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Research Article

Formulation Development and Evaluation of Taste-masked Moxifloxacin Dispersible Tablets for the Treatment of Pediatric Tuberculosis

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ABSTRACT

Moxifloxacin (MOX) is a fluoroquinolone antibiotic, a second-line anti-TB drug widely used in the treatment of multidrug-resistant tuberculosis (MDR TB) and drug-susceptible TB. MOX have taste and smell issues with low patient compliance, especially in the pediatric population. MOX taste-masked dispersible tablets were developed by direct compression method using mannitol, aspartame as a sweetening agent and lemon flavor as a flavoring agent. The prepared granules were evaluated for flow properties and compressed tablets for hardness, friability, content uniformity, weight variation, DT and *in-vitro* drug release. Instrumental analysis like FTIR, DSC and XRD was also performed. The flow properties of the granules of batch F6 were found to be excellent based on the results obtained. The weight variation and content uniformity of the tablets was found to be excellent F6 due to the excellent flow properties of the granules. All of the tablets in the study disintegrated between 22 (F6) to 135 seconds (F1), meeting the official requirement (3 minute) for dispersible tablets. The optimized batch showed complete drug release within 10 minutes time period. The FTIR and DSC study found no incompatibility between the drug excipients. The MOX in the final formulation was present in crystalline form, as shown by XRD. The dispersible MOX tablets could be a better option for treating pediatric TB.

INTRODUCTION

Mycobacterium tuberculosis is an infectious disease that causes tuberculosis (TB). Although *M. tuberculosis* can affect other organs (extrapulmonary TB), it mostly affects the lungs (pulmonary TB).^[1] Most people exposed to *M. tuberculosis* (approximately 95%) already have the primary infection and do not go on to acquire active TB disease (at least initially).^[2] Unfortunately, this is not the case in children. Children have immature immune systems compared to adults and cannot mount a sufficient inflammatory response to prevent the development of TB disease.^[3] TB is a serious health problem for children globally, causing an estimated 80,000 deaths in HIV-uninfected children and from 0.5–1 million new cases each year.

Moreover, there is an alarming increase in the number of children with multidrug-resistant (MDR) and extensively drug-resistant (XDR)-TB.^[4] Unfortunately, pediatric TB treatments are still in the early stages of development compared to adult treatments. Children frequently cannot use them easily available oral immediate-release tablets for adults. The pediatric TB treatment instance is a good example of how children are not little adults and require specially customized and evaluated formulations for this market. Before 2009, the doses of anti-TB drugs for children were extrapolated from those used for adults. However, children were under-dosed for decades due to differing drug metabolism, clearance, and distribution rates compared to adults.^[5] Some of the second-line TB drugs can also be given as liquid solutions or in suspension.

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These, however, have their own set of challenges. These are stored in bulky containers. Liquids are often less stable even when refrigerated, taste masking is challenging, storage, packing, and safe transportation are expensive, and for long-term diseases like HIV, caregivers prefer tablet formulations over suspensions.^[6] In such a scenario, the preferred option is in the form of dispersible tablets which can effectively overcome the challenges associated with the existing drug delivery technologies. Dispersible tablets are easy to store, transport, and administer and can efficiently taste-masked in case of bitter drugs.^[7] Apart from all these advantages, these tablets can be developed with different dosing strengths according to the age and weight of the patient. Furthermore, these tablets can be scored, and dosing flexibility can be achieved.^[8] The extensive literature review showed that no marketed formulation is available for second-line anti-TB drug as dispersible tablets. The second-line anti-tuberculosis drugs are only found in a few numbers of chemical classes, and the majority of them have an unpleasant and bitter taste that children, in particular, have a low tolerance. These medications must be successfully taste-masked when administered to children, and they must also have flavors that are appropriate for children. It has been found that less palatable medications have a detrimental influence on children's treatment adherence, which, in the case of TB, might lead to treatment failure and promotes the spread of MDR-TB.^[9] Moxifloxacin (MOX) is a fluoroquinolone antibiotic, a second-line anti-TB drug widely used in the treatment of multidrug-resistant tuberculosis (MDR-TB) and drug-susceptible TB. Fluoroquinolones along with MOX have taste and smell issues with low patient compliance, especially in the pediatric population.^[10]

Considering all these potential drawbacks of the current treatment options, taste-masked dispersible tablets of MOX using flavors and sugars would be the best approach for the efficient treatment of pediatric TB. The taste-masked dispersible tablets of MOX would potentially overcome the challenges associated with the treatment of pediatric TB.

