, specifically 3:1, 2:1, and 1:1, were quantified and added to 50 ml of deionized water in a glass beaker. The resulting suspension was agitated for 30minutes using a magnetic stirrer and then let to whirl at a temperature of 37 ± 0.5 °C for an additional five hours. The complexes were removed using vacuum filtering, there after rinsed with deionized water to eradicate residual pharmaceuticals and ions, and the material was dried until a stable weight was achieved. The true loading capacity was evaluated via spectrophotometric measurement of the filtrate at a wavelength of 266 nm. The disparity between the initial and residual quantities of drug in the filtrate was utilized to compute the amount of drug incorporated into the complexes [19, 20].

Characterization drug–resin complex (DRC)

The prepared drug–resin complex was characterized to confirm successful complexation and to evaluate its physicochemical properties. Drug loading efficiency was determined by estimating the amount of unbound drug remaining in the filtrate using a validated analytical method.

Fourier Transform Infrared (FTIR) spectroscopy was employed to identify possible interactions between the drug and resin by comparing the spectra of the pure drug, resin, and DRC. Differential Scanning Calorimetry (DSC) and Powder X-Ray Diffraction (PXRD) studies were conducted to assess changes in thermal behavior and crystallinity, respectively, indicating the formation of a complex.

In-vitro taste masking efficiency of the DRC was evaluated by drug release studies in simulated salivary fluid, ensuring minimal drug release under oral conditions while allowing complete release in gastric pH.

FTIR spectroscopy

FTIR spectroscopy was used to investigate the FAM and Carbopol 974P polymer chemical interaction. An infrared spectrometer with fourier transform (Bruker Alpha II) was used to get the samples' IR spectra. The scanning range for The KBr disk method readings ranged from 4000 to 400 cm^{-1}. The outcome is illustrated in Figure 1.

Differential Scanning Calorimetry (DSC)

Differential Scanning Calorimetry (DSC) analyses were conducted on both the pure drug and the resinate to evaluate the molecular condition of the drug within the drug-resin complex. The samples' DSC curves were acquired using a differential scanning calorimeter (TA Instrument HTLP 071). After each sample was put inside an aluminium pan, the aluminium cover was crimped on. The pace of heating was 10 °C per minute. All measurements were performed within the temperature range spans from 0 to 500 °C, utilizing a nitrogen purge at a flow rate of 50 mL/min. The results are depicted in Figure 2.

X-ray Powder Diffraction (XRPD)

An automated X-ray diffractometer (Bruker D2 PHASER) utilizes a Cu K filter and SC70 radiation detector, operating at 40 kV and 30 mA, with a scanning speed of 10 mm/secto conduct X-ray diffraction investigations on materials. Figure 3 presents the findings.

***In-Vitro* Assessment of Drug Release from Drug–Resin Complex under Simulated Oral Cavity Conditions**

An in vitro study was conducted to evaluate the drug release from the FAM-Carbopol complex (Drug-Resin Complex) in the oral cavity following administration. A USP phosphate buffer with a pH of 6.8 was prepared to evaluate the release of the drug from the compound. Twenty milligrams of the drug-resin combination was allocated into two 25 mL glass bottles, subsequently augmented with 5 mL of the buffer solution. The bottles were permitted to stay still for 60 seconds and 120 seconds, respectively. Following During the designated timeframe, the suspensions underwent filtration utilizing a 0.45 µm nylon filters were utilized, and the filtrates obtained were subsequently analyzed for drug concentration [21].

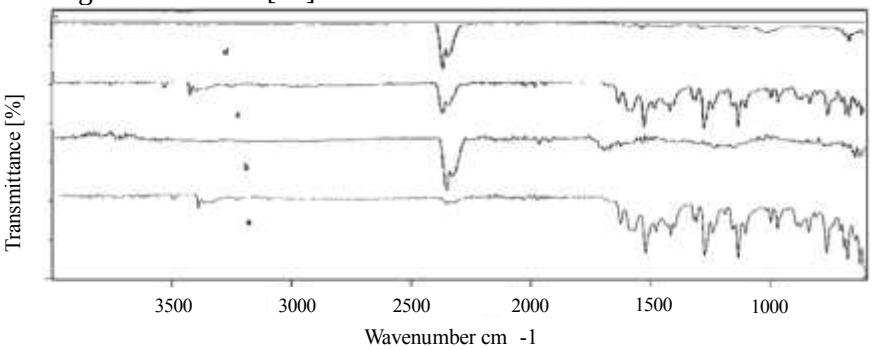

Figure 1. FT-IR spectra of Pure FAM (a),Pure Carbopol974P (b), FAM Carbopol974Pcomplex (c), FAM Carbopol 974P physical mixture (d).

