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FORMULATION AND EVALUATION OF FAST DISSOLVING ORAL FILMS OF GRANISETRON

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ABSTRACT

The present study aimed to formulate and evaluate fast dissolving oral films (FDOFs) of Granisetron to improve patient compliance and provide rapid drug release for the effective management of nausea and vomiting. Granisetron oral films were prepared by the solvent casting method using hydroxypropyl methylcellulose and methyl cellulose as film-forming polymers. Six formulations (F1–F6) were developed with varying polymer concentrations and evaluated for physicochemical properties including weight variation, thickness, folding endurance, surface pH, drug content uniformity, disintegration time, and in-vitro drug release. Drug–excipient compatibility was assessed using Fourier Transform Infrared Spectroscopy (FTIR). Stability studies of the optimized formulation were conducted for three months. FTIR studies confirmed the compatibility of Granisetron with the selected excipients, showing no significant drug–excipient interaction. The prepared films exhibited satisfactory physicochemical characteristics with weight variation ranging from 214.69 ± 0.45 to 216.50 ± 0.10 mg, thickness from 0.24 ± 0.1 to 0.26 ± 0.3 mm, folding endurance from 200 ± 4 to 248 ± 3 folds, surface pH from 6.45 ± 0.05 to 6.75 ± 0.03, and drug content from 95.10% to 98.70%. All formulations disintegrated rapidly within 49–52 s. In-vitro dissolution studies demonstrated rapid drug release, with formulation F4 showing the highest cumulative release of 99.75 ± 3.10% within 10 min. Stability studies revealed no significant changes in drug content, disintegration time, folding endurance, or drug release after three months of storage. The developed Granisetron fast dissolving oral films exhibited excellent physicochemical properties, rapid disintegration, and efficient drug release. Among all formulations, F4 was identified as the optimized formulation owing to its superior mechanical properties, highest drug content, fastest disintegration, and maximum drug release. The study demonstrates the potential of fast dissolving oral films as an effective and patient-friendly delivery system for Granisetron.

KEYWORDS: Granisetron, HPMC, MC, Oral film, Solvent Casting etc.

INTRODUCTION

Oral dosage forms are popular because they are easy to use, convenient for patients, require minimal cleanliness, and can be designed in various ways. However, they can be challenging for certain groups like the geriatric, pediatric, people with swallowing difficulties, and even animals. These systems allow the drug to dissolve quickly in the mouth without needing water, enabling faster absorption into the blood stream and bypassing the liver's first-pass metabolism.

FDOFs should be thin, flexible, stable during manufacturing, packaging, and transport. They need to taste good, feel pleasant in the mouth, and dissolve quickly (within 1 minute).[1] Fast-dissolving medication delivery systems are getting a lot of attention as a solution to these problems. In recent years, oral film strips have become popular as a brand new method of breath freshening. These wafers, which resemble gel, disintegrate swiftly in the mouth to release flavor. Many pharmaceutical corporations have been diverted by recent technical breakthroughs to investigate new possibilities in this technology to give quick, accurate dosing that is anticipated to grow compliance, especially among young people. Transmucosal methods of drug administration have developed significantly in recent years because they have the potential to solve issues related to oral medication administration. The dose of medicine is swallowed after melting without the use of water or measurement. Because the mouth mucosa is highly vascularized and hence extremely permeable, absorbing drugs through it into the systemic circulation is a desirable strategy. As a result, fast-dissolving films have gained popularity as an oral dosage form for many medications since they offer quick disintegration due to their huge surface area.[2,3] Pharmaceutical technologists created a number of mouth-dissolving drug delivery devices to meet these medicinal needs. These films typically dissolve in water at ambient temperature, disintegrate in 30 s, and vanish in a minute. The drug's absorption and beginning of therapeutic impact occur more quickly the faster it dissolves in the solution. Further more, FDOFSs represent a dynamic field of research and development within the pharmaceutical industry. Ongoing investigations explore novel materials, formulation techniques, and drug delivery strategies to expand the scope of FDOFS applications and enhance their performance. In conclusion, FDOFSs have emerged as a valuable asset in contemporary pharmaceutical research, offering innovative solutions to critical challenges related to patient adherence, drug bioavailability, and personalized medicine.[4]

MATERIALS AND METHODS

Materials

Granisetron was received as a gift sample from SM Pharma, Mumbai., India. All other materials used was of analytical grade and procured from commercial sources.