MATERIALS AND METHODS

Materials

Moxifloxacin HCl (MOX) was obtained as gift sample from Macleods Pharmaceuticals Ltd. Mumbai, India. Microcrystalline cellulose (MCC 101) was purchased from Maple Biotech Pvt Ltd., Pune, India, aspartame (Ranbaxy, New Delhi, India). Crospovidone was obtained from Concertina Pharma Pvt., Ltd, Hyderabad, India. Mannitol 100 SD, aspartame and sodium chloride were purchased from signet excipients PVT Ltd. Mumbai, India. Lemon flavor was purchased from Bell flavors and fragrances. Magnesium stearate was purchased from S. D. Fine Chem Ltd., Mumbai India.

Methods

Manufacturing of MOX Dispersible Tablets

MOX dispersible tablets (100 mg) were formulated by direct compression method. The formula composition of all the batches is presented in Table 1. MOX, MCC 101, crospovidone, mannitol 100 SD, sucralose, aspartame and sodium chloride were co-sifted through sieve #40. All these ingredients were properly mixed together in a polybag for 15 minutes. Lemon and peppermint flavor were passed through sieve #40 and blended with previous material for 5 minutes. Magnesium stearate was passed through sieve #80, mixed, and blended with the initial mixture in a polybag. The powder blend was compressed into tablets on a ten-station rotary punch tableting machine (Rimek Mini Press-1) using 8 mm round punch set.

Characterisation of Granules^[11]

Angle of Repose (θ)

For determining the angle of repose, the funnel method was utilized. In the funnel, a weighed quantity of lubricated granules was kept and regulated at a certain height such that the heap of powder just reached the funnel's tip. The heap's diameter was calculated and the following formula was used to calculate the angle of repose:

$$\tan \theta = \frac{h}{r}$$

Where, h = Height of the pile and r = radius of the base

Bulk Density (BD)

Accurately weighed lubricated granules were slowly poured into a measuring cylinder of 50 mL, and the bed was made uniform without disturbing. The volume was measured in milliliters, and the BD was calculated using the formula below:

$$BD = \frac{\text{mass of sample in g}}{\text{volume occupied by sample in mL}}$$

Tapped Density (TD)

Lubricated granules were taken, weighed accurately, and poured in a measuring cylinder placed in a bulk density tester. The initial volume occupied by the sample was noted it was tapped (50-100-250 times) till no change in the volume was observed and noted as tapped volume. TD was determined using the following formula:

$$TD = \frac{\text{Mass of sample in gm}}{\text{tapped volume occupied by sample in mL}}$$

Compressibility Index (CI)

The CI was calculated using the formula below:

$$CI = \frac{TD - BD}{TD} \times 100$$



Table 1: Formula composition of MOX dispersible tablets

Sr. No	Name of ingredient	F1	F2	F3	F4	F5	F6
1	Moxifloxacin	100.0	100.0	100.0	100.0	100.0	100.0
2	Micro crystalline cellulose (MCC 101)	76.5	71.5	66.5	61.5	56.5	51.5
3	Mannitol 100 SD	51.5	51.5	51.5	51.5	51.5	51.5
4	Crospovidone	5.0	10.0	15.0	20.0	25.0	30.0
5	Aspartame	12.5	12.5	12.5	12.5	12.5	12.5
6	Lemon flavor	2.0	2.0	2.0	2.0	2.0	2.0
7	Magnesium stearate	2.5	2.5	2.5	2.5	2.5	2.5
8	Total	250.0	250.0	250.0	250.0	250.0	250.0

Hausner's Ratio (HR)

HR was calculated with the help of below formula:

$$HR = \frac{TD}{BD}$$

Evaluation of Dispersible Tablets^[12]

Thickness and Diameter

For the determination of diameter and thickness, Digital vernier caliper was used. For this test, 10 tablets were randomly selected. The dimensions were calculated in millimeters. The diameter, thickness, and standard deviation were measured.