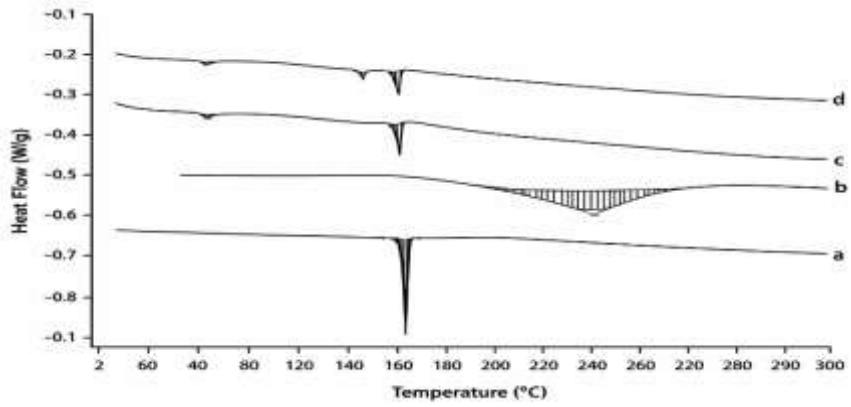

Figure 2. DSC spectra of FAM API (a), Carbopol 974P polymer (b), FAM Carbopol 974Pcomplex (c), FAM and Carbopol 974P physical mixture (d)

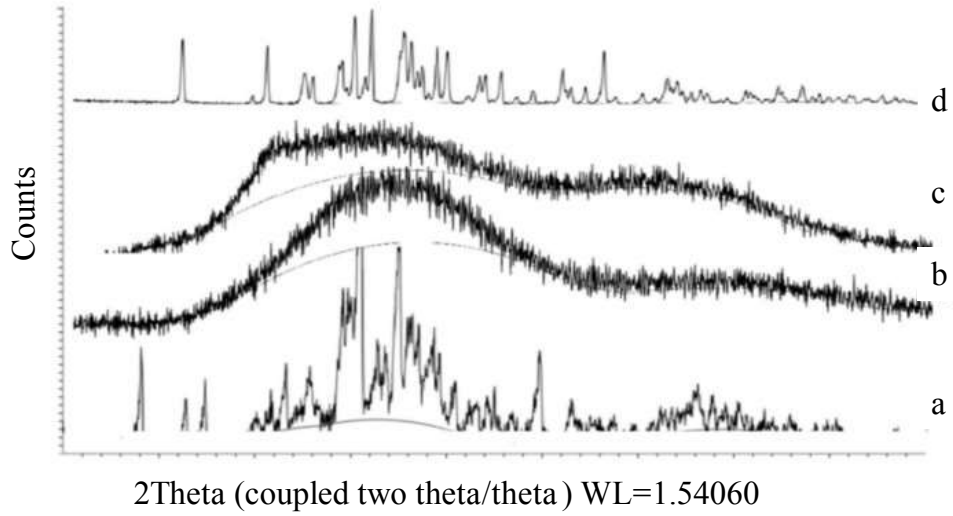

Figure 3. XRD spectra of Pure FAM (a), Pure Carbopol 974P (b), FAM Carbopol 974P complex (c), FAM Carbopol 974P physical mixture (d).

Table 1. In-vitro evaluation of drug release from drug–resin complex in simulated oral cavity conditions.

Sample	Time (s)	Amount of Free drug in 5 ml pH 6.8 Phosphate buffer (mg)	% drug release
FAM Carbopol 974P Resin Complex	60	0.08 ± 0.006	0.40 ± 0.15
	120	0.10 ± 0.013	0.50 ± 0.33

Formulation of taste masked FAM orally disintegrating tablets (ODT)

To get suitable formula for preparation of the FAM orally disintegrating tablets (ODT).40 mg drug resin complex of FAM and Carbopol 974P was utilized along with suitable excipients for each formulation (F1 through F7). The composition of each formulation is presented below in Table 2.To guarantee a homogenous composition, every ingredient was well combined. A tablet press machine was used to compress the lubricated blend of drug resin complex along with other excipients into tablets, adjusting the compression parameters to obtain the required level of hardness and consistent weight. To make sure that compressed tablets met the necessary standards, tests were conducted on the finished product to assess its quality [22-24].

In-vitro disintegration time was determined to assess the rapid disintegration behaviour of the tablets in the oral cavity. In-vitro dissolution studies were carried out using appropriate dissolution media to evaluate drug release profiles and to ensure immediate drug availability after swallowing.

Taste masking efficiency of the final ODT formulation was assessed using in-vitro methods and/or sensory evaluation, confirming patient acceptability and palatability of the dosage form.

Physicochemical Assessment of FAM Orally Disintegrating Tablets (ODT)

Physicochemical parameters FAM orally disintegrating tablets of prepared batches were assessed, and the findings are presented in Table 3.

