

Development and Characterization of Fast Dissolving Oral Films of Orciprenaline Sulphate

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ABSTRACT

Introduction: From past few decades there has been a massive change in designing various drug delivery systems to achieve rapid onset of action to treat sudden surprising disorders like hypertensive reactions. Fast dissolving oral films enhance the efficacy of APIs by dissolving within a minute in oral cavity after the contact with less saliva without chewing and need of water for administration. Orciprenaline Sulfate belongs to the category of bronchodilators, beta-adrenergic agonist. It is very essential that the drug is released rapidly and hence fast dissolving oral films were designed. **Objective:** Present study was undertaken with a view of enhancing the bioavailability and to achieve a rapid onset of action as well as to provide better patient compliance especially in pediatric and geriatric patients. **Method:** The accurately weighed quantity of polymers was kept for soaking overnight in a beaker containing 10 ml of distilled water. The polymeric solution was then stirred for 2 hrs on a magnetic stirrer; Propylene glycol was used as the plasticizer in the concentration of 10%w/w of the polymer concentration. In another beaker weighed quantities of citric acid & sodium saccharine were added and dissolved in sufficient quantity of distilled water and was stirred for another 30 min on a magnetic stirrer. Then the polymeric solution and the drug solution with other excipients was mixed together to get a homogenous solution. Further the solution was casted on the glycerine lubricated petridish and was kept for swelting in an oven at 70°C. **Results:** The surface pH of all the formulations F1 to F8 was found to be neutral in the range of 6.47- 6.82 concluding that films might not cause any potential irritation to the mucosa. All the films showed good disintegration time. Formulation F1 showed the least disintegration time compared to other films. The percentage drug content of all the formulations was found to be in the acceptable range of 94.3-97.9 percent. *In vitro* drug release study showed that all the films released more than 70 percent of drug within 15 min. From all the formulations F1 containing HPMC E15 as the film forming polymer showed the highest and the best drug release of 98.4 percent within 15 minutes. **Conclusion:** The results obtained after formulation oral fast dissolving films of Orciprenaline sulfate clearly indicate that it has improved bioavailability and rapid release rate. The formulation is tested for stability and the results are positive hence the formulation is stable.

Key words: Orciprenaline sulphate, HPMC E15, HPMC E50, Fast-dissolving oral films, drug permeated.

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INTRODUCTION

Orciprenaline Sulphate is a beta adrenergic agonist (bronchodilator) used in treatment of asthma. This drug is known to undergo high first pass metabolism leading to low bioavailability. Formulation of fast dissolving film of Orciprenaline sulfate has been done with a view of enhancing bioavailability of the drug in order to provide quick onset of action & to overcome related drawbacks.

For the past few decades there has been a massive change in designing various drug delivery systems to achieve rapid onset of action in order to treat sudden appearing disorders like hypertensive reactions. Fast dissolving films enhance the efficacy of active pharmaceutical ingredients by dissolving in the oral cavity within a minute after the contact with saliva. The



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crucial factor is bioavailability of the active ingredient that significantly increases as compared to the conventional tablet dosage forms bypassing first pass metabolism. It also resists the friable nature when compared to dispersible tablets. Orciprenaline Sulfate belongs to the category of bronchodilators, beta-adrenergic agonist. It is freely soluble in water and is exclusively used in the treatment of bronchospasm. It undergoes high first pass metabolism. It has a half life of 6 h having bioavailability of 40% (orally) and 3% (inhaled). Present study was undertaken with a view of enhancing the bioavailability and to achieve a rapid onset of action as well as to provide better patient compliance especially in pediatric and geriatric patients.

Materials

Orciprenaline Sulfate was obtained as a gift sample from Zydus Healthcare Goa. HPMC E15 and HPMC E50 were also procured as gift samples from Colorcon Pvt. Ltd., Verna Goa. Propylene glycol was obtained as a gift sample from SD Fine Chemicals Pvt. Ltd. Mumbai. All chemicals and reagents were of analytical and pharmaceutical grade.

