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Formulation and Evaluation of Tablet using Latex Powder of *Jatropha curcas* as a Natural Binder

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ABSTRACT

Purpose of this work was to evaluate binding efficiency of latex powder of *Jatropha curcas* in tablet dosage form. Tablets of BCS class I and II drugs Propoanolol hydrochloride and Oxcarbazepine respectively were prepared by wet granulation method. Various concentrations of latex powder of *Jatropha curcas* were tried for optimization of binder concentration. Tablets prepared were evaluated for weight variation, content uniformity, hardness, disintegration time, friability and drug release. Also tablet with standard binder Poly Vinyl Pyrolidone was prepared and compared with optimized formulations of natural binder. Tablets were successfully prepared by wet granulation method with all evaluation parameters well within official limits for all concentrations of binder for both the drugs. It has been observed that as concentration of binder increases hardness and disintegration time increases with decrease in friability and drug release. As compared with tablet prepared by standard binder, Poly Vinyl Pyrolidone, our optimized formulations have shown comparable results. The study revealed that latex powder of *Jatropha Curcus* can be used as alternative binder than synthetic binders as it is cost effective and easily available.

INTRODUCTION

Tablet is the greatly favored dosage form in the pharmaceuticals than any others as it is most stable, readily portable and consumed dosage form along with patient compliance. Excipients play a key role in the formulation and development of the tablets. Generally most of the synthetic and semi-synthetic compounds were explored as excipients for pharmaceutical drug development, specifically for solid dosage forms like tablets (Lachman et al, 1986). Binder is one of the major excipients necessary for tablet formulation used for binding between drug and other excipients to make a compact intact and rigid and excipients with these properties can be used as binder in the tablet formulations like polyvinyl pyrolidone, starch paste etc (Rowe et al, 2006). Also many of the natural excipients are emerging as binder in the tablet formulations for example Moringa oleifera (Panda *et al.*, 2008), Mangifera indica (Singh *et al.*, 2010), Trapa bispinosa Roxb. Starch (Singh *et al.*, 2011), Acacia arebica (Mishra *et al.*, 2014), Xanthan gum (Mishra *et al.*, 2014), etc. *Jatropha curcas* is a tall bush / shrub or small tree that can grow up to six meters tall, belonging to the family Euphorbiaceae. The genus Jatropha includes seven species distributed in central and South America, South East Asia, India and Africa (Thomas and Sharma, 2010). It is also known as Physic nut, Barbados nut, Black vomit nut, Curcas beans, Purge nut. It is a drought resistance perennial plant growing on marginal soils. This plant is widespread throughout arid, semi-arid tropical regions of the world. The leaf, fruits, latex and bark contain glycosides, tannins, phytosterols, flavonoids and steroidal sapogenins that exhibit antibacterial and antifungal activities (Raju and Ezradanam, 2002). The latex of the plant contains alkaloids including jatrophin, jatropham and curcain with anti-cancer activity. Study has proven that *Jatropha curcas* is nontoxic (Rakshit *et al.*, 2012). It is also used externally against skin diseases and proven anti-inflammatory activity (James, 2011; Mujumdar and Misar, 2004). The fresh latex of *Jatropha curcas* was available in the month of December.

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So far from the available and reported scientific data apart from certain pharmacological activities of the plant the latex power is not used anywhere as an excipients in pharmaceuticals even it is having potential for the same. So the present study is an attempt to establish one of the properties of latex powder of *Jatropha curcas* suitable as excipients used in pharmaceuticals. In this work we have prepared tablet of two drugs Propranolol hydrochloride and Oxcarbazepine of category BCS class I and II respectively with latex powder of *Jatropha curcas* as a binder and compared with tablet prepared by standard binder.

MATERIALS AND METHODS

Materials

Propranolol hydrochlorides (PRH), Oxcarbazepine (OXC) were received as gift samples from Vergo Pharmaceuticals Ltd., Goa. Micro crystalline cellulose, Talc, Magnesium stearate, Polyvinyl pyrrolidine were purchased from Loba Chemicals, Mumbai, India. All the materials used in the research work were of analytical grade.