Evaluation of taste-masked orally disintegrating tablets (ODT)

The prepared ODTs containing the optimized DRC were evaluated for various quality control parameters including weight variation, thickness, hardness, friability, and drug content uniformity as per pharmacopoeial limits.

Table 2. Formulation of taste masked FAM orally disintegrating tablets (ODT)

S. No.	Table Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7
1	Drug Resin Complex (FAM and 974P) equivalent to 20 mg of FAM	40.0	40.0	40.0	40.0	40.0	40.0	40.0
2	Microcrystalline cellulose (Avicel PH 102)	244.3	-	122.2	162.9	183.2	81.4	61.1
3	Lactose Monohydrate (Pharmatose 200M)	-	244.3	122.2	81.4	61.1	162.9	183.3
4	Crospovidone (Polyplasdone XL 10)	9.1	9.1	9.1	9.1	9.1	9.1	9.1
5	Magnesium stearate	2.8	2.8	2.8	2.8	2.8	2.8	2.8
6	Aspartame	3.8	3.8	3.8	3.8	3.8	3.8	3.8
Tablet weight (mg)		**300.0**	**300.0**	**300.0**	**300.0**	**300.0**	**300.0**	**300.0**

Table 3. Physio-chemical evaluation of FAM orally disintegrating tablets (ODT).

Tablet Parameters	F1	F2	F3	F4	F5	F6	F7	F8 (Marketed)
Weight Variation (%)	300 ±1.5	300 ±1.6	300 ±1.4	300 ±1.7	300 ±1.8	300 ±1.6	300 ±1.5	100±0.88
Thickness (mm)	4.0 ± 0.20	4.1 ± 0.15	4.0 ± 0.12	4.0 ± 0.18	4.2 ± 0.14	4.1 ± 0.16	4.1 ± 0.11	1.23±011
Hardness (kg/cm²)	3.8 ± 1.2	3.7 ± 1.1	3.5 ± 0.9	3.6 ± 1.3	3.9 ± 1.2	3.8 ± 0.8	3.7 ± 0.9	3.5±0.17
Friability (%)	0.8	0.7	0.9	0.8	0.7	0.8	0.8	0.48
Disintegration Time (Sec)	25 ± 3	28 ± 3	22 ± 3	20 ± 2	30 ± 3	35 ± 5	18 ± 3	20±20
Drug Content (%)	100.13 ± 0.0.04	98.8 ± 0.40	99.2 ± 0.32	98.9 ± 0.38	99.0 ± 0.34	97.59 ± 0.02	99.1 ± 0.31	99±0.25
Dissolution Profile								
Time (min)	% Drug Release							
5 min	28.5 ± 1.25	26.0 ± 1.15	32.0 ± 1.10	22.5 ± 1.12	24.5 ± 1.20	39.5 ± 1.35	38.0 ± 1.30	5.3 ± 1.23
10 min	55.0 ± 2.20	52.5 ± 2.12	60.0 ± 2.10	47.0 ± 2.18	50.5 ± 2.20	69.5 ± 2.30	68.0 ± 2.25	7.5 ± 1.211
15 min	73.5 ± 2.80	70.0 ± 2.75	78.0 ± 2.85	67.5 ± 2.50	70.5 ± 2.80	89.5 ± 3.20	88.0 ± 2.95	15.5 ± 2.25
20 min	88.0 ± 3.10	85.0 ± 3.25	90.5 ± 3.30	80.0 ± 3.00	83.0 ± 3.15	98.34 ± 0.20	96.13 ± 3.35	20.0 ± 3.15
25 min	97.5 ± 3.35	94.0 ± 3.10	98.0 ± 3.50	90.0 ± 3.25	92.5 ± 3.20	99.5 ± 3.60	99.5 ± 3.50	30.8 ± 3.20
30 min	99.0 ± 3.20	97.0 ± 3.12	98.5 ± 3.10	95.0 ± 2.90	96.5 ± 3.00	99.5 ± 3.30	99.5 ± 3.25	58.34± 3.00

Drug Content Uniformity of Fam Orally Disintegrating Tablets (ODT)

The tablets from the prepared batches were subjected to a content uniformity test. Initially, the tablet was weighed and subsequently ground into a powder. The powdered tablets were subsequently placed into a 100 ml volumetric flask, and 0.1 N HCl was added until the designated spot was attained. The solution that resulted was filtered, and the initial milliliters of the filtrate were eliminated. Using this method, 10 ml of the filtrate was transferred into a 50 ml volumetric flask, and 0.1 N HCl was added to reach the calibration point. The solution underwent spectrophotometric analysis at a wavelength of 266 nm. The drug concentration (μg/ml) remained ascertained utilizing the standard calibration curve pertinent to the specific medication [25, 26].