Hardness

The hardness of the tablets was measured on randomly selected ten tablets using a Stokes Monsanto hardness tester. The average, as well as the standard deviation, was calculated.

Friability

For this test, 20 tablets were chosen at random from individual batches, and the test was run for 100 rotations on an automatic friability. The weight of dedusted tablets was recorded and friability was determined and calculated as the mean of three determinations. The tablets with weight loss of less than 1% were usually deemed to be suitable.

Content Uniformity

A content uniformity test was conducted according to USP protocol on 10 tablets randomly selected from each batch. These tablets were subjected to crushing and kept in a buffer having pH 1.2 for 24 hours to equilibrate. Filtration was done through 0.45 µm filter followed by appropriate dilution to estimate calcium carbonate content with a flame photometer.

Weight Variation

The official procedure was used to calculate the weight variation of each batch. Twenty bilayer tablets were chosen at random and their weights were measured accurately in milligrams. The mean, as well as standard deviations, were determined.

Disintegration test

The test is carried out on six tablets using the disintegration test apparatus. For 900 mL distilled water at 37 ± 0.5°C was used as a disintegration medium and the time taken for complete disintegration of the tablet with no palpable mass remaining in the apparatus was measured in seconds.

In-vitro Release Studies

Dissolution test apparatus (USP type II) was used to determine calcium release, containing pH 7.4 phosphate buffer (900 mL; 37 ± 0.5°C) at 50 rpm for 15 minutes. The samples of 5 mL were taken out at a predetermined time interval (2, 4, 6, 8, 10, 12 and 15 minutes) and replenished with the same amount of freshly prepared buffer to maintain the sink condition. By using 0.45 µm filters the samples were filtered to get clear solutions and MOX content was determined using UV spectroscopy at 240 nm.

FTIR Study

The compatibility of the MOX with other ingredients was determined using FTIR study. The infrared spectra of MOX, MCC 101, mannitol 100 SD, crospovidone, aspartame, lemon flavor, magnesium stearate and optimised formulation was obtained by using an FTIR by the potassium bromide pellet method. The dry samples were mixed separately with potassium bromide in 1:99 proportions and triturated and placed in the sample holder to compress the pellets. The resulting pellets were scanned in the frequency range of 4000–400 cm⁻¹. The spectral analysis was carried out, by standards absorbance range of the functional groups.^[13]

Differential Scanning Calorimetry (DSC) Studies

The DSC analysis of pure MOX and optimised formulation was performed using DSC instrument. Small amount of MOX and crushed formulation (2–3 mg) was accurately balanced in aluminum pan and it was hermetically sealed with the help of crimper. The sample pan and reference pan were kept in DSC analyzer. The sample was heated from ambient temperature 40 to 400°C, with the heating rate of 10°C/min. Inert atmospheres were provided by purging nitrogen gas at 100 mL/min.^[14]

X-ray Diffraction

XRD is a non-invasive technique for characterization of crystalline structures. X-ray Diffraction (XRD): XRD

patterns of pure MOX and optimized formulation were recorded with the following settings: Cu K α radiation with wavelength 1.54 Å, voltage = 45 kV, current = 40 mA. Measurements were made in the 2 θ range of 10 to 80°.^[13]

RESULTS AND DISCUSSION

The flow properties of the lubricated granules were determined and the findings are represented in Table 2. The angle of repose of the granules was observed between 27.114 \pm 0.105 to 35.45 \pm 0.123, BD was ranged from 0.271 \pm 0.011 to 0.501 \pm 0.021 gm/cm³, TD was found between 0.325 \pm 0.023 to 0.517 \pm 0.027. HR was ranged from 1.02 \pm 0.045 to 1.32 \pm 0.023 and CI was found between 2.22 \pm 0.041 to 24.66 \pm 0.025. The granules' flow property is considered excellent if the angle of repose lies between 25–30°.^[15] Based on the granules angle of repose obtained in our batches, the flow of batch F6 was found to be excellent. Also, the higher BD values of the lubricated blend in batches F5 and F6 showed excellent flow properties that directly impacted the HR and CI properties of the lubricated blend. The HR between 1.00 to 1.11 and CI between 0 to 10 indicates the excellent flow properties of the powder.^[16] Overall, the flow properties of the granules (F5 and F6) were excellent as per the compression requirement.