METHODS

Formulation of Orciprenaline sulfate loaded oral films²⁻¹⁵

The accurately weighed quantities of polymers were kept for soaking overnight in a beaker containing 10ml of distilled water. The polymeric solution was then stirred for 2 hr on a magnetic stirrer to obtain a homogenous solution. Propylene glycol was used as the plasticizer in the concentration of 10%w/w of the polymer concentration. It was added to the polymeric solution with continuous stirring. In another beaker, weighed quantities of citric acid & sodium saccharine were added and dissolved in sufficient quantity of distilled water. The above mixture was stirred for 30 m on a magnetic stirrer. The polymeric solution and the drug solution with other excipients were mixed together to get a homogenous solution.

The solution was then continuously stirred for 4 hr. After mixing of solution, it was set aside for removal of air bubbles and further the solution was casted on the glycerine lubricated petridish and was kept for drying in an oven at 70°. The films were carefully removed after drying and cut into 2 × 2 cm² size. Films with any sort of imperfections or defects were ward off from further evaluation. The good quality samples of films

were wrapped in a butter paper followed by aluminium foil and stored properly until used.

Evaluation of fast dissolving oral films³⁻⁷

Physical appearance and surface morphology

This parameter was investigated by visual inspection of films and by scanning electron microscopy. The samples were mounted on SEM sample slab using a double-sided adhesive tape. The samples mounted were coated with gold (200Å) under reduced pressure (0.001 Torr) for 5 min to improve the conductivity using an Ion sputtering device (JEOL, JFC-1100E, and Japan).

Weight of the film¹

The weight of the film was measured by cutting 2×2cm² size of the film at 3 different places from the casted film and was weighed on analytical balance and average weight was calculated.

Thickness of the film

Vernier Calliper was used to measure the thickness of the film. The thickness was measured at three different spots of the film and average was taken and standard deviation was calculated. This is necessary to ascertain uniformity in the thickness of the film as this is directly related to the accuracy of dose in the films.

Folding endurance of the film^{6,8,11}

Folding endurance was determined by repeatedly folding the film (2×2cm²) at the same place until the film breaks. The number of the times the film is folded without breaking was computed as the folding endurance value.

Surface pH^{6,9,10}

The surface pH of fast dissolving film was determined in order to investigate the possibility of any side effect *in vivo*. As an acidic or alkaline pH may cause irritation of the oral mucosa, the films were made slightly wet with the help of water. The pH was measured by bringing the electrode in contact with the surface of the film. The method was performed in triplicate and the average with standard deviation was reported.

Swelling Index

The prepared film sample was weighed and placed on a pre-weighed stainless steel wire mesh. The wire mesh was then submerged in a Petri dish containing 20 ml distilled water. Increase in weight of the film was determined at regular time intervals until a constant weight was obtained and was calculated as difference between the final weight and the initial weight of the film divided by the initial weight.

Tensile strength

Tensile strength is the ability of the film to withstand a pulling force. It is calculated by the applied load at rupture divided by the cross-section area of the film in g/cm². The film was held between two clamps wherein the upper clamp was fixed and the lower is variable. The force of tearing and elongation was determined.

Percentage elongation

Percentage elongation is the maximum stress applied to a point at which the film specimen breaks. It is calculated by increase in the length of the film divided by the original length of the film.

Drug content of films

The films of 2×2cm² from three different places from the casted films were taken and individually dissolved in a beaker containing 50 ml of phosphate buffer pH 6.8 using magnetic stirrer. *Whatman* filter paper was used to filter the solution and was later diluted. After suitable dilutions absorbance was measured at 279 nm and the drug content was estimated from calibration curve.

In vitro disintegration study⁹

In vitro disintegration time was determined visually in the petridish containing 20ml of phosphate buffer having pH 6.8 with swirling every 10 sec. The disintegration time is the time when the film starts to dissolve. Disintegration time provides an indication about the disintegration characteristics and dissolution characteristics of the film. Time taken by the film to disintegrate was measured as *in vitro* disintegration time.