Dissolution Study of FAM Orally Disintegrating Tablets (ODT) in 0.1N HCl

The dissolution study of FAM orally disintegrating tablets of fabricated batches was conducted. Dissolution study of the tablets were conducted using a USP-type II dissolution apparatus. Each flask

in the dissolution apparatus contained 900 cc of buffer (pH 1.2), kept maintained at a temperature of 37 ± 0.5 °C and rotated at a speed of 50 rpm. Tablets stood placed hooked on each flask. At specified intervals, 5 ml of the dissolution media was withdrawn and filetred using a 0.45 μm filter. The filtrate was examined at 266 nm using a UV-visible spectrophotometer. The dissolution data is presented in the table 3 [27, 28].

In-Vivo Evaluation of Taste for Pharmaceutical Resin Complex and FAM Orally Disintegrating Tablets (ODTs)

A trained taste panel of six healthy volunteers aged 20 to 30 years as mentioned in Table 4 undertook an evaluation of the flavor character of the pharmaceutical resin complex and its tablets.

The medication, a resin complex equivalent to 20 mg of FAM, FAM ODT, and FAM marketed tablets (Famonext 20), was held in the mouth for 60 seconds by each volunteer, and the bitterness level was evaluated against the pure drug using a numerical scale. After a duration of 60 seconds, the sample was spitout, and the oral cavity was meticulously rinsed with distilled water. A numerical scale was employed with the subsequent values: 0 = tasteless, 0.5 = aftertaste, 1.0 = slight, 1.5 = slight to moderate, 2.0 = moderate, 2.5 = moderate to strong, 3 = powerful, and 3+ = very strong [29, 30].

In-vivo studies

The animal experiments received approval from the Institutional Animal Ethics Committee (IAEC) at Pinnacle Biomedical Research Institute, Bhopal, which is recognized by the Government of India to oversee and regulate animal research (Protocol approval reference number- PBRI/IAEC/03-06-24/004). The research adhered to the protocols set forth by the Committee for the Purpose of Control and Supervision of Experiments on Animals. The animals were provided with unlimited access to water but were withheld from food for a duration of 6 hours prior to the experiment. The study involved Wistar pests of both genders, each weighing between 300 and 350 grams. The improved formulation, suspended in 1 ml of 0.5% Carboxymethyl Cellulose (CMC) for oral delivery, was delivered to the rats via an oral cannula.

Bioequivalence Study in Wistar Rats

To assess the influence of complexation on the bioavailability of FAM, a bioequivalence study was performed, as mentioned in Table 5, comparing orally disintegrating tablets (ODTs) of FAM containing the drug resin complex (DRC) with a commercially available preparation (Famonext 20) utilizing a parallel study design. The research included two cohorts of Wistar rats, designated as follows:

- *Group 1 (Test Group):* Rats in this group were given orally disintegrating tablets (ODTs) that contained the drug-resin complex in an aqueous suspension at a dose of 50 mg/kg [31].
- *Group 2 (Control Group):* Rats in this group were given the marketed form of FAM (Famonext 20) at a dose of 50 mg/kg, which is the same as the other groups.

Table 4. Bitterness evaluation by taste panel

Samples	Volunteers					
	1	**2**	**3**	**4**	**5**	**6**
FAM	5	6	3	5	3	6
FAM Resinate	0	0	1	0	0	0
FAM ODT	0	0	0	0	0	0
Marketed Product (Famonext 20)	3	3	2	3	4	3

Bitterness level: 0 = tasteless, 0.5 = aftertaste, 1.0 = slight, 1.5 = slight to moderate, 2.0 = moderate, 2.5 = moderate to strong, 3 = strong and 3+ =very strong.

Each group consisted of six Wistar rats to guarantee sufficient statistical power.

Blood samples (0.5 ml) were composed from the retro-orbital plexus of each rat at specified time intervals (30 minutes, 1, 2, 4, 6, 8, 12, 16, 20, and 24 hours) following drug treatment. Blood samples were collected immediately. The sample was centrifuged at 5000 rpm for a duration of 15 minutes, after which the plasma was preserved at -20ºC until it was analyzed illustrated in Figure 4 [32].

Pharmacokinetic parameters, including the maximum plasma concentration of the drug (Cmax), the duration required to attain this peak concentration (Tmax), and the area beneath the plasma concentration-time curve. (AUC), were assessed to ascertain bioavailability of the test formulation in comparison to the commercial product.

The mean plasma drug concentrations at each time interval were used to construct pharmacokinetic profiles for both formulations, allowing a comprehensive assessment of bioequivalence. The pharmacokinetic parameters observed in the study are summarized as follows [33, 34]:

Table 5. Pharmacokinetic parameters of test and marketed formulations.