Collection of latex of *Jatropha curcas*

The plant was identified in the Ghogaon, Karad, Maharahstra, India and authenticated from Dr. S. R. Yadav, Professor and Head, department of Botany, Shivaji University, Kolhapur, Maharashtra, India. The fresh latex was collected in the month of December from Ghogaon, Karad, Maharahstra, India. The latex was collected by incising the bark of the trees and taken into the glass vials.The milky white solution of latex was dried at room temperature and used as latex powder of *Jatropha curcas* (LPJ) for further study.

Drug excipients compatibility study

PRH and OXC were mixed separately with the excipients LPJ, Micro crystalline cellulose (MCC), Talc and Magnesium stearate (MS) in a proportion of 1:1 separately and one batch with drug and all excipients. Prepared mixture was stored in a stability chamber for four weeks at 40 ± 2 ºC and 75 ± 5 % RH. The physiochemical compatibilities of the drug and the excipients was evaluated by assay and Fourier transforms infrared spectroscopy (FTIR) of all mixtures separately at initial level and after four weeks. For assay of PRH, mixture was dissolved in 0.1 N HCl and for OXC assay, mixture was dissolved in 1% w/v SLS solution in distilled water and appropriate dilutions were analyzed spectrophotometrically using Agilent UV-Visible double beam spectrophotometer at 289 and 254 nm respectively. FTIR spectra of pure drug and mixture of drug with all excipients was determined using Agilent ATR FTIR, Carry 630, India. Each spectrum was derived from single average scans collected in the region 4000 to 400 cm^{-1}.

Preparation of tablets

The tablets of PRH and OXC were prepared by wet granulation method using excipients as given in table 1. The following steps were involved in preparation. Raw materials were dispensed as mentioned in table 1. Dispensed materials were sifted through sieve number 40 and manually mixed. Different concentrations of binder 1, 2, 3, 4, 5 and 6 % w/v were prepared in distilled water and used for wet granulation by kneading method. For preparation of tablet with standard binder 3 % w/v PVP solution in distilled water was prepared. The wet mass was passed through sieve number 16 and obtained granules were dried at 40 ºC for1 h in tray dryer. The dried granules were again passed through sieve number 40 and obtained blend was finally lubricated with magnesium stearate for 1 min. Final blend was compressed using Rotary tablet machine with 8 and 12 mm standard concave punch for PRH and OXC respectively. Formulation codes are as given in table 1.

Evaluation of granules

Dried granules were evaluated for bulk density, tap density, Carr's index Hausner's ratio and angle of repose. A 50 ml glass cylinder was weighed and filled with 30 ml of granules. The opening was secured with parafilm. The cylinder was gently reversed once and the powder was carefully leveled without compacting. Bulk volume was determined after one mechanical tap on a tap density tester (Dolphin^{TM}). Tap volume was measured after 2000 taps. Each analysis was repeated twice. Values of bulk density and tap density were used to calculate Carr's index and Hausner's ratio. The angle of repose of the granules were determined by fixed funnel method (Indian Pharmacopoeia, 1996; United States Pharmacopoeia, 2006).

Evaluation of tablets

Tablet weight of 200mg for PRH and 500 mg for OXC was kept constant for all formulations. Assay of the tablets were determined as given in Drug excipients compatibility study. The weight variation of the tablets was evaluated on 20 tablets with an electronic balance. Disintegration time was determined in distilled water using Tablet Disintegration Test Apparatus (Veego, India). Tablet hardness was obtained using Monsanto Hardness Tester (Indian Pharmacopoeia, 1996). Thickness was determined by Vernier Caliper. Friability was determined by Roche friabilator (United States Pharmacopoeia, 2006).

In-Vitro dissolution studies of tablets

The dissolution studies were performed by using USP 26 type II Dissolution Test Apparatus (Veego, India). Dissolution mediums used were 900 ml 0.1 N hydrochloric acid and 1% sodium lauryl sulphate (SLS) for PRH and OXC respectively. The temperature was maintained at 37 ± 2ºC with 100 and 75 rpm stirring for each dissolution study of PRH and OXC respectively. Samples were collected periodically and replaced with a fresh dissolution medium. After filtration through Whatman filter paper 41, concentration of PRH and OXC was determined spectrophotometrically using Agilent UV-Visible double beam spectrophotometer at 289 and 254 nm respectively.

Table 1: Formulation codes with quantities for formulation of tablet.