In vitro dissolution study¹²

In vitro drug release studies of Orciprenaline Sulphate fast dissolving oral films were conducted using USP type I (basket type) dissolution test apparatus containing 300ml of phosphate buffer having pH 6.8 as dissolution medium. The stirrer speed was adjusted to rotate at 50 rpm. The temperature of dissolution medium was maintained at 37±0.5° throughout the experiment. The film specimens were placed in a steel basket made up of wire mesh. The film sample in the basket was immersed into the dissolution medium. Samples (1ml) were withdrawn at time intervals of 0.30,1,2,4,8,10,12,15 min respectively and replaced the same with fresh dissolution medium to maintain a constant volume after each sampling. The withdrawn samples were filtered through *Whatman* filter paper and were analysed spectro-photometrically at 279 nm using UV-visible spectro-photometer.

Ex vivo permeation study^{9,10}

Ex vivo permeation studies were carried out using porcine mucosa using modified *Franz* diffusion cell. The diffusion cell consists of donor compartment and receptor compartment, water jacket and sampling port. The receptor compartment of diffusion cell was filled with phosphate buffer pH 6.8 (40 ml). Small magnetic bead was placed in the receptor compartment for agitating the buffer solution. Porcine oral mucosa was used as the model membrane. The mucosa was mounted between the donor & receptor compartments. Formulated optimized film having dimension 2×2cm² was placed over the porcine oral mucosal membrane. The donor compartment was then positioned and fixed over it with the help of clamps. The donor compartment was filled with 1ml of phosphate buffer of pH 6.8. The whole assembly was placed on a magnetic stirrer and the solution in the receptor compartment was continuously stirred. The temperature was maintained at 37 ± 2°. Samples of 1ml were withdrawn at suitable time interval of 2,4,6,8,10,15,20,30,40,50 and 60 minutes and were analyzed at 279 nm spectro-photometrically by using UV-visible spectrophotome Results of *ex vivo* studies of optimized formulation F2 is shown in Figure 3.

Stability study

Stability studies are essential component allowing the evaluation of active pharmaceutical ingredient stability under the influence of a range of environmental factors such as temperature, humidity and light.

Procedure

Stability study was carried out at two different storage conditions.

Normal room conditions 25°±2°/60% RH ± 5% and Accelerated conditions 40°±2°/75% ± 5% RH for 60 days using stability chamber. Each piece of films of optimized formulation was packed in butter paper followed by aluminium foil. The films were evaluated for drug content, disintegration time and *in vitro* drug release after storage for 30 and 60 days. The values for *in vitro* release from the films were calculated and were compared for change in dissolution profile

RESULTS

Evaluation Parameters of prepared fast dissolving oral films

In the current study eight formulations of fast dissolving oral films of Orciprenaline Sulfate were formulated using HPMC E15 and HPMC E50 as film forming polymers. All the prepared films exhibited good physical appearance and homogeneity without any flaws or imperfections. The weight and thickness of all the films

were found to be uniform showing that increase in polymer concentration increases the weight and thickness of the films. The results of weight and thickness were shown in Surface morphology of optimized patch is shown in Figure 5.

Folding endurance

The folding endurance of the film was found to increase with the increase in the concentration of polymer. The values of folding endurance for all the formulations were shown in Table 2.

Surface pH

Surface pH of all the films were found to be close to the neutral pH indicating that there might be less probability that the films will cause an irritation to the oral mucosa thus promoting patient acceptance. The results were shown in Table 2.

Swelling index

The measurement of swelling index indicated that maximum swelling takes place in the formulations containing higher proportions of polymer HPMC E15 and HPMC E50. Swelling index affects the release of the drug. Higher the percentage of swelling less the drugs release. The swelling index of all the formulations was shown in Table 3.

In vitro disintegration time

All the formulations showed satisfactory disintegration time. The disintegration time for formulation F1 was the least whereas F8 showed maximum disintegration time. Evaluation of disintegration time showed that disintegration time increases with the increase in the polymer concentration. The results were shown in Table 3.

Tensile Strength

Tensile strength of all the formulation was in acceptable range conceding that the films had good flexibility and mechanical strength. The results were shown in Table 3.

Percentage elongation

Percentage elongation also contributes as an important parameter in deciding the physical strength and flexibility of the film. The formulation F4 showed highest elongation among all other films. The results were shown in Table 3.