The diameter of the tablets was found 8.02 \pm 0.03 to 8.07 \pm 0.04 mm (Table 3). Considering the round punch of 8mm diameter the observed diameters were highly acceptable. A wide weight variation was observed, ranging from 0.232 \pm 1.06 to 1.345 \pm 1.21%, while content uniformity was varied from 93.37 \pm 1.12 to 100.01 \pm 1.09%. According to the USP limit for uncoated tablets (7.5% for 130–324 mg weight tablet) the weight variation in our batches was found to be within acceptable limit.^[17] Also, the tablet complies with the content uniformity test as per BP if the average content of each individual content is 85 to 115%.^[17] The initial batches F1 to F4 showed greater weight variation and lower content uniformity due to poor flow properties of the granules as discussed in previous section. Due to poor flow properties, there might be greater chances of improper die filling during compression, resulting in higher weight variation. The tablets' weight variation and content uniformity were found excellent in later batches (F5 and F6) due to the excellent flow properties of the granules.

The complete die filling was achieved during the compression that led to lesser weight variation in the tablets and that ultimately resulted in to the excellent content uniformity of the MOX. The hardness of the tablets was found to be 6.14 \pm 0.15 to 9.55 \pm 0.11 kg/cm². The batches manufactured with granules of lower CI and HR showed lesser compressibility, resulting in lower hardness compared to batches manufactured with granules of higher CI and HR.^[18] The disintegration time of tablets is the most crucial factor that needs to be adjusted in the development of fast-dispersible tablets.^[19] All of the tablets in the study disintegrated between 22 to 135 seconds, meeting the official requirement (3 min) for dispersible tablets.

It has been observed that the disintegration time is directly related to the concentration of crospovidone (5 to 30 mg/tab). Because of its high capillary activity and significant hydration with limited tendency for gel formation, crospovidone tablets disintegrate more rapidly. These findings thus imply that utilizing wicking type disintegrants (crospovidone) will shorten disintegration times.^[20] Crospovidone has already been utilised as super disintegrant in dispersible tablets. C. Mallikarjuna Setty *et al.*, developed fast dispersible tablets of aceclofenac using croscarmellose sodium, sodium starch glycolate and crospovidone and they also observed similar results with crospovidone.^[21] chaulang *et al.*, studied the effect of some physical parameters and crospovidone on directly compressed frusemide tablets and observed similar results.^[22]

In-vitro Release Studies

In vitro drug release studies using directly compressible MOX tablets were conducted in phosphate buffer at pH 7.4. As illustrated in Table 4 and Fig. 1, all of the formulation batches demonstrated greater than 80% DR in 15 minutes. Fig. 1 illustrates how crospovidone concentration affects the dissolution profile of the MOX. The outcomes showed that the dissolution values correlated with the disintegration time of the tablets. The dissolution profile in batches F1 to F6 was rapidly enhanced by the increase of crospovidone concentration (5 to 30 mg/tab). This rapid increase in dissolution profile may be caused by the tablets' rapid swelling and disintegration. The capillary action and hydration of crospovidone are high, and there is considerable agglomeration as well as a little tendency

Table 2: Flow properties of the granules

Batch	Angle of repose (θ)	Bulk Density (gm/cm ³)	Tapped Density (gm/cm ³)	Hausner Ratio	CI
F1	35.45 \pm 0.123	0.271 \pm 0.011	0.325 \pm 0.023	1.19 \pm 0.015	16.61 \pm 0.021
F2	32.180 \pm 0.145	0.282 \pm 0.025	0.357 \pm 0.015	1.26 \pm 0.022	21.09 \pm 0.024
F3	31.612 \pm 0.225	0.278 \pm 0.063	0.369 \pm 0.031	1.32 \pm 0.023	24.66 \pm 0.025
F4	33.342 \pm 0.192	0.290 \pm 0.042	0.379 \pm 0.054	1.30 \pm 0.035	23.48 \pm 0.045
F5	27.114 \pm 0.105	0.501 \pm 0.021	0.517 \pm 0.027	1.03 \pm 0.017	3.09 \pm 0.046
F6	30.220 \pm 0.276	0.396 \pm 0.051	0.405 \pm 0.075	1.02 \pm 0.045	2.22 \pm 0.041