	Formulation Codes	Ingredients (mg/tablet)					
		Drug	LPJ	MCC	Talc	MS	Total
Propranolol Hydrochloride	P1	80	2	109	6	3	200
	P2	80	4	107	6	3	200
	P3	80	6	105	6	3	200
	P4	80	8	103	6	3	200
	P5	80	10	101	6	3	200
	P6	80	12	99	6	3	200
	PVP-P	80	6 (PVP)	105	6	3	200
Oxcarbazepine	O1	300	5	180	10	5	500
	O2	300	10	175	10	5	500
	O3	300	15	170	10	5	500
	O4	300	20	165	10	5	500
	O5	300	25	160	10	5	500
	O6	300	30	155	10	5	500
	PVP-O	300	15 (PVP)	170	10	5	500

FC: Formulation Codes, LPJ: Jatropha Latex Powder, MCC: Micro crystalline cellulose, MS: Magnesium stearate

Table 2: Assay of the drug and mixture of excipients under prefromulation study.

Sr No	Drug + Excipients (1:1)	Drug content (%)	
		Initial	After 4 Weeks
1	PRH	96.7 ± 1	95.1 ± 2
2	PRH + MCC	97.8 ± 1	96.1 ± 1
3	PRH + LPJ	98.4 ± 1	98.1 ± 1
4	PRH + Talc	96.3 ± 1	95.3 ± 2
5	PRH + MS	96.8 ± 1	95.1 ± 1
6	PRH + MCC+ LPJ + Talc + MS	94.1 ± 2	93.8 ± 1
7	OXC	96.3 ± 1	94.8 ± 1
8	OXC + MCC	97.3 ± 1	96.1 ± 1
9	OXC + LPJ	98.6 ± 1	97.6 ± 1
10	OXC + Talc	97.3 ± 1	96.1 ± 1
11	OXC + MS	96.6 ± 1	95.9 ± 1
12	OXC + MCC+ LPJ + Talc + MS	94.6 ± 2	93.8 ± 3

The values after four weeks were not significantly different from the values at initial is $p > 0.1$

Table 3: Evaluation parameters for granules of PRH and OXC.

FC	Bulk density (g/ml)	Tap density (g/ml)	Carr's Index (%)	Hausner's ratio	Angle of repose (θ)
P1	0.2201 ± 0.25	0.2702 ± 0.36	17.83 ± 0.84	1.21 ± 0.17	30.96 ± 0.24
P2	0.2247 ± 0.21	0.2631 ± 0.24	15.61 ± 0.80	1.19 ± 0.19	29.54 ± 0.39
P3	0.2298 ± 0.23	0.2597 ± 0.31	09.12 ± 0.65	1.09 ± 0.28	27.16 ± 0.16
P4	0.2298 ± 0.36	0.2531 ± 0.28	07.46 ± 0.87	1.06 ± 0.34	24.84 ± 0.25
P5	0.2325 ± 0.18	0.2528 ± 0.30	07.13 ± 0.56	1.04 ± 0.37	24.32 ± 0.29
P6	0.2329 ± 0.24	0.2500 ± 0.32	07.0 ± 0.76	1.07 ± 0.74	23.50 ± 0.35
PVP-P	0.2654 ± 0.41	0.2984 ± 0.46	16.10 ± 0.28	1.30 ± 0.36	26.22 ± 0.39
O1	0.2501 ± 0.21	0.3002 ± 0.24	16.66 ± 0.45	1.23 ± 0.21	32.02 ± 0.42
O2	0.2542 ± 0.25	0.2941 ± 0.32	13.56 ± 0.57	1.15 ± 0.18	31.37 ± 0.34
O3	0.2564 ± 0.20	0.2847 ± 0.34	09.64 ± 0.54	1.11 ± 0.25	27.45 ± 0.74
O4	0.2586 ± 0.26	0.2830 ± 0.36	08.62 ± 0.50	1.09 ± 0.37	24.52 ± 0.24
O5	0.2586 ± 0.28	0.2803 ± 0.25	07.72 ± 0.47	1.08 ± 0.41	22.26 ± 0.29
O6	0.2631 ± 0.27	0.2777 ± 0.26	07.15 ± 0.41	1.05 ± 0.10	21.04 ± 0.37
PVP-O	0.2701 ± 0.24	0.2005 ± 0.24	16.66 ± 0.65	1.25 ± 0.52	25.81 ± 0.62

FC: Formulation Codes

Table 4: Evaluation parameters of tablets.