Drug content

The drug content uniformity test was performed to ensure uniform distribution of drug. The results indicated that drug was uniformly distributed in all the formulations as shown in Table 3.

In vitro Drug release studies

The *in vitro* drug release profiles of all the eight formulations in pH 6.8 phosphate buffer show differences in drug release based on their composition as given in Table 1. It was observed that all the prepared films showed more than 70% of drug release in 15 minutes. Study revealed that that drug release from the films containing HPMC E15 as the polymer was more as compared to those containing HPMC E50. The reason behind higher drug release may be due to the lower viscosity of the HPMC E15 polymer. Rapid drug dissolution was observed in formulations F1, F2, F3 and F5 which released 98.4, 96.7, 83.6 and 83.67 percent respectively, at the end of 15 minutes. The results are depicted in Table 3 and Figure 1 and 2. F1 formulation showed highest drug release of 98.4 percent than other formulations. Slow drug release was observed in F4, F6, F7 and F8 with release of 72.7, 76.9, 77.1 and 10.6 percent respectively, at the end of 15 minutes as shown in Table 3, Figure 1 and 2. From all the prepared formulations, formulation F2 showed acceptable results having good physical and mechanical properties with optimum percent drug content, lesser disintegration time and maximum *in vitro* drug release of 96.79 percent. Therefore formulation F2 containing lower concentration of HPMC E15 as polymer was considered to be optimized formulation and was chosen for further study. The *ex vivo* permeation study was carried out to check the permeability of the drug through the porcine oral mucosa. From the *ex vivo* study it was found that 93.9 percent of drug permeated through the porcine oral mucosa within 60 minutes from the optimized formulation F2. The optimized formulation also showed better drug release 77.1 percent when compared with the marketed formulation. The results were shown in Figure 4.

Stability study

Stability studies were performed on the optimized formulation F2 as per ICH guidelines for 60 days. Optimized formulation showed no major changes and revealed that the optimized formulation was stable both at normal and accelerated conditions.

DISCUSSION

Fast dissolving films of Orciprenaline Sulphate were prepared efficiently by employing solvent casting method. All the prepared films had smooth surface texture, were flexible and had superior physical and mechanical properties. The surface pH of all the formulations F1 to F8 was found to be neutral in the range of 6.47- 6.82

Table 1: The formulation used in preparation of Orciprenaline sulfate fast dissolving films

Formulation Ingredients	Formulation code							
	F1	F2	F3	F4	F5	F6	F7	F8
Orciprenaline Sulfate (mg)	10	10	10	10	10	10	10	10
HPMC E50 (%w/v)	1.5	2.5	3.5	4.5	-----	-----	-----	-----
HPMCE 50 (%w/v)	-----	-----	-----	-----	1.5	2.5	3.5	4.5
Propylene Glycol(%v/w)	10	10	10	10	10	10	10	10
Citric acid (% w/v)	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Sodium Saccharine(%v/v)	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25
Distilled water	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s

qs: quantity sufficient

Table 2: Physicochemical properties of fast dissolving oral films of Orciprenaline sulfate

Formulation code	Weight (mg)*	Thickness (mm)*	Folding endurance*	Surface pH*
F1	58.3±0.05	0.12±0	253±2.64	6.47±0.04
F2	62.5±0.05	0.156±0.05	323±3.78	6.56±0.02
F3	64.2±0.10	0.178±0.002	380±1.52	6.68±0.01
F4	65.1±0.10	0.216±0.005	394±2.64	6.82±0.01
F5	47.6±0.05	0.116±0.005	323±4.02	6.77±0.01
F6	52.2±0.05	0.183±0.11	365±3.51	6.73±0.01
F7	55.1±0.15	0.22±0.010	385±1.5	6.82±0.00
F8	61.2±0.01	0.25±0.011	423±3.05	6.75±0.01

Table 3: Evaluation parameters of fast dissolving oral films of Orciprenaline sulfate