Table 3: Post compression parameters of the tablets

Batch	Weight variation (%)	Diameter (mm)	Content uniformity (%)	Hardness (kg/cm ²)	DT (sec)
F1	0.911 ± 1.11	8.03 ± 0.02	93.37 ± 1.12	7.24 ± 0.12	135 ± 5
F2	0.897 ± 1.18	8.02 ± 0.03	94.28 ± 1.65	6.14 ± 0.15	109 ± 4
F3	1.22 ± 1.17	8.04 ± 0.05	94.12 ± 1.52	6.89 ± 0.57	92 ± 3
F4	1.345 ± 1.21	8.07 ± 0.04	95.01 ± 1.21	6.14 ± 0.52	71 ± 6
F5	0.250 ± 1.09	8.03 ± 0.04	99.88 ± 1.61	9.48 ± 0.24	55 ± 5
F6	0.232 ± 1.06	8.04 ± 0.02	100.01 ± 1.09	9.55 ± 0.11	22 ± 3

Table 4: Comparative *in-vitro* MOX release from dispersible tablets

Time (min)	F1	F2	F3	F4	F5	F6
0	0	0	0	0	0	0
2	25	28	30	35	38	40
4	35	42	49	50	53	62
6	49	55	59	62	67	79
8	57	63	70	75	82	92
10	65	71	78	83	87	100
12	72	77	85	92	96	
15	82	86	91	96	100	

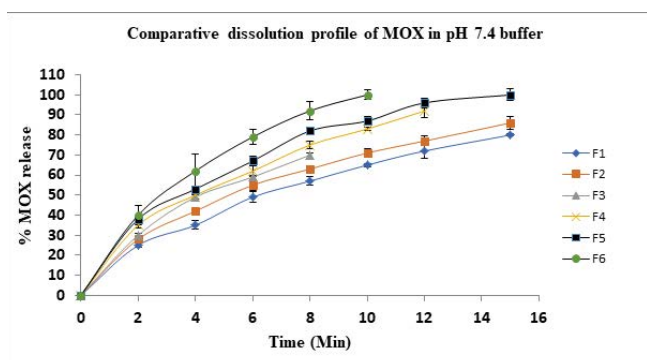
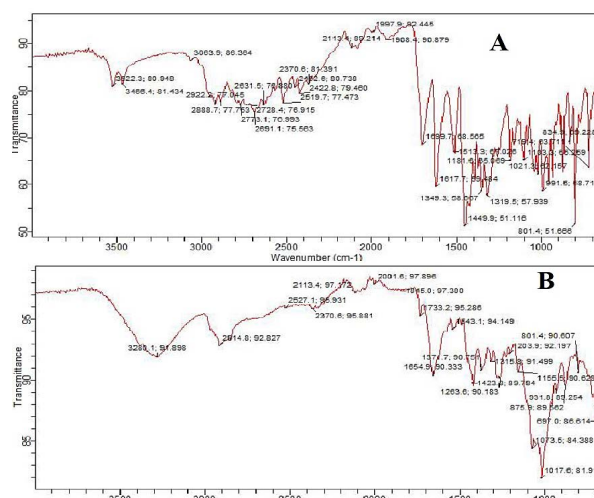
toward gel formation. The tablets dissolve quickly but into bigger masses of aggregated particles.^[20] This rapid release pattern is essential and desirable to get the therapeutic effect in the treatment of TB.

FTIR Study

FTIR spectra of the pure OMX, and optimised formulation F6 are depicted in Fig. 2A and B, respectively. Four characteristic peaks at 3522 cm⁻¹ (secondary N-H stretching), 1699 cm⁻¹ (CO stretching of keto group), 1499 cm⁻¹ (OH bending of COOH) and 1617 cm⁻¹ (CO stretching) were found in FTIR spectra of MOX Hydrochloride (Fig. 2A). Similar characteristic peaks with lower intensity and slight shifting were also observed in IR spectra of F6 formulation (Fig. 2B). This indicates that the characteristic peaks of the drug MOX were retained in the final formulation. Hence, there was no interaction found between the drug and the excipients used in the tablet formulation.