FC	Assay (%)	WV (%)	Thickness (mm)	Hardness (kg/cm^2)	Friability (%)	DT (min)
P1	95.7 ± 1	0.45 ± 0.04	4.1 ± 0.28	3.9 ± 0.38	0.96 ± 0.22	1.2 ± 0.27
P2	96.8 ± 1	0.56 ± 0.07	4.2 ± 0.36	5.6 ± 0.34	0.80 ± 0.02	2.1 ± 0.23
P3	98.4 ± 1	0.32 ± 0.01	4.0 ± 0.21	6.2 ± 0.32	0.46 ± 0.02	3.4 ± 0.18
P4	96.3 ± 1	0.63 ± 0.06	3.9 ± 0.19	7.6 ± 0.28	0.34 ± 0.01	5.2 ± 0. 21
P5	95.8 ± 1	0.64 ± 0.04	3.5 ± 0.30	8.8 ± 0.26	0.28 ± 0.01	6.0 ± 0.19
P6	94.1 ± 2	0.75 ± 0.06	3.8 ± 0.38	9.1 ± 0.24	0.26 ± 0.01	8.3 ± 0.16
PVP-P	96.3 ± 1	0.67 ± 0.06	3.8 ± 0.38	9.1 ± 0.24	0.26 ± 0.01	10.3 ± 0.16
O1	97.3 ± 1	0.71 ± 0.01	5.1 ± 0.29	4.6 ± 0.36	0.57 ± 0.08	2.3 ± 0.24
O2	98.6 ± 1	0.90 ± 0.04	5.1 ± 0.21	5.2 ± 0.34	0.81 ± 0.04	3.1 ± 0.31
O3	97.3 ± 1	0.58 ± 0.02	4.8 ± 0.39	6.0 ± 0.34	0.46 ± 0.04	5.0 ± 0.26
O4	96.6 ± 1	0.63 ± 0.07	4.7 ± 0.46	7.4 ± 0.35	0.34 ± 0.05	7.0 ± 0.30
O5	94.6 ± 2	0.82 ± 0.05	4.5 ± 0.34	8.0 ± 0.30	0.28 ± 0.03	8.3 ± 0.24
O6	96.7 ± 1	0.91 ± 0.04	4.6 ± 0.38	8.6 ± 0.22	0.26 ± 0.02	10.0 ± 0.29
PVP-O	9648 ± 1	0.75 ± 0.06	3.8 ± 0.38	9.2 ± 0.34	0.26 ± 0.01	12.3 ± 0.16
P3*	97.7 ± 1	--	4.0 ± 0.22	6.0 ± 0.37	0.56 ± 0.02	4.4 ± 0.22
O3*	96.4 ± 1	--	4.8 ± 0.38	6.0 ± 0.38	0.51 ± 0.03	5.6 ± 0.32

The values for P3* and O3* were not significantly different from the values of P3 and O3 respectively as $p > 0.1$ FC: Formulation codes, WV: Weight Variation, DT: Disintegration time, * After 3 months stability at 40 ± 2°C and 75 ± 5% RH

Stability study

Accelerated stability study for tablets of optimized batch (P3 and O3) were carried out at 40 ± 2°C and 75 ± 5% RH for a period of 3 months in a stability chamber (Remi, India). The samples were withdrawn at 0 month (Initial level) and after 3 months and evaluated for the drug content, hardness, thickness, disintegration time and friability.

Statistical Analysis

Results are expressed as mean ± S.D. for triplicate samples. The results were statistically analyzed and significant differences among parameters were determined by one-way analysis of variance using 'Graph Pad Instate®'Version 3.05 (USA), statistical analysis program. Statistical significant was considered at $p < 0.05$.

RESULTS AND DISCUSSION

Drug excipients compatibility parameters are as given in table 2. It has been observed that the drug content of PRH and OXC with all excipients after four weeks stability condition was not significantly different than the values at initial level. FTIR spectra of drug and drug with all excipients at initial level and after four weeks stability condition of PRH and OXC are as shown in figure 1 and 2 respectively. It has been observed that even after four weeks stability condition samples exhibited identical FTIR spectra. Thus results of drug excipients compatibility parameters has indicated that all selected excipients were compatible with PRH and OXC.