Methods

Formulation of Fast Dissolving Oral Film of Granisetron

The required quantity of HPMC or Methyl cellulose was dissolved in distilled water with continuous heating and stirring until a clear and uniform polymeric solution was obtained. Separately, the drug granisetron, polyethylene glycol, and citric acid were dissolved in a isopropyl alcohol to prepare a homogeneous drug solution. The prepared API solution was then added gradually into the polymeric base under continuous stirring to ensure uniform mixing and distribution of the drug throughout the formulation. The resulting mixture was subjected to sonication or allowed to stand undisturbed for some time to remove entrapped air bubbles and obtain a bubble-free casting solution. The final solution was poured carefully onto a flat surface petri plate and dried in a hot air oven until complete evaporation of the

solvent occurred, resulting in the formation of a uniform film. After drying, the film was carefully peeled off and cut into specific shapes and dimensions as required for further evaluation studies. The composition re shown in table 1.[5,6]

Table 1: Formulation of Fast Dissolving Oral Film of Granisetron.

Ingredient	F1	F2	F3	F4	F5	F6
Granisetron (mg)	1	1	1	1	1	1
HPMC (mg)	300	-	150	100	200	175
Methyl Cellulose (mg)	-	300	150	200	100	125
Citric Acid (mg)	10	10	10	10	10	10
Saccharin Sodium (mg)	10	10	10	10	10	10
PEG-600 (ml)	1.5	1.5	1.5	1.5	1.5	1.5
Sodium Starch Glycolate (mg)	2	2	2	2	2	2
Iso-Propyl Alcohol (ml)	10	10	10	10	10	10
Distilled Water (ml)	10	10	10	10	10	10

Evaluation Fast Dissolving Oral Film

Drug–Excipient Compatibility Studies

Drug–excipient compatibility studies were carried out using Fourier Transform Infrared Spectroscopy (FTIR) to identify any possible interaction between Granisetron and the selected excipients. The spectra of the pure drug and physical mixtures were compared for characteristic peaks. The absence of significant changes in peak positions confirmed the compatibility of the drug with formulation excipients.

Weight Variation

Weight variation of oral dissolving films was determined by individually weighing randomly selected films using an analytical balance. The average weight and standard deviation were calculated to assess formulation uniformity.

Uniform weight indicated proper distribution of drug and excipients throughout the films.[7]

Thickness of Films

The thickness of films was measured at different points using a micrometer screw gauge, and the average thickness was calculated. Uniform thickness ensured dose accuracy and consistent mechanical properties of the films.

Folding Endurance

Folding endurance was evaluated by repeatedly folding the film at the same position until it broke. The number of folds required to break the film was recorded, indicating the flexibility and mechanical strength of the formulation.[8]

Drug Content Uniformity

Drug content uniformity was determined by dissolving a specified area of film in phosphate buffer pH 6.8, followed by filtration and suitable dilution. The drug content was analyzed spectrophotometrically to ensure uniform distribution of the drug within the films.[9]

Surface pH

Surface pH of the films was measured by moistening the film surface with distilled water and placing the pH electrode in contact with the hydrated film. The average pH value was recorded to evaluate the compatibility of the formulation with the oral mucosa.

In Vitro Disintegration Study

In vitro disintegration time is a critical evaluation parameter for oral dissolving films, as it indicates the time required for the film to break down when exposed to an aqueous medium simulating saliva. In this study, the disintegration time was determined by immersing the film in 25 mL of distilled water placed in a beaker. The beaker was gently shaken and the time at which the film started to crack, swell, or completely disintegrate was observed visually and recorded using a stopwatch. Each formulation was tested in triplicate, and the mean value was calculated to obtain the final disintegration time. A shorter disintegration time indicates rapid film breakdown and faster drug release, which is desirable for immediate therapeutic action. Conversely, longer disintegration time may suggest stronger film structure or higher polymer concentration.[10,11]