Formulation code	Swelling index*	Disintegration time (sec)*	Tensile strength* (g/cm ²)	Percentage elongation* (%)	Drug content* (%)	Drug release (%)
F1	0.041±0.0006	16.04±0.06	14.1± 1.04	10.4±0.115	97.3±1.0%	98.4
F2	0.056± 0.003	26.01±0.01	47.7±1.10	18.91±0.15	97.9±0.4%	96.79
F3	0.058±0.0030	38.05±0.02	55.5±1.32	24.05±0.11	96.3±0.7%	83.62
F4	0.062±0.0029	52.86±0.24	76.1±1.75	29.41±0.11	94.5±1.2%	72.77
F5	0.043±0.0032	21.02±0.02	17.0±2.00	11.76±0.15	95.8±0.4%	83.67
F6	0.049±0.0019	35.01±0.02	38.6±2.08	25±0.25	96.7±0.9%	76.95
F7	0.055±0.003	57.05±0.03	61.3±1.52	21.05±0.15	96.1±0.3%	77.15
F8	0.065±0.0029	60.1±0.02	85.5±1.32	27.71±0.11	94.3±0.7%	70.63

concluding that films might not cause any potential irritation to the mucosa. All the films showed good disintegration time. Formulation F1 showed the least disintegration time compared to other films. The percentage drug content of all the formulations was found to be in the acceptable range of 94.3-97.9 percent. *In vitro* drug release study showed that all the films released more than 70 percent of drug within 15 minutes. From all the formulations F1 containing HPMC E15 as the film forming polymer showed the highest and the best drug release of 98.4 percent within 15 m.

Formulation F2 was selected as the optimized formulation on the basis of drug content, percent CDR 96.79 percent, Disintegration time and folding endurance.

The optimized formulation also showed better drug release when compared with the marketed formulation of Orciprenaline Sulphate. The *ex vivo* permeation study showed that 93.9 percent of drug permeated through the porcine mucosa within 60 minutes from the optimized formulation F2.

Stability study for two months revealed that the formulations were stable at room temperature as well as in the accelerated stability conditions. From the studies performed it can be concluded that the fast dissolving oral films of Orciprenaline Sulphate has potential in the growing market for its safe, efficient, effective treatment of asthma to offer a quick relief.

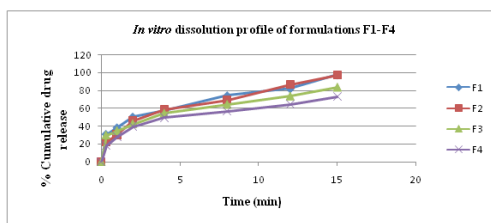


Figure 1: Illustration shows comparative *in vitro* dissolution profile of formulation F1-F4

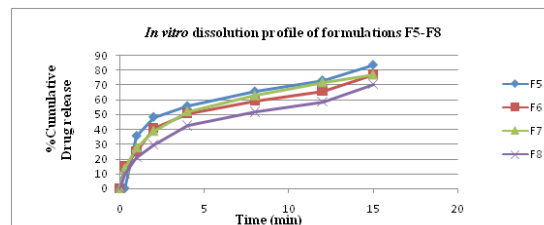


Figure 2: illustration shows comparative *in vitro* dissolution profile of formulation F5-F8

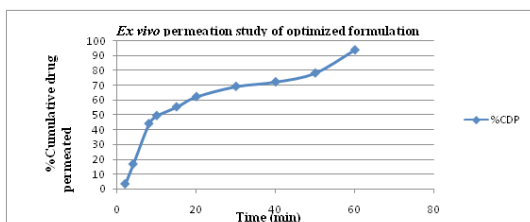


Figure 3: illustration shows *ex vivo* permeation study of optimized formulation F2

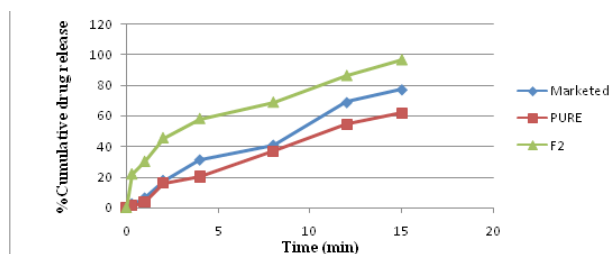


Figure 4: Illustration shows a comparison between *in vitro* drug-release of pure drug, optimized formulation F2 and marketed product.