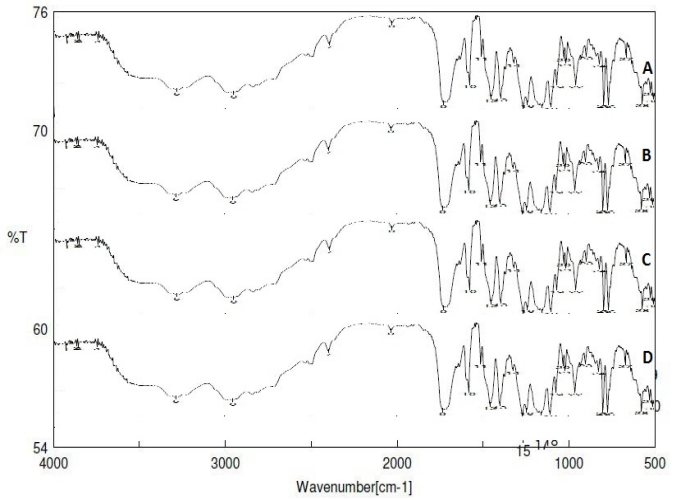

Fig. 1: FTIR spectra of A: PRH and B: PRH with all excipients at initial level, C: PRH and D:PRH with all excipients after four week stability condition.

FTIR spectra revealed that no any chemical transition has occurred in drug during drug excipients compatibility study.Tablets of PRH and OXC were successfully prepared by wet granulation method. Preliminary evaluation parameters of the granules are as given in table 3. Angle of repose, Carr's index and Hausner's ratio values of all the batches were well within the official limits for both the drugs (Indian Pharmacopoeia, 1996; United States Pharmacopoeia, 2006). Preliminary evaluation parameter of the granules has showed its better flowability indicating suitability of the method. Evaluation parameters of tablets are as given in table 4. Assay, weight variation, hardness, disintegration time and friability values were in specified limits for both the drugs (Indian Pharmacopoeia, 1996; United States Pharmacopoeia, 2006) with satisfactory thickness. The study has been designed with the intension for optimization of binder concentration of LPJ, because of that different concentrations of binders were taken.

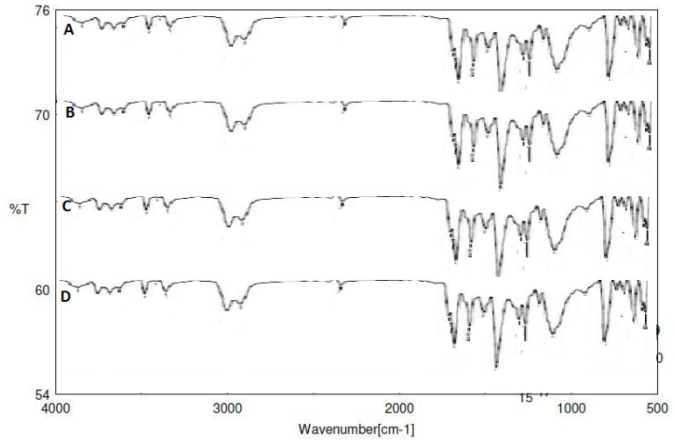

Fig. 2: FTIR spectra of A: OXC and B: OXC with all excipients at initial level, C: OXC and D:OXC with all excipients after four week stability condition.

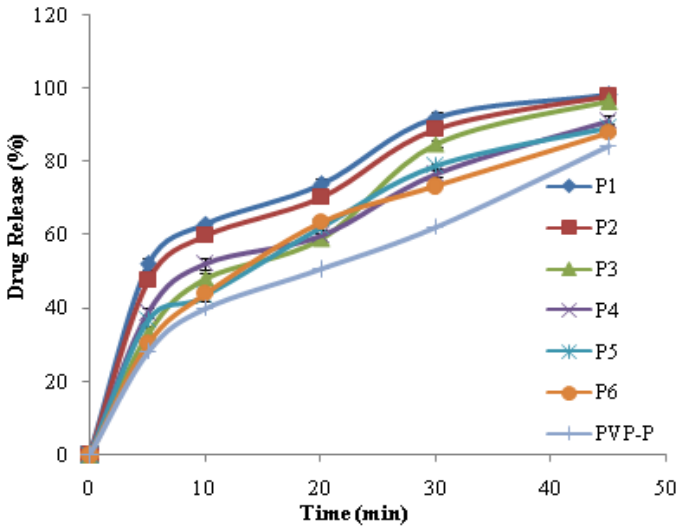

Fig. 3: In-vitro drug release of PRH tablets.