In-Vitro Dissolution Study

The in vitro dissolution study of granisetron oral dissolving films was carried out using a USP dissolution test apparatus Type II (paddle method). The dissolution medium consisted of 900 mL of phosphate buffer pH 6.8, maintained at 37 ± 0.5°C and stirred at 50 rpm. A film equivalent to a known amount of granisetron was placed in the dissolution vessel, and the study was initiated under controlled conditions. At predetermined time intervals, 1 mL aliquots of the dissolution medium were withdrawn and immediately replaced with an equal volume of fresh pre-warmed phosphate buffer (pH 6.8) to maintain sink conditions and constant volume throughout the experiment. The withdrawn samples were filtered through Whatman filter paper to remove any undissolved polymeric material. The filtered samples were suitably diluted, and the concentration of granisetron was determined spectrophotometrically at 302 nm using a UV-Visible spectrophotometer. Phosphate buffer (pH 6.8) was used as blank for calibration.[12,13]

Stability Study

Stability studies of the optimized fast dissolving oral films were carried out according to ICH guidelines to evaluate the physicochemical stability of the formulations under different storage conditions. The films were packed in suitable airtight containers or aluminum foil packs and stored at refrigerated conditions (4 ± 2 °C), room temperature (25 ± 2 °C/60 ± 5% RH), and accelerated conditions (40 ± 2 °C/75 ± 5% RH). Samples were analysed at predetermined time intervals for parameters such as physical appearance, folding endurance, disintegration time, drug content, and in vitro drug release. All evaluations were performed in triplicate, and the results were compared with initial values to assess the stability of the formulations during the study period.[14]

RESULTS AND DISCUSSION

Drug–Excipient Compatibility Studies

The FTIR spectrum of the pure drug exhibited distinct and well-defined characteristic peaks corresponding to its functional groups. A prominent absorption band observed around 3114 cm^{-1} was attributed to N–H stretching vibrations, indicating the presence of amine or amide groups. The peak near 2940 cm^{-1} corresponds to aliphatic C–H stretching. A strong and sharp peak in the region of 1660–1600 cm^{-1} is indicative of C=O stretching, which is a key functional group responsible for the drug's pharmacological activity. Additionally, peaks observed in the fingerprint region (1300–1000 cm^{-1}) were assigned to C–N stretching and S=O vibrations, further confirming the identity and purity of the drug. In the spectra of the physical mixture and formulations containing hydrophilic polymers such as HPMC and methyl cellulose, all the major characteristic peaks of the drug were retained. This indicates that the fundamental chemical structure of the drug remained intact after formulation. Importantly, no

new peaks were observed in the spectra of the formulations, and no significant disappearance of characteristic peaks of the drug was noted. This confirms that no chemical degradation or interaction occurred during the formulation process. The FTIR analysis clearly demonstrates the compatibility of the drug with the selected excipients.

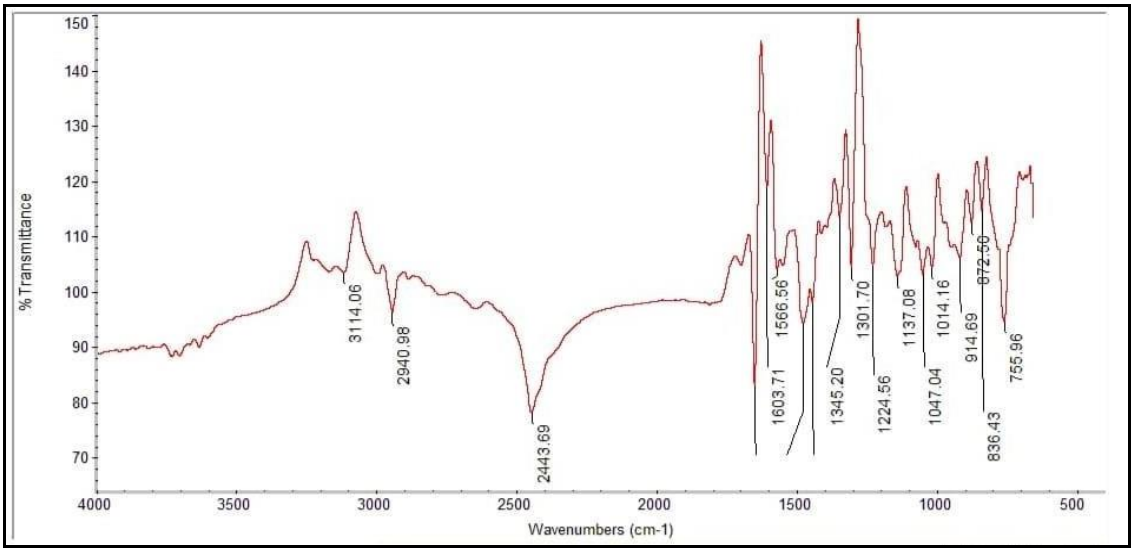

Figure 1: FTIR Spectra of Pure Drug Granisetron.