Parameter	FAM Resin Complex ODT (Test)	FAM Marketed Preparation (Reference)	Statistical Significance
Cmax (ng/mL)	2290.0 ± 180.3	2485.8 ± 155.2	$p < 0.01$ (significant)
Tmax (h)	2.0 ± 0.0	4.0 ± 0.0	$p < 0.05$ (significant)
AUC_0–t (ng•h/mL)	35,422.5 ± 2,150.4	33,811.3 ± 1,980.6	$p < 0.05$ (significant)
AUC_0–∞ (ng•h/mL)	35,995.2 ± 2,240.5	34,289.3 ± 2,100.7	$p < 0.05$ (significant)

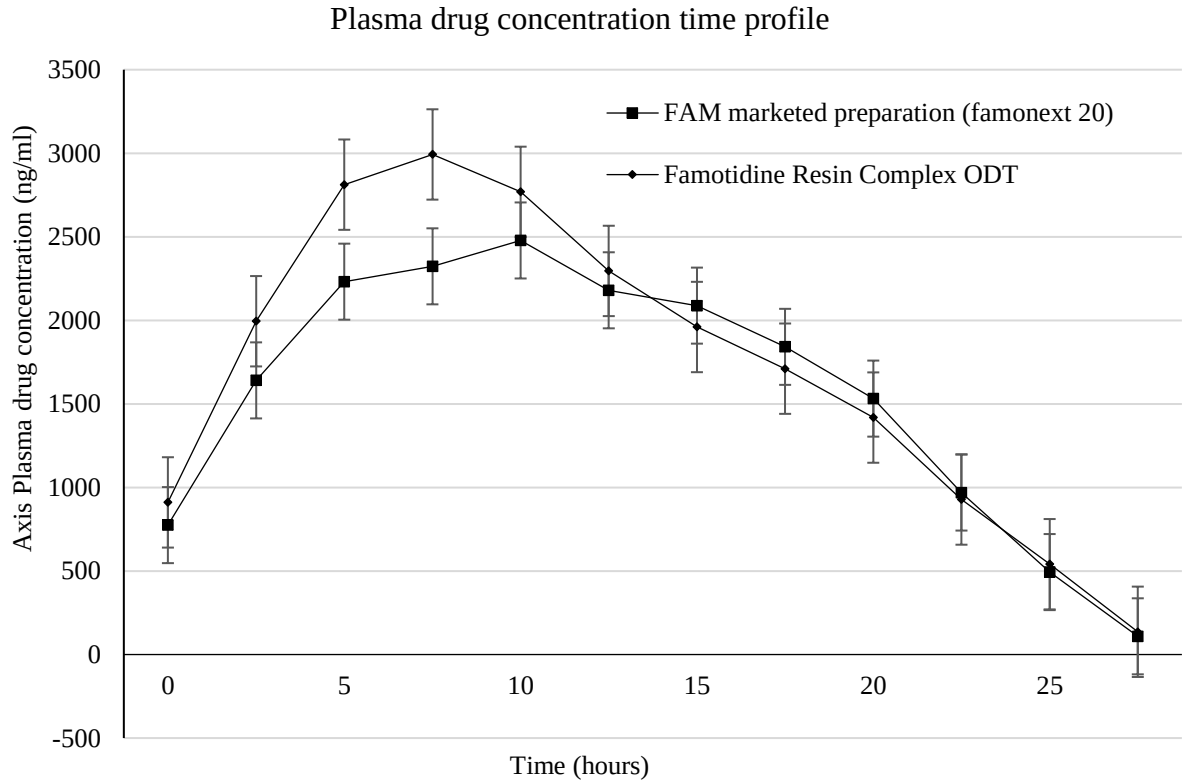

Figure 4. Comparative plasma drug concentration-time profile of FAM resin complex ODT and FAM marketed preparation (Famonext 20)

Statistical analysis

Data were expressed as mean ± standard error (n = 6). Statistical techniques were assessed through one-way analyses of variance, followed by Tukey's multiple comparisons, conducted with GraphPad Prism (version 6.0.1, Graph Pad Software Inc., La Jolla, CA) to evaluate variances across all biochemical parameters. A difference was deemed significant if $p < 0.05$. GraphPad Prism (version 6.0.1, GraphPad Software Inc., La Jolla, CA)

RESULTS AND DISCUSSION

The drug–resin complex demonstrated satisfactory drug loading efficiency, indicating effective binding between the API and the ion-exchange resin. FTIR, DSC, and PXRD studies confirmed the formation of the DRC through the disappearance or shifting of characteristic drug peaks and reduction in crystallinity, supporting successful taste masking.

ODTs prepared with the optimized DRC exhibited acceptable physicochemical properties and complied with pharmacopoeial requirements. Rapid disintegration and minimal drug release in simulated salivary conditions confirmed effective taste masking, while complete and prompt drug release in acidic medium ensured therapeutic efficacy.