The result of hardness, disintegration time and friability has shown that as concentration of binder increases hardness and disintegration time increases with decreases in friability. But for all concentrations of binder these parameters were within the specified limit. Evaluation parameters of tablets has shown that tablets were prepared successfully as no weight variation was observed may be due to reason that granules were free flowing. Also content uniformity was well within the limit indicating optimized mixing of granules with better optimization of all process parameters. The results of hardness has revealed that with

increase in binder concentration binding capacity has increased which might be due to formation of strong cohesive bonding between granules leading to reducing friability. The percentage drug release of all batches of PRH and OXC is as shown in figure 3 and 4 respectively. The drug release study has shown that more than 70 % PRH was released in 30 min and up to 60% OXC was released within 45 min for all formulations. Thus with increase in binder concentration stronger compact was formed causing less penetration of solvent in the tablet pores leading to increase in disintegration time. Consequently it has resulted in reduction in drug release with increasing concentration of binder for both the drugs also which might be attributed to formation of viscous mass with high binder content forming barrier for movement of dissolution medium into the pores of the dosage form (Singh *et al.*, 2011).

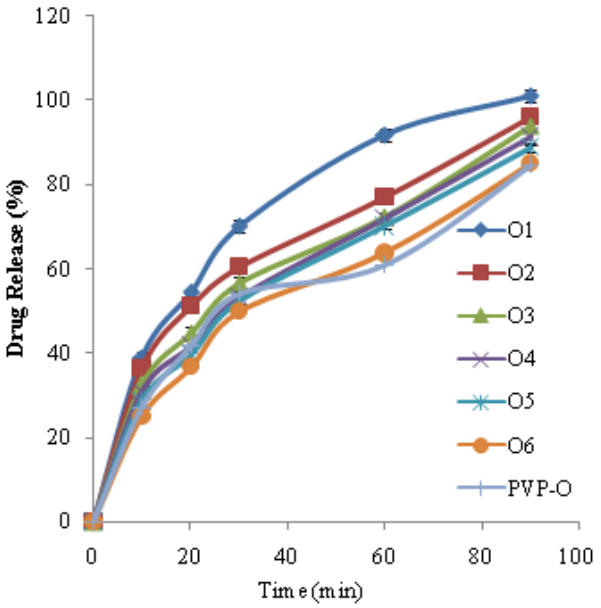

Fig. 4: In-vitro drug release of OXC tablets.

As concentration of binder increases drug release was delayed. Considering all results 3% concentration of LPJ has shown optimized evaluation parameters for both the drugs so formulation P3 and O3 were considered as optimized formulations. The formulation P3 and O3 has shown comparable results as compared with that of formulations PVP-P and PVP-O prepared with standard binder PVP for PRH and OXC respectively as given in table 4. The tablets of formulation P3 and O3 after 3 months stability study at 40 ± 2°C and 75 ± 5% RH has shown no significant difference in drug content, hardness, thickness, friability and disintegration time. Stability study has indicated that formulation P3 and O3 were adequately stable as per regulatory requirements (USFDA Guidance for Industry, 2011).

CONCLUSION

Tablets of PRH and OXC were successfully prepared with all evaluation parameters well within official limits. LPJ has shown not only better binding property but also appropriate disintegration time, friability and drug release. Results were satisfactory for both water soluble and insoluble drug PRH and OXC respectively. Optimized formulation P3 and O3 has shown comparable results as compared with results of tablet prepared with standard binder PVP. The LPJ was found to be effective at low concentrations also it is cost effective and easily available. So it can be concluded that latex powder of *Jatropha curcas* can be used as alternative binder in the pharmaceutical formulations for BCS class I and II drugs.

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