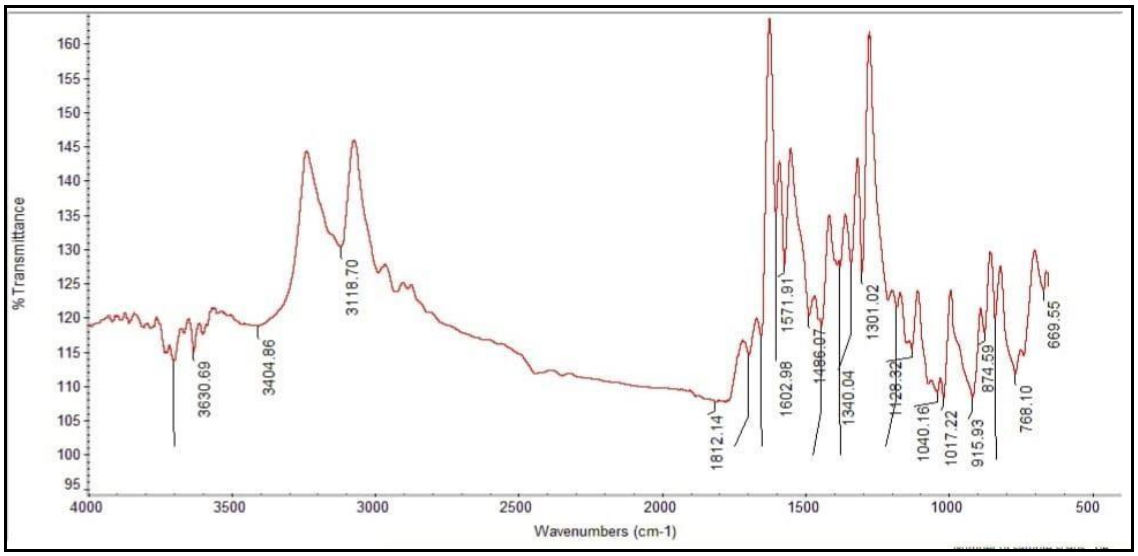

Figure 2: FTIR Spectra of Granisetron with HPMC and Methyl Cellulose.

Weight Variation

The weight variation study of oral films (F1–F6) demonstrated a high degree of uniformity across all formulations, with mean weights ranging from 214.69 mg to 216.50 mg, reflecting effective control over the solvent casting process and uniform distribution of drug and excipients within the film matrix. The slight differences in average weight among formulations may be attributed to variations in polymer concentration, plasticizer content, or solution viscosity, which can influence film thickness. The results confirm that all formulations possess satisfactory weight uniformity, ensuring consistent dose distribution per film strip.

Thickness

The thickness of oral films (F1–F6) was evaluated as an indicator of film uniformity, which influences drug content, mechanical strength, and disintegration behavior. The thickness values ranged from 0.24 ± 0.1 mm to 0.26 ± 0.3 mm, indicating minimal variation among formulations. F2 and F6 exhibited the lowest thickness values with the least variability, while F1 and F5 showed slightly higher variations. These differences may be attributed to variations in polymer concentration, solution viscosity, and plasticizer content. All formulations demonstrated satisfactory thickness uniformity, suggesting consistent film formation and reproducible manufacturing conditions.

Folding Endurance

Folding endurance was assessed to evaluate the flexibility and mechanical strength of the oral films. The values ranged from 200 ± 4 to 248 ± 3 folds, indicating good mechanical resistance in all formulations. F4 exhibited the highest folding endurance (248 ± 3 folds), followed by F6 (244 ± 4 folds) and F5 (241 ± 7 folds), suggesting superior flexibility and structural integrity. In contrast, F1 showed the lowest value (200 ± 4 folds), although it remained within acceptable limits. The observed variations may be due to differences in polymer and plasticizer concentrations. All formulations possessed adequate flexibility and mechanical strength to withstand handling and administration without damage.