Overall, the results indicate that ion-exchange resin-based taste masking is a promising approach for developing patient-friendly orally disintegrating tablets, particularly for bitter drugs, enhancing compliance and clinical acceptability.

HPLC method of analysis for determination of FAM

The standard calibration curve for FAM was established by plotting peak area against concentration, utilizing serially diluted known concentrations (50–500 ng/ml) of FAM through the HPLC technique. The standard curve demonstrated a linear correlation, indicated by a correlation coefficient (R^2) of 0.9997, is seen in Figure 5 below. Under the designated chromatographic conditions, the peaks of FAM and the internal standard was distinctly separated from the endogenous interfering peaks seen in plasma components. Figures 6 a, b, and c present standard chromatograms of blank plasma alongside the studied spiked samples. The average retention durations for FAMO and the internal standard were determined to be 5.1 and 7.4 minutes, respectively, with neither interfering with the analyte peaks.

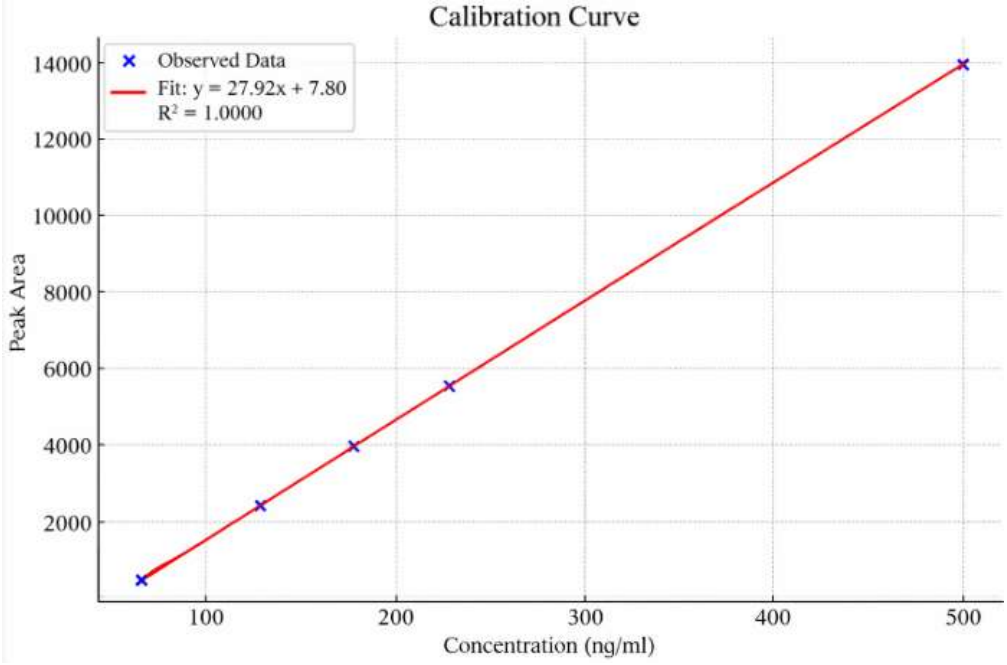

Figure 5. Calibration curve of AMC in rat plasma.