DSC

DSC helps to identify transitions such as melting, glass transition and crystallization during drug development activities. DSC thermograms of the pure MOX and F6 formulation are presented Fig. 3A and B, respectively. MOX exhibited sharp endothermic peak at 255.42°C indicating pure crystalline nature. The DSC thermograph of optimised formulation F6 exhibited an endothermic peak at 168.95°C. Reduction in intensity of MOX endothermic peak suggests increase in amorphous nature of MOX when formulated as dispersible tablets.

**Fig. 1:** Comparative *in vitro* MOX release in pH 7.4 phosphate buffer**Fig. 2:** FTIR spectra of (A): Pure MOX and (B): Optimised formulation F6

X-ray Diffraction

As can be seen from Fig. 4 (A), distinct sharp peaks of MOX were obtained at the diffraction angles 8.44, 10.07, 15.11, and 19.06. Thus, the crystalline nature of pure MOX is evident from its XRD spectrum. The intensity of the crystalline peaks of the pure MOX drug slightly decreased in the optimised formulation as seen in Fig. 4 (B). The high-intensity peaks observed at diffraction angles 28.27, 31.64 might be from other excipients present in the final optimized formulation. These observations clearly demonstrated that the MOX in final formulation was also present in crystalline form.

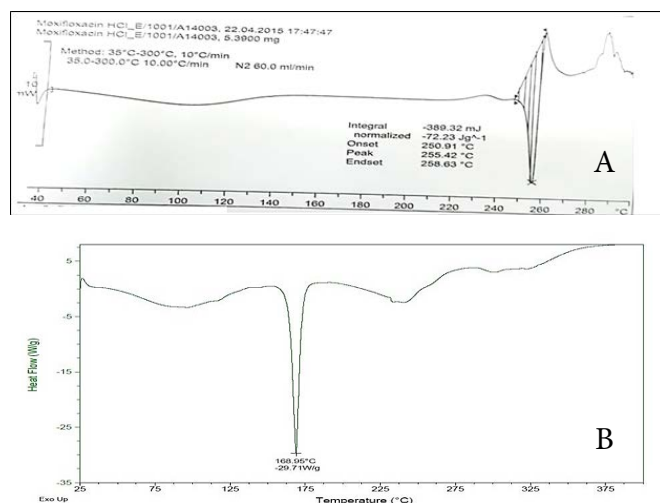


Fig. 3: A: DSC endothermic peak of pure MOX and B: optimised formulation F6

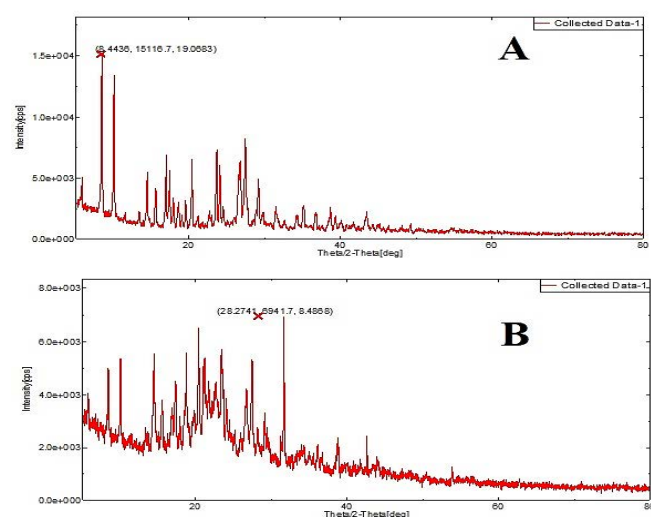


Fig. 4: X ray diffraction pattern of (A): Pure MOX drug and (B): optimised formulation F6

CONCLUSION

It is concluded that, the fast dispersible MOX tablets could be prepared by using crospovidone as super disintegrant and sugar and flavors as taste masking agent. The optimised batch showed excellent flow properties with lesser weight variation and higher content uniformity. The disintegration time was directly related to concentration of crospovidone. The optimised batch showed complete drug release within 10 minutes time period. FTIR and DSC study revealed no drug excipient incompatibility. XRD clearly demonstrated that the MOX in final formulation was present in crystalline form. The dispersible tablets of MOX could be potential alternative for the treatment of pediatric TB.

CONFLICT OF INTEREST

None

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