Drug Content Uniformity

Drug content uniformity of oral films (F1–F6) was evaluated to ensure uniform drug distribution and accurate dose delivery. The drug content ranged from 95.10% to 98.70%, indicating satisfactory incorporation of the drug within all formulations. Formulation F4 exhibited the highest drug content (98.70%), followed by F6 (98.40%) and F5 (98.20%), reflecting excellent content uniformity. Although F1 and F2 showed comparatively lower values, all formulations complied with acceptable pharmacopeial limits. The results confirm uniform drug distribution and suitability of the prepared films for consistent therapeutic performance.

Surface pH

The surface pH of formulations F1–F6 was determined to evaluate their compatibility with the oral mucosa. The surface pH values ranged from 6.45 ± 0.05 to 6.75 ± 0.03, which are close to the physiological pH of saliva. F1 exhibited the lowest pH (6.45 ± 0.05), whereas F6 showed the highest value (6.75 ± 0.03). The minor variations observed may be attributed to differences in polymer composition. All formulations exhibited acceptable surface pH values, suggesting a low risk of mucosal irritation and suitability for oral administration.

Disintegration Time

Disintegration time was assessed to determine the rate of film breakdown in the oral cavity. All formulations showed rapid disintegration, with values ranging from 49 ± 2 to 52 ± 2 seconds. Formulation F4 exhibited the shortest disintegration time (49 ± 2 s), indicating efficient hydration and film erosion, while F1 and F3 showed slightly longer disintegration times (52 ± 2 s). The narrow range of values reflects uniform formulation characteristics and effective film design. These findings demonstrate that all formulations satisfy the requirement for rapid disintegration, supporting prompt drug release and enhanced patient compliance.

Table 2: Evaluation Studies of Fast Dissolving Oral Film of Granisetron.

Batch Tests	Folding Endurance	Thickness (mm)	Weight Variation (mg)	Disintegration (Sec)	Surface PH	Drug Content %
F1	200 ± 4	0.24 ± 0.1	214.69 ± 0.45	52 ± 2	6.45±0.05	95.10
F2	220 ±6	0.26 ± 0.3	216.50 ± 0.10	50 ± 1	6.52±0.04	95.80
F3	235 ± 4	0.24 ± 0.1	215.20 ± 0.25	52 ± 2	6.60±0.03	97.23
F4	248 ± 3	0.25 ± 0.2	216.15 ± 0.15	49 ± 2	6.72±0.05	98.70
F5	241 ± 7	0.24 ± 0.2	215.40 ± 0.30	51 ± 1	6.68±0.04	98.20
F6	244 ± 4	0.25 ± 0.3	215.30 ± 0.25	50 ± 1	6.75±0.03	98.40

Value are SD ± n=3

In-Vitro Dissolution Study

The in-vitro dissolution profiles of Granisetron fast dissolving oral films (F1–F6) demonstrated rapid drug release from all formulations. At 1 min, drug release ranged from 20.47 ± 1.38% (F6) to 35.14 ± 1.20% (F4). A progressive increase in drug release was observed with time, with all formulations releasing more than 90% of the drug within 10 min.

Formulation F4 exhibited the highest cumulative drug release (99.75 ± 3.10%), followed by F1 (98.60 ± 2.45%) and F3 (97.28 ± 2.15%), while F6 showed the lowest release (90.58 ± 2.34%). These findings indicate the rapid dissolution characteristics of the prepared oral films. The drug release profile was influenced by the type and ratio of film-forming polymers. Formulation F4, containing 100 mg HPMC and 200 mg methyl cellulose, showed the highest drug release, which may be attributed to improved hydration, wettability, and rapid erosion of the film matrix. Formulations containing a single polymer (F1 and F2) exhibited slightly lower drug release, whereas formulations with less optimal polymer ratios (F5 and F6) showed comparatively slower dissolution. The presence of sodium starch glycolate further promoted rapid film disintegration and drug release. Overall, F4 demonstrated the most desirable dissolution profile, correlating with its rapid disintegration time and satisfactory physicochemical properties, and was therefore selected as the optimized formulation. The in vitro drug release for all batches of granisetron oral film was shown in figure 3.