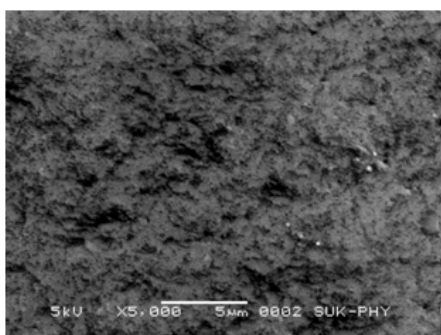


Figure 5: Illustration shows a SEM scanned image of optimized formulation F2.

CONCLUSION

Orciprenaline sulphate is bronchodilator which needs to release immediately allowing rapid distribution in blood. The results obtained after formulation oral fast dissolving films of Orciprenaline sulfate clearly indicate that it has improved bioavailability and rapid release rate. The formulation is tested for stability and the results are positive hence the formulation is stable.

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CONFLICT OF INTEREST

There are no conflict of interests.

ABBREVIATION USED

Rpm: Rotations per minute; μm : Micrometer; % - Percentage; V/v: volume by volume; W/v: weight

by volume; W/w: weight by weight; FT-IR: Fourier Transform Infrared Spectroscopy; UV: Ultraviolet λ_{max} - Maximum Absorbance; DSC: Differential Scanning Colorimeter; RH: Relative humidity; % CDP: Percentage Cumulative Drug Permeated; CLA: Cumulative loss added; PEG: Polyethylene Glycol; R²: Regression coefficients; cP: Centipoises; HPMC: Hydroxy-Propyl-Methyl-Cellulose.

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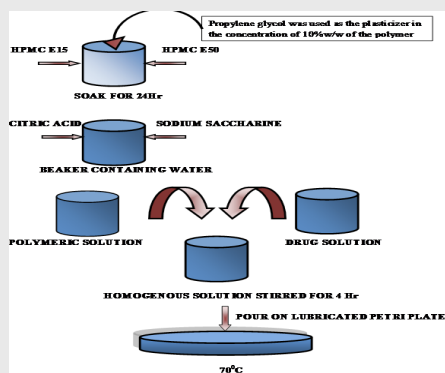
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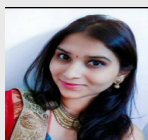
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PICTORIAL ABSTRACT



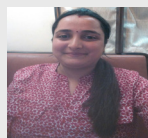
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SUMMARY

- Pre formulation studies were performed to examine the compatibility between drug and polymers. The IR spectra of the drug polymer mixture revealed that the results were found as given in the literature within prescribed limit, there was no interaction between the polymer and drug hence were found compatible.
- Fast dissolving films of Orciprenaline Sulfate were prepared efficiently by employing solvent casting method. All the prepared films had smooth surface texture, were flexible and had superior physical and mechanical properties.
- The surface pH of all the formulations F1 to F8 was found to be neutral in the range of 6.47- 6.82 concluding that films might not cause any potential irritation to the mucosa.
- All the films showed good disintegration time. Formulation F1 showed the least disintegration time compared to other films.
- The percentage drug content of all the formulations was found to be in the acceptable range of 94.3%-97.9%
- In vitro drug release study showed that all the films released more than 70% of drug within 15 minutes. From all the formulations F1 containing HPMC E15 as the film forming polymer showed the highest and the best drug release of 98.4% within 15 minutes.
- Formulation F2 was selected as the optimized formulation on the basis of drug content, %CDR (96.79%), Disintegration time and folding endurance.
- The optimized formulation also showed better drug release when compared with the marketed formulation of Orciprenaline Sulfate.
- The ex vivo permeation study showed that 93.9% of drug permeated through the porcine mucosa within 60 min from the optimized formulation F2.
- Stability study for two months revealed that the formulations were stable at room temperature as well as in the accelerated stability conditions.
- From the studies performed it can be concluded that the fast dissolving oral films of Orciprenaline Sulfate has potential in the growing market for its safe, efficient, effective treatment of asthma to provide a quick relief

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