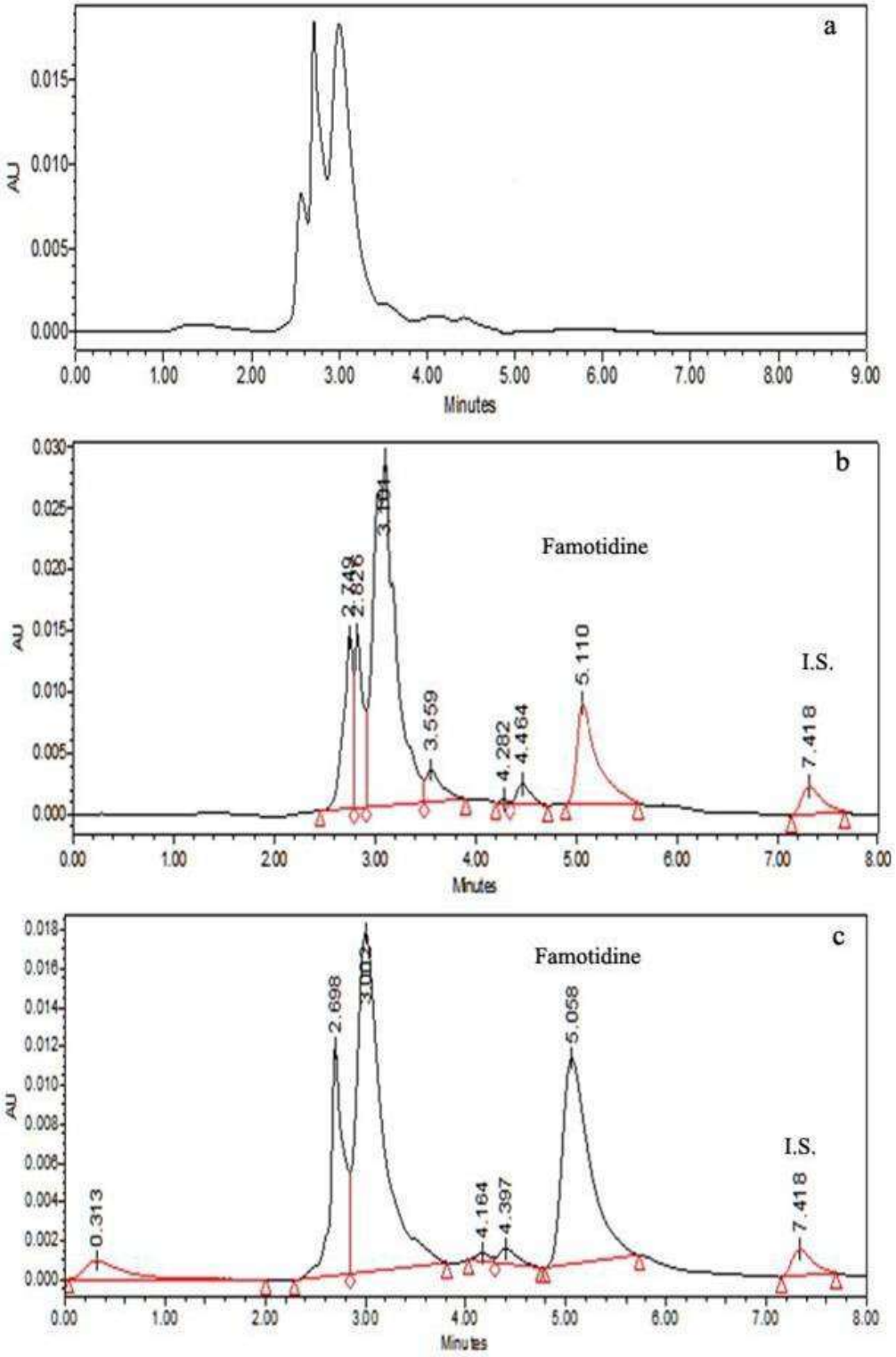

Figure 6. Chromatograms of a) Blank plasma; b) Plasma spiked with famotidine (20 ng/ml; RT=5.11 min) and internal standard (I.S., 200 ng/ml; RT=7.418 min) and c) Plasma spiked with famotidine (50 ng/ml; RT=5.1 min) and internal standard. (200 ng/ml; RT=7.418 min).

Impact of FAM Resin Proportion on Drug Incorporation

The Drug Resin Complex (DRC) were produced with varying ratios of drug to resin (w/w), ranging from 1:1 to 1:3 in an aqueous environment. No substantial improvement in drug loading was seen.

When comparing the ratios from 1:1 to 1:3. Hence, 1:1 ratio was found to be the most suitable for drug-resin complex (DRC) formation.

Evaluation using Fourier-Transform Infrared Spectrophotometry

The FAM spectra (Instrument HTLP 071M) The FT-IR spectra indicate the subsequent observations: N—H stretching is observed at 3349 cm^{-1}, C—H widening at 2892 cm^{-1}, C—H winding at 1426 cm^{-1}, Amide C=O widening at 1642 cm^{-1}, and C—N widening at 1083 cm^{-1}. The FT-IR spectra of both drug-resin complex and physical mixture of the drug had identical peaks, signifying that the drug's structure remained unchanged during the complexation of FAM with Carbopol 974. This finding validates the suitability of the chosen resins and excipients. Moreover, novel maxima were detected in the drug-resin complexes. But the drug peak remained constant, so confirming that the complexes were formed without compromising the drug's characteristics.

Differential Scanning Colorimetric Evaluation

The DSC thermogram of FAM API exhibited a sharp endothermic peak at 165 °C, confirming its melting behaviour. The FAM Carbopol 974P complex (DRC), on the other hand, exhibited a wider peak at 160°C. The DSC thermogram of the drug resin complexes had peaks similar to those of the pure drug; however, it lacked a notable endothermic peak. This discovery indicates that the drug is uniformly dispersed and exists in amorphous form within the drug-resin complex.