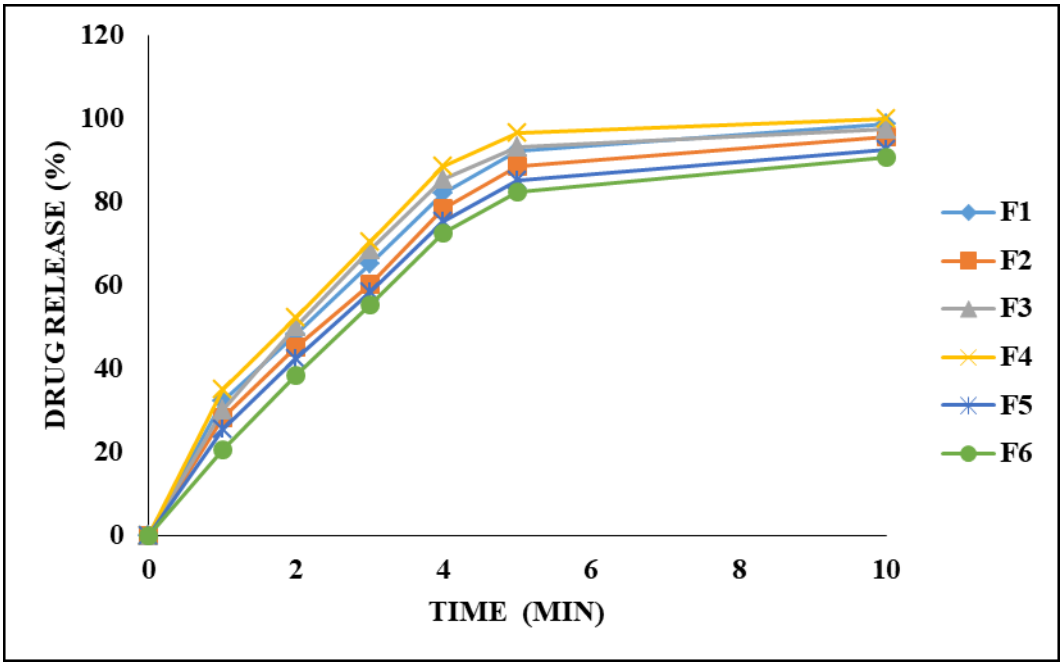

Figure 3: Comparative In-Vitro Dissolution Profile Of Granisetron Oral Film.

Stability Study

The optimized formulation (F4) demonstrated good stability over a three-month storage period, with only minor changes in its physicochemical properties. Folding endurance decreased slightly from 248 ± 3 to 242 ± 6, while disintegration time remained nearly unchanged (49 ± 2 to 50 ± 6 s). Drug content showed a marginal reduction from 98.70% to 97.80%, and drug release decreased from 99.75 ± 3.10% to 98.45 ± 4.25%, both remaining within acceptable limits. These findings indicate that the F4 formulation maintained its mechanical integrity, rapid disintegration, and drug release characteristics, confirming its satisfactory stability during storage.

CONCLUSION

Granisetron fast dissolving oral films were successfully formulated using HPMC and methyl cellulose by the solvent casting method. FTIR studies confirmed the compatibility of the drug with all selected excipients, indicating the absence of any significant drug–excipient interactions. All formulations exhibited satisfactory physicochemical characteristics, including acceptable weight variation, thickness, folding endurance, surface pH, drug content uniformity, and rapid disintegration. Among the developed formulations, F4 demonstrated the most desirable performance, exhibiting the highest folding endurance (248 ± 3 folds), highest drug content (98.70%), shortest disintegration time (49 ± 2 s), and maximum drug release (99.75 ± 3.10% within 10 min). The enhanced performance of F4 may be attributed to the optimized ratio of HPMC and methyl cellulose, which provided improved hydration, wettability, and rapid erosion of the film matrix. Furthermore, the optimized formulation remained stable during the three-month stability study, with no significant changes in physicochemical properties or drug release characteristics.

Therefore, formulation F4 can be considered a promising oral drug delivery system for Granisetron, offering rapid onset of action, improved patient convenience, and enhanced compliance, particularly for patients experiencing nausea and vomiting.

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