X-Ray Diffractometry Evaluation

X-ray diffraction (XRD) analysis confirms that thecomplexation of FAM with Carbopol 974P effectively conceals its bitter taste by diminishing its crystallinity and modifying its molecular structure, thereby obstructing direct interaction with taste receptors. The FAM-Carbopol 974P complex showed that the sharp and intense peaks of crystalline FAM API, like those at 6.35° and 16.12° 2θ, were greatly reduced. This means that some of the FAM API was turned into an amorphous state.This structural change enhances the solubility of FAM, which can lead to improved dissolution and bioavailability. In contrast, the physical mixture retained most of the crystalline peaks, suggesting that simple blending does not achieve the same level of interaction. These findings support the use of Carbopol 974P as an effective carrier for the enhancement of solubility as well as the masking of taste,ultimately improving the therapeutic potential of FAM.

Evaluation of Taste Masking in-Vitro for Drug Resinate

The traditional approach to in vitro dissolving research is constrained in its capacity to accurately emulate the actions of an orally disintegrating tablet (ODT) within the buccal cavity, mostly because of the use of an excessively high volume of dissolution media. To resolve this issue, a more physiologically correct dissolution model, in which drug release was assessed using 5 mL of pH 6.8 phosphate buffer, accurately replicating the pH and volume of saliva. This method was utilized to evaluate the functional surface modification efficacy of the drug-resin complex (DRC). The results indicated that less than 0.50% of the medicine was released after 120 seconds (see Table 1). Furthermore, given that the disintegration time of the ODT was under 20 seconds, the actual drug release upon in vivo administration would be even lower, rendering it insufficient to elicit a bitter taste. The in vivo functional surface modification study results further validated these findings.

Dissolution Studies Evaluation

The dissolving profiles of seven tablet formulations (F1 to F7) were analysed examined, evaluated, and revealing significant differences in drug release over time. Formulation F6 demonstrated the highest release across all time points, reaching 98.34% at 20 minutes, indicating superior dissolution properties. F7 also showed high release, particularly in later stages, achieving 96.13% at 20 minutes. In contrast, F4 consistently had the lowest release, with 80.0 % at 20 minutes, suggesting slower dissolution. These results suggest that F6 is the most promising formulation for rapid and complete drug release.

In-Vivo Evaluation of Taste Masking for FAM Resinate ODT

An assessment of functional surface modification was performed utilizing the time-intensity method with a group of healthy human volunteers. to assess the palatability of FAM formulations. Pure FAM API and marketed tablets (Famonext 20) were perceived as bitter, whereas the drug-resin complex of FAM and its orally disintegrating tablets (ODTs) were reported to be tasteless. These findings indicate that complexation of FAM API with Carbopol 974P effectively masks the unpleasant flavor of the medication, showcasing adequate functional surface modification characteristics.

Animal Study Evaluation

The Test formulation of FAM demonstrates superior pharmacokinetic performance compared to the FAM marketed formulation in this animal study. The higher AUC_0–t (35,422.5ng·h/ml vs. 33811.3ng·h/ml) and C_{max} (2990.0 ng/ml vs. 2485.8 ng/ml) indicate that the Test formulation provides greater systemic drug exposure and achieves higher peak plasma concentrations, suggesting better bioavailability. Additionally, the shorter T_{max} (2 hours vs. 4 hours) for the Test formulation reflects faster absorption, which may lead to a quicker onset of action. Overall, the Test formulation appears to be more efficient in terms of bioavailability and absorption characteristics than the FAM marketed formulation. This enhanced bioavailability can be attributed to the ion-exchange–based mechanism of the Famotidine–Carbopol 974P complex. Upon reaching the acidic gastric environment, the high concentration of H^+ ions rapidly displaces the drug from the polymer backbone, triggering an immediate ion-exchange reaction and freeing Famotidine for absorption. As a result, once exposed to gastric acid, the ion-exchange reaction proceeds very quickly—consistent with dissolution observations—allowing prompt and efficient drug release ensuring faster onset and greater extent of absorption than the traditional marketed preparation.

Polymer Engineering and Composite Performance Perspective

Ion-exchange polymer composites such as Carbomer–Drug complexes demonstrate how polymer networks can serve as functional bio-composite materials. These systems highlight principles of matrix interaction efficiency, controlled ion-exchange behavior, and tunable crosslinked architectures that can inspire the development of sustainable composites for drug delivery, biomedical packaging, and controlled-release devices. Carbomer's biocompatibility, high swelling capacity, and environmentally stable crosslinked structure position it as a sustainable polymer platform suitable for future composite innovations.

CONCLUSION

The study's findings demonstrate that drug-resin complexes not only successfully conceal the unpleasant flavour of FAM but also improve bioavailability as evidenced by higher plasma concentrations up to 24 hours compared to the marketed preparation. The procedure for complexation using Ion-exchange resin is simple cost-effective methods, resulting in a tablet formulation that improves patient compliance and simplifies medication administration.

Conflict of Interest

Authors declares no conflict of interest.

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